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January 31, 2023

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: Confidentiality of Substance Use Disorder Patient Records (RIN: 0945 AA16)

Dear Secretary Becerra:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am pleased to offer our comments on the Notice of Proposed Rulemaking (NPRM) entitled, "Confidentiality of Substance Use Disorder Patient Records," published by the Office for Civil Rights (OCR), Office of the Secretary, Department of Health and Human Services (HHS), and the Substance Abuse and Mental Health Services Administration (SAMHSA). While we appreciate the carefully crafted proposals to protect vulnerable patients, we urge HHS and SAMHSA to be aggressively vigilant to address situations where unintended consequences are discovered, including taking corrective action when necessary. We also encourage HHS and SAMHSA to work with stakeholders to ensure that the objectives of the proposed rule are being met.

The AMA believes that to have truly coordinated care, patients must be willing and active participants in that care. Considering the current drug-related overdose and death epidemic, we believe it is important to not lose sight of the purpose of Part 2—to encourage patients to seek evidence-based treatment for a substance use disorder (SUD). At a point in time where more than 107,000 Americans died in 2021 due to a drug-related overdose, the AMA is focused on doing everything possible to remove barriers to treatment. There must be a balance struck when considering the alignment of federal privacy law and regulations with the Health Insurance Portability and Accountability Act (HIPAA) and applicable state law for the purposes of treatment, payment, and health care operations (TPO). This includes ensuring protections are in place against the use of Part 2 SUD records in criminal proceedings and ensuring that efforts to align Part 2 and HIPAA are truly focused in ways that improve patient safety and enhance the quality and coordination of care.

Efforts to align Part 2 and HIPAA demand careful scrutiny because this is relatively unknown territory that will affect hundreds of thousands of patients with SUD and other illnesses. The alignment will be very challenging given that Part 2 records have previously enjoyed some of the strongest confidentiality protections limiting their disclosure. Now, individuals receiving care in a Part 2 facility will need to understand that their health information may be shared, causing potential fears of discrimination and negative legal consequences resulting from their substance use, even while it also may help some aspects of care coordination. These fears may be well-founded given the potential for downstream redisclosures, and we advocate that the agencies implement regulations requiring a conservative reading of redisclosure to only permit such redisclosure consistent with uses for TPO as intended by Congress. The AMA has long-standing policy to support patient privacy and confidentiality, and in the context of

aligning Part 2 and HIPAA, the following goals will need to be met:

- Honoring a patient's basic right to privacy of their medical information and records, including in the context of gathering and disclosing information for clinical research and quality improvement activities;
- Obtaining informed consent before using personally identifiable health information for any purpose;
- Limiting information disclosed to the portion of the medical record necessary to fulfill the immediate and specific TPO purpose of the disclosure;
- Barring employers and insurers from unconsented access to identifiable medical information lest knowledge of sensitive facts form the basis of adverse decisions about individuals; and
- Requiring court orders or warrants for law enforcement to access private medical information.

Data continue to show that the overwhelming majority of individuals with a SUD do not receive treatment. There are many interconnected and overlapping reasons for this, including the perception that treatment is not necessary, health insurance companies deny and delay care, and the stigma associated with SUDs. The treatment gap also is due to the fact that some patients do not feel comfortable with getting treatment. As previously noted by more than 160 patient advocacy groups and addiction treatment provider organizations, federal SUD confidentiality rules are critical to encouraging those with opioid use disorder and other SUDs or mental illness to enter treatment.[1] Policies that undermine a patient's autonomy by sharing records against the patient's wishes—or that result in unintended disclosure—may jeopardize the patient's trust in his or her physician, stall recovery, or prevent a patient from seeking treatment in the first place. Moreover, Part 2 applies to all SUDs and all individuals who seek care in a Part 2 facility—not just those with an opioid use disorder. Once the information switch is turned on, it may be difficult to control. The AMA urges OCR and SAMHSA to create clear and unambiguous guidelines to ensure that Part 2 records are not inappropriately redisclosed as a byproduct of physician attempts to comply with the information blocking regulations. Vendors, health systems, and physician practices struggle to understand how to square HIPAA requirements with the information blocking regulations. Part 2 disclosures may be swept up in the wave of information being sent by physicians/vendors/health systems to comply with information blocking requirements—increasing the likelihood of unauthorized downstream redisclosures as a result.

If this alignment results in unintended consequences, it could discourage patients from seeking treatment not only for opioid use disorder, but for other substance use or co-occurring mental disorders as well. In addition, while important work is being done to remove stigma from SUD, and we commend the Administration for its leadership in this area, the fact remains that disclosure and unwarranted redisclosure of SUD-related information can have serious consequences and SUDs remain widely stigmatized. These concerns do not change the AMA's support for care coordination among health care professionals and alignment limited to TPO. Our support, furthermore, also does not change the fact that increasing the exchange of SUD data heightens the risk of inappropriate disclosure of such data, the consequences of which are likely to be exponentially more harmful to the patient than the improper disclosure of other medical diseases that are not laden down with stigma and a lack of access to evidence-based care. **We therefore urge continued vigilance to monitor whether the alignment of Part 2 and HIPAA has any negative effects on patients' access to care as well as multiple social**

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[1] Campaign to Protect Patient Privacy Rights, Health Privacy Consensus Principles (Aug. 2018), available at https://lac.org/wp-content/uploads/2018/08/CPPart2-Principles.pdf

determinants of health essential to individuals with a SUD, including loss of housing,[2] loss of child custody,[3] discrimination from medical professionals,[4] loss of benefits,[5] or loss of employment,[6] among others).[7]

Finally, we greatly appreciate that much of OCR and SAMHSA's NPRM is aimed at decreasing burdens on patients and providers, improving coordination, and increasing access to care and treatment, while protecting confidentiality of treatment records. Successful implementation of these proposals will depend upon vigorous and intentional efforts to educate patients and providers on the practical effects of giving consent to use and disclosure and in some instances, redisclosure, of their information under the revised Part 2 rules. The AMA is committed to assisting with educational efforts, not only with respect to the mechanics of information sharing permitted under the law, but also on the benefits to patients of having a care team with access to a patient's full medical picture. Part of this educational campaign should be aimed at ensuring patients understand the implications of the forthcoming final rule.

Data Segmentation

We would be remiss to not reiterate AMA's support for data segmentation in our comments, and we greatly appreciate that OCR and SAMHSA have developed proposals which the agencies deem "will reduce, but not completely eliminate the need for data segmentation or tracking." [8] The AMA has longstanding policy to support the following goals:

- Data interoperability between physicians' practices, public health, vaccine registries, community-based organizations, and other related social care organizations to promote coordination across the spectrum of care, while maintaining appropriate patient privacy;
- Adequate standards and capabilities for electronic health records to effectively tag and protect sensitive data before it can be shared or reshared; and
- Ongoing monitoring and data collection regarding unintended harm to patients from sharing sensitive information.

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[2] Marah A. Curtis, Sarah Garlington, and Lisa S. Schottenfeld, Alcohol, Drug, and Criminal History Restrictions in Public Housing, Cityscape: A Journal of Policy Development and Research, U.S. Department of Housing and Urban Development Office of Policy Development and Research (2013) available at https://www.huduser.gov/portal/periodicals/cityscpe/vol15num3/ch2.pdf.d

[3] Children's Bureau/ACYF/ACF/HHS, Parental Drug Use as Child Abuse, Child Welfare Information Gateway, available at https://www.childwelfare.gov/pubPDFs/drugexposed.pdf.

[4] Leonieke C.van Boekel, Evelien P. M. Brouwers, Jaap van Weeghel, and Henk F. L. Garretsen, Stigma among health professionals towards patients with substance use disorders and its consequences for healthcare delivery: systematic review, Drug Alcohol Dependency (July 1, 2013), available at https://www.ncbi.nlm.nih.gov/pubmed/23490450.

[5] Mikki D. Waid and Sherry L. Barber, Follow-up of Former Drug Addict and Alcoholic Beneficiaries, Research and Statistics Note No. 2001-02 (Oct. 2001), available at https://www.ssa.gov/policy/docs/rsnotes/rsn2001-02.html.

[6] The Americans with Disabilities Act and "Current" Illegal Drug Use, available at https://corporate.findlaw.com/litigation-disputes/the-americans-with-disabilities-act-and-current-illegal-drug.html.

[7] Karla Lopez and Deborah Reid, Discrimination Against Patients With Substance Use Disorders Remains Prevalent And Harmful: The Case For 42 CFR Part 2, Health Affairs Blog (April 13, 2017), available at https://www.healthaffairs.org/do/10.1377/hblog20170413.059618/full/.

[8] Confidentiality of Substance Use Disorder (SUD) Patient Records, 87 Fed. Reg. 74216, 74253 (proposed December 2, 2022).

The AMA urges OCR and SAMHSA to ensure that, going forward, patient information will be tagged and limited to the purpose of TPO. The agencies can incentivize compliance with these goals through enforcement actions and penalties for noncompliance. Fortunately, technology can assist physicians with increasing the flow of information while maintaining privacy and a patient's consent. To do so, information should be "tagged" to identify where the information originated, for what purposes it can be disclosed, and to whom. The need for improved data segmentation technology and capabilities would help ease burden associated with using and disclosing multiple types of sensitive data such as SUD, HIV- status, genetic information, minors' health information, and reproductive health information.

We strongly urge the Administration to demonstrate its commitment to greater interoperability and privacy protections by prioritizing data segmentation in development, testing, and policymaking.

We urge the Administration to recognize the pressing need for data segmentation to be made accessible and affordable to physicians. Such capabilities will enhance interoperability, strengthen the patient-physician relationship through a patient's increased confidence that a physician will not share data in a way that violates the patient's trust, and improve care coordination and patient outcomes resulting from a physician's ability to access sensitive information. Furthermore, such data segmentation capabilities would help to ease the burden stemming from physicians' compliance with state privacy laws. **Congress and HHS should continue to support the development of data segmentation standards and software, while providing positive incentives to ensure that such technology is widely available and affordable.**

Moreover, we encourage HHS to work with the broader community to become more heavily involved in policy development around data segmentation. A key opportunity is for SAMHSA and OCR to consider participating in **Shift**, the independent health care task force for equitable interoperability with a mission to advance safe, equitable, and patient-empowered sharing of health information. Shift has gathered expert stakeholders across the industry with the purpose of maturing granular data segmentation standards and implementation guidance in order to sponsor patient-driven sharing of health information with informed consent and advance interoperability in a more equitable manner. The AMA participates on the governing board of Shift and would welcome the chance to speak with you about this work and how this organization can assist HHS.

Consent Requirements (§2.31)

We applaud SAMHSA's recognition that individuals with SUD can benefit from social service agencies and community-based support programs and understand that such programs often provide significant assistance to individuals who may not otherwise receive it. **We support OCR and SAMHSA's proposed clarification that patients may consent to disclosures of Part 2 information to individuals or entities. We also recommend adding regulatory language to specify that patients may consent to permit both their Part 2 facility and health information exchange networks of their choosing to disclose their health information to past, present, and future treating providers.**

In addition, it is critical that OCR and SAMHSA work with the Office of the National Coordinator for Health IT (ONC) to ensure full alignment between this regulation and 21st Century Cures Act implementation, specifically the work on Information Blocking underway across the Department. Interagency collaboration is necessary to create sub-regulatory guidance on how the 21st Century Cures Act aligns with Part 2 and the HIPAA Privacy Rule. Physicians and patients need to understand what consent and disclosure means as it relates to Part 2 records in terms of data sharing and privacy protections. For example, ONC's information blocking regulations effectively convert HIPAA-permitted

information exchanges into requirements. Meaning that where physicians are allowed to exchange information under HIPAA, ONC's information blocking regulations convert those permissions and direct physicians to make patient information available unless a narrow exception can be identified. The information blocking regulations are confusing and not well-defined. This could lead to confusion and misunderstanding related to the scope of access and patients' consent. Patients may not fully understand who will have access to their Part 2 information downstream of their consent disclosure. **We strongly recommend that HHS create educational resources to ensure that the broader community understands the possibilities and extent of data sharing under Part 2, the Privacy Rule, and the 21st Century Cures Act, as well as where sharing an individual's data intersects among these different policy considerations.**

Conclusion

The AMA believes that the proposed rule will help to decrease burdens on patients and providers, and to increase access to care and treatment, while protecting confidentiality of treatment records. Nonetheless, we reiterate the importance of careful and continuous monitoring and data collection regarding unintended harm to patients from sharing sensitive information. The AMA encourages HHS and SAMHSA to work with stakeholders to ensure that the objectives of the proposed rule are being met; we would appreciate the opportunity to work with the agencies to fulfill these goals.

Thank you for the opportunity to provide comments on this proposal. Please contact Margaret Garikes, Vice President, Federal Affairs at margaret.garikes@ama-assn.org or 202-789-7409 with any questions or concerns.

Sincerely,

James L. Madara, MD