Federation of American Hospitals®
Charles N. Kahn III
President and CEO

June 23, 2020

Mr. 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

SUBJECT: ***OIG–2605–P, Grants, Contracts, and Other Agreements: Fraud and Abuse; Information Blocking; Office of Inspector General's Civil Money Penalty Rules***

Dear Mr. Zajic:

The Federation of American Hospitals (FAH) appreciates the opportunity to provide comments to the Office of Inspector General (OIG), Department of Health and Human Services (HHS) on the *Grants, Contracts, and Other Agreements: Fraud and Abuse; Information Blocking; Office of Inspector General's Civil Money Penalty Rules* (Proposed Rule), published in the *Federal Register* on April 24, 2020 (85 Fed. Reg. 22979). The FAH is the national representative of more than 1,000 leading, tax-paying hospitals and health systems throughout the United States. FAH members provide patients and communities with access to high-quality, affordable care in both urban and rural America. Our members include teaching and non-teaching, acute, inpatient rehabilitation, behavioral health, and long-term care hospitals and provide a wide range of inpatient, ambulatory, post-acute, emergency, children's, and cancer services.

The FAH appreciates the OIG's proposals addressing: (1) the amendment of the Civil Monetary Penalties Law (CMPL) by the *21st Century Cures Act* (Cures Act)[1] authorizing HHS to impose CMPs, assessments, and exclusions upon individuals and entities that engage in fraud and other misconduct related to HHS grants, contracts, and other agreements[2]; (2) the

[1] Public Law 114-255, Sec. 5003.
[2] 42 U.S.C. 1320a–7a(o)–(s).

amendment of the *Public Health Service Act* (PHSA)[3] by the Cures Act authorizing the OIG to investigate claims of information blocking and providing the Secretary of HHS (Secretary) authority to impose CMPs for information blocking; and (3) the increase in penalty amounts in the CMPL effected by the Bipartisan Budget Act of 2018 (BBA 2018).[4]

Our comments focus on the CMPs added for arrangements involving grants, contracts, and other agreements as well as information blocking CMPs. With a Public Health Emergency currently in place throughout the country due to COVID-19, the existing health care environment provides a unique perspective for hospitals and other providers when considering the impact of the proposed modifications set forth in the Proposed Rule. In particular, due to the COVID-19 crisis and the related grants, contracts, and other agreements that have been issued and revised in quick succession during the past few months, the FAH requests that the OIG give consideration to the rapid and sometimes confusing and/or conflicting guidance issued by HHS in addressing the implementation of the final regulations for these arrangements. Similarly, information blocking has been a concern throughout the health care industry as electronic health record usage increases and expands. The FAH asks that the OIG use its discretion in charting the course forward on identifying and categorizing violations and then imposing penalties for such conduct. As discussed more fully below, the FAH requests that the OIG fully consider the impact and timing of decisions related to this Proposed Rule in the context of the constant changes occurring in health care and the responsibility placed upon hospitals and other providers who are working hard and expending great resources to track, understand, and implement these changes in a compliant manner, while at the same time focusing on the exigent needs of their communities during the current health care crisis.

Subpart G - CMPs, Assessments, and Exclusions for Fraud or False Claims or Similar Conduct Related to Grants, Contracts, and Other Agreements

The Cures Act amended the CMPL authorizing HHS to impose CMPs, assessments, and exclusions upon those persons and entities that commit fraud and other misconduct related to HHS grants, contracts, and other agreements. This authority is extremely broad and applies to a wide spectrum of arrangements. The conduct covered includes, among other things, the making of false or fraudulent specified claims to HHS, the submission of false or fraudulent documents to HHS, and the creation of false records related to HHS grants, contracts, or other agreements. The situations to which this authority applies includes those in which HHS provides funding, directly or indirectly, in whole or in part, pursuant to a grant, contract, or other agreement. The Cures Act also created a new set of definitions related to grant, contract, and other agreement fraud and misconduct, outlined the sanctions for violation of the statute, and referenced the procedures to be used when imposing sanctions under the statute.

[3] 42 U.S.C. 300jj–52.
[4] Public Law 115–123.

Although we support the imposition of sanctions on those who exploit the most vulnerable in our society and those who intentionally abuse federal health care programs, the implementation of this new authority raises potential concerns for hospitals and others who, in good faith apply for, and receive funding from, HHS. With such a broad definition of the arrangements to which the authority applies, hospital applicants could incur severe penalties if an error is made and the OIG makes a determination of fraud or other misconduct subject to these CMPs. This is especially daunting during this COVID-19 pandemic where grant funding and related requirements occur on a very rapid and fluid basis, and necessarily so, as the federal government as well as hospitals have had to quickly prepare for and respond to the emergency.

Many of these grants, contracts, and other agreements are very complex and require specific and detailed information and actions from the parties applying for the funds. As the COVID-19 public health emergency has shown, often these programs have been subject to modifications, clarifications, and additional requirements to receive or retain certain funding. The complex nature of these programs is overwhelming for many organizations working to do the right thing and adapt to the changing conditions related to HHS funding. The FAH asks that the OIG take these complexities and ambiguities into consideration when exercising its discretion in enforcing the CMPs and that it do so only where the facts demonstrate truly abusive, egregious, and intentional wrongdoing by the parties applying for or receiving these HHS funds.

§ 1003.700 – Basis for Civil Money Penalties, Assessments, and Exclusions

The proposed regulations offer clarification of the new CMP offenses created by the Cures Act. The regulations focus on fraud and other misconduct involving grants, contracts, and other agreements and include HHS programs that provide billions of dollars in funding every year. The specific categories of fraudulent or otherwise improper conduct related to HHS grants, contracts, and other agreements are included in the proposed regulations, with a focus on *knowing* violations that include, but are not limited to: a specified claim that the person knows or should know is false or fraudulent; false statements, omissions, or misrepresentations of a material fact; the making or use of false records or statements; or knowingly concealing, avoiding, or decreasing an obligation to pay with respect to these arrangements. The FAH believes that OIG discretion is appropriate, and will be critical, in applying these criteria to many of the agreements implicated under the statute and related regulations.

The statutory definition of "other agreements" under 42 U.S.C. 1320a–7a(q)(3) is broad and identifies a nonexclusive list of arrangements that would constitute "other agreements" under the statute. While the FAH realizes that this broad definition is established in the statute, we believe that the experience of hospitals and others applying for, and receiving, grants, contracts, and other agreements related to COVID-19 provides an important demonstration of why OIG discretion in implementation will be so important.

The availability of grants, contracts, and other agreements that offer funding during the COVID-19 public health emergency has greatly assisted the ability to react and respond to the critical health care needs during this time, but it has also created new challenges, and potential

pitfalls, for those providing that care. For example, the CARES Act Provider Relief Fund has caused confusion for those participating or deciding whether to participate. HHS has admirably issued guidance quickly on these newly formed programs, and due to the time pressures of the pandemic, often this guidance is then updated or revised days or weeks later, sometimes after a recipient has agreed to accept a grant and attested to its terms. With the influx of information that our members are trying to track and then implement correctly, while at the same time focusing on providing the health care services that are critically needed during this time, the FAH is concerned that this raises the risk for situations in which inadvertent missteps may lead to potential significant liability under these new CMPs.

This is where the discretion of the OIG is so important. This has been a challenging time and hospitals are working to continue the provision of high-quality care for patients, as well as ensuring the long-term economic survival of the hospitals. The added responsibility of tracking the constant flow of information, updates, and changes related to funding programs that are meant to assist hospitals has been burdensome and extremely challenging.

The FAH believes that it would be inappropriate to specifically target those that accepted funding from HHS during this public health emergency and who are expending great effort and resources to comply with the program requirements. If a party acts in accordance with initial guidance that is then later changed, the FAH does not believe that a party should be held responsible for an inadvertent misstep. Further, because the standard for fraud is "knows or should know," due to the shifting sands of Agency guidance on the terms and conditions of these grants, we urge the OIG to tread lightly before concluding that a provider should have known that it made a false representation that it abided by all of the terms and conditions.

In addition, for errors related to grants, contracts, and other agreements, particularly those related to the COVID-19 crisis, the OIG should use its discretion to focus on those parties who demonstrate a true showing of bad intent. For those parties working to comply with requirements as they evolve and are revised, a demonstration of those efforts should be sufficient to relieve them of potential penalties under these new CMPs. The FAH urges the OIG to consider a presumption that a hospital's actions do not demonstrate knowing behavior that constitutes a violation when the basis of finding such a violation is likely to be rooted in sub or regulatory guidance that has often been ambiguous and subject to frequent modifications. We recognize that the government agencies have made many of these modifications with the best of intentions to provide clarity and have done so under great time pressure; however hospitals have been under the same time pressure to then understand and implement these changes without losing their focus on providing critical health care services in an unprecedented crisis. If providers have exercised a "reasonable good faith interpretation" of grant, contract, and other agreement terms and conditions, the FAH asks that they be shielded against the imposition of CMPs under this authority.

§ 1003.720 – Determinations Regarding the Amount of Penalties and Assessments and Period of Exclusion

The OIG has proposed new § 1003.720 to include factors it may consider in conjunction with § 1003.140 as aggravating and mitigating factors when imposing penalties, assessments, and exclusions resulting from violations of the Cures Act's grant, contract, and other agreement fraud and misconduct offenses. Although the FAH supports the consideration of aggravating and mitigating factors in this context, we are concerned with certain elements of the proposal. The OIG notes that the list of factors is not all-inclusive and that it largely mirrors the list of circumstances already established under § 1003.220 that the OIG may consider as aggravating and mitigating when imposing penalties, assessments, and exclusions for violations of § 1003.200 related to the fraudulent or false submission of health care claims. However, the FAH believes that the financial thresholds established for aggravating and mitigating factors are too low and will result in overly harsh determinations for violations related to the amounts of the grants, contracts, and other agreements.

For example, the OIG proposes to consider as a mitigating circumstance if the total amount claimed or requested related to the violations was less than $5,000. The list of factors that would be considered aggravating circumstances for violations of § 1003.700 includes whether the amount requested or claimed related to the violations was $50,000 or more. The FAH requests that the OIG specifically reconsider the financial thresholds of $5,000 for mitigating factors and $50,000 for aggravating factors.

Establishing a threshold of only $5,000 for a mitigating circumstance is likely going to be too low to truly mitigate grant, contract, and other agreements fraud and misconduct offenses. It does not seem likely that such a low dollar amount is going to be impactful when many of the grants, contracts and other agreements subject to these provisions involve much larger amounts. In a similar way, the proposed threshold of $50,000 as an aggravating factor is far too low. The FAH does not believe that penalties imposed for these grants, contracts, and other agreements should be considered under such a limited lens related to financial terms. Rather, the OIG should recognize both the amount of information required of applicants and recipients, as well as the fact that the complexity of such arrangements as discussed above, significantly increases the potential for inadvertent errors. During the COVID-19 crisis, the financial needs of the hospitals are substantial and, in recognition, Congress and HHS have made significant amounts of funds available so that hospitals can continue to provide care in their communities. For those reasons, the FAH urges the OIG to consider increasing the proposed threshold amounts for mitigating and aggravating factors. At a minimum, our suggested threshold amounts for consideration by the OIG are a threshold of $50,000 as a mitigating factor and amounts over $250,000 for a determination of an aggravating factor when imposing penalties.

§ 1003.710 – Amount of Penalties and Assessments

Additionally, the FAH urges the OIG to use its discretion when imposing CMPs for findings of fraud or misconduct related to grants, contracts, and other agreements. The Proposed Rule notes that OIG will codify at new § 1003.710 the maximum statutory penalties and assessments the OIG may impose for these offenses. The FAH understands that these maximum

ranges are established by the statute. However, the FAH does not believe that the upper limits of the penalties will be appropriate for most of the potential violations that may occur under these new CMPs. Ideally the OIG would reserve the upper limits of the CMP ranges for those violations that are clearly egregious and worthy of such punishment, and not the majority of actual or potential violations related to the grants, contracts, and other agreements. The FAH asks that the OIG consider carefully the facts and circumstances of each actual or potential violation when imposing the CMPs and reserve the upper limits for those who are found to have committed the most deliberate violations and those that lead to the greatest harm to federal health care programs.

Subpart N – CMPs for Information Blocking

§ 1003.1400 – Clarify that Health Care Providers Will not be Considered a Health Information Network or Health Information Exchange (HIN/HIE)

The FAH supports the exclusion of health care providers that act only as providers from the scope of the Proposed Rule and not subjecting them to the proposed civil monetary penalties (CMPs). As the Proposed Rule points out, health care providers are already subject to information blocking prohibitions pursuant to *the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA*) Public Law 114-10.

However, the FAH objects to the Proposed Rule's proposal to subject providers that can be said to perform functions that fall within the definition of HIN/HIE to CMP liability, notwithstanding that such functions may only be a necessary byproduct of their duty to provide care for their patients. The definition of HIN/HIE as promulgated by the Office of the National Coordinator for Health Information Technology (ONC) is broad and includes any entity that determines, controls, or has the discretion to administer any requirement, policy, or agreement that permits, enables, or requires the use of any technology or services for access, exchange, or use of electronic health information for treatment, payment, or health care operations purposes. These are functions that health care providers arguably perform on a daily basis for the purpose of providing care to their patients.

This ambiguity and potential uncertainly in attempting to distinguish between an HIN/HIE and other entities that deal with the exchange of electronic health information (EHI) was contemplated in the ONC Final Rule. The ONC noted that the proposed definition of HIN/HIE could encompass an entity that does not directly enable, facilitate or control the information exchange, but nonetheless exercises control or substantial influence over the policies, technology or services. Concerned about the potential conflict and ambiguity between the terms "health care provider" and "HIN/HIE," ONC narrowed the definition of HIN/HIE by removing the "substantially influences" language (85 Fed. Reg. 25642, 25802 (May 1, 2020)). While the FAH fully recognizes and acknowledges that these ultimate distinctions are properly within the jurisdiction of the ONC in its interpretation of the information blocking rule, we urge the OIG to consider these distinctions in the drafting of *the CMP rule* which it has proposed.

Without more clarity in this distinction, health care providers may be subject to the new CMPs which would frustrate Congress's purpose in providing for a two-tiered system of penalties (*i.e.*, CMPs and appropriate disincentives), and also could result in providers being penalized under both sets of penalties. Therefore, the FAH strongly suggests that Final Rule adopt the position that CMPs may be issued to only those individuals or entities who operate as an HIN/HIE as their *primary* function and purpose. Specifically, the FAH strongly suggests revisions to the proposed text for 42 C.F.R § 1003.1400 such that it would read:

> "The OIG may impose a civil monetary penalty against any individual or entity whose primary purpose and function meets the definition of health information network or health information exchange as those terms are defined in 45 C.F.R. 171.102, which specifically excludes individuals and entities whose primary purpose and function is that of a health care provider as defined under 42 C.F.R. 171.102."

Should the OIG not adopt the FAH's suggestion, at a minimum, the OIG should take into account an entity's primary purpose as a provider (and its concomitant lack of expertise as an HIN/HIE) when exercising its discretion of whether to issue a CMP, and if so, the amount of such CMP. In this regard, the FAH notes that the proposed standard for a knowing information blocking violation is "knows or should know that [a prohibited] practice is likely to interfere with, prevent, or materially discourage the access, exchange, or use of electronic health information" (85 Fed. Reg. 22979, 22980 (April 24, 2020)). Should the OIG not adopt the FAH's suggestion, the Final Rule should make clear that, in employing the "knows or should know" standard, the OIG will take into account the particular individual or entity at issue. Providers that only secondarily act as an HIN/HIE should not be regarded as having the same knowledge as to whether a particular practice is likely to interfere with, prevent, or materially discourage the access, exchange, or use of EHI as would be expected of an entity that is primarily an HIN/HIE.

Extend the Rule's Effective Date to after the COVID 19 PHE

The new compliance requirements necessary under the ONC's information blocking requirements and process implementation steps are complex and present challenges for providers under the best of circumstances. Even in the absence of a pandemic, the time required to implement these changes would require longer than 60 days as set forth in the Proposed Rule. However, considering the uncertainty of COVID, the FAH strongly suggests the effective date be at least six months to a year from the Final Rule's publication and in no circumstances less than six months *after* the cessation of the COVID PHE.

§ 1003.1410 – Limit the Imposition of CMPs to an Overall Practice of Information Blocking as Opposed to Individual Transactions

The Proposed Rule (at 42 C.F.R. § 1003.1410) would provide for the imposition of CMPs per violation, which is a "practice" as defined at 45 C.F.R. § 171.102. When used as a noun, a "practice" is traditionally defined to mean repeated actions, or the customary or systemic way of

doing something.[5] However, under the ONC's rule at 45 C.F.R. § 171.102 it is defined as an act or omission, which the FAH is concerned could be interpreted as more isolated and incremental in nature. The exchange of information is comprised of numerous transactions and/or requests for information. As such, if a "practice" is considered to be a single prohibited information blocking occurrence, the number of acts or omissions resulting from a single transaction or request/exchange of information could be considered multiple "practices," translating into significant penalties (if no exception is applicable). The FAH suggests that the OIG clarify in the Final Rule that a violation is a true practice or behavior as opposed to multiple or incremental acts or omissions pursuant to such systemic practice/behavior. The focus for determining a violation should be the overall impact of the behavior, not the number of specific or separate acts performed by the accused actor.

§ 1003.1410 – The OIG Should Exercise Discretion in Imposing Penalties

Given the significant penalties for information blocking of up to $1 million per violation, the FAH strongly encourages the OIG to utilize its enforcement discretion and focus on information blocking behavior that results in harm to patients and health care providers, as opposed to technical violations of the law that do not have a similar impact.

Further, the FAH suggests that any future enforcement action against health care providers (and/or health care providers that perform HIN/HIE functions) focus first on education and outreach and then transition to a gradual application of enforcement actions, such as a corrective action plan, before assessing monetary penalties. In particular, ONC and OIG should notify a provider that may become the subject of an information blocking investigation and/or enforcement action. Such notification would allow the provider an opportunity to conduct a self-assessment and, if the practice in question requires modification, alter its practice to come into compliance with the regulation. Alternatively, the provider may be able to provide up-front information to ONC and the OIG that favorably resolves the investigation and/or enforcement action. Either scenario preserves ONC and OIG resources while achieving the desired outcome.

If actors fail to implement the corrective action plan satisfactorily or are repeat offenders, penalties would be appropriate, but they should first be given the opportunity to demonstrate that they have learned from their mistake and that they have a process in place so as not to repeat it.

[5] Practice is defined as the following, 1(a) actual performance or application, (b) a repeated or customary action, (c) the usual way of doing something, (d) the form, manner and order of conducing legal duties and prosecutions; 2(a) systematic exercise for proficiency, (b) the condition of being proficient through systematic exercise; 3(a) the continuous exercise of a profession, (b) a professional business. *See,* *https://www.merriam-webster.com/dictionary/practice*.

Support for Safe Harbors and Other Allowances for Compliance with Federal and State Law and Encourage Coordination Among Other Agencies

The ONC recognized in the information blocking final rule that health care providers are required to comply with other federal and state laws concerning privacy and security protections (e.g., HIPAA, 42 CFR Part 2). While the Cures Act makes clear that information blocking provisions are meant to complement rather than supplant existing law, the FAH remains concerned that ONC's very broad information blocking definitions create conflict with these other statutory and regulatory requirements. As such, while the FAH appreciates the ONC's exception to information blocking for practices required by law, we are concerned that limiting the exception to required practices fails to give full force and effect to the other federal and state requirements and limitations on the exchange of information. Examples of these other requirements include the "minimum necessary requirement under HIPAA and numerous, variable and ambiguous state privacy and security laws that are often more stringent than federal laws.

The FAH supports the OIG's inclusion of "actual knowledge" as one of the types of conduct it plans to prioritize for investigations, as evidenced by the presence of "intent." We are concerned, however, that the overlapping statutory and regulatory regimes described above could complicate the determination of "intent" as entities struggle to balance these competing requirements. Given these complexities, is imperative that the OIG work with other agencies that administer these rules to understand the obligations and vagaries of each structure, as well as their interactions, and to implement a safe harbor for practices that occur within this Venn diagram. Further, in the event the OIG contemplates the imposition of CMPs, the OIG should also coordinate with other federal and state agencies and governments to avoid potential duplicative penalties or corrective action.

****

The FAH appreciates the opportunity to comment on this Proposed Rule. We realize that the OIG is working to effectuate the changes and updates to the CMPs in accordance with the authority it is granted to do so. The FAH asks that the OIG consider the impact of the proposals on the healthcare industry during this most unique time, and going forward, to ensure that the CMPs are enforced in a fair and effective manner. If you have any questions regarding our comments, please do not hesitate to contact me or a member of my staff at (202) 624-1500.

Sincerely,