

## Background

The U.S. is in an opioid public health emergency (Opioid PHE). Substance use disorders (SUD) affect over 61.2 million Americans ages 12 and older. According to the Centers for Disease Control and Prevention (CDC), in 2022, over 109,000 overdose deaths occurred in the U.S. It is estimated that three million people have an opioid use disorder (OUD). Yet only 25 percent of the individuals with an OUD receive specialty SUD treatment. Black, American Indian, and Alaska Native people have the highest overdose death rates and limited access to OUD medications.

Medication-assisted treatment (MAT) is effective for patients with a SUD or an OUD. Previously, providers needed an X-Waiver, a special certification required for providers to prescribe buprenorphine for OUDs, from the Drug Enforcement Administration (DEA). At the end of 2022, Congress passed the Mainstreaming Addiction Treatment Act (MAT Act)<sup>v</sup>, which removed the X-Waiver requirement. Since the removal of the X-Waiver, any provider with a National Provider Identifier (NPI) number can prescribe buprenorphine for OUD treatment as long as they attest to completing an eight-hour training on the treatment and management of patients with opioid or other substance use disorders.

<sup>&</sup>lt;sup>1</sup> On July 4, 2022, the Biden Administration renewed the determination that the Opioid PHE exists nationwide.

However, access to MAT continues to be limited for patients. The Ryan Haight Online Pharmacy Consumer Protection Act of 2008vi (Ryan Haight Act) directly influences access to MAT. This Act amended the Controlled Substances Act to require that the prescribing physician conduct an *in-person* evaluation before a provider can issue a prescription for a controlled substance. This includes prescribing buprenorphine, one of three U.S. Food and Drug Administration (FDA)-approved medications indicated for treating OUD. While the Ryan Haight Act allows for some telehealth exceptions, including a special registration obtained from the DEA, the in-person visit requirement has not helped address the increasing need for treatment. A provision in the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) Act<sup>vii</sup> required that the DEA issue a regulation by October 24, 2019, outlining for providers a special registration to prescribe controlled substances without an in-person visit requirement. However, the Administration has not yet created a registration process to better address patient needs and access to MAT.

During the COVID-19 pandemic, the DEA suspended the in-person visit prescribing requirement and allowed telehealth visits to treat SUDs and OUDs. This flexibility was set to expire at the end of the public health emergency (COVID PHE). The DEA promulgated two notices of proposed rulemaking (NPRM) soliciting comments to allow the prescription of controlled substances via telemedicine. The proposed rules create unnecessary barriers to SUD treatment by limiting when patients can be seen via telemedicine without an inperson visit beforehand. In both NPRMs, the DEA also declined to implement a special registration process as directed by Congress. The response from the public was strong, with more than 38,000 regulatory comments submitted regarding the proposed rule, with a majority of those comments opposing the regulation viii. As a result, the DEA delayed the implementation of the proposed regulations, keeping the COVID-19 pandemic flexibilities in place until

November 2023.

Retaining the in-person requirement before prescribing buprenorphine via telemedicine reduces access to care. The data captured during the COVID PHE demonstrate that the risks of diversion in prescribing buprenorphine are low. Removing this policy during the PHE was not associated with increased overdose deaths. On the contrary, it improved access to care and addressed health inequities in primary care programs. Expanded access to MAT is needed now more than ever, and removing barriers to access is critical to providing lifesaving treatment.

ABHW and its member companies are committed to ending the SUD and OUD epidemics and increasing access to treatment. The recommendations below will help achieve these goals.

## Recommendations

- Eliminate the in-person requirement for prescribing buprenorphine. Not all individuals with SUDs have access to an initial in-person visit with a provider due to behavioral health provider shortages or physical difficulty traveling. While ABHW recognizes that in-person visit requirements may be necessary for certain circumstances where it is a clinical best practice, we do not support mandated in-person requirements across the board. ABHW advocates for actions that would eliminate the in-person evaluation requirement before a provider can prescribe MAT. Little evidence supports the in-person requirement, which creates a barrier to medically necessary care.
- Promulgate special registration rules for MAT. ABHW urges the
  immediate promulgation of the regulations required by federal law that
  directs the DEA to move forward with the telemedicine special
  registration process to enable providers to prescribe MAT to patients
  with SUDs through telemedicine.

## **ISSUE BRIEF**

• **Promote the removal of the X-Waiver.** ABHW supports highlighting the removal of the X-Waiver to health systems and practitioners so that more providers will be willing to prescribe buprenorphine to patients with SUDs.

https://pubmed.ncbi.nlm.nih.gov/34175175/; Use of and Retention on Video, Telephone, and In-Person Buprenorphine Treatment for Opioid Use Disorder During the COVID-19 Pandemic, *JAMA Netw Open.* 2022;5(10):e2236298 available at

https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2797201

 $<sup>^{\</sup>rm i}\, \underline{\text{https://www.samhsa.gov/data/release/2021-national-survey-drug-use-and-health-nsduhreleases}}$ 

iihttps://blogs.cdc.gov/nchs/2023/05/18/7365/#:~:text=Provisional%20Data%20Shows%20U.S .%20Drug,100%2C000%20in%202022%20%7C%20Blogs%20%7C%20CDC

iii https://www.psychiatry.org/patients-families/opioid-use-disorder

iv https://www.cdc.gov/nchs/products/databriefs/db457.htm#print

v Public Law 117-328

vi Public Law 110-425

vii Public Law 115-271

 $<sup>\</sup>frac{v^{iii}}{https://bhbusiness.com/2023/03/29/dea-faces-tsunami-of-criticism-in-comments-on-proposed-telehealth-controlled-substances-rules/}$ 

ix <u>Trends and characteristics of buprenorphine-involved overdose deaths before and during the COVID-19 pandemic</u>, January 2023

<sup>&</sup>lt;sup>x</sup> Comparing telemedicine to in-person buprenorphine treatment in U.S. veterans with opioid use disorder, Journal Substance Abuse Treatment, 2022 Feb;133:108492. doi: 10.1016/j.jsat.2021.108492. Epub 2021 May 28.