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January 2, 2024

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U.S. Department of Health and Human Services (HHS)

Centers for Medicare & Medicaid Services (CMS)

Attn: The Honorable Chiquita Brooks-LaSure, Administrator

Office of the National Coordinator for Health Information Technology (ONC)

Attn: Micky Tripathi, PhD, MPP, National Coordinator for Health Information Technology

Re: 21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking Notice of Proposed Rulemaking (HHS-ONC-2023-0018)

Dear Administrator Brooks-LaSure and Dr. Tripathi:

The American Psychiatric Association (APA), the national medical society representing over 38,000 psychiatric physicians and their patients, appreciates the opportunity to comment on information-blocking disincentives and support the Centers for Medicare and Medicaid Services (CMS) and the Office of the National Coordinator for Health Information Technology (ONC)'s efforts to improve patient access to their health information. APA shares the Biden-Harris Administration's commitment to improving equitable access to health information and recognizes HHS's obligation to operationalize the objectives of the 21st Century Cures Act. **APA is concerned that CMS's and ONC's objectives will not be met by this proposed rule and we urge the Agencies to provide incentives and technical assistance to support clinicians in acquiring and maintaining the infrastructure necessary to exchange data.**

APA is concerned that the proposed rule:

1. will disincentivize Medicare participation among psychiatrists, counteracting a key strategic priority of CMS to improve psychiatric care access for Medicare beneficiaries;
2. inadequately acknowledges diverse practice resources, capabilities, and infrastructure, risking enhancing inequity across practices;
3. focuses penalties on the wrong actors by penalizing individual clinicians; and
4. has inadequate protections for clinicians acting in good faith.

To fulfill the 21st Century Cures Act’s mandate for development of “appropriate disincentives” while meeting HHS’ objective of data use for patient empowerment and population health, we recommend that **HHS phase in enforcement, beginning with education and providing physicians with incentives to address structural factors and limitations in provider data-sharing and, if changes are not made followed by notice and corrective action.** CMS, ONC, and the Office of the Inspector General (OIG) have the opportunity to meaningfully improve data exchange by implementing corrective actions and working *with* clinicians and provider organizations as the front line of our health care system rather than against them. Starting with notice and corrective action is consistent with enforcement approaches undertaken in various other HHS efforts, especially when the underlying regulatory approach is novel and complex.

We also strongly urge the Agencies to clarify the significant open questions that remain about the proposed disincentives through supplemental notice-and-comment rulemaking before any enforcement begins. Physicians and their colleagues remain unclear about the definition of information-blocking and its practical implications, including the allocation of responsibility for information-sharing failures caused by health IT vendors. APA has requested clarification from ONC regarding the definition of specific information-blocking activities and exceptions, including examples that will help clinicians and compliance professionals achieve HHS’ objectives. **OIG must define an appeals process and a process for establishing intent through investigation,** a core component of enforcement that remains operationally unclear without OIG clarification or precedent. This rule, when finalized, should describe OIG’s experience with establishing intent among health care providers specifically – the OIG Information Blocking Final Rule published on July 3, 2023, was focused on the developer community and provides very little detail on how the investigatory process will occur for providers.

Clinicians are not willfully or maliciously blocking data. APA’s members represent a diverse cross-section of practice types, including solo and small-group practices, community-based clinics, and hospital systems. Psychiatry has a relatively large percentage of clinicians practicing independently, in solo and small practices. Given the drastic shortage of psychiatrists and other mental health clinicians, it is imperative that HHS understand and reflect the structural features of small and independent practices in this rulemaking – not just hospital systems. A 2021 report to the Medicaid and CHIP Payment and Access Commission (MACPAC) found that only 61% of office-based psychiatrists were using an EHR.¹ For small practices, many of whom lack even the practice management infrastructure to bill Medicare and participate in value-based care programs, their ability to continue to serve the Medicare population is contingent on receiving the reimbursements they have budgeted for and working with the infrastructure they have. **If a clinician cannot fulfill a patient’s request for data due to infrastructural limitations – lack of electronic health record (EHR) functionality, lack of staffing, or lack of time – it is unclear how the Agencies expect those same providers to demonstrate the presence of a valid information-blocking exception or respond to and manage an information-blocking allegation.** Rather than incentivizing data sharing among these clinicians, this simply risks access to care for Medicare beneficiaries.

¹ <https://bhbusiness.com/2021/11/13/behavioral-health-providers-falling-behind-in-ehr-adoption-critical-to-participate-in-value-based-care/>.

The Agencies' objective of expanding disincentives beyond Medicare may be even less effective at promoting information-sharing among psychiatrists that do not participate in Medicare value-based care arrangements. These practices have a lower likelihood of possessing the core technical infrastructure (e.g., EHRs, electronic billing software) that enables Medicare participation and increases feasibility of meeting information-sharing standards. **Focusing the Agencies' efforts on education and support among smaller and less-resourced practices is paramount to expand information-sharing efforts across the market.** Further, we recommend that **HHS establish a centralized coordinating office to implement information blocking disincentives** and provide a point of contact for technical assistance, resolve any issues, and reduce administrative burden on clinicians.

I. Financial disincentives

As the 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."² **We strongly believe that this would be the most appropriate first step in establishing disincentives for clinicians and would likely improve future compliance with the information blocking requirements.** Without such outreach, we are concerned that many psychiatrists and other actors will fail to fully understand and learn how to avoid instances of information blocking, may have limited ability to assess their own conduct, and will ultimately face penalties that could be avoided. In mental health care settings in particular, clinicians have legitimate concerns about balancing patient confidentiality (e.g., in the case of 42 CFR Part 2 records indicating the presence of a substance use disorder) with information sharing. **Technical assistance is necessary to reconcile conflicting legal, technological, and ethical considerations regarding data collection, storage, and dissemination.**

The American Medical Association reports that Medicare physician pay has fallen 26% since 2001, threatening the viability of physician practices and patient access to care.³ **Further reductions to reimbursement will severely hamper access to care for Medicare patients.** The National Association for Behavioral Healthcare reports that the average operating margin for inpatient psychiatric facilities was negative five percent in 2019, with over half of inpatient psychiatric facilities operating in negative margins.⁴ Data from the 2022 Medicare cost report indicated that the *average* operating margin for hospitals overall was at negative 11.7 percent.⁵ Meanwhile, hospitals that provide higher levels of uncompensated or low-compensation care and those that are located in socioeconomically disadvantaged areas are associated with lower operating margins, demonstrating the compounding inequity of focusing disincentives on clinicians and systems with fewer technical and staff resources to deliver data to patients rather than supporting those clinicians and systems.⁶

² <https://www.govinfo.gov/content/pkg/FR-2023-07-03/pdf/2023-13851.pdf>.

³ <https://www.ama-assn.org/system/files/medicare-basics-medicare-economic-index.pdf>.

⁴ <https://www.nabh.org/wp-content/uploads/2019/03/The-High-Cost-of-Compliance.pdf>.

⁵ <https://www.definitivehc.com/resources/healthcare-insights/hospital-operating-margins-united-states>.

⁶ <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2803940>.

Under the proposed rule, physicians could also be subjected to multiple disincentives based simply on their participation in multiple programs, not based on the culpability of their conduct. **This creates the risk that participation in multiple programs would open the physician to duplicative enforcement risk.** A final rule would need to establish a clear process within HHS to reconcile multiple disincentives being applied and to ensure that the resulting punishment is not unfair and disproportionate to the provider's behavior. The Agencies should establish a disincentive clearinghouse process to ensure the disincentives applied are not duplicative, arbitrary, and unduly punitive.

Additionally, APA members have significant concerns about the operational and financial implications of the MIPS-related proposal. **In the draft rule, an information-blocking determination for one physician would affect the score of the entire practice group** if the group reports the MIPS Promoting Interoperability (PI) performance category at the group level. Group practices will have decreased incentive to report at the group level if a single clinician's conduct, outside the other clinicians' control, could result in the penalty being levied against the entire group. This would be even more problematic for virtual group practices that are more loosely associated and with clinicians that may practice in different physical locations and may use different EHR systems. The added complexity of and risk of a group-wide penalty for the conduct of a single clinician **would further complicate MIPS reporting, directly contravening CMS' stated goal of reducing administrative burden in the MIPS program.** The PI program has established hardship exemptions, but the proposed rule does not address specifically how those interact with the proposed disincentives. It is also unclear how the Agencies plan to handle the attestation requirement currently required by the MIPS program to not engage in information blocking, **raising the question of the added utility of additional disincentives and potential duplication of enforcement.**

It has been documented that psychiatrists are currently more likely to incur a negative adjustment to their payments under MIPS than other physicians, and **this proposal will not only jeopardize the ability of psychiatrists to maintain their practice but will disincentivize them from participating in Medicare,** further exacerbating issues of mental health access for Medicare beneficiaries.⁷ APA members are already concerned that the cost of being a top performer in MIPS outweighs the financial benefits of performance incentives.

II. Investigation and appeals processes

The proposed rule does not appear to provide for an appeal mechanism through which physicians could challenge OIG's determination of information blocking – proposed appeal rights only allow physicians to challenge the disincentive itself. Under this proposed rule, there is no mechanism for clinicians to respond to an ongoing investigation and explain why their conduct either did not implicate the information-blocking prohibition, met an exception, was otherwise lawful, or was actually the result of information blocking by another regulated actor, including their health information technology vendor. **In the interests of the time and resources of HHS and clinicians, and access to care for patients, we strongly recommend that HHS develop and formalize a process for clinicians to engage with OIG before it makes an information-blocking determination.** Given that clinicians are the face of the health care system,

⁷ <https://jamanetwork.com/journals/jama-health-forum/fullarticle/2790543>.

patients may misattribute information-blocking activities to their clinician that was, in fact, the responsibility of the health IT vendor, clinician's employer, or other responsible entity.

Under the proposals, information about regulated actors would be posted to the ONC's website, including: the practice; the actors involved; and any settlements of liability, civil monetary penalties levied, and disincentives administered. **Clinicians that are engaged in individualized education efforts or corrective action plans should not be identified as information-blockers**, as they are taking appropriate steps to understand the information-blocking regulations and remedy alleged problematic practices. The Agencies should give clinicians an opportunity to learn and take responsible corrective action, and to appeal an adverse determination and any associated disincentive, before clinicians are added to any list. Additionally, **the Agencies should establish a reasonable threshold and timeframe for including a physician or practice on the information-blocking list.**

Thank you for your review and consideration of these comments. If you have any questions or would like to discuss these comments in more detail, please contact Abby Worthen (aworthen@psych.org), Deputy Director, Digital Health.

Sincerely,

A handwritten signature in blue ink that reads "Saul Levin" with "M.D., M.P.A." written in smaller letters to the right.

Saul M. Levin, M.D., M.P.A., FRCP-E, FRCPSych
CEO and Medical Director
American Psychiatric Association