4-2023

MAT/MATE Acts

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KEY POINTS

- The DATA Waiver (or X waiver) requirement was removed in the Mainstreaming Addiction Treatment (MAT) Act, meaning providers no longer have to register with the DEA to prescribe buprenorphine as part of treatment for opioid use disorder (OUD).
- Federally, providers already authorized to prescribe controlled substances can now prescribe buprenorphine for OUD, but providers must still be aware of and follow any practicing state regulations.
- Whereas state law does not conflict with federal requirements for physicians, Tennessee state law still imposes limitations on buprenorphine prescribing for nurse practitioners (NPs) and physician assistants (PAs).
- With the X-waiver removal, the United States' overdose rates could possibly decline, given the results seen in other countries.

KEY TERMS

- CAA: Consolidated Appropriations Act of 2023
- CMHC: Community mental health center
- FQCHS: Federally qualified health center
- MAT: Medication-assisted treatment
- MAT Act: Mainstreaming Addiction Treatment Act
- MATE Act: Medication Access and Training Expansion Act
- MOUD: Medications for opioid use disorder
- OBOT: Office-based opioid treatment program
- OTP: Opioid treatment program
- OUD: Opioid use disorder

THE DATA WAIVER (X-WAIVER) IS OFFICIALLY ABOLISHED

The DATA waiver, also known as the X-waiver due to the license number beginning in X, came to be through the Drug Addiction Treatment Act of 2000. This act required providers to apply to the DATA Waiver program through the Substance Abuse and Mental Health Services Administration (SAMHSA) before prescribing buprenorphine or any other Schedule III-V medications as treatment or detoxification for addiction if it was outside of a SAMHSA-certified opioid treatment program (OTP). Along with the waiver, physicians had to complete an 8-hour training, and advanced practice providers (such as nurse practitioners and physician assistants) had to complete a 24-hour training. Federal limits were also placed on the number of patients a provider could treat (30, 100, or 275, depending on certain factors).

However, the Consolidated Appropriations Act of 2023 (CAA) (also known as the 2023 Omnibus bill), included the Mainstreaming Addiction Treatment (MAT) Act which removed the X-waiver requirement, so practitioners no longer have to apply for and obtain a waiver to prescribe buprenorphine as a treatment for opioid use disorder (OUD). SAMHSA will no longer take applications and providers are no longer required to put their DATA Waiver ID (or X-number) on written or printed prescriptions.

The CAA also included the Medication Access and Training Expansion (MATE) Act which requires all healthcare providers, aside from veterinarians, to complete a one-time, eight-hour training on managing patients with substance use disorders when receiving or renewing a registration to prescribe potentially addictive drugs. From a federal perspective, any provider already authorized to prescribe controlled substances can now prescribe buprenorphine without additional authorization. No additional authorization or training is required since the MATE Act built substance use disorder training into the certification process for prescribing controlled substances. This means providers registering for the controlled substance certificate for the first time will have to take the training and a provider re-registering will only be required to take the training if they have not yet. However, all state-level prescribing restrictions still apply.

BUPRENORPHINE PRESCRIBING IN TENNESSEE

Because all state regulations still apply, here is what the removal of the X-waiver will look like for Tennessee providers as laid out by the Tennessee Department of Mental Health & Substance Abuse Services (TDMHSAS). While the following includes major points, it is not a comprehensive list and is subject to change with the development of state and federal policy.

What changes for Tennessee:

- Physicians outside of OTPs, primary care providers, for example, may now prescribe buprenorphine for the treatment of OUD. The DATA Waiver ID (also known as the X-number) is no longer required to be put on buprenorphine prescriptions and only the standard DEA number remains required.
- Patient limits for physicians previously associated with the X-waiver no longer exist, meaning **physicians are no longer limited to treating 30, 100 or 275 patients.** Patient limits for PAs and NPs remain unchanged.
- Supervising physicians of NPs and PAs who prescribe buprenorphine are no longer required to apply for and hold an X-waiver.
- The traditional training associated with the X-waiver is no longer required. However, the MATE act requires providers to attend a one-time, eight-hour training on addiction when applying for or re-registering with the DEA to prescribe controlled substances. So, when applying for a DEA controlled substances prescribing license, all first-time applicants will have to take the training, and all those applying to renew the license must take the training if they have not previously done so. After obtaining the one-time training, they will not have to take it again for future renewals.

THE IMPORTANCE OF BUPRENORPHINE

Medications for opioid use disorder (MOUD) include methadone, naltrexone, and buprenorphine. A partial agonist synthetic opioid, meaning that it activates only some of the opioid receptors in the brain while blocking others, buprenorphine is often the first choice for medication-assisted treatment (MAT) as a tapering drug for several reasons, including its clinically significant mortality benefit. Buprenorphine is a schedule III drug, meaning it has moderate to low potential for physical or psychological dependence. However, the most striking feature of buprenorphine is its ceiling effect on respiratory depression, meaning that while there will be some depression of the respiratory system, once it hits a certain threshold it cannot be further depressed, even if the patient takes additional buprenorphine. Clinically, this means that buprenorphine has a much lower risk of fatal overdose compared to methadone or other opioids. There is also a similar ceiling effect on euphoria, meaning that patients cannot get high on it the same way they can other opioids. Many are concerned about the potential for buprenorphine diversion, but multiple studies show that people who illicitly use buprenorphine do so to lessen withdrawal effects or bridge the gap to treatment, which leads to a lower risk of overdose. In most cases, buprenorphine diversion can be attributed to inadequate access to treatment. A recent study has also shown that less than 1 percent of patients with OUD experienced withdrawal when starting buprenorphine in the emergency room, which can lessen the likelihood that they resume use of illicit opioids.

  - » Additionally, the broadening of the addiction training to be required for all controlled substances and not just buprenorphine could have a destigmatizing effect, wherein buprenorphine would no longer be perceived as inherently more dangerous than other controlled substances. For example, a 2022 qualitative study found that some emergency physicians perceived buprenorphine to be particularly dangerous because of the existence of the DEA-X training requirements unique to buprenorphine.

What has not changed for Tennessee:

- Providers must still follow the Tennessee Nonresidential Buprenorphine Treatment Guidelines which were adopted as policy by the Tennessee Department of Health Licensure Board.
  - » These guidelines were made collaboratively by the Tennessee Department of Mental Health and Substance Abuse Services (TDMHSAS) and the Tennessee Department of Health (TDOH) in response to the enactment of Public Chapter 112 in 2017.
  - » The guidelines were developed and are regularly updated standards that assist practitioners authorized by the state to prescribe buprenorphine-containing products for the treatment of OUD.

- The clinical buprenorphine **prescribing limitations for NPs and PAs remain unchanged**, namely the patient limit (see below), and that a supervising physician can only oversee a maximum of four of such advanced practice providers.
- Buprenorphine can only be prescribed via **telehealth** if the prescriber is employed by or contracted with a licensed OBOT, CMHC, FQHC, hospital, or TennCare's enhanced buprenorphine treatment network (BE-SMART). (Tenn. Code Ann. § 63-1-155). In other words, even though significantly more providers will be eligible to prescribe buprenorphine, the ability to do so via telehealth will remain restricted to those prescribers described in this paragraph.
- The criteria to license an OBOT remains unchanged. A practice requires an OBOT license if it is prescribing buprenorphine-based products to 25 percent or more of its patients, or to 150 or more patients at a time.
- The facility rules regarding the clinical use of buprenorphine in current licensed OBOTs remain unchanged. Examples include the requirement that the prescriber must report the fact that the provider dispenses buprenorphine products to the provider's licensing board, and that they must check the controlled substance database prior to dispensing, etc.
- Additional clinical justification and documentation are still required by the provider when prescribing higher doses of buprenorphine.
  - » Tennessee prescribing guidelines define the target range of buprenorphine to be 4 mg–16 mg per day, with 16 mg per day defined as the recommended maximum.
- For all TennCare enrollees, buprenorphine prescribers must bill or seek reimbursement from TennCare and its managed care organizations.
- Continuing a long-standing rule to deter diversion, cash can still not be accepted as payment for treatment if you are a buprenorphine prescriber. There are exceptions which include using cash to pay for copay, coinsurance, or a deductible only after the patient's insurance has been billed.

PRESCRIBING LIMITATIONS FOR NURSE PRACTITIONERS AND PHYSICIAN ASSISTANTS IN TENNESSEE

Federal law permits NPs, PAs, and additional advanced providers other than physicians to prescribe buprenorphine. However, Tennessee law limits buprenorphine prescribing for OUD to individuals who are not physicians. This law was recently amended in 2020 to allow NPs and PAs to prescribe buprenorphine for OUD in only limited practice settings and with additional clinical limitations including the direct oversight of a physician. The removal of the DATA waiver does not change these statutory limits. As of now, NPs and PAs are only permitted to prescribe buprenorphine in the limited care setting of OBOT, FQHC, and CMHC that accept TennCare. These providers will also continue to be limited to 100 patients at OBOTs and 50 patients at FQHCs and CMHCs. Additionally, the overseeing physician must review ALL (100 percent) of the patient charts that are prescribed buprenorphine, and they are limited to overseeing a maximum of four NPs/PAs.

POSSIBLE OUTCOMES

While there is a lack of research on how this policy change will affect the United States or Tennessee specifically, there is existing research that shows other countries' outcomes regarding the relaxation of buprenorphine policies. For example, as of 2019, the United States had around 14 deaths per 100,000 compared to France's two deaths per 100,000 caused by OUD. This difference may be related to France's deregulation of buprenorphine in 1995 where the overdose death rate dropped 79 percent in the three years after. Similarly, Canada had around five deaths per 100,00 in 2019, and it has been suggested that this difference is due to Canada's relaxation of federal control of opioid agonist therapy. Additionally, America saw 10 times as many overdose fatalities as Germany did in 2016, and this contrast in outcomes has been attributed to increased access to treatment due to Germany's prioritization of primary care and coverage for treatment. Though not on the same scale, the U.S. saw related reductions in overdose mortality following the introduction of buprenorphine. For example, the heroin overdose death rate in Baltimore reduced by 37 percent following the introduction of buprenorphine. With the removal of the X-waiver, the US may see a significant impact on overdose fatalities considering the outcomes in other countries and the known clinical mortality benefit of buprenorphine. If so, a potential increase in the involvement of primary care providers in the treatment of OUD due to the removal of the X-waiver could play a major role in this anticipated decrease in overdose deaths.

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