AAMC
Association of
American Medical Colleges
655 K Street, N.W., Suite 100, Washington, D.C. 20001-2399
T 202 828 0400
www.aamc.org

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February 14, 2023

Miriam E. Delphin-Rittmon, PhD
Assistant Secretary for Mental Health and Substance Use
Substance Abuse and Mental Health Services Administration
Department of Health and Human Services
Attention: RIN 0930–AA39
5600 Fishers Lane, Room 13–E–30
Rockville, MD 20857

RE: Medications for the Treatment of Opioid Use Disorder

Dear Assistant Secretary Delphin-Rittmon:

The Association of American Medical Colleges (the AAMC) welcomes this opportunity to comment on the Notice of Proposed Rulemaking (NPRM) entitled "Medications for the Treatment of Opioid Use Disorder" 87 *Fed. Reg.* 77330 (December 16, 2023) issued by the Substance Abuse and Mental Health Services Administration (SAMHSA) which proposes to finalize COVID-19 public health emergency (PHE) flexibilities for the treatment of substance use disorders (SUDs).

The AAMC is a nonprofit association dedicated to improving the health of people everywhere through medical education, health care, medical research, and community collaborations. Its members are all 157 U.S. medical schools accredited by the Liaison Committee on Medical Education; 13 accredited Canadian medical schools; approximately 400 teaching hospitals and health systems, including Department of Veterans Affairs medical centers; and more than 70 academic societies. Through these institutions and organizations, the AAMC leads and serves America's medical schools and teaching hospitals and the millions of individuals across academic medicine, including more than 193,000 full-time faculty members, 96,000 medical students, 153,000 resident physicians, and 60,000 graduate students and postdoctoral researchers in the biomedical sciences. Following a 2022 merger, the Alliance of Academic Health Centers and the Alliance of Academic Health Centers International broadened the AAMC's U.S. membership and expanded its reach to international academic health centers. Learn more at aamc.org.

The AAMC commends the Department's efforts to expand access to medications for the treatment of opioid use disorder (MOUD). Opioid use has devastated communities across the country, and a collaborative effort is needed to stem the tide of opioid and substance use disorders (SUDs). Through their missions of education, research, and clinical care, our teaching hospitals, faculty physicians and other providers are actively responding to this public health crisis and preparing the next generation of health care professionals to address the opioid epidemic.

DEFINITION OF OPIOID TREATMENT PROGRAM (OTP) PRACTITIONER

SAMHSA proposes to expand the definition of OTP practitioner to include any provider appropriately licensed to dispense and/or prescribe approved medications and possesses a waiver to do so. Subsequent to the issuance of this NPRM, Congress passed the Consolidated Appropriations Act of 2023 (CAA), which removed the DATA Waiver (X-Waiver) requirement.[1] SAMHSA acknowledged on its website that "[CAA] 2023 removes the federal requirement for practitioners to submit a Notice of Intent (have a waiver) to prescribe medications, like buprenorphine, for the treatment of [OUD]."[2] **We recommend that SAMHSA update its proposal in light of the provision included in the 2023 CAA which removed the waiver requirement.**

We support the proposal to expand the definition of OTP to allow any provider appropriately licensed to dispense and/or prescribe approved medication to do so. The COVID-19 pandemic has contributed to the already strained workforce necessary to meet the needs of patients with SUDs. Addressing the workforce shortage will require a multipronged approach, including innovation in care delivery, greater use of technology, as well as improved, efficient use of all health professionals on the care team. Once a provider is appropriately licensed to dispense and/or prescribe approved medications for MOUD, we believe they should be permitted to do so without having to navigate any additional barriers that may impede care.

BUPRENORPHINE INITIATION VIA AUDIO-VIDEO AND AUDIO-ONLY TECHNOLOGY

The AAMC strongly supported SAMHSA's PHE policy to allow buprenorphine to be prescribed to new and existing OUD patients via telehealth. We urge SAMHSA to make this change permanent to ensure access to buprenorphine. More than 2 million Americans are afflicted with

[1] *See*, Pub. L. No. 117-328, Consolidated Appropriations Act, 2023, Sec. 1262 (Dec. 29, 2022), Eliminates the requirement that a health care provider apply for a separate waiver through the Drug Enforcement Administration (DEA) prior to dispensing certain narcotic drugs (e.g., buprenorphine).
[2] *See*, SAMHSA's Center for Substance Abuse Treatment, which states "Congress has taken action in the recent Consolidated Appropriations Act, 2023 that impacts federal requirements for Drug Enforcement Administration (DEA) registrants, including those involved in OUD treatment. SAMHSA and DEA are actively working to develop further guidance related to these changes. Please frequently check this webpage for further updates and guidance." (Last accessed February 2, 2023). https://www.samhsa.gov/medications-substance-use-disorders/removal-data-waiver-requirement

OUD, and on average 130 die every day due to overdose.[3] [4] OUD remains the leading cause of accidental deaths in the U.S. Patients who seek treatment of OUD continue to have significant difficulty in accessing treatment options that reflect the most current science.[5] In 2018, for a variety of reasons, only 11.1% of people who needed treatment for substance use received it.[6] Studies have shown that buprenorphine, a MOUD that alleviates opioid withdrawal and decreases drug craving, is an effective and safe treatment for OUD. The effects of opioid withdrawal can force people back to drug use, so there is often a time pressure associated with treatment. Before the PHE, patients with OUD were often instructed to go to the nearest emergency department in the hopes that a physician there would prescribe buprenorphine. However, travel time, particularly in rural areas, and workforce shortages often delayed access to care and resulted in recurrences of OUD.

During the PHE, patients suffering from OUD have received buprenorphine treatment via audio-video and audio-only technology without an initial in-person visit. This has been critical to expanding access and improving wait times to administer buprenorphine. Allowing audio-only technology has been a key step to addressing equity concerns. The lack of video services or discomfort regarding the use of video may disproportionately affect certain populations, some of whom have high-risk and chronic conditions, including older adults, those with low socioeconomic status, those in rural communities, and certain races and ethnicities. In addition, patients in rural areas and those with lower socioeconomic status are more likely to have limited broadband access, making it more difficult to receive telehealth services by audio-video interactions. For these patients, their only time-effective treatment option may be to receive buprenorphine initiation services remotely by phone. **For the reasons discussed above, SAMHSA should permanently allow the initiation of buprenorphine via both audio-video and audio-only technology.**

DRUG ENFORCEMENT ADMINISTRATION (DEA) AND THE RYAN HAIGHT ACT

In general, the Ryan Haight Act requires an in-person visit before prescribing a controlled substance, including buprenorphine. Therefore, even if SAMHSA finalized the proposed policy to permit the initiation of buprenorphine via telehealth, the Ryan Haight Act would prevent patients from doing so without an initial in-person visit unless the DEA implements an exception for telemedicine. Specifically, the Ryan Haight Act permits the practice of telemedicine pursuant to a telehealth registry as a statutory exception to the requirement for an in-person visit.

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[3] Substance Abuse and Mental Health Services Administration. (2019). Key substance use and mental health indicators in the United States: Results from the 2018 National Survey on Drug Use and Health (HHS Publication No. PEP19-5068, NSDUH Series H-54). Rockville, MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. Retrieved from https://www.samhsa.gov/data/

[4] *See* HRSA's Opioid Crisis https://www.hrsa.gov/opioids. Please frequently check this webpage for further updates and guidance." (Last accessed February 2, 2023).

[5] *See* CDC Injuries and Violence Are Leading Causes of Death https://www.cdc.gov/injury/wisqars/animated-leading-causes.html

[6] Wilson N, Kariisa M, Seth P, et al. Drug and Opioid-Involved Overdose Deaths—United States, 2017-2018. MMWR Morb Mortal Wkly Rep 2020; 69:290-297.

Additionally, in 2018 Congress passed legislation that required the DEA to create a telemedicine registry, but the DEA has yet to do so. Without this registry, providers may no longer be able to prescribe buprenorphine via audio-video or audio-only technology without an initial in-person visit once the PHE ends on May 11, 2023.

The in-person requirement would act as a significant barrier to care for those who need the potentially lifesaving treatment, buprenorphine. This barrier will disproportionally affect those in more vulnerable populations who, because of challenges such as lack of flexibility with their workplace, inability to secure care for their dependents, transportation issues or other limitations, are not able to attend an in-person visit. As previously mentioned, time is a critical component to successfully initiating buprenorphine and a delay in treatment caused by the in-person visit requirement may increase the risk of recurrence of OUD. The DEA has announced that they will be releasing a new proposed rule to address prescribing controlled substances via telehealth. **SAMHSA should work with the DEA to create a registry that allows providers to prescribe controlled substances pursuant to the telehealth registry exception under the Ryan Haight Act.**

REMOVAL OF PHYSICAL SIGNATURE REQUIREMENT FOR OTPS

AAMC supports SAMHSA's proposal to allow patients to consent to treatment verbally or with an electronic signature, instead of requiring a physical signature. This is necessary to facilitate the initiation of buprenorphine via audio-video and audio-only technology. Throughout the PHE, we have seen that electronic and verbal signatures have been an effective means of obtaining and recording consent after the patient has been properly informed.

REMOVAL OF THE ONE-YEAR REQUIREMENT FOR OTPS

SAMHSA proposes to eliminate the requirement that a person must have had an addiction to opioids for one year before admission to treatment and receipt of OTP services and permits access for those patients: who meet diagnostic criteria for a moderate to severe OUD; individuals with active moderate to severe OUD, or OUD in remission; or those individuals who are at high risk for overdose or recurrence of use. Subsequently, the CAA 2023 eliminated the requirement that an individual must be addicted to opioids for at least one year prior to being eligible for admittance to an OTP[7]. **AAMC supports removal of the one-year waiting period in favor of a more flexible approach based on the real-time clinical diagnosis by a provider**. This policy will allow providers to determine whether patients would benefit from participating in an OTP

[7] *See*, Pub. L. No. 117-328, Consolidated Appropriations Act, 2023, Sec. 1252(b) (Dec. 29, 2022), stating "[n]ot later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services shall revise section 8.12(e)(1) of title 42, Code of Federal Regulations (or successor regulations), to eliminate the requirement that an opioid treatment program only admit an individual for treatment under the program if the individual has been addicted to opioids for at least 1 year before being so admitted for treatment."

without suffering from OUD for a year, as their condition potentially worsens, before they can receive treatment.

REMOVAL OF STIGMATIZING LANGUAGE

SAMHSA proposes to remove outdated and potentially stigmatizing language used to described OUD and treatment for OUD by administering MOUD in favor of "evidence based and patient-centered terms." **The AAMC applauds SAMHSA for recognizing that language matters.** The AAMC Center for Health Justice co-published a guide with the American Medical Association titled *Advancing Health Equity A Guild to Language Narrative and Concepts*[8] in which we express that a critical component of addressing inequities involves a deep analysis of the language, narrative, and concepts that we use in our work. Stigmatizing language such as "drug abuse", "detoxification" and "legitimate treatment use" can leave patients feeling demeaned and as a result discourage them from seeking the care they need. **The AAMC appreciates SAMHSA's efforts to ensure the language that policymakers use supports patients and creates an environment in which they feel comfortable seeking medically necessary care.**

CONCLUSION

The AAMC thanks SAMHSA for the opportunity to provide input on this important effort to address the OUD epidemic. We would be happy to work with you on any of the issues discussed above or other topics that involve the academic medicine community. Please contact my colleague Ki Stewart (kstewart@aamc.org) with any questions about these comments.

Sincerely,

Jonathan Jaffery, MD, MS, MMM, FACP
Chief Health Care Officer

cc: David Skorton, MD, AAMC President and CEO

[8] American Medical Association and Association of American Medical Colleges. (2021) Advancing Health Equity: Guide on Language, Narrative and Concepts. Available atama-assn.org/equity-guide.