

Public Guidance Regarding Removal of the DATA Waiver

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Disclaimer:

TDMHSAS recognizes that this is an evolving situation and additional changes at the federal and state level are expected. Information contained in this document reflects information that is known at the date it was last updated.

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What Happened?

On December 29th, 2022, President Biden signed the Consolidated Appropriations Act (CAA) of 2023. The CAA incorporated the Mainstreaming Addiction Treatment Act of 2021 (MAT Act) that removes the DATA Waiver requirement for prescribing Schedule III-V (e.g., buprenorphine) medications for maintenance or detoxification treatment outside of a SAMHSA-certified Opioid Treatment Program (OTP).

SAMHSA and the DEA published initial guidance on January 12th, 2023, announcing that the DATA Waiver program has ended and, effective immediately, the DATA Waiver is no longer required to prescribe buprenorphine for Opioid Use Disorder (OUD).

What Does This Change at the Federal level?

- The DATA Waiver requirement for prescribing buprenorphine for OUD is removed.
- The DATA Waiver program at SAMHSA has ended, and no new applications will be accepted.
- The additional training that was required to obtain the DATA waiver has been removed. *
- The federal patient limits (e.g., the prior prescribing limitations of 30, 100, & 275) associated with the DATA Waiver have been removed.
- The DATA Waiver ID (i.e., X-number) is no longer required to be written/printed on prescriptions for buprenorphine.
- From a federal perspective, any prescriber authorized to prescribe controlled substances can prescribe buprenorphine; however, this authorization is subject to Tennessee-specific restrictions.
- All requirements for prescribing controlled substances, in general, still apply.
- SAMHSA and DEA guidance includes language that states restrictions may still apply.

**The CAA contains another provision (MATE Act) that will require a similar 8 hours of additional training, or the equivalent during formal education, that was required for DATA Waiver applicants for all DEA registrants starting in June 2023.*

How Does This Change Buprenorphine Prescribing in Tennessee?

- Physicians in practices outside of an OTP may now prescribe buprenorphine for the treatment of OUD without the DATA waiver.
- The DATA Waiver I.D., or 'X-number,' is no longer required on buprenorphine prescriptions.
- Physicians are no longer limited to treating 30, 100, or 275 patients, limits previously associated with the

DATA waiver.

- Physicians supervising nurse practitioners or physician assistants who prescribe buprenorphine in office-based opioid treatment programs (OBOTs), federally qualified health centers (FQHCs), or community mental health centers (CMHCs) will no longer be required to hold a DATA Waiver.

What has not Changed Regarding Buprenorphine Prescribing in Tennessee?

- Any prescriber who wishes to prescribe buprenorphine in a nonresidential setting must do so in accordance with the Tennessee Nonresidential Buprenorphine Treatment Guidelines. These guidelines have been adopted as policy by the Tennessee Department of Health licensure boards.
- OBOT licensure criteria remain unchanged. Any facility or practice that prescribes buprenorphine-based products to twenty-five percent (25%) or more of its patients or to one hundred fifty (150) or more patients at one time, requires an OBOT license.
- Licensed OBOT facility rules regarding the clinical use of buprenorphine remain unchanged.
- Nurse practitioners (NPs) and physician assistants (PAs) buprenorphine prescribing clinical limitations remain unchanged. Examples include:
 - NPs and PAs are still only permitted to prescribe buprenorphine for OUD at an OBOT, FQHC, or CMHC that accepts TennCare.
 - NPs and PAs will continue to be limited to 100 patients at OBOTs and 50 patients at FQHCs and CMHCs.
 - High-dose buprenorphine, greater than 16 mg per day or its equivalent, and prescribing mono-product continue to be restricted.
 - The supervising physician must still review 100% of patient charts being prescribed buprenorphine.
- Higher doses of buprenorphine still require additional clinical justification and documentation.
- Buprenorphine prescribers cannot accept cash as payment for treatment unless to pay for a copay, coinsurance, or deductible after billing the patient's insurance.
- Buprenorphine prescribers must bill or seek reimbursement from TennCare and its managed care organizations for all TennCare enrollees.
- Buprenorphine cannot be prescribed via telehealth unless the prescriber is employed by or contracted with a licensed OBOT, CMHC, FQHC, hospital, or TennCare's enhanced buprenorphine treatment network (BE-SMART) and the delivery of telehealth is provided on behalf of these entities.

DATA Waiver Removal: FAQs

What is buprenorphine?

"Buprenorphine" is a partial opioid agonist used as an analgesic and as a medication treatment in the management of opioid use disorder. It has been approved by the FDA for maintenance treatment of opioid use disorder. It has high affinity for the μ opioid receptor. It displaces full opioid agonists such as morphine, methadone, or heroin. Due to the lower intrinsic activity, or partial activity at the μ receptor, there is a ceiling effect meaning higher doses have been found in studies not to produce higher effects. This lowers the potential for illicit use and decreases the risk of respiratory depression or accidental overdose. These properties have made buprenorphine the opioid agonist treatment of choice for settings outside of OTPs, although it can also be dispensed as part of treatment in an OTP.

What was the DATA Waiver?

Formerly, the Drug Addiction Treatment Act of 2000 (DATA 2000) amended the Controlled Substances Act to allow practitioners to dispense and prescribe schedule III-V drugs (e.g., buprenorphine) for maintenance or detoxification treatment without annually obtaining a separate narcotic treatment program registration. Instead, practitioners were required to submit a notice of intent (NOI) for a one-time waiver (often referred to as the DATA waiver) as outlined in 21 U.S.C. 823(g)(2).

Is the DATA Waiver Removed?

Yes. As of December 29th, 2022, when the Consolidated Appropriations Act of 2023 was signed, the DATA Waiver Program was eliminated.

Can an individual licensed to prescribe medication still apply for a DATA Waiver?

No. Due to the federal changes described in this document, SAMHSA communicated on its website that the agency would no longer accept notices of intent (NOIs) for practitioners who wish to prescribe buprenorphine. Effectively, clinicians are no longer able to become DATA waived.

Considering these changes, is any additional education needed to prescribe buprenorphine?

No. Previously, 8 hours of additional training for physicians and 24 hours (for all other clinicians with prescriptive authority) were required to obtain the DATA Waiver and prescribe buprenorphine for OUD. The removal of the DATA waiver also removed these associated training requirements. However, an additional piece of the CAA, the Medication Access and Training Expansion (MATE) Act, adds a minimum 8-hour one-time training requirement regarding OUD or other substance use disorders before applying for or renewing an individual's DEA number. If specific curriculum requirements outlined are met, individuals having graduated from their educational program in the five years prior to applying for the DEA will not be required to take the new 8-hour education. Additional details on this training are expected to be provided by the federal authorities at a future date.

Since the DATA Waiver is removed, can nurse practitioners and physician assistants now prescribe buprenorphine for OUD in Tennessee without restrictions?

No. While federal law permits prescribing of buprenorphine by NPs, PAs, and other clinicians who are not physicians, Tennessee law limits buprenorphine prescribing for OUD to individuals who are physicians (TCA § 53-11-311(c)). This statute has been amended by Public Chapters 761 and 771 of 2020 to allow NPs and PAs to be able to prescribe buprenorphine for OUD in only limited practice settings and with additional clinical limitations. The DATA waiver removal does not change these statutory limitations.

Public Chapter 761 of 2020: NP and PA Buprenorphine Prescribing Limitations in FQHCs and CMHCs

- Must be licensed and practice as a family, adult, or psychiatric nurse practitioner or physician assistant. License has had no limitations or conditions imposed by the respective Board in previous 3 years.
- Is employed by a community mental health center (CMHC) or federally qualified health center (FQHC). The CMHC or FQHC shall:

- Employ one or more physicians and have adopted clinical protocols for medication-assisted treatment
- Employ providers that are credentialed and accept TennCare patients for treatment of OUD with buprenorphine-containing products
- Nurse practitioner or physician assistant writes prescriptions for buprenorphine-containing products to 50 patients, or less, at a time.
- Prescriptions for buprenorphine-containing products are limited to patients being treated by the CMHC or FQHC, written for a total daily dose of 16 mg (or its equivalent) or less, and must not be for mono-product (or buprenorphine products that do not contain naloxone).
- Supervising or collaborating physician reviews 100% of all charts for patients receiving buprenorphine products prescribed by the nurse practitioner or physician assistant and does not supervise more than 4 nurse practitioners or physician assistants.
- Initiates and leads a discussion with the patient about their readiness to taper down or taper off the medication at the patient's request but no later than 1 year after initiation of treatment and at least every 6 months thereafter.

Public Chapter 771 of 2020: Relevant to NP and PA Buprenorphine Prescribing Limitations in OBOTs

- Must be licensed and practice as a family, adult, or psychiatric nurse practitioner or physician assistant.
- Is employed by a non-residential office-based opiate treatment facility (OBOT) licensed by the Tennessee Department of mental health and Substance Abuse Services that does not have the authority to dispense buprenorphine-containing products. The OBOT shall:
 - Employ the NP's or PA's supervising physician and is treating patients with buprenorphine-containing products at the same OBOT.
 - Employ providers that are credentialed and contracted to accept TennCare patients and bill TennCare for services for treatment of OUD with buprenorphine-containing products and are accepting new TennCare patients.
- Prescriptions for buprenorphine-containing products are limited to patients being treated at the OBOT, written for a total daily dose of 16 mg (or its equivalent) or less, and must not be for mono-product (or buprenorphine products that does not contain naloxone), except when utilizing the injectable or implantable buprenorphine products.
- Supervising or collaborating physician does not supervise more than 2 nurse practitioners or physician assistants at one time during clinical operations. The supervising physician is responsible for ensuring that all laws, rules, regulations, and guidelines, relevant to the use of prescribing buprenorphine-containing products are being followed.
- Nurse practitioner or physician assistant writes prescriptions for buprenorphine-containing products to 100 patients, or less, at a time.

Does the law for prescribing buprenorphine mono-product change due to the DATA Waiver Removal?

No. The statute which requires that buprenorphine mono-product for treatment of OUD only be prescribed if the patient is pregnant, nursing, has an adverse reaction or hypersensitivity to naloxone, or the medication is being directly administered by the prescriber, is a state-specific statute (TCA § 53-11-311(b)(1)) that does not reference the DATA waiver.

Does the criteria for needing to be licensed as an OBOT change?

No. The statute containing the requirements for needing an OBOT license is specific to buprenorphine prescribing and does not reference the DATA waiver.

TCA § 33-2-402(11)

(A) "Nonresidential office-based opiate treatment facility" includes, but is not limited to, stand-alone clinics, treatment resources, individual physical locations occupied as the professional practice of a prescriber or prescribers licensed pursuant to title 63, or other entities prescribing products containing buprenorphine, or products containing any other controlled substance designed to treat opiate addiction by preventing symptoms of withdrawal to twenty-five percent (25%) or more of its patients or to one hundred fifty (150) or more patients;

(B) For the purposes of subdivision (11)(A), "physical location" means real property on which is located a physical structure, whether or not that structure is attached to real property, containing one (1) or more units and includes an individual apartment, office, condominium, cooperative unit, mobile or manufactured home, or trailer, if used as a site for prescribing or dispensing products containing buprenorphine, or products containing any other controlled substance designed to treat opiate addiction by preventing symptoms of withdrawal;

(C) "Nonresidential office-based opiate treatment facility" does not include any facility that meets the definition of a nonresidential substitution-based treatment center for opiate addiction;

Are pharmacists required to verify buprenorphine prescriptions that do not contain the prescriber's DATA waiver I.D. (i.e., X-number)?

No. The DATA waiver I.D. (i.e., X-number) is no longer required on prescriptions for buprenorphine. Buprenorphine prescriptions now only require those elements required for any Schedule III controlled substance.

Does the DATA waiver removal change a pharmacy's ability to provide medications for patients being prescribed buprenorphine for OUD?

No. All pharmacies are encouraged to make buprenorphine products available for patients. Buprenorphine prescriptions should now be treated the same as any other Schedule III controlled substance regarding safeguards and ensuring legitimate access.

Does the removal of the DATA waiver effect how buprenorphine is used in the inpatient setting?

No. The DATA waiver previously authorized the prescribing of buprenorphine for OUD outside of an OTP, which is a separate activity from the medical orders being provided in an inpatient or certain residential settings. If a patient is to be provided a prescription at discharge, for example, that prescription would need to be prescribed by a physician. NPs and PAs are still only permitted to prescribe buprenorphine for OUD from an FQHC, CMHC, or an OBOT.

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References:

- Consolidated Appropriations Act for 2023
<https://www.appropriations.senate.gov/imo/media/doc/JRQ121922.PDF>
- SAMHSA Notice of Removal of the DATA Waiver Requirement
<https://www.samhsa.gov/medication-assisted-treatment/removal-data-waiver-requirement>
- DEA Notice to Registrants Regarding the Elimination of the DATA Waiver Program
<https://www.deadiversion.usdoj.gov/pubs/docs/A-23-0020-Dear-Registrant-Letter-Signed.pdf>
- Tennessee Nonresidential Buprenorphine Treatment Guidelines
https://www.tn.gov/content/dam/tn/mentalhealth/documents/2018_Buprenorphine_Treatment_Guidelines.PDF
- Tennessee Chronic Pain Guidelines
<https://www.tn.gov/content/dam/tn/health/healthprofboards/pain-management-clinic/ChronicPainGuidelines.pdf>
- Tennessee Code Annotated § 53-11-311: Use of Buprenorphine Products
[Tennessee Code - Lexis Law Link](#)