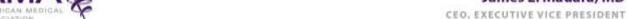
James L. Madara, MD



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March 13, 2023

The Honorable Anne Milgram Administrator Drug Enforcement Administration U.S. Department of Justice 8701 Morrissette Drive Springfield, VA 22152 The Honorable Miriam Delphin-Rittmon, PhD Assistant Secretary for Mental Health and Substance Use Substance Abuse and Mental Health Services Administration 5600 Fishers Lane Rockville, MD 20857

Dear Administrator Milgram and Assistant Secretary Delphin-Rittmon:

On behalf of the American Medical Association (AMA) and our physician and medical student members, I want to thank you for your strong support for increasing access to medications for opioid use disorder (MOUD). Your commitment to removing the X-waiver and increasing access to MOUD as an essential, evidence-based approach to help individuals with OUD will play an important role in ending the nation's overdose and death epidemic.

As you know, in addition to eliminating the X-waiver, the Consolidated Appropriations Act, 2023 also included the Medication Access and Training Expansion (MATE) Act. The AMA strongly supports and has long urged education and training for medical students, residents, and physicians throughout their careers in the assessment, treatment, and management of substance use disorders (SUDs) as an essential component of ending the nation's overdose and death epidemic. The AMA is deeply concerned about the potential for unintended consequences of the MATE Act, however, especially the potential for new barriers to care to arise from its implementation. We write to you today to offer recommendations that we believe can help to avoid these unintended consequences.

The MATE Act will require all physicians and other health care professionals who need a Drug Enforcement Administration (DEA) registration as a condition of employment or to prescribe controlled substances in Schedules II, III, IV, or V to complete eight hours of mandatory education on treatment and medication management of patients with opioid and other SUDs unless they qualify for one of the law's exemptions. The law states that physicians and other health care professionals applying for a new DEA registration or renewing their registration must comply with the one-time eight-hour educational requirement beginning in June 2023. We are deeply concerned that most physicians will not have completed the required education in time, which could result in potentially dangerous lapses in patient care.

Patients across the country are being treated for a variety of serious conditions by DEA-registered physicians who are prescribing controlled substances as part of their treatment plans. If there is a lapse in their DEA registration due to implementation of the MATE Act requirements, patients receiving hospice and palliative care, patients with cancer, undergoing surgery, and those with moderate to severe pain, postoperative pain, sickle cell disease, mental illness, cough, anxiety, seizures, sleeping disorders, and SUDs could lose access to medically necessary care. Emergency departments could be inundated with patients who could no longer receive treatment from their usual source of care, although emergency physicians will also need to comply with the MATE Act's requirements.

To help avert these unintended and very serious consequences, the AMA offers the following recommendations for the agencies' consideration in developing plans for implementing this new law.

The AMA urges broad interpretation of the SUD education and training that qualifies under the MATE Act. There is considerable confusion over the types of education and training that will satisfy the new requirement, the intersection of state and federal law, and how to best implement this requirement given the current general lack of

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education or training about SUDs in medical schools and residency programs. The AMA appreciates the flexibility in the MATE Act that the eight-hour requirement includes training that might have been obtained "through classroom situations, seminars at professional society meetings, communications, or otherwise." The law also states that the organization offering the training must be accredited or recognized by a state medical society or one of several national organizations to provide continuing medical education (CME), but it does not state that the education itself must be accredited CME. The AMA strongly urges that DEA require only that the organization be recognized as a CME provider, to account for situations where a meeting, course, or similar activity may not have formally obtained CME, but "otherwise" fulfills the intent of physicians receiving education and training relating to SUDs.

The AMA and many other national, state, and specialty societies are accredited CME providers and regularly offer CME, as well as non-CME education relating to the nation's overdose and death epidemic. Collectively, the AMA and organized medicine have provided tens of thousands of hours of robust education covering issues ranging from MOUD, reducing stigma, harm reduction, and related areas. The AMA Ed HubTM, which is AMA's online learning platform, features thousands of CME, maintenance of certification, and other educational activities. This includes the Opioid Therapy and Pain Management CME course, which offers more than 42 hours of CME, including opioid guidelines and reviews, research, addiction/COVID-19/SUD treatment, and courses related to opioid-related overdose and mortality. The AMA strongly urges the DEA and SAMHSA to confirm that physicians who have dedicated time to taking SUD-related educational offerings provided by the AMA and other medical societies as described above, including those on the AMA Ed HubTM, satisfy the MATE Act requirement.

The AMA recommends that the time period during which the education requirements can be satisfied be as broadly defined as possible. For example, the MATE Act allows a physician to use state-based CME courses to satisfy the one-time federal requirement, and many states have already been requiring SUD-related education and training as part of a physician's licensing cycle. If a physician has taken a two-hour SUD-related course four times to satisfy four separate licensing cycles, the AMA strongly urges DEA to confirm that this would satisfy the eighthour MATE Act requirement.

The AMA supports former X-waiver training to count for all medical students, residents and physicians. Similarly, the AMA also recommends that physicians who previously received an X-waiver qualify as having fulfilled the requirements under the MATE Act. For years, the AMA and many other stakeholders have urged medical students, residents and practicing physicians to take the X-waiver eight-hour training to educate themselves about SUDs. More than 100,000 physicians and other health care professionals have done so, but the agencies need to issue a statement that having an X-waiver or having completed the training requirements to obtain an X-waiver fulfills the MATE Act requirements.

The AMA recommends that all medical students and residents who have taken eight hours of education and training on SUDs while in medical school or residency be deemed to qualify under

the MATE Act. There is some confusion about the provision referencing education for medical students and residents in "all drugs" to treat SUDs. It is not clear whether medical schools and residency programs are prepared to teach about "all drugs" to treat SUDs, or whether current training available outside of medical schools includes training on "all drugs." While the AMA strongly encourages all medical schools and residency programs to work to add SUD-specific education and training, it is important that medical students and residents who want SUD training to comply with the MATE Act, but whose educational institutions do not offer training in "all drugs" for SUDs, not be disadvantaged by it.

To reduce likely disruption in patient care because of the extremely short timeline for implementation of this new law, the AMA strongly urges the DEA to provide a one-year grace period for physicians to fulfill the educational requirement while maintaining their DEA registration. We are very concerned that most physicians will be unaware of the new requirements or how to fulfill them until it is time for them to renew or apply for their DEA registration. Without a grace period, many would have to rapidly schedule a full day away from their practices in a very short window of time, and there is a clear danger that their registration would lapse, and their patients

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would be left without access to medically necessary care. A grace period could help to prevent these lapses and smooth the implementation process significantly.

The DEA should allow physicians to attest that they have fulfilled the new educational requirements when they apply to obtain or renew their DEA registration and not require submission of paperwork verifying the details of their coursework. Such administrative requirements would only add to the burden associated with this new requirement for physicians and for the agencies.

The AMA strongly urges the DEA to take needed steps to reduce barriers to accessing MOUD, including reversing its recent guidance about "suspicious orders" for buprenorphine. The AMA greatly appreciates the DEA, SAMHSA and the Biden Administration's broad support for removing the X-waiver to increase access to treatment for those with OUD. We appreciate SAMHSA and the DEA encouraging physicians in a national notice on January 12 to treat individuals with OUD. These positive steps have been accompanied, however, by reminders from the DEA to manufacturers and distributors that suspicious order reports must be filed for orders of unusual size and frequency, including for orders of buprenorphine. Elimination of the X-waiver restrictions combined with more medical students, residents, physicians, and other health professionals receiving training in SUDs means that it is not unreasonable to expect that more patients will receive prescriptions for MOUD. There are already reports of difficulties obtaining buprenorphine from pharmacies. We have serious concerns that if orders increase, then manufacturers and distributors will limit distribution out of fear of DEA action.

We greatly appreciate your consideration of these recommendations. The AMA wants to remain very engaged with the DEA and SAMSHA as you move forward to implement the MATE Act. By working together, we can help ensure that the new educational requirements are meaningful and operationally realistic. If you have any questions or would like to arrange a meeting, please contact Margaret Garikes, Vice President for Federal Affairs, at margaret.garikes@ama-assn.org or 202-789-7409.

Sincerely,

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James L. Madara, MD