AMA
AMERICAN MEDICAL ASSOCIATION

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September 25, 2019

The Honorable Elinore F. McCance-Katz
Assistant Secretary for Mental Health and Substance Use
Substance Abuse and Mental Health Services Administration
U.S. Department of Health and Human Services
5600 Fishers Lane
Rockville, MD 20857

Re: Confidentiality of Substance Use Disorder Patient Records (RIN: 0930-AA30)

Dear Assistant Secretary McCance-Katz:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am writing to express our opposition to the Notice of Proposed Rulemaking (NPRM) entitled, "Nondiscrimination in Health and Health Education Programs or Activities," published by the Substance Abuse and Mental Health Services Administration (SAMHSA). We have heard from numerous physicians and patient groups about the potential negative consequences of giving law enforcement access to patient records to investigate criminal activity. This NPRM, which would remove the phrase "allegedly committed by the patient" from 42 CFR 2.63, would open the doors even further by giving law enforcement the ability to use patient records to investigate criminal activity that does not involve the patient. **While SAMHSA states that the NPRM would "merely correct" the regulation, this proposal is substantive, will significantly impact how law enforcement interacts with physicians and their patients, and could deter thousands of patients from seeking substance use disorder (SUD) treatment.** We urge SAMHSA to withdraw the proposal.

The AMA's approach to privacy is governed by our Code of Medical Ethics and long-standing policies adopted by our policymaking body, the House of Delegates, which support strong protections for patient privacy and, in general, require physicians to keep patient medical records strictly confidential. AMA policy and ethical opinions on patient privacy and confidentiality provide that a patient's privacy should be honored unless waived by the patient in a meaningful way, de-identified, or in rare instances when strong countervailing interests in public health or safety justify invasions of patient privacy or breaches of confidentiality. When breaches of confidentiality are compelled by concerns for public health and safety, those breaches must be as narrow in scope and content as possible, must contain the least identifiable and sensitive information possible, and must be disclosed to the fewest entities and individuals as possible to achieve the necessary end. These policies and ethical opinions are designed not only to protect patient privacy, but also to preserve the patient-physician relationship. This is particularly important in scenarios involving sensitive health information.

SAMHSA states that the proposed change will clarify that a court may authorize disclosure of a patient's confidential communications when the disclosure is necessary in connection with investigation or prosecution of an extremely serious crime, even if the extremely serious crime was not allegedly committed by the patient. Confidential communications include both objective and subjective information

provided by the patient to the Part 2 program in the course of diagnosis, treatment, or referral for treatment.[1] **The protection of confidential communications is at the heart of Part 2: to encourage patients to seek treatment for addiction knowing that their health information will not be shared, thereby easing fears of discrimination and negative legal consequences resulting from their substance use.** Considering the current opioid epidemic, it is imperative that SAMHSA not lose sight of this purpose.

SAMHSA claims in the NPRM that "it has come to [the agency's] attention that the phrase 'allegedly committed by the patient' may hinder federal enforcement efforts targeted at rogue doctors and pill mills that have contributed to the opioid crisis," yet it fails to present any evidence to support this statement. Specifically, the NPRM provides no support for its assertions that:

- Rogue doctors and pill mills exist in Part 2 programs;
- The opioid crisis has increased because of rogue doctors and pill mills in Part 2 programs; or
- Current regulation hinders federal enforcement efforts aimed at rogue doctors and pill mills in Part 2 programs.

In fact, the NPRM notes in its analysis of the proposal's intersection with the Regulatory Flexibility Act that the proposal would "avoid a *possible* interpretation that *could* hamper or impede federal enforcement efforts in the fight to address the opioid crisis" (emphasis added). It also makes no justification for why it should be permitted to review patient records when its stated target is "rogue doctors and pill mills," particularly given that Part 2 programs treat individuals with alcohol use disorder, not just opioid use disorder. SAMHSA does not include in its proposal any targeting or narrowing language. In other words, it proposes no guardrails to limit the scope of an investigation to patient records with some nexus to an alleged crime. Rather, it sets the stage for courts to authorize law enforcement access to a patient's most intimate information without any criteria justifying such an invasion of privacy. **Making a regulatory change that will expose the confidential communications of hundreds of thousands of individuals—including those seeking treatment for alcohol use—for the mere possibility that current regulation *might* hamper law enforcement efforts that may or may not help fight the opioid crisis is unconscionable and contrary to the purpose of the law.**

The current regulations define an "extremely serious crime" as one which "directly threatens loss of life or serious bodily injury, including homicide, rape, kidnapping, armed robbery, assault with a deadly weapon, or child abuse and neglect."[2] The scope of this list was addressed in the regulations promulgated by SAMHSA in its 1987 final rule (1987 Rule). The 1987 Rule deleted "sale of illicit drugs" from the list of examples in the proposed rule, noting that many commenters asserted that including it "would make almost all patients in drug rehabilitation or treatment programs vulnerable to investigation or prosecution by means of court-ordered use of their own treatment records." We agree with this assertion. While important work is being done to remove stigma and regard SUD as a medical issue like any other medical issue, the fact remains that most substance abuse is illegal.[3] Patients seek care in Part 2 programs precisely because such programs offer extra confidentiality, encouraging patients to honestly discuss their substance use with their health care providers. **Allowing law enforcement to access patient records and investigate individuals who are not the subject of a criminal matter is wrong and dangerously sets**

[1] 52 Fed. Reg. 21796, 21801 (June 9, 1987) and 42 CFR Part 2.63(a).
[2] 42 CFR 2.63(a)(2).
[3] https://www.wkbn.com/ohio-news/overdose-victims-cited-in-one-ohio-city/1067863977

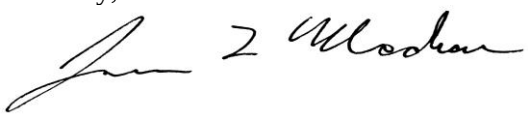
the stage to deter people from seeking treatment. It jeopardizes the patient-physician relationship, one that is built on trust and confidentiality to establish a foundation for care, recovery, and healing. It also increases the risk of such information being inappropriately shared and used against them: examples of harm include loss of housing,[4] loss of child custody,[5] discrimination from medical professionals,[6] loss of benefits,[7] and loss of employment,[8] among others.[9]

The 1987 Rule goes on to note that a court still has the authority to find in some circumstances that sale of illicit drugs is an extremely serious crime. Yet, it makes this statement in the context of a court's order being used to obtain a patient's treatment records to *prosecute the patient*. In fact, the discussion of SAMHSA's rationale is included under the section heading "Extremely Serious Crime as Criterion for a Court Order to Investigate or Prosecute *a Patient*" (emphasis added). Accordingly, SAMHSA's addition of the phrase "allegedly committed by the patient" in its 2017 Final Rule merely reflects regulatory policy that had been in place for over three decades. Removal of the phrase now, particularly without additional support and rationale for the change by SAMHSA, would amount to a significant and substantial change. Relatedly, we question why SAMHSA provided only a 30-day comment period for this NPRM given the significant effect the proposal would have on patients and Part 2 programs. SAMHSA should have permitted 60 days for comments to allow all impacted individuals a reasonable opportunity to comment.

In sum, the AMA opposes this proposal. SAMHSA does not provide support for its premise that the phrase "allegedly committed by the patient" impedes law enforcement efforts. The agency does not provide support for its assumption that Part 2 programs harbor rogue doctors and pill mills. The agency also fails to provide justification for invading the privacy of individuals having no nexus with an extremely serious crime and does not offer any proposal to limit the scope of law enforcement efforts to the narrowest scope of information necessary. Finally, SAMHSA did not provide sufficient time for commenters to provide feedback on this proposal. We again urge SAMHSA to withdraw this proposal.

Thank you for the opportunity to comment on this NPRM. If you have any questions or wish to discuss our comments further, please contact Laura Hoffman, Assistant Director, Federal Affairs, at laura.hoffman@ama-assn.org or 202-789-7414.

Sincerely,



James L. Madara, MD

[4] https://www.huduser.gov/portal/periodicals/cityscpe/vol15num3/ch2.pdf
[5] https://www.childwelfare.gov/pubPDFs/drugexposed.pdf
[6] https://www.ncbi.nlm.nih.gov/pubmed/23490450
[7] https://www.ssa.gov/policy/docs/rsnotes/rsn2001-02.html
[8] https://corporate.findlaw.com/litigation-disputes/the-americans-with-disabilities-act-and-current-illegal-drug.html
[9] https://www.healthaffairs.org/do/10.1377/hblog20170413.059618/full/; see also https://www.macpac.gov/wp-content/uploads/2018/06/Substance-Use-Disorder-Confidentiality-Regulations-and-Care-Integration-in-Medicaid-and-CHIP.pdf, p. 25.