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The Honorable Elinore F. McCance-Katz, MD, PhD
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-AA32)

Dear Assistant Secretary McCance-Katz:

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 Substance Abuse and Mental Health Services Administration (SAMHSA). We applaud your efforts to address the country's epidemic of opioid-related overdose deaths and facilitate care coordination for individuals with a substance use disorder (SUD). Information sharing is a critical component of those efforts, including how records are shared under 42 CFR Part 2 (Part 2). The AMA seeks to ensure that physicians have access to a patient's entire medical record to review and care for their patients. We encourage patients to consent to share SUD information to enable clinicians to provide appropriately coordinated and holistic care. However, while increased access to information can help with care, sharing such information beyond the clinical community can increase risk of inappropriate access and discriminatory impact on patients, particularly from law enforcement, housing agencies, and employers, which may jeopardize their recovery. Accordingly, we urge SAMHSA to incorporate its desire to "ensure that patient identifying information is only disclosed to those individuals and entities on the health care team with a need to know this sensitive information"[1] in all of its finalized policies.

The AMA believes that to have truly coordinated care, patients must be willing and active participants in that care. Considering the current opioid epidemic, we believe it is important to not lose sight of the purpose of Part 2: to encourage patients to seek treatment for a substance use disorder knowing that their health information will not be shared, thereby easing fears of discrimination and negative legal consequences resulting from their substance use. A recent SAMHSA study found that lack of patient demand is the most common primary barrier to clinicians prescribing buprenorphine to treat opioid use disorder or prescribing to their authorized patient limit.[2] This lack of demand is likely caused by many things, including that some patients do not feel comfortable with getting treatment. As noted by over 160 patient advocacy groups and addiction treatment provider organizations, federal SUD confidentiality rules

[1] 84 Fed. Reg. 44568, at 44573 (Aug. 26, 2019).
[2] Christopher M. Jones and Elinore F. McCance-Katz, *Characteristics and prescribing practices of clinicians recently waivered to prescribe buprenorphine for the treatment of opioid use disorder* (March 2019), available at https://www.ncbi.nlm.nih.gov/pubmed/30194876.

are critical to encouraging those with opioid and other SUDs to enter treatment.[3] Policies that undermine a patient's autonomy by sharing records against the patient's wishes may jeopardize the patient's trust in his or her physician, stall recovery, or prevent a patient from seeking treatment in the first place (i.e., the perceived "lack of demand"). Moreover, Part 2 applies to all SUDs—not just opioid use disorder. Weakening privacy protections for Part 2 information impacts all patients who seek treatment at a Part 2 program and could therefore discourage patients from seeking treatment not only for opioid use disorder, but for other substance use or co-occurring mental disorders as well. Furthermore, while important work is being done to remove stigma from SUD, the fact remains that "disclosure of SUD-related information can have serious consequences" and SUDs are "widely stigmatized."[4] We also highlight that substance use by individuals with SUD often involves illegal substances, which is decidedly unlike any other medical issue.[5] As much as the medical community might wish for SUD treatment to be viewed like management of other chronic conditions, such as hypertension, the reality is 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 one's hypertension (examples include loss of housing,[6] loss of child custody,[7] discrimination from medical professionals,[8] loss of benefits,[9] or loss of employment,[10] among others[11]).

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. AMA policy seeks to ease the barriers to sharing SUD information for treatment, payment, and health care operations to improve patient safety and enhance the quality and coordination of care. Those goals must be balanced against patient privacy protections, including (but not limited to) the following:

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[3] 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

[4] Medicaid and CHIP Payment and Access Commission (MACPAC), *Report to Congress on Substance Use Disorder Confidentiality in Regulation and Care Integration in Medicaid and CHIP* (June 2018), available at https://www.macpac.gov/wp-content/uploads/2018/06/Substance-Use-Disorder-Confidentiality-Regulations-and-Care-Integration-in-Medicaid-and-CHIP.pdf, p. 25.

[5] Patty Coller, *Police say people who overdose in one central Ohio community will now be charged with a criminal offense*, WKBN First News (Mar. 3, 2017), available at https://www.wkbn.com/ohio-news/overdose-victims-cited-in-one-ohio-city/1067863977.

[6] 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.

[7] 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.

[8] 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.

[9] 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.

[10] *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.

[11] 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/.

- 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;
- Barring employers and insurers from unconsented access to identifiable medical information lest knowledge of sensitive facts form the basis of adverse decisions about individuals;
- Limiting information disclosed to the portion of the medical record necessary to fulfill the immediate and specific purpose of the disclosure;
- Requiring court orders or warrants for law enforcement to access private medical information;
- Narrowly defining "health care operations" to include only those activities and functions that are routine and critical for general business operations and that cannot reasonably be undertaken with de-identified information; and
- Obtaining informed consent before using personally identifiable health information for any purpose.

Finally, we greatly appreciate that much of SAMHSA's NPRM is aimed at clarifying existing regulation, as we believe that there is a fundamental misunderstanding on the part of many stakeholders of how Part 2 information may be shared. We note that the Medicaid and CHIP Payment and Access Commission (MACPAC) stated in its June 2018 Report to Congress on Substance Use Disorder Confidentiality in Regulation and Care Integration in Medicaid and CHIP that "Additional clarifying guidance on the existing regulations…would be a meaningful step to help providers, payers, and patients understand rights and obligations under the current law as well as existing opportunities for information sharing."[12] 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.

Definitions (2.11) and Applicability (2.12)

SAMHSA proposes to amend and clarify the definition of "Records" in §2.11 in a manner that aligns with its proposed revision to the applicability requirements in §2.12. Essentially, the agency intends to clarify that oral communications from a Part 2 provider to a non-Part 2 provider occurring with consent of the patient are not subject to Part 2. The non-Part 2 provider may memorialize the conversation in writing without concern that those records would be subject to Part 2's requirements. SAMHSA also clarifies in §2.12 that a non-Part 2 provider receiving SUD records from a Part 2 facility (following consent of the patient) should be able to subsequently engage in an independent conversation with the patient, informed by the information from the patient's Part 2 record, and document information related to that conversation without fear that such documentation would become subject to Part 2. **The patient's initial consent for the non-Part 2 provider to receive the Part 2 information is a critical component of these scenarios.**

This proposal could be viewed as a logical extension of existing regulation, which permits a clinician to record information a patient discloses about his or her SUD in a non-Part 2 setting and share that information as permitted by the Health Insurance Portability and Accountability Act. Nevertheless, we

[12] Medicaid and CHIP Payment and Access Commission (MACPAC), *Report to Congress on Substance Use Disorder Confidentiality in Regulation and Care Integration in Medicaid and CHIP* (June 2018), available at https://www.macpac.gov/wp-content/uploads/2018/06/Substance-Use-Disorder-Confidentiality-Regulations-and-Care-Integration-in-Medicaid-and-CHIP.pdf, p. 23.

recommend that SAMHSA devote resources toward ensuring that a patient understands the implications of this policy since he or she may not contemplate the nuance between a "record" and information in the record. In other words, when a patient consents to the release of a Part 2 record to a non-Part 2 provider, he or she must understand that they are not simply consenting to use of the information for a one-time conversation with the non-Part 2 provider, but rather they are consenting to the information potentially becoming a part of his or her "main" medical record. Failure on the part of the Part 2 provider to make this clear could have a significant chilling effect on patients seeking SUD treatment, as those patients may believe that their right to confidentiality has been removed. Similarly, non-Part 2 clinicians should discuss this with their patients and be sure to explain to the patient how the information may be used in the future so that the patient is not caught off-guard. When appropriate, we encourage clinicians to work with patients to ensure that they are comfortable with the information the physician enters into the non-Part 2 record.

Relatedly, we applaud SAMHSA's inclusion of language in the preamble addressing the possibility that a non-Part 2 provider might "transcribe extensively from a [P]art 2 record without having a clinical purpose for doing so" and the agency's explicit statement that this is not the intent of the proposal. **We strongly urge SAMHSA to incorporate this concept into regulatory text so that non-Part 2 providers and other lawful holders are on notice that the intent behind SAMHSA's revised definition of "records" is to facilitate a treatment discussion between a non-Part 2 provider and a patient—not a loophole to circumvent patient privacy and consent.** Both §2.11 and §2.12 should reference this principle. Specifically, §2.11 should note that oral communications from Part 2 providers to payers or other third parties are not to be used as the basis of the creation of separate record streams for patients. SAMHSA's stated intent behind the revisions to §2.11 and §2.12 is to promote a **clinical purpose—**the example provided in the preamble is "a treatment note based on a direct clinical encounter with the patient"—**and the agency should make that clear in the regulations. Short of this clarification, SAMSHA should not revise the definition of Records to exclude oral communications.**

Data Segmentation

We would be remiss to not discuss data segmentation in our comments, and we greatly appreciate SAMHSA highlighting its utility for health records. At times, providers more tightly restrict the flow of data because of uncertainty about how the law applies to it. 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 note that while technology exists to segregate data and software can help to electronically manage patient consent (e.g., Consent2Share), we have heard from physicians and health systems that such segregation functionality is costly to implement, and that open-source consent management software can be prohibitively expensive to incorporate into a customized electronic health record. 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 incentives to ensure that such technology is widely available and affordable.**

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 agree that having to name an individual at a program to receive a patient's SUD information may make it more difficult for a patient to receive these services. We again note the importance of maintaining a patient's ability to control the flow of their data outside of the health care system, particularly for purposes beyond treatment, so we appreciate efforts to ensure the consent process is not burdensome to patients or clinicians. To that end, **we support 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.**

Disclosures to Prevent Multiple Enrollments (§2.34)

SAMHSA is proposing to expand the scope of §2.34 to permit non-Part 2 programs to query a central registry. We agree that this could help with care coordination. We again note the importance of a patient providing consent to disclose their information to the central registry in the first place as well as the requirement that the querying provider must have a treating provider relationship with the patient. We are unclear, however, whether central registries are subject to state and/or federal privacy protections. Since non-members would be able to query the registry under this proposal, we urge SAMHSA to ensure that there are sufficient privacy and security protocols in place to guarantee that access is appropriately limited.

Disclosures to Prescription Drug Monitoring Programs (PDMPs) (§2.36)

The AMA supports physicians registering for and using PDMPs as part of the clinical decision-making process when appropriate. SAMHSA suggests that increased enrollment in and submission of data to PDMPs would "allow for greater patient safety, better patient treatment, and better care coordination among the patient's providers," which is potentially true in some cases.[13] Still, policymakers should not confuse a data tool with a clinical tool. A prospective look at how PDMPs can impact the nation's opioid epidemic found that "interventions such as prescription drug monitoring programs are unlikely to lead to major decreases in the number of deaths from opioid overdose in the near future"[14] and a recent comprehensive study found that "PDMPs were not associated with reductions in drug overdose mortality

[13] We note that two of the studies SAMHSA provides as support for its proposal (citations 7 and 9) do not have any data linking PDMPs to reduced mortality. Citation 8 looks only at four states from 2010-2012/13, and in those states the death toll has increased.

[14] Qiushi Chen, PhD, Marc R. Larochelle, MD, MPH, Davis T. Weaver, BS, et al., *Prevention of Prescription Opioid Misuse and Projected Overdose Deaths in the United States*, JAMA Network Open (Feb. 1, 2019), available at https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2723405.

rates and may be related to increased mortality from illicit drugs and other, unspecified drugs."[15] We include this information not to suggest there is no role for PDMPs or that there are no other data showing positive effects of PDMPs, but rather that an overreliance on PDMPs to solve the nation's opioid epidemic will not likely lead to widespread, positive impacts. In addition to using a state PDMP when necessary, the AMA supports physicians engaging in discussions with their patients about substance use, particularly if they are concerned about drug interactions with prescribed methadone and buprenorphine, pain relievers, heroin, or other substances with which prescribed opioid analgesics can have serious consequences.

Additionally, the AMA has significant privacy concerns about law enforcement's and other non-health care entities' access to PDMPs. Entities accessing PDMPs can learn not only of a patient's history of SUD, but also of gender transition, mental illness, HIV/AIDS, abortion, or other medical conditions historically subject to stigmatization. PDMPs are not subject to federal or state privacy laws that protect personal health information, resulting in a failure to adequately address and protect individual rights and confidentiality that can have "negative impacts on a population level."[16] PDMPs in several states send both solicited and unsolicited reports of SUD information to state law enforcement authorities.[17] "As of August 2018, 34 states permit law enforcement agencies to perform unlimited PDMP searches on any individual as long as there is an 'active investigation' open."[18] In fact, before enacting a law requiring that police and prosecutors obtain warrants before searching in sensitive patient information in the state's prescription monitoring database, Massachusetts allowed police and prosecutors to view patient medical records without warrants nearly 11,000 times—or about 20 times per day—between August 2016 and March 2018.[19] SAMHSA's acknowledgement of this practice—"PDMPs operated by law enforcement agencies are already receiving some patient data related to SUD treatment"[20]—as justification for allowing it to continue is alarming. SAMHSA states that "law enforcement would still require a court order meeting the requirements of 42 U.S.C. 290dd-2(c) to access the covered records"[21] of a Part 2 facility patient, but why would law enforcement bother to seek a court order when it can simply seek out the clinical information it wants in the PDMP? Unauthorized access also can occur when law enforcement inappropriately pressures pharmacists to query a PDMP without judicial oversight.

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[15] Young Hee Nam, PhD, Dennis G. Shea, PhD, Yunfend Shi, PhD, and John R. Moran, PhD, *State Prescription Drug Monitoring Programs and Fatal Drug Overdoses*, The American Journal of Managed Care (May 26, 2017), available at https://www.ajmc.com/journals/issue/2017/2017-vol23-n5/state-prescription-drug-monitoring-programs-and-fatal-drug-overdoses.

[16] Colleen Paddon Simek, JD, LLM, *Do Prescription Drug Monitoring Programs Compromise Patient Privacy By Remaining Outside Federal and Most States' Privacy Standards?*, Journal of Health Care Finance (Summer 2019), available at https://healthfinancejournal.com/index.php/johcf/article/view/182.

[17] Prescription Drug Monitoring Program, Training and Technical Assistance Center, *PDMPs Authorized and Engaged in Sending Solicited and Unsolicited Reports to Law Enforcement Entities* (Aug. 15, 2019), available at https://www.pdmpassist.org/pdf/Law_Enforcement_Entity_Table_20190816.pdf.

[18] Colleen Paddon Simek, JD, LLM, *Do Prescription Drug Monitoring Programs Compromise Patient Privacy By Remaining Outside Federal and Most States' Privacy Standards?*, Journal of Health Care Finance (Summer 2019), available at https://healthfinancejournal.com/index.php/johcf/article/view/182.

[19] Kate Crockford, *Police in Massachusetts Must Get a Warrant to Access Patient Data*; American Civil Liberties Union Massachusetts (Aug. 9, 2018), available at https://www.aclum.org/en/publications/victory-police-massachusetts-must-now-get-warrant-access-sensitive-patient-data.

[20] 84 Fed. Reg. 44568, 44577 (Aug. 26, 2019).

[21] *Id*.

Furthermore, this proposal is unnecessary to accomplish SAMHSA's intended goal. A patient can always consent to provide his or her prescription history directly with a treating provider, central registry, or health information exchange, all of which have more robust patient privacy protections than PDMPs do.

In short, while a patient may authorize and provide consent for disclosure to the PDMP, allowing other health care professionals who treat the patient to view the information, *any* authorized user of a PDMP could view the patient's prescription history once it is entered into the PDMP. Until a PDMP has much more advanced controls and sufficient privacy protections for patients, entering a patient's prescription history into the PDMP would almost certainly mean widespread disclosure well beyond those involved in the patient's care. Given the lack of data showing the benefits of additional information or use of the PDMP to mitigate the epidemic's harms, the AMA believes that the balance clearly edges toward patient privacy as opposed to opening the door to adverse effects on patients who receive—or might be deterred from seeking—care in a Part 2 program. **We oppose SAMHSA's proposal until such time SAMSHA can provide the requisite patient protections to prevent patient information in PDMPs from disclosure or re-disclosure to non-health care professionals.**

Research (§2.52)

SAMHSA is proposing to allow research disclosures of Part 2 patient data by a HIPAA covered entity to individuals and organizations who are neither HIPAA covered entities, nor subject to the Common Rule, for the purpose of conducting scientific research. The NPRM also clarifies that research disclosures may be made to members of the workforce of a HIPAA covered entity for purposes of employer-sponsored research, as well as to permit research disclosures to recipients who are covered by FDA regulations for the protection of human subjects in clinical investigations (at 21 CFR Part 50). As stated above, AMA policy states that employers should be barred from unconsented access to identifiable medical information and that a patient's informed consent should be sought in the context of gathering and disclosing information for clinical research. Accordingly, we oppose the proposals to revise §2.52.

Audit and Evaluation (§2.53)

We recognize that Part 2 already permits audit and evaluation activities without patient consent. Our understanding is that the NPRM is aimed at clarifying which activities fall within the terms "audit and evaluation" and does not necessarily expand or increase the activities already allowed. However, the "Activities Included" language, which permits "reviews of appropriateness of medical care, medical necessity, and utilization of services" could easily empower payers to reduce coverage and benefits, which is antithetical to the administration's goal of increasing SUD treatment. We have heard from providers of SUD treatment that they fear this proposal will empower third-party payers to interfere in treatment plans and limit care. **We recommend that SAMHSA not include this new regulatory language**, particularly because those activities could arguably be accomplished through health care operations activities already permitted under §2.33(b), following patient consent.

Orders Authorizing the Use of Undercover Agents and Informants (§2.67)

The AMA opposes SAMHSA's proposal to allow undercover officers to set up in Part 2 facilities for up to 12 months. SAMHSA does not include any data from its own research or the Department of Justice demonstrating why this change is necessary or appropriate. Both this proposal and SAMHSA's proposal to modify §2.63 (RIN 0930-AA30) would profoundly compromise the confidentiality of all patients in

treatment and serve as disincentives for people needing SUD services to seek treatment. Placing law enforcement in clinical settings will breed mistrust, especially in communities that routinely have a significant law enforcement presence (such as communities of color, low-income neighborhoods, and immigrant communities), and likely increase unnecessary and harmful interactions with the criminal justice system.[22] It could additionally discourage these populations from seeking SUD treatment, leading to further disparate racial and ethnic health outcomes.

Conclusion

Health care information is one of the most personal types of information an individual can possess and generate—regardless of whether it is legally defined as "sensitive"—and policymakers must be very cautious in discussions of how to relax regulation around privacy. We must always ask whether relaxing privacy controls will encourage patients to seek care or potentially deter them. Privacy risks include re-identification of patients through de-identified (or partially de-identified) data; misunderstanding or disregard of the scope of a patient's consent; patient perception of loss of their privacy leading to a change in their behavior; embarrassment or stigma resulting from an unwanted disclosure of information or from fear of a potential unwanted disclosure; perceived and real risks of discrimination including employment and access to or costs of insurance; and law enforcement accessing data repositories beyond their intended scope.

Thank you again for the opportunity to provide comments on this proposal. Please contact Laura Hoffman, Assistant Director, Federal Affairs at laura.hoffman@ama-assn.org or 202-789-7414 with any questions or concerns.

Sincerely,

James L. Madara, MD

[22] Jonathan Mummolo, *Police Militarization Fails to Protect Officers and Targets Black Communities, Study Finds*, Proceedings of the National Academy of Sciences of the United States of America (July 2, 2018), available at https://www.pnas.org/content/pnas/115/37/9181.full.pdf (showing that militarized police units are more often deployed in communities with large numbers of African American residents, even after controlling for local crime rates); Mycah Hatfield, *Immigrant Communities A "Ghost Town" During Threat of ICE Raids in Houston*, ABC13 Eyewitness News (July 15, 2019), available at https://abc13.com/society/immigrant-communities-a-ghost-town-during-threat-of-ice-raids/5394994; Alyssa C. Mooney, M.P.H., *et al., Racial/Ethnic Disparities in Arrests for Drug Possession After California Proposition 47, 2011-2016*, 108 American Journal of Public Health 987 (Aug. 2018), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6050868/pdf/AJPH.2018.304445.pdf (noting that reducing criminal penalties for drug possession can reduce racial/ethnic disparities in criminal justice exposure and has implications for improving health inequalities linked to social determinants of health).