

Congress of the United States
Washington, DC 20515

July 29, 2021

The Honorable Miriam Delphin-Rittmon
Assistant Secretary for Mental Health and Substance Use
U.S. Department of Health and Human Services
5600 Fishers Lane
Rockville, MD 20857

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

The Honorable Regina LaBelle
Acting Director
Office of National Drug Control Policy
The White House
1600 Pennsylvania Ave., NW
Washington, DC 20500

Dear Assistant Secretary Delphin-Rittmon, Administrator Milgram, and Acting Director LaBelle,

We write to urge you to ensure that individuals with opioid use disorder (OUD) can continue to access effective treatment as the country recovers from the COVID-19 pandemic. The federal government's response to the pandemic has included the grant of several regulatory flexibilities that improved access to substance abuse disorder treatment for individuals with OUD, while also protecting the health and safety of patients and providers.¹ Maintaining and extending those flexibilities post-pandemic is in the best interests of all those dealing with, and those helping to treat, OUD.

The Substance Abuse and Mental Health Services Administration (SAMHSA), in conjunction with the Drug Enforcement Administration (DEA), granted these flexibilities, and SAMHSA and the Office of National Drug Control Policy (ONDCP) have said they intend to review and consider extending them. We urge SAMHSA, ONDCP, and DEA to 1) move quickly to make permanent the regulatory flexibilities they have implemented, specifically the greater use of telehealth to initiate and continue controlled medications for addiction treatment (MAT) and expanded take-home methadone; 2) maintain these regulatory flexibilities while these agencies consider any permanent regulatory changes; and 3) use this opportunity to evaluate other potential regulatory changes that could increase access to OUD care, including allowing Opioid Treatment Programs (OTPs) to provide methadone to new OTP patients via a telehealth evaluation, as well as pharmacy dispensing of methadone prescribed by an OTP-affiliated authorized prescriber.

Before the start of the COVID-19 pandemic, the United States was experiencing an unfortunate reversal in the decline in overdose deaths.² That deadly trend accelerated during the pandemic. During 2020, it is estimated that approximately 93,000 Americans lost their lives to a drug overdose— a record for a 12-

¹ Substance Abuse and Mental Health Services Administration, *Coronavirus (COVID-19), Guidance for OTPs* (last updated June 21, 2021), <https://www.samhsa.gov/coronavirus>; Drug Enforcement Administration, Diversion Control Division, *COVID-19 Information Page, Medication Assisted Treatment (MAT)*, <https://www.deadiversion.usdoj.gov/coronavirus.html>.

² National Institute on Drug Abuse, *Overdose Death Rates*, <https://www.drugabuse.gov/drug-topics/trends-statistics/overdose-death-rates> (last updated Jan. 29, 2021).

month period and a 30-percent increase over the prior period.³ Despite these dire numbers, the most effective treatment for OUD—MAT—continues to be underutilized, in part due to barriers to treatment.⁴

Medication for addiction treatment is often part of an evidence-based treatment plan that includes counseling and behavioral therapies to treat OUD. These medications are proven to be safe and effective; studies show MAT reduces opioid use, opioid overdose deaths, criminal activity, and transmission of infectious diseases.⁵ One study found MAT reduces fatal opioid overdoses by almost 60 percent for patients receiving methadone and 38 percent for patients receiving buprenorphine.⁶ MAT continues to be underutilized in part due to regulations that require patients to make frequent trips to OTP clinics to receive their medication.⁷ This makes it more difficult for patients in rural areas, patients who work, or patients discouraged by stigma to adhere to MAT regimens. Furthermore, these barriers exacerbate existing racial and socioeconomic disparities in access to substance use disorder treatment.⁸

In response to the COVID-19 pandemic, SAMHSA took a number of significant steps to reduce barriers to care while allowing people to comply with public health guidance around social distancing and reducing unnecessary in-person interactions with others. Specifically, SAMHSA and the DEA allowed providers to prescribe buprenorphine to new patients via telehealth and to care for patients on buprenorphine or methadone using telehealth. SAMHSA also allowed expanded use of take-home methadone, with stable patients able to receive up to a 28-day take-home supply and less stable patients to receive up to a 14-day supply.⁹ In addition to protecting patients and providers from exposure to COVID-19, these flexibilities significantly improved OUD treatment by reducing the need for patients to make frequent visits to OTP clinics, making it easier for patients to adhere to treatment regimens.¹⁰

Expansion of MAT is critical to reducing opioid addiction levels and overdose deaths. We are pleased that the Biden-Harris Administration Statement of Drug Policy Priorities for Year One included as its top priority expanding access to evidence-based treatment.¹¹ Reevaluation of regulations on MAT is vital to

³ Centers for Disease Control and Prevention, National Center for Health Statistics *Provisional Drug Overdose Death Counts*, <https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm> (last updated July 14, 2021).

⁴ *Medications for Opioid Use Disorder Improve Patient Outcomes*, The Pew Charitable Trusts (Dec. 17, 2020), <https://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2020/12/medications-for-opioid-use-disorder-improve-patient-outcomes>.

⁵ National Institute on Drug Abuse, *Effective Treatments for Opioid Addiction* (last updated November 2016), <https://www.drugabuse.gov/publications/effective-treatments-opioid-addiction>.

⁶ Marc R. Larochelle et al., *Medication for Opioid Use Disorder After Nonfatal Opioid Overdose and Association With Mortality*, 169 *Annals of Internal Medicine* 3, 137-145 (2018).

⁷ Bridget C.E. Dooling & Laura Stanley, *Extending Pandemic Flexibilities for Opioid Use Disorder Treatment: Telemedicine & Initiating Buprenorphine Treatment*, The George Washington University Center for Regulatory Studies (Feb. 23, 2021), https://regulatorystudies.columbian.gwu.edu/sites/g/files/zaxdzs3306/f/downloads/PEW_Opioids/GW%20Reg%20Studies_REPORT_Telemedicine%20and%20Buprenorphine_BDooling%20and%20LStanley.pdf.

⁸ *Double Jeopardy: COVID-19 and Behavioral Health Disparities for Black and Latino Communities in the U.S.*, Substance Abuse and Mental Health Services Administration. (Last visited July 7, 2021), <https://www.samhsa.gov/sites/default/files/covid19-behavioral-health-disparities-black-latino-communities.pdf>.

⁹ Substance Abuse and Mental Health Services Administration, *Coronavirus (COVID-19), Guidance for OTPs* (last updated June 21, 2021), <https://www.samhsa.gov/coronavirus>.

¹⁰ Christine Vestal, *COVID-19 Eased Drug Treatment Rules—And That Saved Lives*, The Pew Charitable Trusts (Dec. 18, 2020), <https://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2020/12/18/covid-19-eased-drug-treatment-rules-and-that-saved-lives>.

¹¹ Executive Office of the President Office of National Drug Control Policy, *The Biden-Harris Administration's Statement of Drug Policy Priorities for Year One* (Apr. 1, 2021), <https://www.whitehouse.gov/wp->

meeting this priority. The regulatory flexibilities SAMHSA granted in response to the COVID-19 pandemic are an important step for expanding access to care, and the nature of the pandemic-driven changes provide SAMHSA and ONDCP the opportunity to evaluate their effectiveness using real-world evidence.

However, SAMHSA and agency partners must move expeditiously to evaluate these regulatory flexibilities and must ensure that they are not ended prematurely. Many patients with OUD have come to rely on the flexibilities granted in response to COVID-19. Ending these flexibilities prematurely could disrupt treatment for patients, with the potential for increased instances of relapse and overdose. Further, SAMHSA should use this opportunity to review the necessity of other burdensome requirements on OTPs, such as the in-person evaluation requirement for initiating methadone treatment. SAMHSA authorized use of telehealth for initiating treatment of OUD with buprenorphine and monitoring methadone treatment; allowing use of telehealth to initiate methadone treatment could further expand access to this care. More than 88 percent of rural counties have a shortage of OTPs.¹² Allowing the use of telehealth for the provision of methadone to new OTP patients could help address these shortages.

We appreciate the steps taken to respond to the opioid crisis during the COVID-19 pandemic. We urge the Biden-Harris Administration to maintain these regulatory flexibilities and to use the opportunity provided by the COVID-19 pandemic to examine ways to further reduce barriers to MAT.

Sincerely,



Edward J. Markey
United States Senator



Ann McLane Kuster
Member of Congress



Elizabeth Warren
United States Senator



David Trone
Member of Congress



Tammy Baldwin
United States Senator



Lori Trahan
Member of Congress

[content/uploads/2021/03/BidenHarris-Statement-of-Drug-Policy-Priorities-April-1.pdf?fbclid=IwAR2TBk34U_XRqlqK_pAYnUd_9f7zY3IbCQI9KxI6S5eYeRJdFzI9B09hZ84](https://www.samhsa.gov/content/uploads/2021/03/BidenHarris-Statement-of-Drug-Policy-Priorities-April-1.pdf?fbclid=IwAR2TBk34U_XRqlqK_pAYnUd_9f7zY3IbCQI9KxI6S5eYeRJdFzI9B09hZ84).

¹² Andrew W. Dick et al., *Growth In Buprenorphine Waivers For Physicians Increased Potential Access To Opioid Agonist Treatment, 2002–11*, 34 *Health Affairs* 6, 1028-1034 (2015).

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Cory A. Booker
United States Senator

A handwritten signature in blue ink, appearing to read 'Lisa Blunt Rochester'.

Lisa Blunt Rochester
Member of Congress

A handwritten signature in blue ink, appearing to read 'Sheldon Whitehouse'.

Sheldon Whitehouse
United States Senator