August 28, 2019

Brenda Destro
Deputy Assistant Secretary for Planning and Evaluation (HSP)
US Department of Health and Human Services
Office of the Assistant Secretary for Planning and Evaluation
Office of Science and Data Policy
200 Independence Ave SW, Room 434E
Washington, DC 20201

Re: EPAEDEA Report Feedback

Dear Ms. Destro,

On behalf of the American Society of Addiction Medicine (ASAM), a professional medical specialty society representing more than 6,000 physicians, clinicians, and associated health professionals who specialize in the prevention and treatment of addiction, thank you for the opportunity to comment on the report required by the Ensuring Patient Access and Effective Drug Enforcement Act of 2016 (EPAEDEA). Specifically, we would like to provide comments regarding an important public health issue which may be negatively affecting patient access to certain medications for the treatment of opioid use disorder (OUD); the many educational tools and resources ASAM offers on addiction, appropriate prescribing practices of opioid analgesics, and pain management, and some recommendations for enhancements to State prescription drug monitoring programs (PDMPs).

Obstacles to Legitimate Patient Access to Controlled Substances

Some of our members have informed ASAM that recent efforts by distributors may be inadvertently restricting patient access to schedule III medications used in the treatment of OUD, such as buprenorphine. While we understand the responsibility of distributors to maintain effective controls against diversion of controlled substances as required by law, we are concerned that these actions may be adversely impacting patient access to evidence-based addiction treatment.

The prescribing and dispensing of medications used in the treatment of OUD may be conflated by regulators and members of the drug supply

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chain with the prescribing and dispensing of opioids for the treatment of pain, resulting in incorrect inferences about the appropriateness of quantities or treatments. The treatment of addiction differs from treating chronic pain, and the risks, benefits, and safe medication dosages of longitudinal treatment with opioids differ as well. Entities such as the Centers for Medicare & Medicaid Services (CMS) recognize a need to treat medications for the treatment of OUD differently than medications indicated for pain and carve out buprenorphine for the treatment of OUD when evaluating patients' morphine milligram equivalents (MME) of opioids in policies aimed to curb opioid overutilization.

Unfortunately, to comply with requirements related to suspicious orders to prevent diversion, we are concerned distributors may be inappropriately treating buprenorphine used for OUD no differently than commonly misused opioid medications used for the treatment of pain. To further complicate matters, while the introduction of buprenorphine in 2002 in the United States for the treatment of OUD has raised concerns about its diversion, the primary reason for its diversion may be the inability to obtain legitimate access to the medication for the treatment of OUD.[1] In fact, the latest National Survey on Drug Use and Health by the Substance Abuse and Mental Health Services Administration (SAMHSA) noted that only 30% of individuals with an OUD received treatment in the last year.[2] Further, research, including the Drug Enforcement Agency's (DEA) Economic Impact Analysis, indicates that diversion of buprenorphine is likely not motivated by addiction to buprenorphine, but instead as a method to treat addiction and ease withdrawal symptoms.[3]

Therefore, to determine the best approach to balance patient access to needed medications for the treatment of OUD with diversion concerns, we recommend that the DEA assess current opioid order systems and monitoring programs to more fully understand the potential negative implications for patient access to buprenorphine and other controlled substance medications used to treat OUD. At a minimum, the DEA should review controlled substance order systems and reports to determine the frequency in which a pharmacy places an order for buprenorphine and when that order is not fulfilled by the distributor or reported by the distributor as suspicious. The DEA should also use available data to analyze whether pharmacy orders for buprenorphine and subsequent patient access is being unnecessarily stifled and consider solutions.

ASAM remains deeply concerned that current policy prioritizes efforts to reduce diversion of buprenorphine and disregards patients' access to needed OUD treatment. Without clear action from the DEA directing distributors to treat buprenorphine for OUD differently from opioids used for pain, distributors may not be willing to change their practices since doing so may support an allegation that a distributor violated their duty related to suspicious orders.

Availability of Medical Education, Training Opportunities, and Comprehensive Clinical Guidance for Pain Management and Opioid Prescribing and Gaps that Should be Addressed

ASAM is the largest provider of addiction medicine education offering more Continuing Medical Education (CME) on addiction related topics than any other organization. ASAM's online e-Learning Center offers hundreds of hours of CME on a wide selection of topics. This competency-based online content has been offered since 2015 and the number of users and content continues to grow. Of ASAM's many education offerings, many specifically focus on the prescribing of opioids and pain management. For example, ASAM offers an 8-hour course on Pain and Addiction. This course explores the latest research and clinical approaches to treating the complex overlap between pain and addiction. Finally, The ASAM Handbook on Pain and Addiction is an evidence-based tool for clinicians to manage the complex relationship between pain and addiction. We hope that by highlighting these educational tools and resources, we can help fill some perceived gaps in pain and addiction related topics.

Beneficial Enhancements to State Prescription Drug Monitoring Programs

PDMPs can be a useful tool to support safer prescribing and dispensing practices for scheduled medications. An American Medical Association survey found that 87% of responding physicians supported PDMPs because they help prescribers become more informed about a patient's prescription history.[4] PDMPs may also be a helpful tool to identify patients who merit an assessment for a substance use disorder (SUD).

With that said, PDMPs need to be functional, efficient, timely, user-friendly, and integrated into clinical work-flow by integrating them as much as possible with electronic health records and pharmacy dispensation systems. PDMP data should be accessible only for clinical treatment and/or evaluation (including consultations by clinicians who are not treating the patient) and for public health purposes by authorized clinicians and researchers, including for ongoing public health analysis that can critically evaluate the impact of any interventions on prescribing practices. On a case-by-case basis, law enforcement officials can be allowed access to PDMP data through subpoena and within a tightly regulated process.

Additionally, medications reportable to the PDMP should be expanded by states to include methadone and buprenorphine from OTPs, and cannabis obtained through a prescriber recommendation. It is critical that prescribers and dispensers know of their patient's use of these medications, particularly if the patient has a history of or current substance use disorder. Relatedly, ASAM recommends that prescribers and dispensers should be required to enroll in and query their state's PDMP, either directly or by delegating access to office staff, when initiating a prescription for any controlled substance and at least every 3 months (quarterly) thereafter as treatment continues, consistent with the Centers for Disease Control and Prevention prescribing guidelines. Mandates should be implemented in conjunction with education about how to engage patients whose PDMP report suggests potential substance misuse and the risks of abruptly discontinuing chronic, prescribed opioid or benzodiazepine therapy.

ASAM looks forward to collaborating with the ASPE in developing strategies that will improve public health for people with substance use disorder and their families. Again, ASAM thanks the ASPE for the

opportunity to share ASAM's comments. If you have any questions or concerns, please contact Kelly Corredor, ASAM's Senior Director of Advocacy and Government Relations, at kcorredor@asam.org or at 301-547-4111.

Sincerely,

Paul Earley, MD, DFASAM
President, American Society of Addiction Medicine

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[1] Lofwall, M. R., & Havens, J. R. (2012). Inability to access buprenorphine treatment as a risk factor for using diverted buprenorphine. Drug and alcohol dependence, 126(3), 379-383.
[2] Substance Abuse and Mental Health Services Administration. (2018). Key substance use and mental health indicators in the United States: Results from the 2017 National Survey on Drug Use and Health (HHS Publication No. SMA 18-5068, NSDUH Series H-53). Rockville, MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. Retrieved from https://www.samhsa.gov/data/
[3] Drug Enforcement Administration, Department of Justice. (2018). Implementation of the Provision of the Comprehensive Addiction and Recovery Act of 2016 Relating to the Dispensing of Narcotic Drugs for Opioid Use Disorder. Final rule. Federal register, 83(15), 3071.
[4] Survey: Physicians support PDMPs, face limits with non-opioid therapy [press release]. Chicago, IL: AMA News Room; February 18, 2016. https://www.ama-assn.org/content/national-survey-finds-physicians-support-pdmps-encounter-barriers-providing-non-opioid

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