January 2, 2024

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Mr. Micky Tripathi
Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
Attention: 21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking Proposed Rule
Mary E. Switzer Building
Mail Stop: 7033A
330 C Street, SW
Washington, DC 20201

Re: 21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking Proposed Rule [RIN 0955–AA05]

Dear Mr. Tipathi:

The Pharmaceutical Care Management Association (PCMA) appreciates the opportunity to comment on the proposed rule titled "21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking" issued by the U.S. Department of Health and Human Services (HHS or Department) Office of the National Coordinator of Health Information Technology (ONC) in coordination with the U.S. Centers for Medicare & Medicaid Services (CMS), and published in the *Federal Register* on November 1, 2023 ("proposed rule").[1]

PCMA is the national association representing America's pharmacy benefit companies, which administer prescription drug plans and operate home delivery and specialty pharmacies for more than 275 million Americans with health coverage through Medicare, Medicaid, public and private employers, labor unions, retiree plans, the Federal Employees Health Benefits (FEHB) program, and exchange plans.

PCMA strongly supports the goals of interoperability and the information blocking rule, including promoting health care efficiency and care coordination by facilitating access to and the exchange of health information. We also support the imposition of penalties for information blocking, including penalties for health care providers who are found to have engaged in information blocking. This will act as a deterrent on information blocking practices, and so advance sharing of electronic health information (EHI) by health care providers to support safer, more coordinated care for all patients. We are optimistic about the Administration's approach to these issues based on its most recent final rule on health information technology, including the significant level of detail it provided in its numerous examples.[2]

[1] 88 Fed. Reg. at 74947.
[2] Published online December 13, 2023. Available at https://www.healthit.gov/sites/default/files/page/2023-12/hti-1-final-rule.pdf. Not yet published in the Federal Register.

Pharmaceutical Care Management Association
325 7th Street, NW, 9th Floor
Washington, DC 20004
www.pcmanet.org

Health care providers are required to navigate increasingly restrictive privacy laws, such as the 42 CFR Part 2 rules on the confidentiality of substance use disorder patient records and state laws imposing greater protections for certain types of sensitive data, such as mental health records, as they determine whether to share EHI in response to a request that could implicate the information blocking rule. Given that SAMHSA and OCR are revising the Part 2 rules, enforcement of information blocking requirements should take into consideration the rapidly changing regulatory landscape. Further, providers may hesitate to share EHI for risk of facing legal consequences, and the Department should consider extending the privacy exceptions enumerated in the recent HTI-1 final rule in these situations, as well. Extenuating circumstances could include any blocking that protects the unreserved right to privacy for their patients.

We also support the proposed priorities of the HHS Office of the Inspector General (OIG) in investigating health care providers for information blocking practices that potentially harm patients or significantly impact another provider's ability to care for patients. We recommend that OIG also prioritize information blocking practices that significantly impact care coordination and management by health plans, since it is often health plans and their business associates, such as pharmacy benefit managers (PBMs) that are in the best position to communicate with prescribers and other health care providers about gaps in care, drug interactions, and potential medication errors. To the extent patients obtain drugs or other care that is not covered by their health plan, it is important for health plans to be able to obtain this information to have a full and complete record of the patient's care. Health care providers should be encouraged to share these records to the extent permitted by applicable privacy laws.

The preamble to the proposed rule also discusses the process OIG intends to follow in investigating allegations or complaints of information blocking by providers and how OIG will consult and coordinate with ONC and/or the HHS Office for Civil Rights (OCR) to obtain technical assistance before making a determination of information blocking. We support this type of coordination since it is important that OIG have a full understanding of the situation and be confident in its findings before making a finding of information blocking that can result in significant financial and other penalties. However, we are concerned that there is no mention in this description of providing technical assistance or education to health care providers before making a determination of information blocking, even though HHS appears to recognize by its reference to technical consultations and assistance from other agencies, how complex and nuanced potential instances of information blocking can be. This is particularly the case for health care providers, most of which are HIPAA covered entities and so subject to multiple federal and state privacy restrictions on sharing EHI, while at the same time already subject to a HIPAA mandate to share EHI with patients and their personal representatives.

Considering these complexities, and as the Department is doing in its recent HTI-1 final rule, we recommend that HHS prioritize providing detailed examples to the public and technical assistance to health care providers before embarking on the referral process for the imposition of disincentives. Punishment should be pursued only as a last resort after education, assistance, and corrective action plans have failed, and that the health care provider fully understood the rules and nevertheless chose to engage in information blocking. A less punitive approach is not only likely to result in greater compliance but will also give HHS greater insight into areas where additional guidance would be helpful to all actors.

Notably, HHS did not propose disincentives for post-acute care facilities, community health centers, laboratories, or pharmacies. To the extent that these provider types qualify under the programs for which disincentives are proposed (e.g., as ACO participants or eligible clinicians), they would incur financial penalties if they engage in information blocking practices referred by OIG to CMS.

However, as HHS points out, these health care providers are generally not eligible for, and therefore do not participate in, the CMS programs identified for the imposition of disincentives. We agree with HHS that the information blocking regulations will not be as effective or achieve the goals of the 21st Century Cures Act unless all health care providers face appropriate disincentives for engaging in information blocking.

In this regard, we recommend that HHS consider broadening the list of entities that are considered health care providers under the information blocking rule to include durable medical equipment (DME) suppliers. DME suppliers play a central role in providing needed medical equipment to patients and coordinating with health care facilities, pharmacies, and medical professionals to ensure that patients are equipped to manage their health conditions. This is clear from the fact that Medicare treats DME suppliers and pharmacies similarly under current regulations. Based on the definition of "health care provider" in the regulation, HHS clearly has the authority to categorize DME suppliers as a type of health care provider, and we recommend that HHS take this step so that a key participant in the health care delivery system is subject to the same requirement not to engage in information blocking and will face appropriate disincentives if it does.

Our comments above regarding corrective action plans and technical assistance would apply to DME suppliers and the other categories of health care providers not addressed by the proposed rule. Given that the Medicare program makes direct payments to all of these provider types under Part A or Part B, CMS could consider similar types of approaches as they have proposed above, after appropriate rounds of technical assistance and opportunities for corrective action.

For instance, clinical laboratories that are repeatedly referred for engaging in information blocking could face the loss of annual market basket payment rate increases under the Clinical Laboratory Fee Schedule or Physician Fee Schedule, as appropriate. Crafting appropriate disincentives for these types of health care providers is essential since even though the instances of information blocking by these providers will hopefully be rare, they would be especially troubling, given the informational nexus that lab results play in health care decision-making.

Similarly, it is also imperative that pharmacies share information within the health care ecosystem. Fulsome data sharing can reduce medication errors and drug-drug interactions, avoid the over-dispensing of controlled substances like opioids, and allow plan sponsors to accumulate costs toward a Part D beneficiary's maximum out-of-pocket obligations, for example. While most pharmacy reimbursement in the Medicare program occurs under the voluntary Part D benefit, pharmacy reimbursement for a select set of retail prescription drugs and vaccines under Medicare Part B is based upon the Average Sales Price (ASP) or Average Wholesale Price (AWP) of the drug or vaccine dispensed or administered. While CMS cannot change the statutory payment rates for these items, it could propose to reduce or withhold the payments for the professional services associated with dispensing or administering them, for the following payment year, upon receipt of a referral from OIG following previous corrective action and technical assistance. As with laboratories, pharmacies exchange EHI with many different participants in the health care delivery system, and while instances of information blocking by them would likely be highly exceptional, it would also be extremely damaging to patient care.

In addition to financial disincentives to health care providers, HHS proposes to publicly post information on ONC's website about actors that have been determined by OIG to have committed information blocking. HHS states that this would provide insight into how and where information blocking conduct is impacting the broader nationwide health information technology (HIT) infrastructure, consistent with the requirement in section 3001(c)(4) of the Public Health Services Act

(PHSA) that ONC maintain an internet website ‘‘to ensure transparency in promotion of a nationwide health information technology infrastructure.’’

While we support transparency and a better understanding of the impact of information blocking on the HIT infrastructure, we do not believe it is necessary to publicly post the names of violating actors in order to provide this type of transparency. Rather than promoting transparency, this type of posting will merely impose a significant second layer of reputational punishment on violating actors that have already been penalized once financially. If ONC truly believes that publicly posting the identity of violators on its website would have a deterrent effect, at a minimum, we recommend that it reserve this type of posting for especially egregious incidents of information blocking, such as actors that have been financially penalized on multiple occasions and nevertheless continue to engage in information blocking practices.

Thank you for the opportunity to comment on this proposed rule, which is an important component of the information blocking regulatory framework being established to ensure the appropriate and beneficial flow of EHI in the health ecosystem.

Sincerely,

Tim Dube

Tim Dube
Vice President, Regulatory Affairs

cc: Debjani Mukherjee, Senior Director, Regulatory Affairs, PCMA