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1895-1989

December 2, 2021

U.S. Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

RE: Docket No. FDA-2021-N-0951 for Reconsidering Mandatory Opioid Prescriber Education Through a Risk Evaluation and Mitigation Strategy (REMS) in an Evolving Opioid Crisis

To Whom It May Concern:

On behalf of the American Society of Addiction Medicine (ASAM), a national medical specialty society representing more than 6,600 physicians and associated healthcare professionals who specialize in the prevention and treatment of addiction, thank you for the opportunity to provide input on the Food and Drug Administration's (FDA) "Reconsidering Mandatory Opioid Prescriber Education Through a Risk Evaluation and Mitigation Strategy (REMS) in an Evolving Opioid Crisis" public workshop. We greatly appreciate your efforts to help ensure that licensed healthcare professionals who prescribe opioid analgesics do so safely and responsibly.

ASAM has long contended that additional, mandatory education for physicians and other healthcare professionals licensed to prescribe controlled medications is an essential component of a comprehensive response to the addiction and overdose crisis. In addition, ASAM continues to reiterate that said education should include how to recognize and appropriately treat patients with substance use disorders (SUDs). While the medical community has made great strides in expanding educational opportunities for healthcare professionals related to safer opioid prescribing, pain management, and SUD, there remains no mandatory federal education requirement, as well as a dearth of state continuing education (CE) requirements, on the identification and treatment of SUD in particular.

While it is true that a majority of states now have CE requirements related to safer opioid prescribing or pain management, only about 20% of state CE requirements for physicians mention educational content on addiction or SUD.¹ Compounding the problem, some of those states mention this content as merely one option. In addition, while a recent survey showed that 87% of medical schools teach students something about pain, pain management, and SUD, just 55% of surveyed schools assess students on these topics.²

Further, education gaps on addiction treatment have also been found in other healthcare professional programs.³ Taken together, these statistics indicate that enhanced federal initiatives are necessary to reach more prescribers and expand awareness on SUD and its treatment.

Given the increasing incidence and growing prevalence of SUD and drug overdose deaths, as well as the fact that few clinicians receive sufficient education on SUD identification and treatment, **ASAM recommends that the Opioid Analgesics (OA) Risk Evaluation and Mitigation Strategy (REMS) Blueprint be expanded to include an additional module on the identification and treatment of patients with SUDs, including opioid use disorder; ASAM does not, however, recommend that the FDA exercise its authority to make the OA REMS program mandatory for prescribers of opioids.** Such an approach would be far too limited, potentially burdensome to administer in a way that could negatively affect patients, and does not allow clinicians sufficient flexibility to meet a federal educational requirement. **Instead, ASAM continues to advocate for tying mandatory prescriber education on SUDs to clinicians' registrations with the Drug Enforcement Agency (DEA) to prescribe controlled medications.**

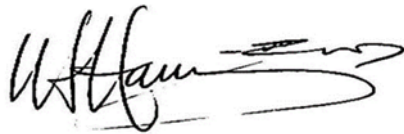
To that end, ASAM strongly supports concurrent passage of the Medication Access and Training Expansion (MATE) Act (S 2235/HR 2067) and the Mainstreaming Addiction Treatment (MAT) Act (S 445/HR 1384). Together, these pairing legislative initiatives would streamline the process for obtaining a DEA license to prescribe controlled medications, including buprenorphine for opioid use disorder, while also conditioning an applicant's approval upon self-attestation of a minimum number of educational hours on the treatment and management of patients with SUDs.

Specifically, the MATE Act would:

- Require most DEA-licensed prescribers to attest - on either one initial or renewal DEA application - that they are an addiction specialist physician or have completed at least 8 hours of education on treating and managing patients with SUDs from one or more accredited organizations or an accredited health professional school or residency program;
- Not prevent the use of this education both for purposes of satisfying the one-time DEA registration requirement and for other purposes, such as satisfying state licensing requirements;
- Allow accredited health professional schools and residency programs to deliver the education through comprehensive SUD curricula. This would normalize and mainstream addiction medicine education and phase out the need to complete federally mandated educational hours after graduation/residency training; and
- Authorize federal grants to professional associations, universities, and other schools to develop and implement high-quality, comprehensive curricula on identifying and treating SUD.

We look forward to continuing our work with the FDA and other collaborators to deliver high-quality and impactful education on safer opioid prescribing, pain management, and SUD identification and treatment to more healthcare professionals. If you have any questions or concerns, please contact Kelly Corredor, ASAM's Chief Advocacy Officer, at kcorredor@asam.org.

Sincerely,

A handwritten signature in black ink, appearing to read "William F. Haning, III". The signature is fluid and cursive, with a long horizontal stroke at the end.

William F. Haning, III, MD, DLFAPA, DFASAM
President, American Society of Addiction Medicine

¹ Duke-Margolis Center for Health Policy. Margolis-FDA Convening: Reconsidering Mandatory Opioid Prescriber Education Through a Risk Evaluation and Mitigation Strategy (REMS) in an Evolving Crisis <https://healthpolicy.duke.edu/sites/default/files/2021-10/Landscape%20Analysis%20-%20Reconsidering%20Mandatory%20Opioid%20Prescriber%20Education%20Workshop.pdf>.

Accessed November 22, 2021 (citing Federation of State Medical Boards. 2021, June 17) *Continuing Medical Education: Board-by-Board Overview*. FSMB. Retrieved from <https://www.fsmb.org/siteassets/advocacy/key-issues/continuing-medical-education-by-state.pdf>).

² Id. (citing Howley, L., Whelan, A., & Rasouli, T. (2018). Addressing the Opioid Epidemic: U.S. Medical School Curricular *Approaches Analysis in Brief*.)

³ Id.