



CHiME
College of Healthcare
Information Management Executives

June 22, 2020

Principal Deputy Inspector General Christi Grimm
Office of the Inspector General
200 Independence Ave., SW
Washington, DC 20201

Submitted Virtually Through [Regulations.gov](https://www.regulations.gov)

Dear Inspector General Grimm,

The College of Healthcare Information Management Executives (CHIME) welcomes the opportunity to submit comments in response to the Office of the Inspector General's (OIG's), HHS proposed rule "Grants, Contracts, and Other Agreements: Fraud and Abuse; Information Blocking; Office of the Inspector General's Civil Money Penalty Rules" published in the *Federal Register* on April 24, 2020.

CHIME is an executive organization dedicated to serving chief information officers (CIOs), chief medical information officers (CMIOs), chief nursing information officers (CNIOs) and other senior healthcare IT leaders. With more than 3,200 members, CHIME provides a highly interactive, trusted environment enabling senior professional and industry leaders to collaborate; exchange best practices; address professional development needs; and advocate for the effective use of information management to improve the health and healthcare in the communities they serve.

We appreciate the Administration's efforts to hold those who inappropriately deny patients and providers access to patient data accountable. As the 21st Century Cure's Act (Cures Act) outlines, it is essential to ensure patient data continues to move with the patient to better enable interoperability and allow providers to better care for the whole patient. Having firm penalties in place punishing those who hold this patient data hostage will continue to push the nation's health system further into the future.

Despite the need for health data to flow and be accessible, the current pressures providers across the nation face in responding to the COVID-19 public health emergency (PHE) limit their ability to prepare for these requirements to take effect. While this proposed rule does not explicitly govern providers, many providers do also function as a health information network (HIN) or health information exchange (HIE). With many now predicting an inevitable second wave of COVID-19, it is inappropriate to potentially punish good actors as part of the healthcare system that is unable to comply with these regulations due to the extenuating circumstances.

While your proposed rule outlines the civil monetary penalties (CMPs) that were previously outlined in the Cures Act, your rule requests comment related to when these enforcement actions should begin. CHIME has already provided comment¹ to both the Office of the National Coordinator for Health Information Technology (ONC) and the Centers for Medicare and Medicaid Services (CMS) related to their information blocking and interoperability proposed rules. We made recommendations for establishing enforcement mechanisms, including: 1) not subjecting providers to penalties when they are acting in the capacity of an HIE/HIN; 2) establishing an appeals process to the penalty structure for providers reserved under the Cures

¹ <https://chimecentral.org/wp-content/uploads/2019/05/CHIME-letter-to-CMS-and-ONC-on-interop-FINAL.pdf>

Act for other actors; and 3) giving adequate time for providers who were not eligible for incentives offered under the Health Information Technology for Economic and Clinical Health (HITECH) Act.

ONC's final rule states on page 25800, in relation to providers who function as both a provider and an HIE/HIN, "a healthcare provider that may have ownership of a HIN/HIE, would not be considered a HIN/HIE, but instead a 'health care provider' with respect to situations that involve their behavior as a healthcare provider, such as denying another healthcare provider's ability to access, exchange or use EHI for treatment purposes or denying an individual's access to their EHI via the healthcare provider's patient portal." ONC then later clarifies that the reference to the three types of activities (access, exchange, use) does not limit the application of the HIN/HIE definition to individuals or entities that are considered covered entities (CEs) or business associates (as defined in HIPAA); and that the three activities serve as elements of the definition such that if an individual or entity meets them, then the individual or entity would be considered a HIN/HIE under the information blocking regulations for any practice they conducted while functioning as a HIN/HIE. There is sufficient ambiguity around how providers who act as an HIE/HIN will be treated. We have queried ONC on this matter and to date have not received further clarification. It is imperative that providers that function as an HIE/HIN and do so for the purpose of furthering interoperability to improve patient care are not subjected to punitive enforcement. **We strongly believe these actors should always be treated as providers and not as HIEs/HINs for enforcement purposes.**

With CHIME's previous requests in mind, **CHIME also recommends OIG delay enforcement of the CMPs related to ONC and CMS' information blocking and interoperability final rules until CY 2023 or until the end of the PHE, whichever comes later.** By delaying the enforcement of these actions, actors are better equipped to focus on the COVID-19 PHE. The requirements contained within both final rules are lengthy, complicated and have the potential to be costly to actors who have not had adequate time to plan due to their work focused on the PHE. As previously outlined, when the second wave of COVID-19 hits the nation, a time now likely expedited and already underway in some states, actors will need to focus all of their attention on assisting patients and caring for their wellbeing in order to ensure they can get the care they need. During this time, actors will be unable to focus on these requirements and, as a result, could be inappropriately penalized by the government for focusing on patient health instead of lengthy governmental program requirements.

Additionally, CHIME is in the process of providing comment on the CMS FY2021 Inpatient Prospective Payment System (IPPS) for Acute Care Hospitals and Long-Term Care Hospital (LTCH) Prospective Payment System (PPS) proposed rule, asking them to delay any alignment activities within future iterations of this rule until at least CY 2023 or the end of the Public Health Emergency, whatever comes later.

Allowing actors to have enough time to ensure they can implement these information blocking and interoperability requirements is crucial to ensuring the success of the information blocking and interoperability requirements themselves. CHIME's recommendation of waiting until at least CY 2023 allows for all of the requirements within both of the previously mentioned ONC and CMS final rules to arrive at their compliance dates². All actors should have enough time to work together within the program to support each other as they work to implement these needed information blocking provisions. The final major compliance deadline within the ONC and CMS rules is May 1, 2022, when provider API implementation is required, and the definition of electronic health information (EHI) is updated to include all electronic protected health information (ePHI). By waiting until 2023, these requirements have time to be put into place and for each actor to ensure they function to meet the true intent of the requirement. Rushing providers, and other actors to implement complicated key requirements only creates an opportunity for work to be incomplete, or insufficient, failing to truly solve the information and interoperability problems within the health system. **In a recent survey of our members focused on the impact of COVID-19, 75% of respondents reported they were concerned about their ability to meet future information blocking requirements.**

As OIG continues to evaluate how and when to begin the CMP portion of the Cures Act requirements, it is also crucial they work with both ONC and CMS to ensure any penalties levied against an actor are

² <https://chimecentral.org/wp-content/uploads/2020/04/ONC-CMS-Timelines-Chart.pdf>

considered proportional to the violation itself. Not all violations will be malicious, as some actors may not have had the appropriate time to implement systems, policies and procedures required to meet these requirements due to the PHE and the economic, as well as the personnel strain, it has placed on their organizations. OIG should ensure all CMPs are coordinated with all referring agencies to ensure actors who fall into multiple designations, such as providers who also act as a health information exchange (HIE), are not punished twice for a single violation. It is together through coordination between actors and the government that the success of the information blocking and interoperability programs can be assured.

We appreciate the opportunity to comment and welcome the chance to help inform the critical work being done by OIG. We look forward to continuing to be a trusted stakeholder on addressing healthcare as this PHE continues to evolve and as new information blocking and interoperability compliance deadlines continue to move into effect. Should you have any questions about our letter, please contact Andrew Tomlinson, Director of Federal Affairs, at atomlinson@chimecentral.org.

Sincerely,



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