May 12, 2021

The Honorable Charles Schumer Majority Leader U.S. Senate Washington, DC 20510

The Honorable Richard Durbin Majority Whip U.S. Senate Washington, DC 20510

The Honorable Mitch McConnell Minority Leader U.S. Senate Washington, DC 20510

The Honorable John Thune Minority Whip U.S. Senate Washington, DC 20510 The Honorable Nancy Pelosi Speaker U.S. House of Representatives Washington, DC 20515

The Honorable Steny Hoyer Majority Leader U.S. House of Representatives Washington, DC 20515

The Honorable Kevin McCarthy Minority Leader U.S. House of Representatives Washington, DC 20515

The Honorable Steve Scalise Minority Whip U.S. House of Representatives Washington, DC 20515

RE: The Mainstreaming Addiction Treatment Act (H.R. 1384 / S. 445)

Dear Congressional Leaders:

The 120 undersigned organizations 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. In the face of a relentless and accelerating overdose crisis, <u>we ask you to pass the bipartisan</u> <u>Mainstreaming Addiction Treatment Act with the urgency that the overdose epidemic demands</u>. The Mainstreaming Addiction Treatment Act is a common-sense solution to the overdose crisis that cuts through federal red tape to prevent overdoses, increase participation in treatment, and reduce stigma. The time to enact this life-saving legislation is now.

As organizations and leaders who are on the front lines of the overdose epidemic, we have witnessed the profound loss and suffering that substance use disorder has wrought across the country. The Centers for Disease Control and Prevention estimates that an average of 247 Americans died from overdoses every day in the twelve months leading up to September 2020 – a nearly 30% increase from the previous year.ⁱ More Americans lost their lives to an overdose in that timeframe than at any time in history and nearly three-quarters of those deaths involved opioids.ⁱⁱ The COVID-19 pandemic has fueled an already devastating overdose crisis. Americans and their families need help now.

Each of these lives lost is a tragedy that is made even more devastating by the fact that many of those deaths could have been prevented with buprenorphine, a life-saving overdose prevention medicine. Buprenorphine cuts the risk of overdose death in half.ⁱⁱⁱ By preventing painful withdrawal symptoms, buprenorphine helps people secure long-term recovery so they can earn a living, take care of their families, and contribute to their communities.^{iv} The medication has been FDA-approved since 2002, is available in generic, and is one of the most cost-effective forms of treatment for opioid use disorder.^v During the COVID-19 pandemic, buprenorphine is the only medication for opioid use disorder that can be initiated via telehealth.^{vi} Buprenorphine is one of the most important tools we have to help end the overdose crisis.

Under your leadership, Congress has consistently acted to expand access to this medication so that it can be available in primary care practices, emergency departments, and correctional facilities.^{vii} The federal government has spent millions of taxpayer dollars to ensure that buprenorphine reaches people with opioid use disorder. Following your leadership to build universal access to buprenorphine, the Biden Administration announced steps on April 27th to loosen some federal restrictions on prescribing the medication to patients with opioid use disorder.^{viii} Under Practice Guidelines issued by the Department of Health and Human Services, healthcare providers who treat up to 30 patients with opioid use disorder at a time no longer need to take mandatory training on buprenorphine or certify their ability to refer patients to counseling and ancillary services. But, before they can prescribe buprenorphine to patients with opioid use disorder that a special registration with the federal government (a process that can take 2-3 months). If they treat more than 30 patients at a time, healthcare providers must still take 8-24 hours of training on the medication and comply with the counseling referral requirement. In issuing the Practice Guidelines, the Biden Administration noted that these remaining restrictions are legislative and only an act of Congress can remove them.^{ix}

The Biden Administration's actions follow similar steps initiated by the Trump Administration this past January to remove barriers to buprenorphine.^x These actions from both the Biden and Trump Administrations demonstrate the broad, bipartisan support for removing the federal restrictions on prescribing buprenorphine.

These executive actions, while a step in the right direction, are unlikely to increase access to buprenorphine to the extent needed to prevent significant numbers of overdose deaths. Most healthcare providers choose not to prescribe buprenorphine to patients with opioid use disorder in part due to the remaining federal restrictions. These federal restrictions isolate the treatment of opioid use disorder from normal healthcare. They disproportionately tax healthcare providers' time, limit support from their peers and clinical staff, and foster stigma towards patients with opioid use disorder.^{xi} As a result, up to 4 in 10 physicians may choose not to pursue the federal registration needed to prescribe buprenorphine for opioid use disorder even after they have taken the 8-hour training course on the medication.^{xii} In addition, of those healthcare providers who obtain the federal registration for buprenorphine, fewer than 1 in 3 actually prescribe the medication.^{xiii} Providers who have the federal registration reject up to half of patients who request buprenorphine.^{xiv} The evidence demonstrates that, even with the Biden Administration's actions, most healthcare providers will be unlikely to provide this life-saving treatment to patients in need.

The federal restrictions on buprenorphine are outside the bounds of evidence and foster stigma towards people with opioid use disorder. Most notably, these restrictions apply only when treating opioid use disorder – healthcare providers with a standard controlled medication license can prescribe buprenorphine

to a person in pain without being subject to these bureaucratic requirements. Some argue that the restrictions are needed to prevent diversion of the medication, but federal officials, including the Drug Enforcement Administration, have found that the primary reason for buprenorphine diversion today is a lack of access to treatment and that expanding access to buprenorphine through the healthcare system will likely reduce diversion.^{xv} Buprenorphine makes up only 1.35% of illicit drugs identified in the United States.^{xvii} And, its non-prescribed use is lower than the non-prescribed use of antibiotics and allergy medications.^{xviii} Moreover, rates of diversion decline as more people with opioid use disorder can access buprenorphine.^{xviii} Most people who use non-prescribed buprenorphine do so to manage withdrawal symptoms because they cannot otherwise access treatment.^{xix} 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.^{xx} The National Academy of Sciences, Engineering, and Medicine has found that these restrictions are not supported by evidence and has called on Congress to remove the remaining federal barriers to prescribing buprenorphine.^{xxi} By singling out patients with opioid use disorder and severely limit access to proven, life-saving treatment.

The federal restrictions on buprenorphine will continue to leave most of the over 2.3 million Americans with opioid use disorder without access to the medication, causing multitudes of preventable deaths. As few as 1 in 5 Americans with opioid use disorder receive buprenorphine.^{xxii} And fewer than 7 in 100 doctors, advanced practice registered nurses, and physician assistants possess the special federal registration to prescribe buprenorphine to people with opioid use disorder.^{xxiii} More than twenty million Americans live in a county without a provider who has the federal registration to prescribe buprenorphine for opioid use disorder.^{xxiv} Americans residing in rural communities, veterans, pregnant people, and Black, Indigenous, and People of Color all suffer disproportionately from a lack of access to buprenorphine, fueling overdose deaths and contributing to rising maternal mortality.^{xxv}

The Mainstreaming Addiction Treatment Act removes the federal barriers to prescribing buprenorphine and treats it just like any other essential medicine. The bill allows all healthcare providers with a standard controlled medication license to prescribe buprenorphine for opioid use disorder in the course of their normal medical practice. The bill also launches a national education campaign to connect healthcare providers to already available, free education resources on best practices for treating substance use disorder (including programs such as SAMHSA's Providers Clinical Support System that is already federally funded). The Mainstreaming Addiction Treatment Act will prevent overdoses and help end stigma.

In issuing its executive action, the Biden Administration stated that only Congress can remove the remaining barriers to prescribing buprenorphine. <u>We urge you to pass the bipartisan Mainstreaming</u> <u>Addiction Treatment Act</u>. With overdose deaths estimated to have claimed over 90,000 Americans in the twelve months leading up to September 2020, the time has come to expand access to this life-saving medication so Americans can heal and so their families can take comfort in knowing their loved ones are safe.

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

CC:

The Honorable Patty Murray, Chair, Committee on Health, Labor, Education and Pensions The Honorable Frank Pallone, Chair, Committee on Energy and Commerce The Honorable Jerrold Nadler, Chair, Committee on the Judiciary The Honorable Richard Neal, Chair, Committee on Ways and Means The Honorable Richard Burr, Ranking Member, Committee on Health, Labor, Education and Pensions The Honorable Cathy McMorris Rodgers, Ranking Member, Committee on Energy and Commerce The Honorable Jim Jordan, Ranking Member, Committee on the Judiciary The Honorable Kevin Brady, Ranking Member, Committee on Ways and Means

Sincerely,

American Academy of PAs	American Academy of Pediatrics
American Association of Nurse Anesthetists	American Association of Public Health Physicians
American College of Emergency Physicians	American College of Medical Toxicology
American Foundation for Suicide Prevention	American Medical Association
American Nurses Association	American Pharmacists Association
Association for Ambulatory Behavioral Healthcare	Association for Behavioral Health and Wellness
Association of American Medical Colleges (AAMC)	Association of Prosecuting Attorneys
Big Cities Health Coalition	C4 Recovery Foundation
Civil Citation Network	College of Healthcare Information Management Executives (CHIME)
College of Psychiatric and Neurologic Pharmacists (CPNP)	Drug Policy Alliance
End Substance Use Disorder	Families for Sensible Drug Policy
Global Alliance for Behavioral Health and Social Justice	HIV Alliance

Law Enforcement Action Partnership	National Association of Addiction Treatment Providers
National Association of Attorneys General	National Association of Boards of Pharmacy
National Association of Pediatric Nurse Practitioners	National Council for Behavioral Health
National District Attorneys Association	National Families in Action
National Harm Reduction Coalition	National Health Care for the Homeless Council
National League for Nursing	National Prevention Science Coalition to Improve Lives
National Safety Council	National Viral Hepatitis Roundtable
OCHIN	People's Action
Shatterproof	The Kennedy Forum
The Pew Charitable Trusts	The Police, Treatment, and Community Collaborative (PTACC)
Young People in Recovery	ACLU of Washington
Adolescent Substance Use & Addiction Program, Boston Children's Hospital	Alaska Primary Care Association
ARNPs United of Washington State	Association for Utah Community Health
Blue Mountain Heart to Heart	Bluebonnet Trails Community Services
Bobby E. Wright Comprehensive Behavioral Health Center, Inc.	Camden Coalition of Healthcare Providers
Care Plus NJ	CARMAhealth
Cherry Hill Women's Center	Children's Aid and Family Services

CHOICE Regional Health Network and Cascade Pacific Action Alliance	Columbia University Mailman School of Public Health Department of Epidemiology
Community Health Center of Snohomish County	Community Psychiatric Institute
COPE Center, Inc.	Country Doctor Community Health Centers
Dave Purchase Project/Tacoma Needle Exchange	Elevate Health
Family Health Centers	Gather Church/Gather Meds First
Greater Columbia Accountable Community of Health	Hepatitis Education Project
Indiana Primary Health Care Association	Iowa Primary Care Association
King County, WA	Last Overdose
Medical Society of New Jersey	Mental Health Association in New Jersey
Mid-Atlantic Association of Community Health Centers	Monterey County Prescribe Safe Initiative
Moore Health Solutions	Neighborcare Health
New Jersey Association of Mental Health and Addiction Agencies	New Jersey Coalition for Addiction Recovery Support (NJ-CARS)
New Jersey Harm Reduction Coalition	New Jersey Leadership Team, American Academy of Emergency Medicine (DVAAEM)
New Jersey Organizing Project	New Jersey Reentry Corporation
North Sound Accountable Community of Health	Northwest Health Law Advocates
Ohio Association of Community Health Centers (OACHC)	Olympia Bupe Clinic at Capital Recovery Center
Pennsylvania Association of Community Health Centers (PACHC)	Preferred Behavioral Health Group

Public Defender Association	PursueCare
Rights & Democracy	Texas Association of Addiction Professionals
Texas Criminal Justice Coalition	Texas Recovery Network Solutions
The Peoples Harm Reduction Alliance	The University of Texas at Austin PhARM Program
The University of Texas at Austin, UT Health Austin	University Hospital, Newark
University of Texas Health Science Center at Houston	University of Washington School of Medicine
USC Institute for Addiction Science	Vantage Health System
VNA of Central Jersey Children & Family Health Institute	VOCAL-NY
VOCAL-WA	Washington Academy of Family Physicians
Washington Association for Community Health	Washington Association for Sheriffs and Police Chiefs
Washington Chapter of the American College of Emergency Physicians	Washington Recovery Alliance
Washington Recovery Helpline	Washington State Association of Drug Court Professionals
Washington State Hospital Association	Washington State Medical Association
Washington State Medical Group Management Association	We Care Daily Clinics

ⁱⁱ Id.

ⁱⁱⁱ National Academy of Sciences, Engineering, and Medicine, *Consensus Study Report: Medications for Opioid Use Disorder Save Lives*, Nat'l Acad. Press (2019).

^{iv} See id.

^v Congressional Research Svc., *Buprenorphine and the Opioid Crisis: A Primer for Congress* (2018); National Academy of Sciences, Engineering, and Medicine (2019); Substance Abuse and Mental Health Svcs. Admin. ("SAMHSA"), *Treatment Improvement Protocol (TIP) 63: Medications for Opioid Use Disorder* (2020).

^{vi} See U.S. Dep't of Justice, Drug Enforcement Admin. ("DEA"), Guidance Document on Telemedicine Prescription of Buprenorphine During the National Public Health Emergency (Mar. 31, 2020).

^{vii} 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").

viii Practice Guidelines for the Administration of Buprenorphine for Treating Opioid Use Disorder, 86 F.R. 22,439 (Apr. 28, 2021).

^{ix} See SAMHSA, *FAQs About the New Buprenorphine Practice Guidelines* (Apr. 27, 2021) ("Why not just eliminate the X waiver? Removal of the requirement to apply for a waiver to treat those with OUD with buprenorphine, as set forth in the Controlled Substances Act (CSA), requires legislative action.").

* U.S. Dep't Health and Human Svcs. ("HHS"), HHS Expands Access to Treatment for Opioid Use Disorder (Jan. 14, 2021).

xⁱ See 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); 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).

xⁱⁱ See, e.g., Adam J. Gordon, M.D., M.P.H. et al., Outcomes of DATA 2000 Certification Trainings for the Provision of Buprenorphine Treatment in the Veterans Health Administration, 17 Am. J. on Addictions 459-62 (2008).

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

xiv Andrew S. Huhn, Ph.D. and Kelly E. Dunn, Ph.D., *Why Aren't Physicians Prescribing More Buprenorphine?*, 78 J. Substance Abuse Treatment, 1-7 (2017).

^{xv} 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).

xvi DEA, NFLIS-Drug 2019 Annual Report (2019) Table 1.1.

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

^{xviii} Id.

^{xix} Id.

xx 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).

xxi National Academy of Sciences, Engineering, and Medicine (2019); National Academy of Sciences, Engineering, and Medicine (2020).

xxii Haffajee et al. (2019).

xxiii See SAMHSA, Practitioner and Program Data (data accessed May 4, 2021).

xxiv Nat'l Inst. of Health, Physician-pharmacist collaboration may increase adherence to opioid addiction treatment (2021).

xxv See U.S. Government Accountability Office, Report to Congressional Committees: Veterans Healthcare, Services for Substance Use Disorders, and Efforts to Address Access Issues in Rural Areas (Dec. 2019); HHS, Geographic Disparities Affect Access to Buprenorphine Services for Opioid Use Disorder (2020); SAMHSA, The Opioid Crisis and the Black/African American Population: An Urgent Issue (2020); SAMHSA, The Opioid Crisis and the Hispanic/Latino Population: An Urgent Issue (2020); RADM Michael E. Toedt, MD, FAAFP, Chief Medical Officer, Indian Health Service, Testimony Before the Senate Committee on Indian Affairs, Oversight Hearing: "Opioids in Indian Country: Beyond the Crisis to Healing the Community" (Mar. 14, 2018); Pooja A. Lagisetty, M.D., M.Sc. et al., Buprenorphine Treatment Divide by Race/Ethnicity and Payment, 76(9) JAMA Psychiatry 979-81 (2019); Max Jordan Nguemeni Tiako, M.S. et al., Prevalence and Geographic Distribution of Obstetrician-Gynecologists Who Treat Medicaid Enrollees and Are Trained to Prescribe Buprenorphine, 3(12) JAMA Network Open (Dec. 11, 2020).

¹ Centers for Disease Control and Prevention, 12 Month-Ending Provisional Number of Drug Overdose Deaths (September 2020).