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April 28, 2021

The Honorable Patty Murray
Chairman
United States Senate
Committee on Health, Education,
Labor and Pensions
428 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Richard Burr
Ranking Member
United States Senate
Committee on Health, Education,
Labor and Pensions
727 Hart Senate Office Building
Washington, DC 20510

Dear Chairman Murray and Ranking Member Burr,

With more than 570,000 Americans lost to COVID-19, we must not forget that before the pandemic, our nation was already in the midst of an opioid overdose crisis that continues to kill hundreds of Americans each day. While we do not yet know the full impact the pandemic will have on the opioid overdose crisis, provisional data from the Centers for Disease Control and Prevention (CDC) predicts that more than 90,000 people died of an overdose in the 12-month period ending in September 2020, the vast majority involving opioids.[1] This represents a nearly 29% increase in one year—a staggering and growing death toll is impacting communities from coast to coast. Every state and the District of Columbia has seen overdose deaths rise, and it has accelerated during COVID-19.

Thank you for holding the hearing "Examining Our COVID-19 Response: Using Lessons Learned to Address Mental Health and Substance Use Disorders." This hearing is not only timely, but the lessons learned could have a life-saving impact long after the pandemic.

The Pew Charitable Trusts (Pew) is an independent, nonpartisan research and policy organization. Through its Substance Use Prevention and Treatment Initiative, Pew works with states and at the federal level to address the nation's opioid overdose crisis by developing solutions that improve access to timely, comprehensive, evidence-based, and sustainable treatment for opioid use disorder (OUD).

Over the past year, our team has monitored the impact of the COVID-19 pandemic on the U.S. substance use treatment system. The pandemic has underscored the need for policy changes that increase access to life-saving treatment for OUD.

Eliminate barriers to medications for opioid use disorder (MOUD)

The devastating loss of life from opioid overdose is even more tragic because it is preventable. OUD is a chronic brain disease that, like other chronic diseases, can be successfully treated with medications approved by the Food and Drug Administration (FDA). A conclusive body of research demonstrates that medication for opioid use disorder (MOUD) is the most effective way

to treat the disease and substantially reduces mortality from overdoses. Two of the medications approved by FDA to treat OUD— methadone and buprenorphine— have been found to reduce mortality from OUD by up to 50 percent.[2]

Prior to the pandemic, individuals with OUD struggled to get effective care: In 2019, only 18.1 percent of the 1.6 million people aged 12 or older with opioid use disorder received MOUD. As the pandemic continues to strain the U.S. health care system, it is creating even greater hardships for individuals seeking OUD treatment.

Of the three medications approved by FDA to treat OUD, access to buprenorphine in particular has proven to be critical in response to COVID-19. Unlike opioids commonly prescribed to control pain, buprenorphine has a ceiling effect, meaning that its effects will not increase even with repeated dosing, minimizing the risk of respiratory depression leading to fatal overdose compared to other opioid medications. Prescribing buprenorphine for OUD is no more complex to manage than other chronic conditions treated in primary care and is safe to dispense from a pharmacy and take at home.

During the pandemic, buprenorphine is the only FDA-approved medication for OUD that can be prescribed without an in-person visit to a doctor or treatment facility. While COVID-19 had made this medication even more critical for people experiencing self-isolation and quarantine, outdated federal regulations continue to limit access to the medication.

Yet despite the relative safety of the drug, federal rules established by the DATA 2000 Act require practitioners who prescribe buprenorphine to receive additional training, registration, and oversight, as well as obtain an additional waiver (known as the X-waiver) from the Drug Enforcement Administration (DEA). DEA data show that only about 6% of American doctors have chosen to obtain an X-waiver, and 2020 HHS Office of Inspector General report found that 40% of U.S. counties did not have a single waivered provider who can prescribe buprenorphine.[3] This lack of providers leaves millions of Americans, disproportionately in rural areas, without access to local health care providers who can prescribe this life-saving medication.

On Tuesday, April 27, the Biden Administration announced prescribing guidelines for buprenorphine that go into effect today. These guidelines will exempt eligible practitioners (including physicians and mid-level practitioners) from required training for prescribing buprenorphine to as many as 30 patients. This action signals a significant step forward in expanding access to MOUD. However, the Administration does not have the authority to eliminate the X-waiver in its entirety without legislative action by Congress, and the new policy's prescribing flexibility leaves critical procedural requirements and patient count limitations in place—legislation is still needed to fully ensure that all prescribers can assist OUD patients.

Pew strongly encourages Congress to pass the Mainstreaming Addiction Treatment Act (S. 445). This bipartisan legislation would remove the outdated and burdensome federal rules established by the DATA 2000 Act that require health care practitioners to obtain a waiver from the DEA before prescribing buprenorphine to treat OUD. As the U.S. health care system is being

pushed past its capacity by the pandemic, having regulations in place that further limits OUD treatment to a small minority of physicians can no longer be justified.

Telehealth for buprenorphine initiation

The telehealth regulatory flexibilities during the COVID-19 emergency that allow patients to initiate buprenorphine after a telehealth consultation with a prescriber have expanded access to OUD treatment for people who would otherwise be without care. In particular, audio-only telehealth for buprenorphine initiation has been able to reach people facing economic hardship—like individuals leaving incarceration or experiencing homelessness—or living in areas with inadequate broadband access who are less likely to have technology for audiovisual telehealth visits.[4] Audio-only flexibility is also spurring innovative approaches to engage people in treatment, such as Rhode Island's 24/7 telephone hotline that initiated buprenorphine for 74 new patients from mid-April 2020 to mid-November 2020, and linked them to community providers for ongoing care.[5]

As evaluations showing positive outcomes from new telehealth programs continue to emerge, there is still no evidence that in-person visits are more effective than telemedicine visits in improving treatment outcomes or curtailing diversion.[6] In fact, studies show no difference in adverse events or 30-day retention between patients initiating buprenorphine treatment at home compared to in-office, and suggest that patients are less likely to no-show for telehealth appointments versus in-person visits.[7]

Given the transformative impact on access to treatment from these telehealth flexibilities, practitioners and public health experts are concerned about returning to restrictive telehealth regulations once the COVID-19 emergency declaration ends. A recent report by George Washington University's Center for Regulatory Studies found that DEA and the Substance Abuse and Mental Health Services Administration (SAMHSA) jointly have authority to continue allowing practitioners to prescribe buprenorphine without first conducting an in-person medical evaluation.[8] Accordingly, Congress should use its oversight role to encourage the agencies to make this policy permanent.

Take home methadone dosing

Though methadone initiation requires an in-person visit, patients have benefited from more flexible take-home policies as a result of the COVID-19 flexibilities that allow state regulatory authorities to request blanket exceptions for patients to be able to take home more medication doses—up to 28 days for "stable" patients and up to 14 days for "less stable" patients—and receive counseling via telehealth. This removes a critical barrier to treatment since most methadone patients must visit an opioid treatment program daily to receive their medication.[9]

Recent data shows that these take-home flexibilities are working: at three North Carolina opioid treatment programs, more than 90% of patients received take-home methadone doses versus 68% prior to the pandemic, and the programs reported that diversion of the medication was uncommon.[10] In addition, allowing patients to have a take-home supply early in treatment has been shown to increase retention.[11] Accordingly, SAMHSA has emphasized the importance of

accommodating take-home policies that promote individualized care and can encourage people to enter into and remain in treatment.[12]

To continue this promising new expansion of methadone treatment post-COVID-19 emergency declaration, Congress should use its oversight role to encourage SAMHSA to make this flexibility permanent, which the agency can do through its statutory authority.[13]

Thank you for your continuing efforts to support expanding access to OUD treatment and for taking swift action to address the coronavirus pandemic. As the committee's work continues on this issue continues, Pew encourages the Committee to prioritize proposals that increase the availability of comprehensive and evidence-based treatment for OUD and improve care provided to vulnerable populations. Pew welcomes the opportunity to work with you to reduce the human toll related to the opioid crisis.

Sincerely,

Elizabeth Connolly
Director, Substance Use Prevention and Treatment Initiative

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