

HARM REDUCTION AND OVERDOSE PREVENTION Fact Sheet

Removal of the “X-Waiver” Requirement


Background

On December 29, 2022, President Biden signed the 2023 Consolidation Appropriations Act (“the Act”) into law.¹ Among many other provisions, the Act included substantial regulatory changes to remove barriers and promote access to evidence-based treatment of substance use disorders (“SUD”). In particular, the Act removed legal barriers to the prescription of buprenorphine for opioid use disorder (“OUD”). It also requires almost all prescribers to obtain training in the identification and treatment of SUD. Although it will add a small educational burden to most providers who prescribe controlled substances, these changes should make it easier for all prescribers to provide buprenorphine treatment to individuals with OUD and significantly expand the base of prescribers who receive at least some training in identifying and treating individuals with SUD.

History of buprenorphine regulation

From 1972 to 2002, methadone was the only controlled substance permitted to be prescribed for OUD treatment in the United States.² Although methadone can be prescribed for pain by any provider authorized by federal and state law to prescribe controlled substances, methadone treatment for OUD is highly regulated, with restrictions on who can provide it as well as where and how it can be provided.³ One of these many requirements, added by the 1974 Narcotic Addict Treatment Act, requires medical professionals treating OUD with “narcotic drugs” to obtain a separate Drug Enforcement Administration (“DEA”) registration in addition to the registration that all providers who prescribe controlled substances are required to obtain.⁴

In late 2000, Congress passed the Drug Addiction Treatment Act of 2000.⁵ This law amended the Controlled Substance Act to allow some practitioners to prescribe and dispense Schedule III, IV, and V controlled substances approved by the Food and Drug Administration (“FDA”) for SUD treatment and waived most of the requirements that apply to methadone treatment for such substances, including obtaining a separate DEA registration.⁶ In 2002, the FDA approved buprenorphine for OUD treatment, and the DEA rescheduled it from Schedule V to Schedule III.⁷



Because this law “waived” many of the requirements that otherwise apply to the treatment of OUD with narcotic drugs and prescribers who were granted this waiver were issued a new DEA number that begins with an “X,” this registration became known as the “X-waiver”. To obtain one, the prescriber was required to submit an application to the Secretary of Health and Human Services (“HHS”).⁸ Among other requirements, the application was required to contain a certification that the applicant was qualified to prescribe medication for treating opioid dependence, had the capacity to provide their patients with “appropriate counseling and other appropriate ancillary services” directly or by referral⁹ and would comply with limitations on the total number of patients that they could treat at a time.¹⁰ Providers were originally limited to treating thirty patients at any one time during the first year after they obtained a waiver, and 100 patients thereafter.¹¹ A 2016 modification permitted certain qualified practitioners who had held a 100-patient waiver for at least a year to treat a maximum of 275 patients at a time.¹² In April 2021, the Biden Administration issued practice guidelines that permitted all individuals who are eligible to obtain an X-waiver to treat up to 30 patients without having to complete the otherwise required training. However, all other requirements to obtain the waiver continued to apply to those individuals.¹³


Prior to the Act, most prescribers were required to complete an eight-hour training to obtain an X-waiver. This training was required to include information on opioid maintenance and detoxification; appropriate clinical use of all drugs approved by the FDA for the treatment of OUD; initial and periodic patient assessments (including substance use monitoring); individualized treatment planning, overdose reversal, and relapse prevention; counseling and recovery support services; staffing roles and considerations; diversion control; and other best practices, as identified by the HHS Secretary.¹⁴

While originally only physicians were permitted to obtain an X-waiver, the Comprehensive Addiction and Recovery Act of 2016, amended existing law to temporarily allow certain nurse practitioners and physician assistants to prescribe buprenorphine for OUD treatment.¹⁵ The SUPPORT for Patients and Communities Act made those changes permanent and expanded the types of advanced practice nurses that were permitted to obtain an X-waiver.¹⁶ Non-physician prescribers were generally required to obtain 24 hours of relevant training to qualify for a waiver.¹⁷ If those providers were required by state law to be supervised by or work in collaboration with a physician, that physician was also required to be waived for the non-physician prescriber to prescribe buprenorphine for OUD.¹⁸

In addition to the training requirements, practitioners who did not hold a subspecialty board certification in addiction medicine or addiction psychiatry were required to practice in a “qualified practice setting.”¹⁹ These qualified practice settings were required to ensure patients could access emergency care when the practice is closed, provide access to case management services, use health information technology systems such as electronic health records, utilize their state prescription drug monitoring program, and accept third-party payment.²⁰

Changes made by the 2023 Consolidation Appropriations Act

As noted above, “practitioners who dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment” were previously required to obtain “a separate registration for that purpose.”²¹ Section 1262 of the Act, which was previously introduced as a separate bill called the Mainstreaming Addiction Treatment (“MAT”) Act, modified that language to exclude narcotic drugs in schedules III, IV, or V from the separate registration requirement. It also removes the entirety of the section that specified the requirements for obtaining an X-waiver. The practical effect of this change is to exclude buprenorphine, a schedule III controlled substance, from the requirements that apply to methadone for OUD treatment. These include all limitations on



the types of providers otherwise qualified to prescribe controlled substances who can prescribe the medication and the number of patients that can be treated.²²


Section 1263 of the Act enacts most of the language that was previously introduced as the Medication Access and Training Expansion (“MATE”) Act. This section requires prescribers, as a condition of obtaining or renewing what is typically referred to as a “DEA number” that enables a provider to prescribe controlled substances, to meet certain requirements related to controlled substances education.²³ Unlike the training that was previously required only for providers who sought to become waived to prescribe buprenorphine for OUD treatment, these new requirements apply to all controlled substance prescribers other than veterinarians. Holding a board certification in addiction psychiatry or addiction medicine continues to satisfy these requirements, and funding is earmarked to encourage these specialties through various programs.²⁴

The details of the training requirements under the Act are similar to those under the old law, but with several differences. Most importantly, the new training requirements are broader, requiring training on “the treatment and management of patients with opioid or other substance use disorders, or the safe pharmacological management of dental pain and screening, brief intervention, and referral for appropriate treatment of patients with or at risk of developing opioid or other substance use disorders.”²⁵ The organizations that are permitted to provide the training are more numerous, and include any organization accredited by a State medical society accreditor that is recognized by the Accreditation Council for Continuing Medical Education (“ACCME”) or the Commission for Continuing Education Provider Recognition (“CCEPR”), any organization accredited by the American Osteopathic Association to provide continuing medical education, or any organization approved by the Assistant Secretary for Mental Health and Substance Use, the ACCME, or the CCEPR.²⁶

Further, providers are deemed to meet the requirements if they graduated in good standing from an accredited school of allopathic medicine, osteopathic medicine, dental surgery, or dental medicine in the United States in the five-year period prior to first registering with the DEA or renewing their registration after the requirements came into effect. Such graduates are deemed compliant only if they completed a comprehensive medicine, dental medicine, or dental surgery curriculum or accredited medical residency that included at least 8 hours of training in treating and managing patients with opioid or other substance use disorders, including the appropriate clinical use of all drugs approved by the FDA for the treatment of a substance use disorder or the safe pharmacological management of dental pain and screening, brief intervention, and referral for appropriate treatment of patients with or at risk of developing opioid and other substance use disorders.²⁷ It is not yet known how it will be determined whether a curriculum meets these requirements.

The requirements related to graduation for non-physicians are similar to those for physicians; a non-physician applicant must have “successfully completed a comprehensive physician assistant or advanced practice nursing curriculum that included not fewer than 8 hours of training on treating and managing patients with opioid and other substance use disorders, including the appropriate clinical use of all drugs approved by the Food and Drug Administration for the treatment of a substance use disorder.” The eight-hour training requirement, whether satisfied during formal education or through a stand-alone training, apply beginning 180 days after the Act went into effect.

These changes do not require any further action by the DEA, Substance Abuse and Mental Health Services Administration (SAMHSA), or any other agency. They became effective as of the signing of the Act. The DEA has sent a letter to registrants giving its full support to the changes and confirming that, though there will be further guidance regarding training requirements, the X-waiver no longer exists.²⁸ The Department of Health and Human Services has proposed a rule that would remove the provisions of DATA 2000 that created the X-waiver restrictions.²⁹ SAMHSA has likewise confirmed that it will no longer be accepting applications for the



waiver, as all practitioners with “current DEA registration that includes Schedule III authority, may now prescribe buprenorphine for Opioid Use Disorder.”³⁰

Conclusion

The 2023 Consolidation Appropriations Act took important steps forward in making buprenorphine for OUD easier to access. While significant barriers remain, these changes will likely improve access, decrease stigma, and encourage equitable access to treatment for all.

Support for the Network is provided, in part, by the Robert Wood Johnson Foundation. The views expressed in this document do not necessarily reflect the views of the Foundation.

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References

- ¹ Consolidated Appropriations Act, 2023, H.R. 2617, 117th Cong. (2022) (enacted).
- ² C.S. Davis & D. Carr, *The Law and Policy of Opioids for Pain Management, Addiction Treatment, and Overdose Reversal*, 14 INDIANA HEALTH LAW REVIEW (2017).
- ³ See 42 C.F.R. § 8 (2015). These regulations underwent major revision in 2001. See Opioid Drugs in Maintenance and Detoxification Treatment of Opiate Addiction Final Rule, 66 Fed. Reg. 4076 (Jan. 17, 2001)(codified at 21 CFR § 291, 42 C.F.R. § 8).
- ⁴ See 21 U.S.C. § 823(h)(1)(amended 2022). These requirements were previously located in 21 U.S.C. § 823(g), and many existing materials reference that section. The requirements were relocated to 21 U.S.C. § 823(h) on Dec. 2, 2022 by the Medical Marijuana and Cannabidiol Research Expansion Act, Pub.L. 117-215, Title I, §§ 101, 102(a), 103(a) (136 Stat. 2258, 2261).
- ⁵ Children's Health Act of 2000, Pub. L. No. 106-310, 114 Stat. 1101, § 3501-3502.
- ⁶ 21 U.S.C. § 823(h)(2)(amended 2022).
- ⁷ Schedules of Controlled Substances: Rescheduling of Buprenorphine from Schedule V to Schedule III, 67 Fed. Reg. 62,354 (Oct. 7, 2002) (21 C.F.R. pt. 1308). The DEA specifically cited DATA 2000's allowing office-based MAT with buprenorphine as a factor in rescheduling the drug. See *id.* at 62,357. Methadone remains a schedule II controlled substance under federal law. 21 U.S.C. § 812.
- ⁸ 21 U.S.C. § 823(h)(2)(B)(amended 2022); 21 C.F.R. § 1301.28(b)(1).
- ⁹ 21 C.F.R. § 1301.28(b)(1)(ii).
- ¹⁰ 21 U.S.C. § 823(h)(2)(B)(iii)(amended 2022).; 21 C.F.R. § 1301.28(b)(1)(iii).
- ¹¹ *Id.*
- ¹² 42 C.F.R. § 8.610.
- ¹³ See Corey S. Davis, *Recent Federal Policy Changes Improve Buprenorphine Access, but X-Waiver Remains a Barrier for Opioid Use Disorder Treatment*, NETWORK FOR PUBLIC HEALTH LAW, (October 20, 2021), <https://www.networkforphl.org/news-insights/recent-federal-policy-changes-improve-buprenorphine-access-but-x-waiver-remains-a-barrier-for-opioid-use-disorder-treatment>; Practice Guidelines for the Administration of Buprenorphine for Treating Opioid Use Disorder, 86 Fed. Reg. 22439 (April 28, 2021).
- ¹⁴ 21 U.S.C. § 823(h)(2)(G)(ii). The training requirement was waived for certain prescribers, such as those who were board certified in addiction psychiatry or addiction medicine or participated as an investigator in one or more clinical trials leading to the approval of a narcotic drug in schedule III, IV, or V for maintenance or detoxification treatment.
- ¹⁵ 21 U.S.C. §§ 823(g)(2)(G)(iv)(I) (2016).
- ¹⁶ C. S. Davis, *The SUPPORT for Patients and Communities Act - What Will It Mean for the Opioid-Overdose Crisis?*, 380 N ENGL J MED (2019).
- ¹⁷ 21 U.S.C. § 823(h)(2)(G)(iv)(II)(aa). The training for those providers was required to be provided by the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic Association, the American Nurses Credentialing Center, the American Psychiatric Association, the American Association of Nurse Practitioners, the American Academy of Physician Assistants, or any other organization that the Secretary determines is appropriate.
- ¹⁸ 21 U.S.C. § 823(h)(2)(G)(iv)(III).
- ¹⁹ 42 C.F.R. § 8.610(b). (The practitioner must also not have "had his or her enrollment and billing privileges in the Medicare program revoked under § 424.535 of this title" and not have "been found to have violated the Controlled Substances Act pursuant to 21 U.S.C. 824(a)").
- ²⁰ 42 C.F.R. § 8.615.
- ²¹ 21 U.S.C. 823(h)(1). While "dispense" is generally thought of as providing a drug to the ultimate user, for purposes of the federal Controlled Substance Act the term includes the prescribing of a controlled substance. 21 U.S.C. 802(10).
- ²² Notably, this change means that federal law no longer forbids pharmacists who are permitted to prescribe buprenorphine under state law from prescribing that medication for the treatment of OUD.
- ²³ Prescribers of controlled substances are required to renew their registrations every three years. 21 C.F.R. § 1301.13(e)(1)(iv).
- ²⁴ Explanatory Statement, Division H-Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2023, 13-14; 21, <https://www.appropriations.senate.gov/imo/media/doc/Division%20H%20-%20LHHS%20Statement%20FY23.pdf>.
- ²⁵ 21 U.S.C. 823(l)(1)(A)(iv).
- ²⁶ *Id.*
- ²⁷ Although intent was likely that the first requirement applies to physicians and the second applies to dentists, the regulations do not explicitly state this.
- ²⁸ Letter from Anne Milgram, Administrator, U.S. Department of Justice, Drug Enforcement Administration, to all DEA Registrants (January 12, 2023), <https://www.deadiversion.usdoj.gov/pubs/docs/A-23-0020-Dear-Registrant-Letter-Signed.pdf>.
- ²⁹ Medications for the Treatment of Opioid Use Disorder: Removal of the DATA-2000 Waiver Requirements, 88 Fed. Reg. 9221 (proposed February 13, 2023)(amending 42 C.F.R. Part 8).
- ³⁰ Substance Abuse and Mental Health Services Administration, Removal of DATA Waiver (X-Waiver) Requirement, last updated January 25, 2023, <https://www.samhsa.gov/medication-assisted-treatment/removal-data-waiver-requirement>.