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April 14, 2020

Dr. Elinore McCance-Katz, Assistant Secretary
Substance Abuse and Mental Health Services
Administration
5600 Fishers Lane
Rockville, MD 20857

Mr. Uttam Dhillon, Acting Administrator
Drug Enforcement Administration
600 Army Navy Drive
Arlington, VA 22202

Dear Assistant Secretary McCance-Katz and Acting Administrator Dhillon:

The Pew Charitable Trusts (Pew) is a global research and public policy organization dedicated to serving the public. Operated as an independent, nonpartisan non-profit, Pew applies a rigorous, analytical approach to improve public policy, inform the public, and invigorate civic life. For the past several years, Pew has performed in-depth research and analysis on strategies to address the nation's opioid crisis. Through its Substance Use Prevention and Treatment Initiative, Pew collaborates with states in their efforts to improve access to timely, comprehensive, evidence-based, and sustainable treatment for opioid use disorder (OUD).

The CDC estimates that drug overdoses killed more than 67,000 Americans in 2018. Of those deaths, most (69.4 percent) involved an opioid.¹ Unfortunately, the coronavirus is expected to heighten these already devastating figures as economic and social stresses created by the pandemic will lead many Americans to need substance use treatment.

As the American health system is being pushed to the brink by the coronavirus, access to medications for the treatment of OUD is critical in stopping overdose deaths and preventing hospitals already overwhelmed with COVID-19 cases from being flooded with patients suffering from overdoses or withdrawal. Pew applauds ongoing efforts by the Drug Enforcement Administration (DEA) and Substance Abuse and Mental Health Services Administration (SAMHSA) to enable greater access to these medications to support individuals to OUD, such as increased flexibility of prescribing via telehealth.

Buprenorphine can now be prescribed without a visit to a doctor or treatment facility; it is the only one of the three medications approved by the Food and Drug Administration to treat OUD for which this is the case. This flexibility is vitally important for people experiencing self-isolation and quarantine. However, because of existing regulations, this life-saving flexibility is only available to a limited number of Americans.

Federal rules require health care practitioners to receive additional training and obtain a waiver (known as the X-waiver) from the DEA before they can prescribe buprenorphine. These regulations have contributed to a nationwide shortage in OUD treatment providers. A 2019 report by the National Academies of Science, Engineering and Medicine suggests that as few as

two to three percent of practitioners have a waiver.² As of 2017, 44 percent of U.S. counties did not have a single waived physician authorized to prescribe buprenorphine for OUD treatment,³ leaving millions of Americans without local access to physicians who can treat them at home during the pandemic.

In focus groups of opioid treatment program patients following Hurricane Sandy, patients indicated that barriers to accessing treatment during the disaster led them to return to using street drugs in order to stave off withdrawal.⁴ However, a study of patients in office-based buprenorphine treatment found that fewer than eight percent reported returns to or increases in illicit opioid use post-Hurricane Sandy, suggesting the resilience of buprenorphine treatment during emergencies.⁵

Pew strongly encourages SAMHSA and DEA to suspend immediately the X-waiver requirements to allow non-X waiver prescribers to prescribe buprenorphine through the durations of the national public health emergency. The National Academies recently concluded that no evidence base supports the X-waiver process.⁶ As the health care system is being pushed past its capacity, having regulations that further limits OUD treatment to a small minority of physicians can no longer be justified.

Thank you for your continuing efforts to support expanding access to OUD treatment and for taking swift action to address the coronavirus pandemic. Pew welcomes the opportunity to work with you. Please do not hesitate to contact my colleague Libby Jones at ejones@pewtrusts.org or 202-540-6516 with any questions.

Sincerely,



Elizabeth Connolly
Director, Substance Use Prevention and Treatment Initiative

Cc: Mr. James Carroll, Director of National Drug Control Policy, Executive Office of the President
Admiral Brett Giroir, Assistant Secretary for Health

¹ Holly Hedegaard, M.D., Arialdi M. Miniño, M.P.H., and Margaret Warner, Ph.D., “Drug Overdose Deaths in the United States, 1999–2018,” *NCHS Data Brief*, No. 356, January 2020.

² National Academies of Sciences, “Medications for Opioid Use Disorder Save Lives,” (2019), 2-3.

³ C. Holly A. Andrilla et al., “Geographic Distribution of Providers With a DEA Waiver to Prescribe Buprenorphine for the Treatment of Opioid Use Disorder: A 5-Year Update,” *The Journal of Rural Health* (2018), <https://doi.org/10.1111/jrh.12307>; Roger A. Rosenblatt, et al., “Geographic and Specialty Distribution of US Physicians Trained to Treat Opioid Use Disorder,” *Annals of Family Medicine* 13, no. 1 (2015): 23-26. doi: 10.1370/afm.1735.

⁴ Harlan Matusow, Ellen Benoit, Luther Elliott, Eloise Dunlap, and Andrew Rosenblum. "Challenges to opioid treatment programs after Hurricane Sandy: Patient and provider perspectives on preparation, impact, and recovery." *Substance use & misuse* 53, no. 2 (2018): 206-219.

⁵ Babak Tofighi, Ellie Grossman, Arthur R. Williams, Rana Biary, John Rotrosen, and Joshua D. Lee. "Outcomes among buprenorphine-naloxone primary care patients after Hurricane Sandy." *Addiction science & clinical practice* 9, no. 1 (2014): 3.

⁶ National Academies of Sciences, "Medications for Opioid Use Disorder Save Lives."