



Charles N. Kahn III
President and CEO

December 22, 2023

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, S.W.
Washington, DC 20201

Micky Tripathi, PhD
National Coordinator for Health Information Technology
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, DC 20201

RE: RIN 0955-AA05, 21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking; 88 Fed. Reg. 74,947 (November 1, 2023)

Dear Administrator Brooks-LaSure and Dr. Tripathi:

The Federation of American Hospitals (FAH) is the national representative of more than 1,000 leading tax-paying community 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 areas across 46 states, plus Washington, DC, and Puerto Rico. Our members include 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 opportunity to provide the Department of Health and Human Services (HHS), the Office of the National Coordinator for Health Information Technology (ONC) and the Centers for Medicare & Medicaid Services (CMS) with feedback on the proposed rule regarding the *21st Century Cures Act: Establishment of Disincentives for Health Care*

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Providers That Have Committed Information Blocking (Proposed Rule). The FAH continues to believe in the importance of health information sharing to improve the quality and efficiency of care provided to patients. The FAH appreciates HHS's commitment to improving interoperability and patient access to information and recognizes that the proposed rule implements statutory requirements to penalize acts of information blocking by health care providers.

HHS proposes to establish a framework for penalties for all providers, as broadly defined in the *21st Century Cures Act*. However, the Proposed Rule only includes specific penalties for certain providers participating in Medicare programs: IPPS hospitals, critical access hospitals, clinicians in the Merit-based Incentive Payment System (MIPS), and ACOs/participants in the Medicare Shared Savings Program (MSSP). The Proposed Rule also would establish a public-facing website listing the amounts of penalties and other information about entities that have been found to have engaged in information blocking. The FAH offers the below comments and recommendations regarding these proposals to ensure that any disincentives are implemented fairly and focus on egregious acts of information blocking. Our comments focus on the disincentive proposals for hospital providers, but the approaches and recommendations outlined in our comments below also apply with respect to applying the disincentives to the Merit-Based Incentive Payment System (MIPS) under the Quality Payment Program and Medicare Shared Savings Program.

Disincentives Should Be Educational Rather Than Punitive

Disincentives for hospitals and other providers under the Proposed Rule should take an educational and not a punitive approach, at least initially, until agencies and providers have much greater experience with investigating claims and working with providers to remedy any potential information blocking. Hospitals systems and other health care providers face a multitude of varying types of requests from different individuals and organizations, and providers' ability to share patient health information may be limited by the *Health Insurance Portability and Accountability Act* (HIPAA), other federal or state laws, or by professional ethics or judgment, based on the particular facts and circumstances of the request for that information.

On top of this existing web of privacy requirements, the information blocking rules add a new and complex set of prohibitions with nine exceptions, each of which has multiple conditions and preconditions. Some of the exceptions, such as the harm or privacy exception, require individual clinicians to make judgements about how the disclosure of protected health information (PHI) might impact the well-being of individual patients and any other individuals who may have information included in a patient record (such as a spouse or dependent). For many decades, clinicians have been trained to withhold data, as appropriate, especially for sensitive data, such as that relating to oncology or genetics. It takes time and experience to ensure that clinicians appropriately share sensitive data without running afoul of HIPAA. Further, in many cases, providers face state or local laws that require the withholding of information that would be sharable under HIPAA, such as in the case of adolescents or with respect to sensitive information. This complexity is compounded by the timing of the

information blocking rules, which were promulgated during the height of the COVID-19 pandemic, when providers were focused on addressing a global and unprecedented public health emergency.

Given these unique circumstances, as discussed above, the FAH urges HHS to begin enforcement of the information blocking rules with an educational approach. For example, HHS could begin with initial investigations of complaints against providers that are educational in nature and allow for development of a corrective action plan, while using enforcement discretion regarding the amount of the monetary penalties. Specifically, HHS 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 HHS that favorably resolves the investigation and/or enforcement action. Either scenario preserves HHS 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.

As the HHS Office of Inspector General (OIG) discussed in its information blocking civil monetary penalty (CMP) final rule issued earlier this year, HHS has the ability “to conduct individualized education and corrective action plans when an actor has committed information blocking.”¹ Further, CMS uses this type of approach in its survey and certification program, where common problems and best practices are identified and shared to support a culture of continuous improvement. A period of investigation with a focus on sharing lessons learned would provide time for HHS to create a more balanced approach across providers, rather than only establishing penalties for a subset of Medicare providers. Health care providers should not be subject to potentially significant and egregious penalties for inadvertent errors or circumstances not envisioned by either the agencies or health care providers during the initial implementation of the information blocking rules.

CMS and HHS have previously implemented nonenforcement policies when implementing new programs or policies in order to permit individuals or entities additional time to transition to a new set of requirements imposed upon them without fear of facing substantial penalties for inadvertent errors or unintended noncompliance. Periods of nonenforcement are designed to afford the agencies and the regulated stakeholders a smooth transition period during which stakeholders develop a full understanding of the scope of the new requirements and the steps required to come into full compliance with them. It also provides the agencies with regular feedback from and ongoing dialogue with stakeholders about compliance complications and unintended consequences associated with the regulations as initially implemented.

¹ See 88 Fed. Reg. 42,824 (July 3, 2023) discussing HHS’s ability under the Public Health Service Act (PHSA) and other regulations to engage in education and to establish corrective action plans in response to information blocking.

While ONC has provided general education on information blocking, providers have very limited understanding of how best to comply with the complex information blocking prohibitions and document compliance with the multi-part exceptions when circumstances make the sharing of information inadvisable (e.g., harm or privacy concerns) or infeasible due to technology or other constraints. Physicians and small hospitals, in particular, have not had the time or resources to fully understand the many nuances of the information blocking rules. Therefore, we urge ONC to publish examples, drawn from the hundreds of information blocking complaints that have been received to date, to educate providers on the practices that are acceptable and those that are not, including providing distinctions for what ONC would deem intentional or otherwise.

Providers Need More Transparency Around the OIG Investigatory Process

The Proposed Rule references an OIG final rule regarding civil money penalties (CMP) for other actor types covered by the information blocking prohibition (i.e., developers of certified health IT and health information exchanges/networks). That rule states that the OIG will conduct investigations of providers using the following priorities to identify complaints to investigate:

- Patient harm;
- Impact on a provider's ability to care for patients;
- Duration of practices; and
- Financial loss to federal health care programs or other government or private entities.

These proposed priorities are appropriate. We also support the OIG's efforts to coordinate with other necessary agencies to investigate information blocking claims and implement appropriate disincentives. **However, providers need much greater transparency and additional guidance on the investigatory process and how the OIG and other agencies would carry out their respective investigations. The Proposed Rule does not provide sufficient information for providers and therefore there is not an adequate opportunity for providers and other interested stakeholders to provide comments about the investigation process.**

As discussed in further detail below, the Proposed Rule does not outline key components of an investigation, such as defining "harm," proving intent, or how providers would be notified of an information blocking claim. These factors and more are critical for a provider to understand a claim and to implement a remedy if information blocking has occurred. For example, if a provider is not aware of how they would be notified of an information blocking claim, an attempt by an agency to notify a multi-hospital health system could get lost in the system if the correct, identifiable person is not notified and thus the provider could not timely act to respond or remedy the issue, if needed.

Further, the above-referenced OIG final rule implementing information blocking CMPs for actors other than providers explicitly states that rule does not apply to providers. Specifically, that rule states:

“[S]ection 3022(b)(2)(B) of the PHSA provides that any health care provider determined by OIG to have committed information blocking shall be referred to the appropriate agency to be subject to appropriate disincentives using authorities under applicable Federal law, as the Secretary of HHS sets forth through notice and comment rulemaking. **This final rule does not implement section 3022(b)(2)(B) of the PHSA.**”² (Emphasis added.)

It further states:

“To improve public understanding of how we anticipate we will approach information blocking CMP enforcement, we further provide in section III of this preamble an informational statement to supplement the discussion set forth in the proposed rule. **We note that this discussion of anticipated approach is limited to our investigation of those entities subject to CMPs and does not apply to the investigation of health care providers that may be referred for disincentives under section 3022(b)(2)(B) of the PHSA.**”³ (Emphasis added.)

In accordance with these statements, we urge the OIG to engage in additional rulemaking to allow providers an opportunity for notice and comment, or at a minimum provide detailed guidance to providers before any enforcement action is taken. As discussed above, this rulemaking or guidance must address key questions, such as:

- How will a provider be informed that an investigation is underway? In a large hospital system, many actors could be subject to these claims. Hospitals and other providers have little insight as to how the OIG would contact a provider for an investigation or how another agency within HHS would contact a provider when levying penalties.
- If an individual clinician is employed by a hospital or health system or has multiple practices sites, will the OIG contact the clinician or the hospital/health system?
- What information will a provider be given about a complaint that is under investigation? What opportunity will a provider have to bring forward evidence in support of their decision making in response to a given request? What kinds of documentation or other evidence will the OIG be looking to review?
- How will the OIG:
 - Interpret particularly challenging and subjective aspects of the information blocking rules, such as determining the likelihood of harm and how harm would be defined (e.g., financial, physical, emotional harm)?

² Id at p. 42,822.

³ Ibid.

- Interpret and evaluate complex decisions where providers use their best judgment and decide not to respond to a request because of competing requirements to comply with multiple federal, state, and local privacy rules?
- Evaluate the complex information systems that are used by health care providers that may still lack the technical feasibility to share information in response to a given request?
- Determine knowledge, intent, and what is reasonable in a certain situation, given that, by regulation, a provider must **know** that a practice is **unreasonable** and is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information?
- In the event that a provider self-develops technology that is also commercialized for third parties, how will the OIG determine whether an organization is being investigated as a provider or a developer? The FAH urges that providers always be considered as such, and not both, however, the definitions provided by ONC present significant ambiguity and uncertainty.

None of the information provided to date by HHS or OIG addresses these critical questions. Even after they are answered, a period of educational investigations with wide dissemination of the results to identify common problems and best practices before financial penalties are assessed would allow the provider community to learn how best to balance information sharing with other compliance responsibilities.

Providers Must Have an Opportunity to Appeal the OIG’s a Finding of Information Blocking and CMS’s Imposition of Appropriate Disincentives

In its final rule, the OIG made clear that developers and HIEs/HINs will have both an opportunity to engage in a potential settlement negotiation and be able to appeal a finding of information blocking and the related CMP. In presentations, the OIG has shared the following process⁴:

General process for administrative cases and civil monetary penalties

- 1) Complaint or referral received
- 2) Investigation
- 3) Informal notice / potential settlement negotiation
- 4) Notice of penalties to defendant consistent with 42 CFR 1003.1500
- 5) Appeal of penalty to Department Appeals Board consistent with 42 CFR 1005.2

In contrast, the Proposed Rule makes no reference to an appeal process for an OIG determination of information blocking with respect to a provider. The Proposed Rule only references the ability of providers to appeal a penalty to the extent that appeal rights are part of the underlying regulatory structure (such as the promoting interoperability program, or PIP). It is

⁴ OIG presentation to the Health IT Advisory Commission, Nov 9, 2023.

completely silent on the ability to receive an informal notice and engage in a potential settlement negotiation. However, CMS stated during a presentation to the Health IT Advisory Committee on November 9, 2023, that there are no appeal rights for the proposed penalties for IPPS hospitals, CAHs, and MIPS, yet there is nothing in statute that prohibits an appeal process for providers or that limits its scope.

Providers must have an opportunity to appeal both: (i) an OIG finding of information blocking; and (ii) CMS’s confirmation of the information blocking violation and application of any disincentive thereunder. Providers also should be given notice by CMS of a possible penalty with the ability to engage in a potential settlement negotiation. This would provide them the opportunity to remediate any deficiencies before a penalty is assessed. The need for appeal rights is a basic due process concern, which is heightened by the central role of intent in determining whether an action was, in fact, information blocking. It also is a question of fairness, given that some actors will have appeal rights, while others will not if the rule is finalized as proposed.

Information Blocking Penalties Should be Scaled Proportionate to the Circumstances of the Violation

For hospitals, CAHs, and clinicians participating in MIPS, CMS would impose a penalty equal to a failure to meet the definition of a “meaningful EHR user” on any provider referred by OIG for information blocking. **This one-size-fits-all approach is egregious, is not appropriate, and would not take into account the severity of the act or allow consideration of extenuating circumstances.** This also is inconsistent with the finalized approach that the OIG is taking in assessing penalties for developers and HIEs/HINs, where the OIG lays out specific factors that it will consider when establishing the amount of the penalty, as noted below:

§ 1003.1420 Determinations regarding the amount of penalties. In considering the factors listed in § 1003.140, the OIG shall take into account:

- (a) The nature and extent of the information blocking including where applicable:
 - (1) The number of patients affected;
 - (2) The number of providers affected; and
 - (3) The number of days the information blocking persisted; and
- (b) The harm resulting from such information blocking including where applicable:
 - (1) The number of patients affected;
 - (2) The number of providers affected; and
 - (3) The number of days the information blocking persisted.

Further, the PIP encompasses a range of digital health activities beyond what might be impacted by an act of information blocking. In addition to sharing health information with patients and other organizations, eligible hospitals and clinicians engage in a range of other activities, such as use of certified EHR technology, electronic prescribing, querying of prescription drug monitoring programs, reporting to public health, implementing the Safety

Assurance Factors for EHR Resilience (SAFER) Guides, completing a security risk assessment, and submitting electronic clinical quality measures. It is unclear why a single referral for information blocking should equate to failure to meet all of the PIP, rather than a portion of the requirements. There is nothing in statute that would require this all-or-nothing approach; in fact, the statute calls for an “appropriate disincentive,” which implies that discretion and proportionality should be applied.

Accordingly, the FAH urges that CMS reconsider the approach for applying disincentives and scale the information blocking penalty proportionate to the violation, as well as the facts and circumstances of the case, including any resultant harm. If CMS believes it needs to tie the penalty to the definition of a meaningful EHR user, and therefore the PIP, CMS could establish an upper cap that is equal to the full PIP penalty for only the most egregious acts of information blocking. CMS should then assess a partial penalty for other violations scaled to the severity of the act of information blocking or if there are extenuating circumstances.

For hospitals, the link to the PIP could result in dramatically different penalties for the same act, depending on the market basket increase in the year that the penalty is assessed. For example, a loss of $\frac{3}{4}$ of the market basket increase is much more significant in years when inflation is high:

- $\frac{3}{4}$ of 4 percent market basket increase would result in the loss of 3 percent of Medicare payments;
- $\frac{3}{4}$ of a 2 percent market basket increase would result in the loss of 1.5 percent of Medicare payments.

Imposing such vastly different penalties based solely on the year in which they are assessed is inappropriate, as well as arbitrary and capricious. We also note that the Proposed Rule estimates a median disincentive amount of \$394,353, and a 95 percent range of \$30,406 to \$2,430,766 across eligible hospitals. The Proposed Rule does not provide enough information on this simulated disincentive calculation to effectively determine the reasonableness of this estimate. We encourage CMS to provide such information and to reconsider this simulation as we understand that there is much confusion across the hospital industry regarding the basis and rationale for calculating this estimate, as well as differences in industry estimates when attempting to replicate CMS’s simulation.

Further, as noted in the Proposed Rule, for clinicians participating in MIPS, failure to meet the PIP due to a referral for information blocking will almost certainly lead to a negative payment adjustment. Given the complexity of the program, the many reporting requirements, and the limited ability to earn a positive incentive, participation in MIPS is onerous. Large information blocking penalties for a single instance of information blocking could dissuade providers from continuing to strive to improve their performance in the other categories, such as clinical quality measures. Receiving an automatic MIPS penalty for a single instance of

information blocking also could tip the scales toward non-participation, which could adverse consequences, including access challenges for Medicare beneficiaries.

Further, CMS has proposed that penalties for clinicians that participate in MIPS will apply to the TIN associated with a given clinician. This means that all members of a given TIN could be penalized if a single clinician has been found to have engaged in information blocking. This kind of collective penalty is inappropriate, particularly when a TIN can include hundreds of clinicians. And, while CMS notes that a group may modify its TIN before a penalty is assigned, that is generally not a feasible remedy, given that a TIN may be used in multiple circumstances, including contracting with private payers and other legal and financial arrangements. In addition, the use of group practice reporting has conveyed significant operational and reporting benefits under MIPS that would be undone if a TIN was modified as outlined by CMS.

The FAH supports HHS's proposal to use the date of referral instead of the date of the occurrence of information blocking to assess penalties. This would allow providers to plan for a penalty and avoid the need to reprocess claims. As stated above, penalties should only be assessed after providers have had the opportunity to assess and refute the claims against them, engage in corrective action if necessary, and appeal both the finding of information blocking and the imposition of a disincentive.

The Complex Web of Privacy Rules Needs to Be Simplified

The ability for health care providers to comply with information blocking is complicated by multiple, possibly contradictory privacy requirements at the federal, state, and local levels. Providers also are seeing claims of information blocking when responding to a request would not comply with HIPAA. Some parties, including payers, may cite information blocking as a reason to access information that they are not legally entitled to receive, putting providers in a difficult position as sharing the data would violate HIPAA.

The FAH urges HHS to work with Congress to establish a national privacy law that protects sensitive information under a single set of rules, regardless of the entity that has the information. The FAH also urges HHS to provide more general education on the HIPAA right of access for both individuals and providers, to ensure that patients can access their information and limit the confusion of concerns regarding right of access and information blocking. Finally, HHS should consider whether there is a need to monitor requests for information by payers and other parties that are clearly not permissible under the HIPAA Privacy Rule.

Transparency Provisions Should Not Be Punitive

The Proposed Rule would establish a public website listing information about entities that have been penalized for information blocking. For providers, ONC proposes to publicly report

health care providers names, business addresses, information blocking practices, penalty amounts, and links to any additional information about the violation.

The FAH believes that transparency should start with education and not be a “wall of shame.” Therefore, we urge that ONC delay the launch of this website until regulated providers and the various federal agencies involved have had sufficient experience with investigations and referrals for disincentives. While transparency into where information blocking conduct occurred would benefit the broader health information infrastructure, we believe it would be in the best interest of all stakeholders to not publicize cases of information blocking penalties until actors receive clearer guidance. If ONC chooses not to implement a delay, we recommend that violations be listed in a de-identified manner.

The FAH also urges that the following guardrails be implemented to avoid confusion about the website:

- Health care providers should not be listed publicly on the website until after they have had an opportunity to appeal the information blocking determination and any disincentive that has been imposed. Similarly, providers undergoing education and/or corrective action plans should not be listed publicly as information blockers.
- ONC should specifically state the year in which the information blocking violation occurred. Otherwise, patients will be confused as to whether a provider is currently engaging in information blocking or doing so on an ongoing basis.
- ONC should establish a policy to remove providers from the website after a certain number of years after the violation occurred, or after a provider has remediated a violation, whichever is sooner. It is not appropriate, and also is confusing, to imply that a provider continues to engage in information blocking by keeping a listing for a long period of time, or after the violation has been corrected.
- ONC should establish criteria outlining significant impacts that warrant placing a provider on the website. This avoids confusing minor acts of noncompliance with systematic violations and is parallel to the process OCR follows, which only lists breaches of unsecured PHI affecting 500 or more individuals.⁵

Clarifications

The FAH respectfully asks that HHS clarify the following:

- Only one penalty will be assessed in a given year, including when multiple acts/years of information blocking were included in the OIG investigation that is referred to CMS as this would be an appropriate course of action.

⁵ [U.S. Department of Health & Human Services - Office for Civil Rights \(hhs.gov\)](https://www.hhs.gov/)

- If an information blocking complaint to ONC or OIG turns out to be a concern about individual access rights under HIPAA (or other HIPAA issues), and not information blocking, will the complaint be referred to OCR and will OCR then conduct its own investigation?
- How will CMS assess penalties for entities or clinicians where ownership or employment has changed due to mergers and acquisitions? Entities should not be penalized for the past behavior of a newly acquired provider organization or newly employed clinician.

The FAH appreciates the opportunity to provide comments on the Proposed Rule. We look forward to continued partnership with HHS as we strive to advance the use of health information technology to improve our nation's health care system. 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,

