April 13, 2021

The Honorable Xavier Becerra Secretary U.S. Department of Health and Human Services 200 Independence Avenue SW Washington, DC 20201

Re: Immediate Action Requested to Combat the Dire Addiction Crisis

Dear Secretary Becerra,

The undersigned organizations write to emphasize the urgency of addressing the ongoing addiction crisis, which has been severely exacerbated by the COVID-19 pandemic. Forty-two states have reported significant increases in overdose deaths since the onset of the pandemic. To immediately save lives, we urge you to take decisive action to eliminate the X-Waiver, which is required by the Drug Addiction Treatment Act of 2000 (DATA 2000) to prescribe buprenorphine, one of three FDA-approved medication-assisted treatments (MAT) indicated for the treatment of opioid use disorder (OUD).

Significant Access Challenges and Barriers

Despite the overwhelming evidence of buprenorphine's effectiveness for treating OUD, it remains highly underutilized with only about 20 percent of individuals with an OUD receiving any treatment¹, and even less receiving MAT. The waiver requirement has prevented those with OUD from receiving life-saving care, because more than 95 percent of practitioners lack the Xwaiver and thus are unable prescribe buprenorphine. Forty percent of U.S. counties do not have a single provider that can prescribe buprenorphine for OUD in an office setting, according to an important January 2020 report by the Department of Health and Human Services (HHS) Inspector General.² The treatment gap is even greater in rural communities, with two-third of those counties representing individuals that live in rural areas³.

Perpetuating Stigma

The horrendous irony of the opioid epidemic has been that any DEA-licensed prescriber can prescribe powerful opioids that can, in a short period of time, lead to OUD. The existence of the X-Waiver sends a terrible message to practitioners and the public alike: that treating OUD with

https://oig.hhs.gov/oei/reports/oei-12-17-00240.pdf.

¹ Saloner B and Karthikeyan S. Changes in Substance Abuse Treatment Use Among Individuals With Opioid Use Disorders in the United States, 2004-2013. JAMA. 2015 October; 314(14): 1515-1517.

² Office of Inspector General, U.S. Department of Health and Human Services, *Geographic Disparities Affect* Access to Buprenorphine Services for Opioid Use Disorder, January 2020,

³ Shatterproof, *County buprenorphine access in the United States*, April 2020, https://www.shatterproof.org/sites/default/files/2020-04/Shatterproof%20OUD%20Brief R03 42220.pdf

buprenorphine requires separate, stigmatizing rules and that buprenorphine is inherently more dangerous than the powerful opioids that have fueled this crisis.

The Urgent Need

The current need could not be greater. During the ongoing COVID-19 pandemic, fatal drug overdoses have skyrocketed, with the Centers for Disease Control and Prevention estimating that more than 81,000 Americans died from drug overdoses during a 12-month period ending in May 2020.⁴ This dramatic increase, which reflects only a few months of the pandemic's negative effects, has undone all the gains in reducing fatal overdoses.

In an attempt to address this escalating crisis, the prior administration released new practice guidelines ("Notice") on January 14, 2021, that would have made a number of changes to the X-Waiver. Specifically, the Notice gave physicians the option to prescribe buprenorphine, for up to 30 patients, without needing to satisfy some of the requirements to obtain an X-Waiver.⁵ While we do not believe the Notice would have completely resolved the issues for patients to access buprenorphine for OUD, our organizations lauded this as a strong first step in that direction.

While the subsequent pulling of the Notice on January 21, 2021, was a disappointment due to its potential to save lives, we understand that HHS must be confident that its actions comply with federal law. Nonetheless, because the severity of the crisis persists, we urge HHS to immediately take any actions within its power to reduce the disproportionately high barrier to life-saving OUD treatment with buprenorphine created by the X-Waiver. Further, we urge the Administration to publicly call upon Congress to eliminate the X-Waiver completely. It should also call upon Congress to include provisions to increase substance use disorder education for all DEA-licensed prescribers in order to increase early identification and treatment of these disorders.

These actions would be fully consistent with what the President called for during the 2020 presidential campaign, when he pledged to "ensure that any undue restrictions on [buprenorphine] prescribing are lifted..."⁶ and cited a *JAMA Psychiatry* article estimating that eliminating the X-Waiver could save more than 30,000 American lives each year.⁷ This estimate was made prior to the rising overdose deaths associated with the pandemic. By taking immediate action within its powers, clearly communicating with stakeholders, and unambiguously calling upon Congress to eliminate the X-Waiver, the Administration can proactively steer our country

⁴ "Overdose Deaths Accelerating During COVID-19," *Centers for Disease Control and Prevention*, December 17, 2020, <u>https://www.cdc.gov/media/releases/2020/p1218-overdose-deaths-covid-19.html</u>.

⁵ Announcement of Practice Guidelines for the Administration of Buprenorphine for Treating Opioid Use Disorder, Department of Health and Human Services,

https://www.hhs.gov/sites/default/files/mat-physician-practice-guidelines.pdf, last visited March 10, 2021. ⁶ "THE BIDEN PLAN TO END THE OPIOID CRISIS," *Biden-Harris Campaign Website*, https://joebiden.com/opioidcrisis/.

⁷ Fiscella K, Wakeman SE, Beletsky L. Buprenorphine Deregulation and Mainstreaming Treatment for Opioid Use Disorder: X the X Waiver. *JAMA Psychiatry*. 2019;76(3):229–230. doi:10.1001/jamapsychiatry.2018.3685

in the direction necessary to fulfill its promise that all individuals living with OUD have access to potentially life-saving treatment.

There is no time to lose. With the Administration's leadership, we can finally end this discriminatory and stigmatizing provision that costs far too many lives. We look forward to working with you to realize the vision of all Americans with a substance use disorder receiving the treatment they need.

Sincerely,

Association for Behavioral Health and Wellness The Kennedy Forum Shatterproof America's Health Insurance Plans American Academy of Physical Medicine and Rehabilitation American Association for Psychoanalysis in Clinical Social Work American College of Medical Toxicology American Foundation for Suicide Prevention Array Behavioral Care Ascension Assisted Recovery Centers of America Association for Ambulatory Behavioral Healthcare **Big Cities Health Coalition** Blue Cross Blue Shield Association Centerstone Central City Concern Cigna **Cities Thrive Coalition** City of New York College of Healthcare Information Management Executives (CHIME) College of Psychiatric and Neurologic Pharmacists (CPNP) **Community Catalyst** Global Alliance for Behavioral Health and Social Justice Harm Reduction Coalition Healthcare Leadership Council Health Innovation Alliance **HIV** Alliance innovaTel Telepsychiatry Inseparable The Levenson Foundation Live4Lali Magellan Health Mass General Brigham

Mental Health America NACBHDD and NARMH National Alliance on Mental Illness National Association of Addiction Treatment Providers National Association of Attorneys General National Association of Pediatric Nurse Practitioners National Council for Behavioral Health National Health Law Program National Safety Council New Directions Behavioral Health **OCHIN** Partnership to End Addiction PAs in Virtual Medicine and Telemedicine Pharmaceutical Care Management Association (PCMA) Police, Treatment, and Community Collaborative (PTACC) Psychotherapy Action Network Advocacy PursueCare OueerDoc SMART Recovery Stop Stigma Now Student Coalition on Addiction The International Society for Psychiatric Nurses The Voices Project Treatment Advocacy Center Treatment Communities of America **UPMC** USC Institute for Addiction Science Well Being Trust Young People in Recovery

Cc: Tom Coderre (Substance Abuse and Mental Health Services Administration) Merrick Garland (U.S. Department of Justice)
D. Christopher Evans (U.S. Drug Enforcement Administration) Regina LaBelle (Office of National Drug Control Policy) Representative Paul Tonko (D-NY) Representative Antonio Delgado (D-NY) Representative Anthony Gonzalez (R-OH) Representative Mike Turner (R-OH) Senator Maggie Hassan (D-NH) Senator Lisa Murkowski (R-AK)