

United States Senate

WASHINGTON, DC 20510

May 4, 2023

The Honorable Merrick B. Garland
Attorney General
U.S. Department of Justice
950 Pennsylvania Avenue, NW
Washington, DC 20530-0001

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

RE: Proposed Rules on Expansion of Induction of Buprenorphine via Telemedicine Encounter
RIN 1117-AB78

Dear Attorney General Garland and Administrator Milgram:

After the COVID-19 pandemic was declared a Public Health Emergency (PHE) in March 2020, the Drug Enforcement Administration (DEA) made it easier for people to access opioid use disorder (OUD) medication treatment by allowing them to get it through telemedicine. Now that the declared COVID-19 PHE is coming to an end, we are pleased that the DEA has proposed regulations to make some of these flexibilities permanent.¹ But we are concerned that the proposed regulations are overly restrictive for people trying to obtain and maintain access to buprenorphine, an evidence-based medication treatment for OUD.

Generally, medication treatment for OUD helps people maintain remission and recovery.² Buprenorphine is one of three medications approved to treat OUD,³ and because it is one of only two medications for OUD that is not restricted to an opioid treatment program, it is one of the

¹ Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation, 88 Fed. Reg. 12875 (proposed March 1, 2023) (to be codified at 21 C.F.R. pts. 1300, 1304, 1306), <https://www.federalregister.gov/documents/2023/03/01/2023-04248/telemedicine-prescribing-of-controlled-substances-when-the-practitioner-and-the-patient-have-not-had>; Expansion of Induction of Buprenorphine via Telemedicine Encounter, 88 Fed. Reg. 12890 (Mar. 1, 2023) (to be codified at 21 C.F.R. pts. 1300, 1304, 1306), <https://www.federalregister.gov/documents/2023/03/01/2023-04217/expansion-of-induction-of-buprenorphine-via-telemedicine-encounter>.

2

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

³ *Information about Medication Assisted Treatment*, U.S. Food and Drug Administration (Feb. 2019), <https://www.fda.gov/drugs/information-drug-class/information-about-medication-assisted-treatment-mat>.

more accessible medications in outpatient settings and pharmacies.⁴ Along with methadone, buprenorphine is considered a treatment of choice for people who are pregnant and breastfeeding,⁵ and is associated with decreased risks for HIV, Hepatitis C infections, unemployment, and imprisonment.⁶

Recognizing buprenorphine's benefits, both Congress and the Biden administration have acted to increase access to it. In December 2022, Congress removed a separate DEA certification requirement for practitioners who prescribe buprenorphine for OUD, facilitating buprenorphine's prescription. The Biden administration has quickly moved to implement these changes.

Additionally, the DEA made necessary changes to guarantee access to buprenorphine despite the COVID-19 pandemic. In particular, the DEA allowed medical providers to prescribe buprenorphine to treat OUD through telemedicine, without the requirement of an in-person patient visit.⁷ Before March 2020, individuals were required to have at least one in-person medical examination before being prescribed buprenorphine through telemedicine.⁸ These flexibilities were essential for ensuring access to medication treatment for OUD and, in a study conducted by researchers at the National Institute on Drug Abuse and the Centers for Disease Control and Prevention, they "were not associated with an increased proportion of overdose deaths involving buprenorphine."⁹ Instead, the flexibilities resulted in more people enrolling in treatment, remaining in treatment longer, and reducing their risks for overdose.¹⁰

Moreover, research shows that buprenorphine is rarely viewed by patients in treatment for OUD as their primary drug of misuse.¹¹ Most individuals who used diverted buprenorphine

⁴ *What is Buprenorphine*, University of Arkansas for Medical Sciences Psychiatric Research Institute (2023), <https://psychiatry.uams.edu/clinical-care/cast/buprenorphine/>.

⁵ *Buprenorphine*, Substance Abuse and Mental Health Services Administration (Jan. 25, 2023), <https://www.samhsa.gov/medications-substance-use-disorders/medications-counseling-related-conditions/buprenorphine>.

⁶ Amy Goldstein, *Biden Administration Eases Restrictions on Prescribing Treatment for Opioid Addiction*, Washington Post (Apr. 27, 2021), https://www.washingtonpost.com/health/biden-administration-eases-restrictions-on-prescribing-treatment-for-opioid-addiction/2021/04/27/9a1c8fa4-a776-11eb-8d25-7b30e74923ea_story.html.

⁷ Covid-19 Information Page, U.S. Department of Justice Drug Enforcement Administration, Diversion Control Division, <https://www.deadiversion.usdoj.gov/coronavirus.html> (last visited Mar. 16, 2023).

⁸ *COVID-19 Information Page*, U.S. Department of Justice, Drug Enforcement Administration, <https://www.deadiversion.usdoj.gov/coronavirus.html> (last visited Mar. 16, 2023).

⁹ Lauren J. Tanz et al., *Trends and Characteristics of Buprenorphine-Involved Overdose Deaths Prior to and During the COVID-19 Pandemic*, JAMA Network (Jan. 20, 2023), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2800689?utm_source=For_The_Media&utm_medium=referral&utm_campaign=ftm_links&utm_term=012023; News Release: Overdose Deaths Involving Buprenorphine Did Not Proportionally Increase with New Flexibilities in Prescribing, Nat'l Inst. on Drug Abuse (Jan. 20, 2023), <https://nida.nih.gov/news-events/news-releases/2023/01/overdose-deaths-involving-buprenorphine-did-not-proportionally-increase-with-new-flexibilities-in-prescribing>.

¹⁰ *Id.*

¹¹ *Medications to Treat Opioid Use Disorder Research Report*, National Institute of Drug Abuse (Dec. 2021), <https://nida.nih.gov/publications/research-reports/medications-to-treat-opioid-addiction/what-treatment-need-versus-diversion-risk-opioid-use-disorder-treatment>.

reported difficulty finding OUD treatment and a preference for prescribed buprenorphine.¹² The benefits of making buprenorphine more medically accessible to prevent the use of illicit opioids, overdoses, and deaths, far outweigh the risks of buprenorphine-involved diversion.

With the impending end of the COVID-19 PHE, the DEA is now rolling back some of these needed flexibilities in proposed regulations to create permanent telehealth rules¹³ — an avoidable retrenchment. Although the proposed new rules are a step forward in telehealth access compared to pre-pandemic rules, they will now require any new OUD patient who starts buprenorphine treatment through telemedicine to find and see a provider in-person to renew their prescription beyond an initial 30 days.¹⁴ Receiving a limited 30-day prescription of buprenorphine with no guarantee of continued treatment poses significant risks for individuals experiencing OUD and may result in a return to illicit drug use, overdose, or even death.¹⁵

The in-person medical appointment requirement is especially problematic. Individuals may face barriers attempting to secure an in-person appointment with a medical provider, particularly in rural areas and medically underserved communities, due to lack of availability, stigma associated with OUD, and transportation challenges.¹⁶ With fentanyl-related overdoses now the leading cause of death for people under age 50¹⁷ and the majority of people who need OUD treatment not receiving it,¹⁸ any gap between OUD prevalence and the availability of treatment has adverse and, in some cases, catastrophic consequences. For each day someone with OUD takes buprenorphine, there is an approximately 70 percent reduction in the likelihood that they will die from an overdose.¹⁹

¹² *Id.*

¹³ Expansion of Induction of Buprenorphine via Telemedicine Encounter, 88 Fed. Reg. 12890 (Mar. 1, 2023) (to be codified at 21 C.F.R. pts. 1300, 1304, 1306), <https://www.federalregister.gov/documents/2023/03/01/2023-04217/expansion-of-induction-of-buprenorphine-via-telemedicine-encounter>.

¹⁴ Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation, 88 Fed. Reg. 12875 (proposed March 1, 2023) (to be codified at 21 C.F.R. pts. 1300, 1304, 1306), <https://www.federalregister.gov/documents/2023/03/01/2023-04248/telemedicine-prescribing-of-controlled-substances-when-the-practitioner-and-the-patient-have-not-had>.

¹⁵ Hilary S. Connery & Roger D. Weiss, *Discontinuing Buprenorphine Treatment of Opioid Use Disorder: What do We (not) Know?*, *American Journal of Psychiatry* 177(2), 104-106 (2020), <https://ajp.psychiatryonline.org/doi/10.1176/appi.ajp.2019.19121245>.

16

Sara Heath, *Average Patient Appointment Wait Time Is 26 Days in 2022*, Xtelligent Health Media (Sept. 15, 2022), <https://patientengagementhit.com/news/average-patient-appointment-wait-time-is-26-days-in-2022>; Shoshana V. Aronowitz et al., *Lowering the Barriers to Medication Treatment for People with Opioid Use Disorder*, Penn Leonard Davis Institute of Health Economics (Jan. 12, 2022), <https://ldi.upenn.edu/our-work/research-updates/lowering-the-barriers-to-medication-treatment-for-people-with-opioid-use-disorder/>.

¹⁷ Arthur Robin Williams & Harold Alan Picus, *Don't Throw the Buprenorphine out with the Bathwater!*, *Health Affairs* (Feb. 8, 2023), <https://www.healthaffairs.org/content/forefront/don-t-throw-buprenorphine-out-bathwater>.

18

Noa Krawczyk et al., *Has the treatment gap for opioid use disorder narrowed in the U.S.?: A yearly assessment from 2010 to 2019*, *International Journal on Drug Policy* (2022), <https://pubmed.ncbi.nlm.nih.gov/35934583/>.

¹⁹ Arthur Robin Williams & Harold Alan Pincus, *Don't Throw the Buprenorphine Out with the Bathwater!*, *Health Affairs* (Feb. 8, 2023), <https://www.healthaffairs.org/content/forefront/don-t-throw-buprenorphine-out-bathwater>.

Our concerns are echoed by many medical organizations, stakeholders, and OUD treatment recipients worried about the transition from the COVID-19 Public Health Emergency to a post-pandemic era. In March 2022, a group of 72 organizations, including the American Psychiatric Association, American Medical Association, and American Telemedicine Association, wrote to the DEA and HHS, expressing concern that numerous individuals, especially new patients, would lose access to care.

In December 2022, the American Hospital Association (AHA), which represents approximately 5,000 member hospitals, health systems, and other care organizations, expressed concern that, upon the end of the COVID-19 Public Health Emergency and the telehealth flexibilities, providers would have to halt services, leaving patients without access to lifesaving OUD treatment.²⁰ The AHA asked the DEA to issue a regulation that would establish a special registration process for telemedicine and waive the in-person visit requirement in accordance with the Ryan Haight Act of 2008.²¹ However, in the more than 14 years since enactment of the Ryan Haight Act, the DEA has still not implemented the law’s special registration process. The DEA has not acted despite Congress reiterating the DEA’s obligation in the SUPPORT for Patients and Communities Act of 2018, which required the Attorney General to promulgate regulations specific to the special telemedicine registration within one year of enactment—2019.²² But the DEA failed to create a pathway for providers to obtain a special telemedicine registration. Instead, in promulgating these new rules, the DEA has claimed that a telemedicine registration process would be “potentially burdensome for both prospective telemedicine providers and patients.”²³ Further, the Ryan Haight Act permits the Administration to allow the practice of telemedicine “under any other circumstances that the Attorney General and the Secretary have jointly, by regulation, determined to be consistent with effective controls against diversion and otherwise consistent with the public health and safety.”²⁴

According to the Centers for Disease Control and Prevention, telemedicine has increased access to care in medically underserved areas and is often seen as a more efficient way to provide care in rural areas where medical services are limited.²⁵ Evidence that telehealth services can be equivalent or superior to in-person care and can result in increased OUD treatment

20

AHA Urges DEA to Release Regulation for Prescribing Controlled Substances via Telehealth after COVID-19 Public Health Emergency, American Hospital Ass’n (Dec. 1, 2022), <https://www.aha.org/news/headline/2022-12-01-aha-urges-dea-release-regulation-prescribing-controlled-substances-telehealth-after-covid-19-public>.

²¹ Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (P.L. 110-425).

²² 21 U.S.C. § 831 (2018).

²³ Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation, 88 Fed. Reg. 12875 (proposed Mar. 1, 2023) (to be codified at 21 C.F.R. pts. 1300, 1304, 1306), <https://www.federalregister.gov/documents/2023/03/01/2023-04248/telemedicine-prescribing-of-controlled-substances-when-the-practitioner-and-the-patient-have-not-had>.

²⁴ 21 U.S.C. §802 (54)(G) (2008).

25

Telehealth and Telemedicine: A Research Anthology of Law and Policy Resources, Centers for Disease Control and Prevention (March 3, 2023), <https://www.cdc.gov/phlp/publications/topic/anthologies/anthologies-telehealth.html>

initiation and retention should help alleviate concerns about telemedicine's effectiveness.²⁶ Furthermore, telehealth's ability to transform the healthcare system, improve patient outcomes, address health disparities, reduce the cost of care, and enhance the safety and effectiveness of care²⁷ has been widely recognized.

The challenges experienced during the COVID-19 pandemic have exacerbated the opioid epidemic²⁸ and militate in favor of the DEA expanding, not limiting, access to buprenorphine for OUD. The DEA should continue to allow audio-video real-time interactive examination, rather than an in-person visit. This would permit medical providers to both see and hear the patients they are evaluating, without reintroducing barriers to care such as limited provider availability, poor transportation accessibility, and long travel times — all exacerbating rural health disparities.²⁹ Indeed, considering the DEA's proposal to allow for an initial 30 days of buprenorphine for OUD without any in-person medical evaluation, the DEA itself appears to acknowledge that a legal prescription for buprenorphine for OUD can occur solely via telemedicine.³⁰ When and whether an in-person evaluation occurs thereafter should remain a clinical decision.

Given the opioid epidemic's scope, we must ensure that all OUD medication treatment options are accessible to everyone, regardless of their geographic location,³¹ economic status, or ability.³² Although the DEA's proposed rules take a step forward in incorporating telehealth, they scale back flexibilities that people relied on to access OUD medication treatment. With more than 200 U.S. overdoses each day, we must not reinstitute barriers to treatment.³³ Now is

²⁶ Christopher M. Jones et al., *Receipt of Telehealth Services, Receipt and Retention of Medications for Opioid Use Disorder, and Medically Treated Overdose Among Medicare Beneficiaries Before and During the COVID-19 Pandemic*, *JAMA Psychiatry* 79(10):981-992 (2022), <https://jamanetwork.com/journals/jamapsychiatry/fullarticle/2795953>.

27

Press Release, American Telemedicine Ass'n, Major Vote of Confidence For Telehealth With President Biden Signing Omnibus Into Law With Two-Year Extensions For Virtual Care Provisions (Jan. 3, 2023), <https://www.americantelemed.org/press-releases/major-vote-of-confidence-for-telehealth-with-president-biden-signing-omnibus-into-law-with-two-year-extensions-for-virtual-care-provisions/>.

28

Chris Sweeney, *A crisis on Top of a Crisis: COVID-19 and the Opioid Epidemic*, Harvard T.H. Chan School of Public Health (Feb. 16, 2021), <https://www.hsph.harvard.edu/news/features/a-crisis-on-top-of-a-crisis-covid-19-and-the-opioid-epidemic/>.

²⁹ Meena Seshamani et al., *Addressing Rural Health Inequities in Medicare* (Feb. 10, 2023), <https://www.cms.gov/blog/addressing-rural-health-inequities-medicare#:~:text=The%20shortage%20of%20health,applicants%20in%20rural%20areas>.

³⁰ See 21 CFR § 1306.04 (“A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.”).

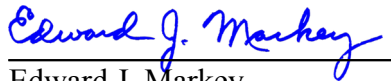
³¹ Penelope Mitchell et al., *Geographic disparities in access to Medication for Opioid Use Disorder across US Census Tracts Based on Treatment Utilization Behavior*, *Social and Science Magazine*, 302, 1 (2022), <https://www.sciencedirect.com/science/article/abs/pii/S0277953622002982?via%3Dihub>.

³² Julia Zur et al., *Medicaid's Role in Financing Behavioral Health Services for Low-Income Individuals*, KFF (June 29, 2017), <https://www.kff.org/medicaid/issue-brief/medicaids-role-in-financing-behavioral-health-services-for-low-income-individuals/>.

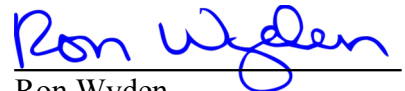
³³ Centers for Disease Control & Prevention, *Vital Statistics Rapid Release: Provisional Drug Overdose Death Counts*, (Feb. 2, 2022) <https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm>.

the time to do everything in our power to give people access to the medications they need to live healthy and productive lives.

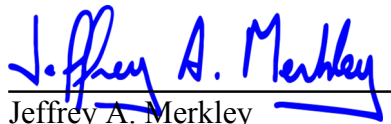
Sincerely,



Edward J. Markey
United States Senator



Ron Wyden
United States Senator



Jeffrey A. Merkley
United States Senator



Martin Heinrich
United States Senator



Sheldon Whitehouse
United States Senator



Elizabeth Warren
United States Senator
