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December 2, 2019

The Honorable Frank Pallone
Chairman
House Energy and Commerce Committee
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Greg Walden
Ranking Member
House Energy and Commerce Committee
2322 Rayburn House Office Building
Washington, DC 20515

The Honorable Jerrold Nadler
Chairman
House Judiciary Committee
2132 Rayburn Building
Washington, DC 20515

The Honorable Doug Collins
Ranking Member
House Judiciary Committee
2142 Rayburn House Office
Washington, DC 20515

The Honorable Richard Neal
Chairman
House Ways and Means Committee
1102 Longworth House Office Building
Washington D.C. 20515

The Honorable Kevin Brady
Ranking Member
House Ways and Means Committee
1139 Longworth House Office Building
Washington D.C. 20515

Dear Chairmen Pallone, Nadler and Neal, Ranking Members Walden, Collins, and Brady:

The Pew Charitable Trusts (Pew), is a global research and public policy organization dedicated to serving the public. Operated as an independent, nonpartisan non-profit, Pew applies a rigorous, analytical approach to improve public policy, inform the public, and invigorate civic life.

For the past several years, Pew has performed in-depth research and analysis on strategies to address the nation's opioid crisis. Through its Substance Use Prevention and Treatment Initiative, Pew collaborates with states in their efforts to improve access to timely, comprehensive, evidence-based, and sustainable treatment for opioid use disorder (OUD).

Pew applauds the introduction of the Mainstreaming Addiction Treatment Act (the MAT Act, H.R. 2482). This bipartisan legislation would remove the federal rules established by the DATA 2000 Act that require health care practitioners to obtain a waiver (known as an X-waiver) from the U.S. Drug Enforcement Agency (DEA) before prescribing buprenorphine to treat OUD. For the roughly two million Americans who met criteria for OUD in the past year,[1] this legislation will help expand access to life-saving care.

We make the following key points:

1. **Medication for addiction treatment is the gold standard**

Buprenorphine, one of three drugs approved by the Food and Drug Administration (FDA) to treat OUD, alleviates the painful symptoms associated with OUD and reduces mortality by up to 50 percent.[2] People who receive medication for OUD not only are less likely to die of an overdose, they are also less likely to use illicit opioids and contract infectious diseases such as HIV and hepatitis C.[3] Patients on buprenorphine stay in treatment longer than those not on medication,[4] which decreases their risk of overdose death.[5] Patients who receive medication also report a better quality of life compared to individuals with OUD not receiving medication to treat the disorder.[6]

Though counseling in addition to medication may be appropriate for some patients, medication alone has proven to be effective for many.[7,8] A randomized study of patients receiving buprenorphine observed no difference between patients receiving physician medication management and physician medication management plus cognitive-behavioral therapy: both groups showed similar reductions in self- reported frequency of illicit opioid use.[9] The National Academies of Science, Engineering, and Medicine (National Academies) recently concluded that given the efficacy of the medications, a lack of available psychosocial supports should not be a barrier to initiating medication treatment.[10]

Evidence of the effectiveness of medication for OUD medication led to support for the Medication First approach to treatment in which patients initiate buprenorphine prior to assessments with no required counseling. In 2017, Missouri expanded access to medication treatment for OUD and found that compared to clients at the same agencies prior to Medication First implementation, clients treated through the Medication First approach are more likely to be retained in care at one month, three months, and six months. [11]

2. **Additional medical training is not necessary to safely prescribe buprenorphine**

Unlike opioids commonly prescribed to control pain, buprenorphine has a ceiling effect, meaning that its effects will not increase even with repeated dosing. Therefore, risk of respiratory depression leading to fatal overdose when taking buprenorphine is minimal compared to other opioid medications.[12]

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. In contrast, any health care provider with a DEA license to prescribe controlled substances can write a prescription for codeine, morphine, hydrocodone, oxycodone or fentanyl. Counterintuitively, federal law thus makes it easier to prescribe opioids than to treat someone with opioid use disorder.

The National Academies recently concluded that no evidence base supports the X-waiver process. [13] Prescribing buprenorphine for opioid use disorder is no more complex to manage than

other chronic conditions treated in primary care,[14,15,16,17] causing the training to obtain an X-waiver to be overly burdensome given the relative safety and simplicity of the medication.

3. The X waiver deters providers from treating patients with OUD

Several studies have found that the added administrative and oversight burden from the DEA act as a barrier to treating substance use disorder. Nearly 40 percent of respondents to a 2015 survey of family physicians in New Hampshire and Vermont cited cumbersome regulations as a barrier to prescribing buprenorphine.[18] In a survey of two major medical associations, not knowing how to obtain a waiver was the second most common reason for not being waivered.[19] In a New York City study, 67 percent of buprenorphine prescribers felt that the 8-hour time commitment to complete the training requirement is a deterrent to obtaining a buprenorphine waiver.[20]

Furthermore, more than half of study participants in the New York City survey considered the DEA a disincentive to offering buprenorphine treatment or getting waivered due to concerns over increased surveillance by the agency.[21] Respondents felt that buprenorphine-waivered prescribers were subject to greater scrutiny than other physicians. Providers noted that the DEA's approach often seemed "threatening" and that they felt "harassed" by the regulatory agency—fears that have heightened in recent years as the DEA has increased the number of raids, audits, and investigations of waivered providers. In addition, delays in receiving the waiver discouraged colleagues from following through with obtaining one, especially for those who experienced months of delay before their buprenorphine waiver was finalized.[22]

4. The threat of buprenorphine misuse is overstated

While buprenorphine misuse and diversion have been historical concerns, today's abuse-deterrent formulations combine buprenorphine with naloxone and have significantly reduced misuse.[23] An analysis of data from the Research Abuse, Diversion and Addiction-Related Surveillance System which tracks the rates of misuse and diversion of medications estimated a 16 percent rate of misuse and diversion for the buprenorphine/naloxone formulation, which is lower than the diversion rates of 25 and 21, respectively, for prescribed antibiotics and allergy medications.[24]

The National Academies asserts that provider concerns about the diversion of medication are not supported by available data. [25] In fact, buprenorphine diversion is often the result of self-medication by people who use opioids who are unable to access treatment, and increased access to buprenorphine in the treatment system can lead to a decline in rates of both misuse and diversion. [26]

We urge Congress, with leadership from your Committees, to pass the MAT Act expeditiously. Given the toll of the opioid epidemic–47,000 Americans lives in 2017 alone[27]— unnecessary and counterproductive regulations should be eliminated to facilitate access to evidence-based care.[28]

Thank you for your continuing efforts to support expanding OUD treatment and for your continued dedication to addressing the nation's opioid crisis. Pew welcomes the opportunity to

work with you to reduce the human toll related to the opioid crisis. Please do not hesitate to contact me at econnolly@pewtrusts.org or 202-540-6735 with any questions.

Sincerely,

Elizabeth Connolly
Director, Substance Use Prevention and Treatment Initiative

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