The Honorable Anne Milgram
Administrator
U.S. Drug Enforcement Administration
8701 Morrissette Drive
Springfield, VA 22152

July 13, 2021

Dear Ms. Milgram:

Congratulations on your confirmation as Administrator of the U.S. Drug Enforcement Administration ("DEA"). We represent and serve millions of Americans, including people and families with substance use disorder, healthcare and behavioral health providers, law enforcement professionals, recovery and harm reduction providers, social justice advocates, and public health experts. As Americans on the front lines of the overdose crisis, we thank you for committing to confront the opioid epidemic head on with results-oriented, public health solutions that can make our communities safer. **We ask you to support the complete removal of the federal X-Waiver so that millions of Americans in need can access life-saving treatment for opioid use disorder.**

You will lead the DEA at a time of crisis and mourning for our country. Since 1999, drug overdoses have claimed the lives of nearly 841,000 children and parents.[i] This suffering has deepened during the COVID-19 pandemic. In the twelve months leading up to September 2020, the Centers for Disease Control and Prevention estimates that an average of 247 Americans died from overdoses every day – a nearly 30% increase from the previous year.[ii] If we do not take decisive action to ensure that evidence-based solutions reach Americans in need, the overdose crisis will continue to devastate our families and our communities.

As you noted during your confirmation hearing, the overdose crisis is especially tragic because millions of our loved ones with opioid use disorder lack access to the treatment and support they need to heal. One of the most important treatments to help end the overdose crisis is the life-saving overdose prevention medication, buprenorphine. Buprenorphine is a safe medication that has been FDA-approved for the treatment of opioid use disorder for nearly twenty years and is available in generic.[iii] By preventing painful withdrawal symptoms and cravings, buprenorphine helps people with opioid use disorder secure long-term recovery and cuts the risk of overdose death in half.[iv]

But due to an outdated federal policy, it is more difficult for patients with opioid use disorder to access buprenorphine than to access prescription opioids like Oxycontin. As few as 1 in 5 Americans with opioid use disorder receive buprenorphine even though the risk of overdose immediately decreases when a patient starts the medication.[v] Under federal law, healthcare providers with a standard controlled medication license can prescribe buprenorphine to people in pain, but they are subject to burdensome requirements to prescribe the same medication to a person with opioid use disorder. To prescribe buprenorphine to a person with opioid use disorder, healthcare providers must register with SAMHSA and the DEA and adhere to strict limits on the number of patients they can treat. If healthcare providers need to care for more than 30 patients at a time, they must take 8-24 hours of federally mandated training on the medication and have the

ability to refer patients to counseling and ancillary services. These barriers are generally referred to as the "DATA 2000 Waiver" or the "X-Waiver."[vi]

The X-Waiver is an outdated policy that lacks evidence, endangers our loved ones, and stigmatizes both people with opioid use disorder and the treatments that can help them heal. The National Academy of Sciences, Engineering and Medicine has noted that "no evidence base supports the waiver process itself" and has called on Congress to remove these barriers.[vii]

Indeed, the patient safety record of buprenorphine is compelling. Buprenorphine has a safety feature known as a ceiling effect, which minimizes the risk of overdose.[viii] Due to this ceiling effect, buprenorphine is safer and easier to manage than commonly prescribed medications like insulin and blood thinners.[ix] And, buprenorphine is effective when prescribed on its own, regardless of whether a patient has access to counseling or other behavioral interventions. According to the National Academy of Sciences, Engineering, and Medicine: "The life-saving aspects of these medications have been established even in the absence of accompanying behavioral interventions. Given the resource limitations faced in many settings, it is critical that providers do not withhold medications from their patients just because behavioral interventions are not available."[x] The evidence demonstrates that buprenorphine is safe and protects Americans from overdose.

In addition, diversion of buprenorphine today is rare and removing the X-Waiver will likely reduce the small amounts of diversion that currently occur. The DEA itself has found that the primary reason for buprenorphine diversion today is a lack of access to the medication through the healthcare system.[xi] The DEA has further found that expanding access to buprenorphine will likely reduce diversion.[xii] These findings are grounded in the fact that most people who use non-prescribed buprenorphine do so to manage withdrawal symptoms because they cannot otherwise access treatment.[xiii] People with opioid use disorder who obtain non-prescribed buprenorphine for even a handful of days experience significantly fewer overdoses and reduce their use of heroin and fentanyl.[xiv] Significantly, rates of diversion decline as more people with opioid use disorder can access buprenorphine.[xv] Buprenorphine makes up only 1.35% of illicit drugs identified in the United States.[xvi] And, its non-prescribed use is lower than the non-prescribed use of antibiotics and allergy medications.[xvii] Imposing barriers to buprenorphine on the grounds of diversion is not supported by the evidence and endangers public safety.

Recognizing the critical importance of buprenorphine in ending the overdose crisis, HHS Secretary Xavier Becerra recently took action to reduce federal barriers to prescribing buprenorphine. Under new practice guidelines, healthcare providers who treat fewer than 30 patients at a time can now register with SAMHSA and the DEA to prescribe buprenorphine for opioid use disorder without taking 8-24 hours of training or having the ability to refer patients to counseling and ancillary services.[xviii] Secretary Becerra's actions come after similar steps by the Trump Administration to remove barriers to buprenorphine[xix] and by Congress, which has consistently acted to expand access to this medication.[xx] These bipartisan actions reflect the broad recognition that buprenorphine needs to be widely available in primary care practices, emergency departments, and hospitals across the country to help end the overdose crisis.

But, as Secretary Becerra has noted, more must be done to increase access to buprenorphine.[xxi] The remaining elements of the X-Waiver continue to stigmatize an evidence-based treatment for opioid use disorder that can help save tens of thousands of lives every year from overdoses.[xxii] The fact remains that as many as 1.8 million Americans with opioid use disorder lack access to buprenorphine.[xxiii] Even relative gains in the number of healthcare providers who obtain the X-Waiver will fail to leave many with opioid use disorder without access to this medication and will cause many preventable overdose deaths. More than twenty million Americans live in a county without a provider who has the federal registration to prescribe buprenorphine for opioid use disorder and communities of color face significant disparities in access to care.[xxiv] Incremental approaches to increasing access to buprenorphine have consistently failed to ensure that all in need can access this life-saving medication. In the midst of an accelerating overdose crisis that claims hundreds of American lives every day, we are looking to you to take decisive, results-oriented action to make this overdose prevention medication more available than the opioids that have sickened and taken the lives of millions of our family members.

The time has come for the X-Waiver to be removed in its entirety. A public health crisis requires public health solutions. The clear choice is to support the complete removal of the federal X-Waiver to protect millions of Americans from the scourge of overdoses and to help ensure that all Americans with opioid use disorder have access to safe, effective medication that can help them heal. We urge you to support the complete removal of the federal X-Waiver and to stand with our families and communities in ensuring that effective treatment reaches those in need, without stigma or shame.

Thank you for your consideration. Please contact Erin Schanning, President of End Substance Use Disorder, with questions at erin@endsud.org.

Sincerely,

American Academy of PAs	American Academy of Physical Medicine and Rehabilitation
American Association of Public Health Physicians	American College of Medical Toxicology
American Jail Association	Americans for Prosperity
Association for Ambulatory Behavioral Healthcare	Association for Behavioral Health and Wellness
Association of American Medical Colleges	Big Cities Health Coalition
College of Healthcare Information Management Executives (CHIME)	College of Psychiatric and Neurologic Pharmacists (CPNP)
Community Catalyst	End Substance Use Disorder

Global Alliance for Behavioral Health & Social Justice	Healthcare Leadership Council
Law Enforcement Action Partnership	National Association of Attorneys General
National Association of Board of Pharmacy	National Association of Pediatric Nurse Practitioners
National District Attorneys Association	National Families in Action
National Health Care for the Homeless Council	National Health Law Program
National Prevention Science Coalition to Improve Lives	National Safety Council
National Sheriffs' Association	New Directions Behavioral Health
OCHIN	Pharmaceutical Care Management Association (PCMA)
People's Action	Police, Treatment, and Community Collaborative (PTACC)
The Kennedy Forum	The National Council for Mental Wellbeing
The Voices Project	Well Being Trust
Young People in Recovery	ARNPs United of Washington State
Assisted Recovery Centers of America	Better Health Together
Blue Mountain Heart to Heart	CARMAHealth
Cascade Pacific Action Alliance	CHOICE Regional Health Network
Community Health Center of Snohomish County	Country Doctor Community Health Centers
Elevate Health	End Overdose Together
Iowa Primary Care Association	Last Overdose

Live4Lali	Monterey County Prescribe Safe Initiative
Neighborcare Health	New Jersey Harm Reduction Coalition
New Jersey Organizing Project	New Jersey Reentry Corp
Ohio Association of Community Health Centers	Olympia Bupe Clinic
PursueCare	Rx Recovery
Showing Up for Racial Justice Ohio	Texas Criminal Justice Coalition
Texas Recovery Network Solutions	USC Institute for Addiction Science
Visiting Nurse Association of Central Jersey	VOCAL-WA

[i] Centers for Disease Control and Prevention ("CDC"), *The Drug Overdose Epidemic: Behind the Numbers* (2020).

[ii] CDC, *12 Month-Ending Provisional Number of Drug Overdose Deaths* (September 2020).

[iii] Congressional Research Service, *Buprenorphine and the Opioid Crisis: A Primer for Congress* (2018); National Academy of Sciences, Engineering, and Medicine, *Consensus Study Report: Medications for Opioid Use Disorder Save Lives*, Nat'l Acad. Press (2019).

[iv] National Academy of Sciences, Engineering, and Medicine (2019).

[v] Rebecca Haffajee, Ph.D., J.D., M.P.H. et al., *Policy Pathways to Address Provider Workforce Barriers to Buprenorphine Treatment*, 54 Am. J. Prev. Med. S230-42 (2019).

[vi] *See* Practice Guidelines for the Administration of Buprenorphine for Treating Opioid Use Disorder, 86 F.R. 22,439 (Apr. 28, 2021).

[vii] National Academy of Sciences, Engineering, and Medicine (2019); National Academy of Sciences, Engineering, and Medicine, *Consensus Study Report: Opportunities to Improve Opioid Use Disorder and Infectious Disease Services*, Nat'l Acad. Press (2020).

[viii] Substance Abuse and Mental Health Svcs. Admin. ("SAMHSA"), *Treatment Improvement Protocol (TIP) 63: Medications for Opioid Use Disorder* (2020).

[ix] *See* Sarah E. Wakeman, M.D. and Michael L. Bennett, M.D., *Primary Care and the Opioid-Overdose Crisis – Buprenorphine Myths and Realities*, 379 New England J. of Med. 1-4 (2018).

[x] National Academy of Sciences, Engineering, and Medicine (2019).

[xi] U.S. Drug Enforcement Admin. ("DEA"), *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* (Jan. 2018).

[xii] *Id.*

[xiii] National Academy of Sciences, Engineering, and Medicine (2019).

[xiv] Robert G. Carlson et al., *Unintentional drug overdose: Is more frequent use of non-prescribed buprenorphine associated with lower risk of overdose?,* 79 Int'l J. of Drug Policy 4 (May 2020).

[xv] National Academy of Sciences, Engineering, and Medicine (2019).

[xvi] DEA, *NFLIS-Drug 2019 Annual Report* (2019).

[xvii] National Academy of Sciences, Engineering, and Medicine (2019).

[xviii] U.S. Dep't Health and Human Svcs. ("HHS"), *HHS Releases New Buprenorphine Practice Guidelines, Expanding Access to Treatment for Opioid Use Disorder* (Apr. 27, 2021).

[xix] HHS, *HHS Expands Access to Treatment for Opioid Use Disorder* (Jan. 14, 2021).

[xx] *See, e.g.,* Comprehensive Addiction and Recovery Act of 2016 ("CARA"), Pub. Law 114-198, 130 Stat. 720-23 (2016); Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities ("SUPPORT") Act, Pub. Law 115-271 § 3201, 132 Stat. 3843-44 (2018); Further Continuing Appropriations Act, 2021, and Other Extensions Act, Pub. Law No. 116-125 § 1302, 134 Stat. 1046 (2020) (provisions known as the "Easy MAT Act").

[xxi] *See* Sec. Xavier Becerra, HHS, Testimony Before the House Energy and Commerce Subcommittee on Health, Hearing on "The Fiscal Year 2022 HHS Budget" (May 12, 2021).

[xxii] Kevin Fiscella, M.D., M.P.H., Sarah E. Wakeman, M.D., Leo Beletsky, J.D., M.P.H., *Buprenorphine Deregulation and Mainstreaming Treatment for Opioid Use Disorder: X the X Waiver*, 76(3) JAMA Psychiatry 229-30 (2018).

[xxiii] *See* SAMHSA, *TIP 63* (2020); Haffajee, et al. (2019).

[xxiv] Nat'l Inst. of Health, *Physician-pharmacist collaboration may increase adherence to opioid addiction treatment* (2021); William C. Goedel, et al., *Association of Racial/Ethnic Segregation with Treatment Capacity for Opioid Use Disorder in Counties in the United States*, 3(4) JAMA Netw. Open (2020).