

May 26, 2020

Alex Azar
Secretary
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW.
Washington, DC 20201

Dear Secretary Azar:

On behalf of our 40,000 members, the American College of Emergency Physicians (ACEP) would like to express our strong support for legislative and regulatory actions that would help ensure 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.

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 for Americans between the ages of 20 and 50.

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 decreases overdose deaths. 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).

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. 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

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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. 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.

Removing the X-waiver would require legislation from Congress, and we strongly support H.R. 2482, the “Mainstreaming Addiction Treatment Act of 2019,” which would accomplish this goal. On the regulatory side, we encourage you to modify 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, 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.

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.

Sincerely,

A handwritten signature in black ink that reads "William P. Jaquis". The signature is written in a cursive, flowing style.

William P. Jaquis, MD, MSHQS, FACEP
ACEP President