GREATER NEW YORK HOSPITAL ASSOCIATION
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Via Electronic Mail

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue, SW
Washington, DC 20201

Micky Tripathi, PhD
National Coordinator for Health Information Technology
Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

RE: Proposed Rule: **RIN 0955-AA05: 21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking (*Vol. 88, No. 210*, November 1, 2023)**

Dear Administrator Brooks-LaSure and Dr. Tripathi:

On behalf of the 222 voluntary and public hospitals and health systems in four states that make up the acute care membership of Greater New York Hospital Association (GNYHA), I appreciate this opportunity to respond to the US Department of Health and Human Services' (HHS) proposed rule that establishes significant financial disincentives for health care providers that have committed information blocking.

GNYHA members are committed to the underlying goals of the information blocking rule. They are sharing more and more information electronically with requestors such as other treating providers and patients. They acknowledge there is room for education and remediation as providers work through the complexities of meeting those goals in an age of increasing—and increasingly complex—health care technology advancements.

Unfortunately, the proposed rule veers too far in the direction of punitive measures. The financial disincentive structure runs contrary to what we believe is the most appropriate policy: allowing providers to learn and correct their behavior. And the proposed penalties themselves are so draconian that they risk undercutting the ability of hospitals—especially struggling safety net hospitals—to keep up with the technological and workforce requirements necessary to comply with the information blocking rule in the first place. If finalized, this rule could end up creating a vicious cycle of noncompliance, an unintended and truly unfortunate consequence. Providers may be forced to curtail certain services they provide not just to patients, but also to their community partners.

For these reasons, we ask that HHS rethink the proposed approach and instead develop one that, in most cases, focuses on technical assistance and education in lieu of imposing financial disincentives. We also urge HHS to answer the many open questions about how the investigation and enforcement processes will work, which we detail in our attached comments.

Thank you again for this opportunity.

Sincerely,

Kenneth E. Raske
President

Detailed Comments

Background; Damaging Financial Impacts

It is important to recognize the various ways the proposed rule could financially impact hospitals. If it is finalized as written, the median disincentive among GNYHA members would be $952,000, based on our internal analysis. This is almost three times the amount that HHS estimates as the median for hospitals across the US. The largest disincentive in our membership would be a devastating $15.8 million. As if this were not bad enough, the HHS estimates fail to account for other penalties that providers may be subject to. In this regard, almost all GNYHA members participate in the Promoting Interoperability (PI) program and are subject to the same penalties under that rule as proposed here. While HHS proposes that PI penalties not be imposed in the same calendar year as penalties under this rule, back-to-back penalties would nevertheless be catastrophic. Some of our members also take on the work of providing health information technology (HIT) functionality or health information exchange (HIE) services to their community partners, such as community-based organizations working on social needs, to provide whole-person care. These members may consequently be subject to the $1-million-per-violation penalty scheme directed at HIEs, health information networks (HINs), and HIT developers. Lastly, several GNYHA members could face removal from CMS's Shared Savings Program for information blocking violations, which would deprive them of that program's financial benefits and negatively impact patient case management and care coordination.

It is just as important to understand the reality facing New York hospitals and why the proposed financial penalties could severely harm them. Based on an analysis GNYHA conducted with our state hospital association, New York hospitals, on average, have a negative 3.7% margin, which represents a decrease from pre-pandemic levels. Four out of five New York hospitals report negative or unsustainable operating margins. Labor costs have risen by 17% since 2019. This not only results from the need to rely on contract labor due to chronic and structural workforce shortages, but also significant increases in compensation to unionized labor. While our workers deserve to be well-paid, Medicaid and Medicare do not come close to covering labor and other costs of running a hospital. In New York State, Medicaid shortfalls amount to approximately 30% of overall costs. Statewide, we have approximately 30 hospitals receiving significant State subsidies just to meet payroll, as they have under 15 days' cash on hand.[1]

Given this bleak context, it is clear that some hospitals may have to curtail services if they are subject to financial disincentives of the size contemplated under the proposed rule. It is therefore vitally important that HHS instead create a more reasonable, staged, and transparent enforcement structure so that the facts and circumstances underlying substantiated instances of noncompliance are considered and unintended harm is avoided. HHS also must provide direction on how providers can respond to investigations or challenge findings, since so much is at stake financially. Furthermore, much remains unknown about compliance with the information blocking rule (e.g., how the requisite intent standard is met and whether certain clinical situations would meet exception criteria). HHS should provide more examples and insight into how information blocking violations occur.

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[1] *See e.g., New York State's Hospital Vital Access Provider Assurance Program*; https://www.health.ny.gov/facilities/hospital/vapap/ (last accessed December 22, 2023)

Finally, the US Supreme Court's decision in *Dobbs v. Jackson Women's Health* has heightened the longstanding challenges with sharing information instantly in an increasingly complex HIE environment. Like other providers, GNYHA members are considering how to share reproductive health information where the intent of requestors may be unknown and the patient's safety may be at issue in the future. Unfortunately, the Office for Civil Rights' (OCR) proposed rule on reproductive health care—which is not yet finalized—does not address the routine flow of information. As HHS is aware, there remain technical and policy challenges with segmenting and withholding health information.[2] This concern is not unique to reproductive health information. Concerns have also been raised across the US about other types of information, such as behavioral health and gender identity information. This concern is yet another reason why HHS should consider a technical assistance and educational approach to compliance with the information blocking rule, rather than the severe financial penalties proposed.

For all of these reasons, we urge HHS to do the following:

Technical Assistance or Education in Lieu of Financial Penalties

We urge HHS not to finalize the proposed rule as written, which aligns the penalty scheme with the PI Program. We recognize that HHS is required to tie the appropriate disincentives to an existing penalty scheme. **Instead of aligning the penalties under this rule to the PI Program, we ask that HHS align the appropriate disincentives with the penalty process and structure that exists for HIPAA violations.** HIPAA's tiered penalty structure is well known to providers, and OCR routinely provides technical assistance to providers to help them enhance their compliance efforts. For the most part, financial penalties are imposed when the provider fails to correct violations, or the violations are serious and persistent, including with rules that are longstanding, well-developed, and known to providers. That cannot be said of the information blocking rule, which was only promulgated in 2020. This approach will allow providers to learn about and remediate non-compliance, which is of the upmost importance as health care technology continues to evolve.

Fairness During the Investigative Process

The proposed rule's penalty structure is significant on its own, but the impact is exacerbated by the fact that much remains unknown about the investigative process. Although HHS references that the OIG may

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[2] *See ONC's final rule on Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing*, page 409 (unreported version)*;* https://www.healthit.gov/sites/default/files/page/2023-12/hti-1-final-rule.pdf (last accessed December 29, 2023) (explaining that proposals to patient restriction criterion is not finalized because, among other things, " . . there was no clear consensus on whether and how to proceed either with immature and untested standards or without the required use of specific standards for the certification criterion at []. We agree with the concerns on the high risk of allowing Health IT Modules to implement a wide variety of misaligned standards and implementation specifications, as well as increased burden on developers of certified health IT, care providers, health information exchange networks, and a high probability of confusion for patients."); *See also*, Bedgood M, Kuelbs CL, Jones VG, Pageler N. *Organizational Perspectives on Technical Capabilities and Barriers Related to Pediatric Data Sharing and Confidentiality*. *JAMA Netw Open*. 2022;5(7):e2219692. doi:10.1001/jamanetworkopen.2022.19692 (explaining that inability to segment components of data, such as specific laboratory results, medications, or problems, on a granular level when they are deemed confidential is a barrier to data sharing).

collect evidence during the investigation, the process of being notified of an investigation, as well as rules around responding, remain unclear. By contrast, the investigative process for HINs, HIT developers, and HIEs is quite clear.[3] **We ask that providers be given the same due process as these other actors and that HHS clarify that its current regulations that govern investigations apply to the investigation and information blocking determination.**

The proposed rule also notes that OIG will "coordinate" with the appropriate agency to which it plans to refer its determination of information blocking so that the agency is aware of the potential referral and has the necessary information to act. It appears the appropriate agency is only involved for logistical reasons and will not be involved in the investigation and information blocking determination. This is problematic because OIG does not have primary oversight responsibility for health information exchange and related matters. **The Office of the National Coordinator for Health IT (ONC), Centers for Medicare & Medicaid Services, and OCR should have more formal roles in the information blocking determination.**

In addition, the proposed rule explains that providers may appeal the imposition of the disincentives yet is silent on whether and how providers can challenge the OIG's finding of information blocking. Importantly, the appropriate HHS agency that OIG coordinates with is *required* to impose the financial disincentive and cannot override the OIG's finding. This underscores the need for the relevant agencies to be involved at the investigative stage. Further, it is critical there be a right to challenge the information blocking determination itself. **We urge HHS to include such a process. Like with the investigative process, HHS should tie this to existing rules around appeals.**

Finally, we urge HHS to delay the finalization of this rule until the other HHS agencies have completed notice and comment rulemaking as it relates to appeals of their disincentives. This will allow providers and others to have a holistic understanding of how an information blocking case will be conducted across the spectrum of HHS agencies.

Transparency around Knowledge Standard

There are still aspects of the information blocking rule that remain vague. This is particularly true of the intent standard for providers, which is a knowledge standard. OIG explains that it has "significant experience and expertise investigating and determining whether to take enforcement action based on other laws that are intent-based (for example, the Federal anti-kickback statute, and Civil Monetary Penalties Law)."[4] OIG goes on to say that this history will inform the use of OIG's discretion to investigate health care providers that OIG believes may have the requisite intent.

However, there is ample guidance and decades of case law that address the knowledge standard in OIG's other rules. By contrast, the information blocking rule was finalized in 2020 and there has been no guidance or case law on what constitutes knowledge that one is information blocking, including within

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[3] *See Information Blocking*; https://oig.hhs.gov/reports-and-publications/featured-topics/information-blocking/ (last accessed December 22, 2024) (depicting a flow chart of the investigative process for other actors, which includes conducting interviews and allowing actors to respond).

[4] *See this proposed rule*, pg. 74952; https://www.govinfo.gov/content/pkg/FR-2023-11-01/pdf/2023-24068.pdf

the ONC's own FAQs.[5] There are still many unanswered questions, including whether nuanced contract provisions between a provider and a non-HIPAA covered entity (with whom providers have little negotiating power) may be viewed as information blocking, or whether complex clinical situations would meet exception criteria, particularly where patient harm is at issue. While ONC has provided information on the total number of complaints received, the type of complainant, and the type of actor,[6] it has not provided information on what the actor did to warrant a complaint. **We ask that HHS provide more transparency into the current information blocking claims, in a redacted format, so that providers and others can better understand what HHS considers information blocking and, importantly, how the requisite intent standard is met.**

Compounding Penalties

The provider disincentives alone could have a devastating financial impact on GNYHA members, which could in turn curtail their ability to provide services. This impact is worsened when a hospital or health system is also functioning as an HIN, HIE, HIT developer, or accountable care organization (ACO) participant. They often take on these roles as part of payment program activity or simply because it is necessary for patient care. **We ask HHS to hold providers to only one penalty scheme. We also ask that HHS not finalize the disincentive that bars provider-ACO participants from participating in the Shared Savings program in future years if found to be information blocking one time.** This runs contrary to CMS's broader goals, as the removal of a provider from the program would disrupt care coordination in most circumstances.

Conclusion

We urge HHS to adopt a cautious approach given the newness of the information blocking rule and the potential for a draconian penalty scheme to undercut the efforts of hospitals to comply with the rule in the first place.

Thank you for the opportunity to comment.

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[5] *See ONC's Frequently Asked Questions*; https://www.healthit.gov/faqs (last accessed December 22, 2024)
[6] *See Information Blocking Claims: By the Numbers*; https://www.healthit.gov/data/quickstats/information-blocking-claims-numbers (last accessed December 22, 2024)