



June 23, 2020

Mr. Aaron S. Zajic
Office of Inspector General
Department of Health and Human Services
Washington, DC 20201

Dear Mr. Zajic:

On behalf of the Healthcare Information and Management Systems Society ([HIMSS](#)) and the Personal Connected Health Alliance ([PCHAlliance](#)), we are pleased to provide written comments in response to the [Grants, Contracts, and Other Agreements: Fraud and Abuse; Information Blocking; Office of Inspector General's \(OIG's\) Civil Money Penalty \(CMP\) Rules](#) Proposed Regulation, published in the Federal Register April 24, 2020. HIMSS and PCHAlliance appreciate this opportunity to utilize our members' expertise in offering feedback in support of implementing the [21st Century Cures Act](#), the Office of the National Coordinator for Health IT's (ONC's) [Interoperability and Information Blocking Final Regulation](#), broader data exchange across the entire healthcare ecosystem and enforcement around occurrences of information blocking as well as CMPs.

HIMSS is a global advisor and thought leader supporting the transformation of the health ecosystem through information and technology. As a mission-driven non-profit, HIMSS offers a unique depth and breadth of expertise in health innovation, public policy, workforce development, research and analytics to advise global leaders, stakeholders and influencers on best practices in health information and technology. Through our innovation engine, HIMSS delivers key insights, education and engaging events to healthcare providers, governments and market suppliers, ensuring they have the right information at the point of decision. Headquartered in Chicago, Illinois, HIMSS serves the global health information and technology communities with focused operations across North America, Europe, the United Kingdom, the Middle East and Asia Pacific. Our members include more than 80,000 individuals, 480 provider organizations, 470 non-profit partners and 650 health services organizations.

PCHAlliance, a membership-based HIMSS Innovation Company, accelerates technical, business and social strategies necessary to advance personal connected health and is committed to improving health behaviors and chronic disease management via connected health technologies. PCHAlliance is working to advance patient/consumer-centered health, wellness and disease prevention. The Alliance mobilizes a coalition of stakeholders to realize the full potential of personal connected health. PCHAlliance members are a vibrant ecosystem of technology and life sciences industry icons and innovative, early stage companies along with governments, academic institutions and associations from around the world.

[HIMSS and PCHAlliance have long advocated](#) for many of the issues that are critical to facilitate greater nationwide interoperability and information exchange. We fully support the efforts from across the Department of Health and Human Services (HHS) to

provide patients with secure access to actionable information that assists them in directing their own healthcare as well as inhibits the blocking of information that contributes to more seamless care delivery. In addition, HIMSS and PCHAlliance appreciate the opportunity to help HHS tackle these issues and put our health system and stakeholders on a path to transform healthcare. Moreover, we support OIG's work in this area to assist patient safety efforts, make our health system more efficient and effective, as well as protect the integrity of HHS programs.

OIG's role and program funding are critical to interoperability success

It is important to note how integral OIG's Proposed Regulation is to promoting greater interoperability across the healthcare ecosystem. The work to clearly define what information should move between health system stakeholders and what the consequences are when that information does not appropriately move between participants sets the parameters and expectations for the entire exchange enterprise. HIMSS and PCHA have observed, through OIG's engagement with healthcare community stakeholders at our Global Conference and other activities, that proper enforcement of government regulations is dependent on community understanding of the expectations. OIG's role must be to educate stakeholders on government parameters and hold them accountable for their actions when they intentionally do not share information.

However, OIG cannot successfully fulfill its duties without adequate resources to develop sub-regulatory guidance and advisory opinions that inform the community's actions. The inclusion of \$5.3 million in the fiscal year (FY) 2021 President's Budget is a down payment for the work that OIG must undertake to execute new information blocking investigative and enforcement authorities, but it is not enough. OIG should be investing in hiring additional personnel as well as developing new training programs and educational resources on information blocking.

We see any additional OIG funding as an opportunity to build up the robust directory of informal guidance documents that the community needs in order to understand the importance of broadly sharing information. We encourage the Administration to provide more resources to ensure OIG can meet this goal and fulfill its critical responsibilities to educate the community.

Moreover, HIMSS and PCHAlliance acknowledge that this Proposed Regulation does not apply to healthcare providers as actors subject to information blocking CMPs. As discussed later in this letter, we expect a future Proposed Regulation will include details about how healthcare providers will be subject to OIG enforcement and referral to other federal agencies for appropriate disincentives.

Overall, this Proposed Regulation provides much of the information the community needs on OIG's approach, enforcement priorities and intended areas of focus. For our public comment, we offer the following thoughts and recommendations on the points included in this document, with the goal of creating an environment where health system stakeholders have the appropriate knowledge and necessary tools to ensure health data is being broadly shared.

Coordinate with ONC to clarify and appropriately promulgate all the compliance and enforcement dates related to information blocking

With the pre-publication of ONC's Final Interoperability Regulation in March and formal publication in May, the community received information on when stakeholders had to comply as well as the timeline for when each piece of the regulation would be enforced. However, given the COVID-19 Public Health Emergency (PHE), ONC also announced a period of enforcement discretion for certain provisions that provides an additional three months before many of the requirements start. Layered on top of ONC's Regulation is OIG's work on information blocking enforcement and a set of different, but related, dates and requirements.

HIMSS and PCHAlliance ask that OIG coordinate and align with ONC to ensure the community is better informed about all of the interoperability and information blocking compliance and enforcement dates and how the regulations intersect and overlap. When finalized, this information should also be cross-referenced on each agency's website so stakeholders have easy access to both sets of implementation dates and requirements. We support OIG's statement in the Proposed Regulation on close coordination with ONC given its separate, but related, authority under the Public Health Service Act and its program expertise related to the information blocking regulations. These actions should also translate into taking steps to better coordinate on implementation dates.

The information should also accompany clarifying details on the regulated actors under information blocking. As OIG is planning to incorporate ONC's regulations, OIG enforcement will rely on the regulatory definition of information blocking and the related exceptions. There remains significant uncertainty across stakeholders about which entities should be considered health information networks/health information exchanges, healthcare providers, or meet the definition of both regulated actors. More clarification and examples from OIG and ONC would be helpful to the community as they implement the interoperability regulations.

Finally, it is important to note the devastating impact COVID-19 is having across the health ecosystem, upending technology implementation plans and timelines. As the attention of many health systems is focused on managing growing demands for care, and ensuring they have the products, equipment and supplies to support clinicians to deliver quality care, OIG and ONC should consider these factors when finalizing timelines for information blocking compliance and enforcement. ONC has already implemented one period of enforcement discretion and discussed the possibility of additional considerations. OIG should ensure it is taking COVID-19-related challenges into account when finalizing any implementation dates.

Establish the formal enforcement date when CMPs will be applied to six months after publication of the Final Regulation

HIMSS and PCHAlliance appreciate that information blocking is newly-regulated conduct, and we agree with OIG that it has significant experience undertaking other

CMP investigations and enforcement in areas beyond information blocking. The agency should use this institutional knowledge to ensure effective enforcement of this provision, but its specific knowledge of information blocking will be limited in the early stages of implementation. Healthcare stakeholders will be in a similar position to OIG, as they will encounter a steep learning curve about how best to interpret and implement these new regulations.

Moreover, HIMSS and PCHAlliance agree with OIG's goal of exercising enforcement discretion to provide individuals and entities that are taking necessary steps to comply with information blocking with time to do so while putting the industry on notice that penalties will apply to information blocking conduct within a reasonable time period.

Therefore, we ask OIG to exercise its enforcement discretion and delay imposing CMPs for six months after the effective date of the regulation. HIMSS and PCHAlliance envision that the effective date of OIG's Regulation will be 60 days after the Final Regulation is published. For the period between the effective date and six months after Final Regulation publication, OIG should focus on providing regulated actors with informal guidance about how the agency is interpreting specific actions that actors have undertaken that could be considered information blocking. During this period, OIG should refrain from imposing any information blocking CMPs as the agency uses clearly articulated requirements and real world examples to educate healthcare stakeholders. Focusing enforcement during the first six months of the regulation's implementation on providing informal guidance, rather than CMPs, is consistent with OIG's goal.

In addition, OIG should be explicit that its information blocking investigations and enforcement will not be retroactive to any period prior to the effective date of the Final Regulation. As previously discussed, how the OIG Regulation intersects with ONC's Final Regulation raises many questions for regulated actors that are tracking all implementation dates. More emphasis from OIG that it will not be investigating potential information blocking conduct that occurs before the regulation's effective date will provide greater certainty to regulated actors.

Prioritize the development of sub-regulatory guidance to keep the community updated on OIG's current thought processes on information blocking

HIMSS and PCHA encourage OIG to use sub-regulatory or informal guidance to keep the community updated about its latest thinking on information blocking and how it is approaching various instances of potential violations during investigations. The Proposed Regulation discusses how OIG has discretion to choose which information blocking complaints to investigate as well as how it plans to maximize efficient use of its resources by selecting cases for investigation that are consistent with enforcement priorities. We understand the agency wants to maintain this discretion, but explicit information in the form of sub-regulatory guidance will help stakeholders prepare for OIG regulatory requirements.

In addition, as OIG's priorities evolve and new situations arise, using sub-regulatory guidance as a tool to guide stakeholders would be extremely helpful. We recognize

how it may be challenging for OIG to regularly publish guidance documents, but in lieu of any formal advisory opinions that OIG is able to release, these documents are indispensable.

Sub-regulatory guidance would also be helpful to the community in not just understanding when to impose a CMP, but also specifics around the amount of the penalty. We recommend that OIG periodically publish formal advisory opinions to help guide the data exchange processes of stakeholders, but given OIG's push to maintain broad discretion, HIMSS and PCHAlliance endorse the expanded use of informal guidance documents to advise the community.

Align the factors that OIG should consider for investigations with similar work undertaken across HHS

HIMSS and PCHAlliance generally agree with the factors that OIG includes in the Proposed Regulation related to how it will determine whether to impose a CMP for an information blocking violation. We suggest OIG look to align the work it is undertaking on information blocking with the factors that the HHS Office of Civil Rights (OCR) uses to investigate Health Insurance Portability and Accountability Act of 1996 (HIPAA) Violations.

Many stakeholders are already familiar with how OCR is evaluating potential HIPAA investigations, so OIG alignment with OCR factors would provide the community with a higher degree of certainty around expectations. Based on OCR's work, OIG should consider incorporating the following factors:

- The nature and extent of the violation, which may include the number of individuals affected and the time period during which the violation occurred
- The nature and extent of the harm resulting from the violation, including whether the violation caused physical or financial harm or hindered an individual's ability to obtain healthcare
- The actor's history of prior compliance with relevant provisions, including violations, and whether the current violation is the same as or similar to previous indications of noncompliance, the extent corrective actions were taken to address previous indications of noncompliance, and responses to prior complaints
- The actor's financial condition, including whether financial difficulties affected its ability to comply, or whether the imposition of a CMP would jeopardize the ability of the actor to continue to provide, or to pay for, healthcare

In addition, given the COVID-19 PHE, HIMSS and PCHAlliance ask that OIG integrate potential challenges facing regulated actors that may have shifted priorities and diverted staff to address the PHE, thereby decreasing an actor's ability to focus on non-COVID-19 related data exchange capabilities. The COVID-19 PHE will likely have a significant impact on our health system for the near future. Such resource constraints should be factored in before OIG determines whether to impose an information blocking CMP.

However, OIG should also take into account whether a potential information blocking violation impedes the ability of a health system stakeholder to address a COVID-19-related issue or challenge. Given the magnitude of COVID-19 cases and the possibility of a future second wave, OIG should highlight the importance of fulfilling data exchange requests that could positively impact a response to the virus.

Moreover, OIG should create a factor for consideration that takes into account the size and reach of an entity that could potentially be the target of information blocking. We want to ensure small, rural, under-resourced entities and entities that treat underserved populations are not disproportionately impacted by information blocking given the smaller number of patients and providers that may inherently be included in their networks. Such entities may have fewer resources to devote to address these issues, but OIG needs to support their role in broad-based data exchange across the care continuum.

Ensure that OIG's enforcement priorities include a public health focus

HIMSS and PCHAlliance support the inclusion of the priorities noted in the Proposed Regulation and emphasize the importance of including conduct that "resulted in, is causing, or had the potential to cause patient harm." Specifying that OIG is reviewing actions that could potentially cause harm is particularly important for addressing difficulties before they result in harm toward patients, and holds regulated actors accountable for this conduct before harm actually occurs.

We also ask OIG to add an enforcement priority on the degree to which information blocking affects public health/community health, not just individual health. It is especially important in the face of the current COVID-19 PHE, when the pandemic is impacting entire regions or communities at different times, and as the federal government and states prepare to implement policy actions that help position the U.S. for a prolonged PHE.

Define information blocking intent

We recognize OIG's plans to limit pursuing information blocking claims against actors that have requisite intent to commit such actions and not use enforcement measures against actors making seemingly innocent mistakes. HIMSS and PCHAlliance ask OIG to clearly define how intent will be determined and provide specific illustrative examples that regulated actors can use to better understand what it means to have requisite intent as well as what innocent mistakes look like to OIG.

We understand OIG has significant experience and expertise investigating and determining whether to take an enforcement action based on other laws that are intent-based, but given the novelty of the information blocking regulations, many regulated actors do not have the same level of experience and require more specifics from OIG as broader, community-wide information exchange occurs.

Clarify definitions for single and multiple violations of information blocking

HIMSS and PCHAlliance appreciate the examples that OIG included in the Proposed Regulation for a single violation as well as multiple violations. We ask OIG to provide additional details, examples and scenarios to ensure the community fully understands the difference and how OIG is evaluating these distinctions. It would also be helpful for OIG to partner with ONC to tie these examples to the Information Blocking Exceptions in ONC's Final Interoperability Regulation and explain why a specific exception did not apply in this case. Such a step would provide more information on how organizations should consider the reasonable actions they should take to broadly share data.

Based on the examples already included, we also propose that OIG modify what it considers multiple violations to be focused on the principle of the practice that is considered to have resulted in an information blocking claim. Specifically, we note that when an organization's policy results in the consistent and repetitive application of an information blocking practice, the organization's established policy should be considered the violation. Each time such a policy is applied to a data exchange process should not be considered a single, independent violation.

Prepare healthcare providers for the upcoming rulemaking around implementing information blocking "provider disincentives"

HIMSS and PCHAlliance understand OIG's focus in the Proposed Regulation is on the regulated actors other than healthcare providers. OIG's proposal conveys how providers are not subject to the imposition of CMPs, and that the community should expect a forthcoming Proposed Regulation that describes how information blocking enforcement will be applied to healthcare providers by OIG, including the other agencies to refer providers, and the appropriate disincentives to be applied thereafter. We ask that OIG ensure the new rulemaking provides considerable details around the process the agency intends to implement and how it will evaluate what agencies to refer a healthcare provider that committed information blocking. In addition, OIG should specify how the overall intake process for complaints will work and the level of involvement from OIG after it refers a healthcare provider to another agency.

Given the previously discussed complexities associated with compliance and enforcement dates in this Proposed Regulation as well as with ONC's Final Interoperability Regulation, OIG should provide clarity to healthcare providers and a well-defined runway around information blocking impact.

Moreover, clarifying details should be added on how information blocking provider disincentives will intersect with the three interoperability-related measures that providers are required to attest to as part of the Centers for Medicare & Medicaid Services (CMS) Promoting Interoperability Program. More details about how OIG anticipates using the information collected by CMS in its information blocking work would be extremely helpful to healthcare providers. In general, more visibility and transparency around how these processes will be incorporated is of significant benefit to the community when thinking about provider attestation liability questions.

Conclusion

Overall, HIMSS and PCHAlliance want to facilitate greater nationwide interoperability that leads to information exchange. OIG's work on information blocking is critical to the overall success of the program — its Proposed Regulation is directionally appropriate, and many of our comments focus on OIG providing additional clarity on several topics, including: compliance and enforcement dates; factors to consider; enforcement priorities; and how intent is defined. In addition, we ask that OIG prioritize the development of sub-regulatory guidance to help better inform the community on where OIG is headed in terms of enforcement, and alignment with other CMP processes occurring across HHS. The work underway from OIG and across HHS on interoperability will definitively put our health system and stakeholders on a path to transform healthcare.

We look forward to the opportunity to discuss these issues in more depth. Please feel free to contact Jeff Coughlin, HIMSS Senior Director of Government Relations, at jcoughlin@himss.org, or Robert Havasy, Managing Director of PCHAlliance, at rhavasy@pchalliance.org, with questions or for more information.

Thank you for your consideration.

Sincerely,

A handwritten signature in black ink, reading "Harold F. Wolf III". The signature is written in a cursive style with a long horizontal stroke extending to the right.

Harold F. Wolf III, FHIMSS
President & CEO