January 27, 2021

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

Dear Acting Secretary Cochran:

On behalf of the hundreds of thousands of physicians and the patients to whom they provide care who our collective organizations represent, we want to thank the Biden Administration for its strong commitment to addressing the novel coronavirus (COVID-19) public health emergency. We look forward to working with you on implementing President Biden's national strategy and stand ready to be solid partners in our collective effort to get this pandemic under control. However, as you know, another epidemic that continues to plague this nation is the opioid crisis. In fact, according to the Centers for Disease Control and Prevention (CDC), over 81,000 drug overdose deaths occurred in the United States in the 12 months ending in May 2020, the highest number of overdose deaths ever recorded in a 12-month period. The CDC believes that the latest numbers "suggest an acceleration of overdose deaths" during the pandemic."[1]

We are therefore writing to you today to request that the Department of Health and Human Services (HHS) take steps to eliminate federal policies that inhibit access to vital treatment. On January 14, 2021, HHS released *Practice Guidelines for the Administration of Buprenorphine for Treating Opioid Use Disorder*[2], which creates significant exemptions to the X-waiver requirement for physicians. As described below, these critical guidelines address a major barrier to care, and if implemented, will save lives. **While we understand that there may be some challenges with finalizing these guidelines in their current form, we strongly request that HHS continue to strive to send them to the Federal Register as soon as possible.**

As background, buprenorphine is the most important medication in our arsenal for treating opioid use disorder (OUD). However, it is the one controlled substance in the United States where there is a major obstacle to "legitimate" patient access. We have seen great results with utilizing buprenorphine to help start patients on the path towards recovery. For example, patients on doses of buprenorphine of 16 mg per day or more were found to be 1.82 times more likely to stay in treatment than placebo-treated patients.[3] As well, initiating medication assisted treatment (MAT) in the emergency department

---

[1] The Centers for Disease Control and Prevention, *Overdose Deaths Accelerating During COVID-19,* 17 December, 2020. https://www.cdc.gov/media/releases/2020/p1218-overdose-deaths-covid-19.html.

[2] Department of Health and Human Services, Announcement of Practice Guidelines for the Administration of Buprenorphine for Treating Opioid Use Disorder, 14 January, 2021. https://www.hhs.gov/sites/default/files/mat-physician-practice-guidelines.pdf.

[3] Mattick RP, Breen C, Kimber J, Davoli M. Buprenorphine maintenance versus placebo or methadone maintenance for opioid dependence. Cochrane Database Syst Rev. 2014;(2):CD002207. doi:10.1002/14651858.CD002207.pub4.

(ED) helps individuals stay in treatment longer, reduces illicit opioid use and infectious disease transmission, and decreases overdose deaths.[4] Furthermore, studies of patients with OUD in California and elsewhere have demonstrated an instantaneous reduction in mortality after buprenorphine-assisted detoxification, justifying its use even when access to long-term maintenance and follow-up is not available.[5] These guidelines will also increase access to treatment for pregnant individuals, who often face additional barriers to receiving MAT, which is the recommended therapy for those with OUD during pregnancy. [6,7] 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 requirement has been one our top priorities, and while fully eliminating the requirement would require legislation from Congress, we believe the practice guidelines released on January 14 represent a critical intermediary step as we wait for Congressional action. These guidelines create a broad exception to the X-waiver requirement for physicians. We are also strongly in support of the provision that exempts hospital-based physicians, such as ED physicians, from any patient limitations. **Overall, these guidelines would provide the regulatory relief that our organizations believe will address one of the greatest existing barriers to treatment for patients with OUD.**

We understand that the Biden Administration wants to evaluate all regulatory actions that were taken in the last few weeks of the previous administration, including the guidelines specifically. **However, in this case, there is no time to waste**. In addition, as practice guidelines, the Biden Administration has the authority and will soon have the opportunity to revise and update the guidelines as it deems appropriate. In fact, the guidelines themselves call for the creation of an interagency working group to monitor how they are being implemented. The working group will meet at least twice a year and

---

[4] 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.

[5] 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.

6 Nguemeni Tiako MJ, Culhane J, South E, Srinivas SK, Meisel ZF. Prevalence and Geographic Distribution of Obstetrician-Gynecologists Who Treat Medicaid Enrollees and Are Trained to Prescribe Buprenorphine. JAMA Network Open. 2020;3(12):e2029043. doi:10.1001/jamanetworkopen.2020.29043

7 Opioid use and opioid use disorder in pregnancy. Committee Opinion No. 711. American College of Obstetricians and Gynecologists. Obstet Gynecol 2017;130:e81–94.

make formal recommendations to the HHS Secretary on whether the guideline should be continued, discontinued, or modified.

In all, there are appropriate guardrails already built into the guidelines that allow the Administration to make adjustments to them over time. Thus, by releasing these guidelines now, HHS would not be ruling out any further actions on this important policy, but rather would giving physicians the flexibility they need NOW during the height of the opioid crisis to provide the best available treatment to their patients and save lives.

Thank you for your attention to this important issue. If you have any questions, please contact Laura Wooster, ACEP's Associate Executive Director for Public Affairs at lwooster@acep.org.

Sincerely,

American College of Emergency Physicians
American Academy of Clinical Toxicology
American Academy of Physical Medicine and Rehabilitation
American College of Obstetricians and Gynecologists
American College of Osteopathic Emergency Physicians
American Medical Association
American Osteopathic Association
American Society of Regional Anesthesia and Pain Medicine
CA Bridge
California Medical Association
End SUD
Massachusetts Medical Society
Shatterproof
Society of Hospital Medicine
Vituity
Well Being Trust

CC:
Regina Labelle, Acting Director, Office of National Drug Control Policy
Darrell C. Evans, Acting Administrator, Drug Enforcement Administration