



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](#)

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 mobilizes a coalition of stakeholders to 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

CMP

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

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

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 t-5.3 (tn)10.2 (e)- (l)-16n..6 (cl)-166 -1.21(l)-11.15 (s)-1>

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, appearing to read "Harold F. Wolf III". The signature is written in a cursive style and is positioned above the typed name.

Harold F. Wolf III, FHIMSS
President & CEO