



August 29, 2019

Brenda Destro, Ph.D  
Deputy Assistant Secretary for Planning and Evaluation (ASPE)  
Department of Health and Human Services  
200 Independence Avenue, SW  
Washington, DC 20201

**Re: Request for Information— Ensuring Patient Access and Effective Drug Enforcement**

Dear Dr. Destro:

On behalf of our 40,000 members, the American College of Emergency Physicians (ACEP) appreciates the opportunity to comment on ensuring appropriate access to controlled substances, including opioids.

As emergency physicians, we see every day the devastating effects that the opioid crisis has had on the communities we serve. While we believe that opioids that are administered or prescribed in the emergency department (ED) and other health care settings should be used for their intended purposes, and therefore support efforts to reduce diversion, we also believe that there are numerous federal policies in place that inhibit access to vital treatment. We appreciate that various agencies in the Department of Health and Human Services (HHS) are working with the Departments of Defense and Veteran Affairs to issue a report to Congress on this extremely important issue. Our comments below focus on the six areas of the report on which HHS is requesting feedback.

**Obstacles to Legitimate Patient Access to Controlled Substances**

ACEP believes that buprenorphine is the one controlled substance in the United States where there is a major obstacle to “legitimate” patient access. Buprenorphine is the most important medication in our arsenal for treating opioid use disorder (OUD), which is currently the most lethal disease in the USA for Americans between the ages of 20 and 50.<sup>1</sup>

We are extremely supportive of using medication-assisted treatment (MAT) to help treat OUD in the ED and have seen great results with utilizing buprenorphine to help start patients on the path towards recovery. Initiating MAT in the ED helps individuals stay in treatment longer, reduces illicit opioid use and infectious disease transmission, and

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<sup>1</sup> Centers for Disease Control and Prevention. “Opioid Overdose: Understanding the Epidemic”. [www.cdc.gov/drugoverdose/epidemic/index.html](http://www.cdc.gov/drugoverdose/epidemic/index.html).

decreases overdose deaths.<sup>2</sup> In addition, the available data demonstrate that patients with OUD who are started on buprenorphine in the ED -- and for whom there is a clinic to maintain treatment after treatment in the ED -- are twice as likely at 30 days to remain in treatment for OUD, than patients who receive a referral alone (78 percent of patients started on MAT in the ED remain in treatment at 30 days, compared to only 37 percent of those who receive a referral alone).<sup>3</sup>

Furthermore, studies of patients with OUD in California and elsewhere have demonstrated an instantaneous reduction in mortality after buprenorphine-assisted detoxification, justifying its use in the ED even when access to long-term maintenance and follow-up is not available.<sup>4</sup> Finally, a study conducted using a retrospective chart review of 158 patients treated at a single ED with buprenorphine for opioid withdrawal found no instances of precipitated opioid withdrawal (a potential medical complication of buprenorphine), and a greater than 50 percent reduction (17 percent versus 8 percent) in return-rate to the same ED for a drug-related visit within one month, compared to the return-visit rate for usual care.<sup>5</sup> In all, research suggests that the sooner we can start patients on the right path, and keep them engaged in treatment, the more successful their recovery can be.

Despite the effectiveness of utilizing buprenorphine for treatment purposes, there are currently significant barriers to its use—the greatest of which is the “X-waiver” requirement mandated by the Drug Addiction Treatment Act (DATA) of 2000. Under the DATA 2000 law, physicians wishing to prescribe buprenorphine outside of opioid treatment programs (OTPs) must take an 8-hour course and receive a waiver from the Drug Enforcement Administration (DEA). It also often takes 60 to 90 days to receive the waiver once the course is completed and the license application is submitted. We firmly believe that the presence of this X-waiver requirement has led to misperception about MAT and has increased stigma about OUD and the treatment of this disease. Due to the stigma, some clinicians are not willing to pursue this DEA license or even engage in treatment of patients with OUD.

While removing the X-waiver would require legislation from Congress, on the regulatory side, **we also strongly support a modification to the current “three-day rule”** (Title 21, Code of Federal Regulations, Part 1306.07(b)). This rule represents a significant barrier to treatment since it requires providers to administer buprenorphine one day at a time, and makes patients come back to the ED or other settings each day to receive treatment. EDs (even without having clinicians with X-waivers) should be able to dispense a three-day supply of buprenorphine or administer a dose which will last for at least 3 days (e.g. a depot intramuscular (IM) injection of a buprenorphine product).

Eliminating the X-waiver barrier and addressing the “three-day rule” are of paramount importance. However, we must further note, that (in large part because of the obstacles, stigma, and misperception created by the X-waiver process) there are other obstacles to overcome:

- Some clinicians do not believe in treating opioid withdrawal with opioids (full or partial agonists);
- Many clinicians are still not familiar with the buprenorphine or its side effects/dosing;

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<sup>2</sup> Bao YP, Wang RJ, et al. Effects of medication-assisted treatment on mortality among opioids users: a systematic review and meta-analysis. *Mol Psychiatry*. 2018 Jun 22.

<sup>3</sup> D'Onofrio G, O'Connor PG, Pantalon MV, et al, *JAMA*. 2015 Apr 28;313(16):1636-44.

<sup>4</sup> Elizabeth Evans et al., "Mortality Among Individuals Accessing Pharmacological Treatment for Opioid Dependence in California, 2006-10," *Addiction* 110, no. 6 (June 2015): 996-1005.

<sup>5</sup> Berg ML, Idrees U, Ding R, Nesbit SA, Liang HK, McCarthy ML. Evaluation of the use of buprenorphine for opioid withdrawal in an Emergency Department. *Drug Alcohol Depend*. 2007;86:239-244.

- Many clinicians cannot prescribe buprenorphine even if they have a waiver because it is either not stocked in the ED, or not stocked in the hospital pharmacy at all (usually due to misperception, stigma, and/or not understanding the X-waiver rules);
- In most states there is a pre-authorization (PA) approval requirement by payors to prescribe buprenorphine. This is a major obstacle to initiating buprenorphine in the ED, as only 25 percent of the patients in the ED present during normal office hours. While some states (e.g. New Mexico) have removed the PA for buprenorphine for patients on Medicaid, the PA requirement persists in most states for most payors.

Overall, to really improve access to OUD treatment, we may need to engage in a broader educational campaign, and ACEP stands ready to work with HHS to help educate providers about the benefits of MAT and help reduce the stigma and misperception about OUD as a disease and buprenorphine as treatment.).

Finally, it is imperative that the Food and Drug Administration (FDA) not continue to provide orphan drug status to “Sublocade,” a once-monthly depot subcutaneous buprenorphine formulation developed and marketed by Indivior. ACEP disagrees with the decision to provide orphan drug status (and thus four additional years of market exclusivity) for “Sublocade.” The current impact of this decision incurs serious public health ramifications of limiting access to treatments for OUD.<sup>6</sup> In the midst of this deadly epidemic of OUD, America must be encouraging new product development and price competition, and not limiting access to other long acting depot injectable formulations of buprenorphine.

## **Issues with Diversion of Controlled Substances**

As stated above, ACEP strongly believes that opioids used for treatment of OUD should be used for their intended purposes and support efforts taken by the Federal Government to reduce diversion. However, with respect to the diversion of buprenorphine, current research suggests that removing the X-waiver requirement and taking other actions to increase access to treatment will actually reduce the amount of buprenorphine that is diverted.<sup>7,8</sup>

## **How Collaboration Between Federal, State, local, and Tribal Law Enforcement Agencies and the Pharmaceutical Industry can Benefit Patients and Prevent Diversion and Abuse of Controlled Substances**

As emergency physicians, and therefore advocates for expanding access to medical care, including mental health care and addiction treatment, and access to lifesaving and life-transforming medications, **for the benefit of patients**, allow us to reiterate the key points of the first two topic discussions:

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<sup>6</sup> Chua, Kao-Ping “Orphan Drugs For Opioid Use Disorder: An Abuse Of The Orphan Drug Act.” Health Affairs. <https://www.healthaffairs.org/doi/10.1377/hblog20190724.795814/full/>.

<sup>7</sup> Lofwall M and Havens, J: Inability to access buprenorphine treatment as a risk factor for using diverted buprenorphine. *Drug Alcohol Depend.* 2012 Dec 1; 126(3): 379–383.

<sup>8</sup> Economic Impact Analysis of Implementation of the Provision of the Comprehensive Addiction and Recovery Act of 2016 Relating to the Dispensing of Narcotic Drugs for Opioid Use Disorder, [Docket No. DEA-450], Drug Enforcement Administration, U.S. Department of Justice, January 2018.

- **ACEP strongly supports the removal of the X-waiver requirement**, which would require legislation from Congress. There are bipartisan bills in both the U.S. House (H.R. 2482) and U.S. Senate (S. 2074) which would eliminate the X-waiver requirements.
- **ACEP strongly supports a modification to the current “three-day rule”** (Title 21, Code of Federal Regulations, Part 1306.07(b)), so as to allow emergency physicians, who do not have a X-waiver, to prescribe, dispense, and/or administer a three-day supply of buprenorphine, for the purpose of treating OUD.
  - This change will improve the ability to initiate MAT in the ED and increase the probability of patients successfully bridging to outpatient addiction treatment.
- ACEP strongly supports the revocation of the FDA orphan drug status for “Sublocade,” a monthly injectable formulation of buprenorphine.
  - America must not limit access to other long acting depot injectable formulations of buprenorphine.
- As will be outlined in the last two topic discussions, for the benefit of patients, and to reduce unnecessary prescribing and diversion of controlled substances, ACEP advocates for an accelerated advancement in the technology, interoperability, data reporting capability, and mandatory participation in PDMPs and an ED Information Exchange (EDIE™).

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

Medical schools must start providing much more education about the types of pain and treatments for pain. Approximately 20 percent of the United States population suffers from chronic pain. However, most clinicians receive only a perfunctory lesson in the pathophysiology of pain, a superficial understanding of treatment modalities, and barely a skimming of the complex biopsychosocial phenomenon that is chronic pain. Medical schools must teach a curriculum built on the most up-to-date, evidence-based ways to manage and treat (not just mask) acute and chronic pain. This curriculum must continue through all residency programs, as nearly all physician specialties will prescribe medications for pain.

Another area of medical education which must be improved is the treatment of addiction. Drug overdose is now the primary cause of death for Americans under the age 50, and life expectancy in America is dropping because drug overdoses (the great majority of which involve opioids), are so disproportionately claiming the lives of young people.

Our educational priorities much change. It is time to directly deal with the crisis that is already upon us and start to mobilize an army of well informed, sympathetic, and passionate young physicians to lead us out of, and prevent a recurrence of, this crisis.

## **Beneficial Enhancements to State Prescription Drug Monitoring Programs, Including Enhancements to Require Comprehensive Prescriber Input and to Expand Access to the Programs for Appropriate Authorized Users**

In general, ACEP supports effective and interoperable Prescription Drug Monitoring Programs (PDMPs) that push prescription data to emergency physicians, rather than requiring them to sign into and pull the data from the PDMP separately. The government should work to integrate the PDMP into the electronic medical record. This has been done in several health systems already, and greatly improves ease of access for providers.

Unfortunately, not all states have optimally functional PDMPs, resulting in highly variable usability and trustworthiness. In addition, patients may cross state lines for care, and not all states are part of InterConnect, which shares interstate information about dispensed prescriptions. Although interstate data sharing has improved, it is still difficult to access; we should work towards replacing the piecemeal state-based PDMPs with one highly functional national system, as was envisioned nearly 20 years ago when the National All Schedules Prescription Electronic Reporting Act (NASPER) law was signed -- but not funded. The Office of the National Coordinator (ONC) for Health Information Technology could also take action by requiring all PDMPs to be interoperable and to include specific standards, such as privacy and security protocols that protect patient-sensitive information.

Another specific initiative that ACEP supports is the Collective Medical Technologies' (CMT) EDIE™ (a.k.a. PreManage ED) software. EDIE™ is an information exchange that provides EDs with critical information on patients, such as how many ED visits patients have had in the last year, where they presented, their medication history, other providers who are involved with the patients, and, finally, whether there is a patient-specific care management plan that could guide treatment. The platform improves patient care by allowing emergency physicians to make more informed clinical decisions and better direct a patient's follow-up care. It can also help identify individuals that have gone to the ED frequently. Finally, it lowers health care costs through a reduction in redundant tests and through better case management that reduces hospital readmissions. Washington state, in the first year alone, experienced a 14 percent reduction of super-utilizer visits, and state Medicaid savings of more than \$32 million.<sup>9</sup> However, hospitals (and especially EDs) often are responsible for the fees to use this service, even though they greatly benefit the health system overall.

While PDMPs have evolved greatly over the past several years, there is still much work to be done. For example, most PDMPs provide a list of prescriptions without any suggestion for interpretation of the data, making the determination of the prescriber subjective. Graphical representations of the data and identification of "red flags" when risk factors are present may be a solution. It is imperative that government evaluate the current situation in which one vendor provides the PDMP for 44 states; evaluation of data security and the great expense to states to provide the PDMP should be considered, as should the feasibility of a government-programmed system that would not incur an annual expense to states (e.g. as has been done in Wisconsin).

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<sup>9</sup> Anderson, S. "Emergency Department Information Exchange Can Help Coordinate Care for Highest Utilizers," ACEPNow, <https://www.acepnow.com/article/emergency-department-information-exchange-can-help-coordinate-care-highest-utilizers/2/>.

## **Steps to Improve Reporting Requirements So That the Public and Congress Have More Information Regarding Prescription Opioids, Such as the Volume and Formulation of Prescription Opioids Prescribed Annually, The Dispensing Of Such Prescription Opioids, and Outliers and Trends Within Large Data Sets**

PDMP data, which represents prescriptions that are filled (not just those which are written and not filled) and also filled regardless of the payer (including cash payments), are extremely powerful surveillance tools. Unfortunately, because PDMPs are fragmented at the state level, obtaining meaningful data is difficult. The federal government should work to merge PDMP data amongst states for the purpose of reporting, particularly to determine cross-state prescribing activity and as a powerful tool to monitor where opioid prescriptions are both written and filled.

We appreciate the opportunity to share our comments. If you have any questions, please contact Jeffrey Davis, ACEP's Director of Regulatory Affairs at [jdavis@acep.org](mailto:jdavis@acep.org)

Sincerely,

A handwritten signature in black ink, appearing to read "Vidor E. Friedman". The signature is fluid and cursive, with a large, sweeping loop at the end.

Vidor E. Friedman, MD, FACEP  
ACEP President