

February 15, 2023

Robert M. Califf, M.D.
Commissioner
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Docket No. FDA-2020-N-2123

RE: Public Health Focused Essential Meds, MCM and Their Critical Inputs List to Address Section 3(c) of Executive Order (EO) 13944

On behalf of our 40,000 members, the American College of Emergency Physicians (ACEP) appreciates the opportunity to provide an addendum to our previous [comments](#) on the provisional list of essential medicines, medical countermeasures, or their critical inputs, as required by Executive Order 13944.

We respectfully request that the Food and Drug Administration (FDA) consider adding **buprenorphine** to the list of essential medicines.

The FDA list is often used as a reference on what emergency departments (EDs) are required to stock, and because buprenorphine is not currently recognized as an essential medicine, many EDs do not carry it and are not required to stock buprenorphine and other medications for opioid use disorder (MOUD) by accrediting bodies or government agencies.¹ Further, as discussed more below, since buprenorphine is classified as a “suspicious order” according to current Drug Enforcement Agency (DEA) regulations, many community pharmacies are hesitant to stock buprenorphine, and there is a misperception that there are limits around how much of the medication pharmacies can carry at one time. **Adding buprenorphine to the list of essential medicines would help address all of these barriers and ensure that individuals are able to access to this important medication.**

ACEP strongly believes that buprenorphine is a necessary treatment option for every emergency department (ED) patient with opioid use disorder (OUD) or in opioid withdrawal, especially during the current public health crisis surrounding opioids in the United States. EDs that do not stock buprenorphine are unable to provide this critical, potentially life-saving medication which is the highest quality of evidence-based care for patients with OUD or who are in opioid withdrawal.

Initiating MOUD in the ED helps individuals stay in treatment longer, reduces illicit opioid use and infectious disease transmission, and decreases overdose deaths.² 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

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¹ Pham S, Haigh A, Barrett E. Statewide Availability of Buprenorphine/Naloxone in Acute Care Hospitals. *J Addict Med.* 2022;16(1):e48-e51. doi:10.1097/ADM.0000000000000833

² 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.

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 MOUD in the ED remain in treatment at 30 days, compared to only 37 percent of those who receive a referral alone).³ Additional studies also demonstrate that the initiation of MOUD in the ED leads to increased participation in treatment.^{4 5}

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.⁶ A study conducted using a retrospective chart review of 158 patients treated at a single ED with buprenorphine for opioid withdrawal also found 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 after usual care.⁷ Finally, a recent article from *JAMA Psychiatry* showed that the use of telehealth for the treatment of OUD among Medicare beneficiaries significantly increased during the COVID-19 pandemic. Beneficiaries who received these services were more likely to stay in treatment and less likely to experience an overdose.⁸

Although certain barriers to prescribing buprenorphine have been removed, including the elimination of the “X-waiver” requirement by the *Consolidated Appropriations Act, 2023* (Pub. L. 117-328, December 29, 2022), other perceived barriers still remain. **As referenced earlier, ACEP is especially concerned that buprenorphine counts as a “suspicious order” according to current DEA regulations.** On October 23, 2019, the DEA launched the Suspicious Orders Report System (SORS) Online, a centralized database required by the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act, Pub. L. 115-271). The SUPPORT Act requires that all DEA registrants that distribute controlled substances report suspicious orders to DEA. Reporting a suspicious order to the centralized database established by DEA (SORS Online) constitutes compliance with the reporting requirement under 21 U.S.C. 832(a)(3).

The SUPPORT Act states the term “suspicious order” may include, but is not limited to: an order of a controlled substance of unusual size; an order of a controlled substance deviating substantially from the normal pattern, and; orders of controlled substances of unusual frequency as per 21 U.S.C. 802(57) and 21 C.F.R. 1301.74(b). Reporting to SORS Online satisfies the requirement to report such orders to the Administrator of the DEA and the Special Agent in Charge of the Division Office of the DEA for the area in which the registrant is located or conducts business.

Due to the requirement to report suspicious orders, some ED and community pharmacies refuse to stock buprenorphine, thereby severely limiting the ability of patients who need it urgently to receive it. Other ED and community pharmacies can limit the number of prescriptions that physicians can fill, causing physicians to cancel and resend prescriptions multiple times. In addition, pharmacies can implement other burdensome requirements before

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

⁴ Kaucher K, Caruso E, Sungar G, et al. Evaluation of an emergency department buprenorphine induction and medication-assisted treatment referral program. *Am J Emerg Med*. 2019 Jul 30.

⁵ Hu T, Snider-Adler M, Nijmeh L, Pyle A. Buprenorphine/naloxone induction in a Canadian emergency department with rapid access to community-based addictions providers. *CJEM*. 2019 Jul;21(4):492-498.

⁶ 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.

⁷ 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.

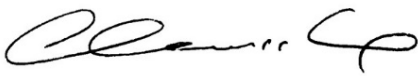
⁸ Jones CM, Shoff C, Hodges K, et al. Receipt of Telehealth Services, Receipt and Retention of Medications for Opioid Use Disorder, and Medically Treated Overdose Among Medicare Beneficiaries Before and During the COVID-19 Pandemic. *JAMA Psychiatry*. Published online August 31, 2022. doi:10.1001/jamapsychiatry.2022.2284.

a prescription is allowed to be filled, adding an additional barrier to patient access. There is also a common misconception that, because buprenorphine is classified as a suspicious order, there are limits on how much of the medication a pharmacy can stock. The DEA however has confirmed that it has set no such limit on this important medication.

By designating buprenorphine as an essential medicine, the FDA could help address the perceived barriers that limit the amount of the medication that pharmacies are willing to stock. It would also vastly improve access for patients with OUD—and again, we strongly recommend that every ED and community pharmacy stock buprenorphine so that patients with opioid use disorder or in opioid withdrawal may receive the best evidence-based care.

We appreciate the opportunity to add our additional comments. If you have any questions, please contact Jeffrey Davis, ACEP's Director of Regulatory and External Affairs, at jdavis@acep.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Chris Kang", written in a cursive style.

Christopher S. Kang, MD, FACEP
ACEP President