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Become a Buprenorphine Waivered Practitioner

Learn how to become a buprenorphine waivered practitioner to treat opioid use disorder (OUD).

Qualified practitioners can offer buprenorphine, a medication approved by the Food and Drug Administration (FDA), for the treatment of opioid use disorders (OUD). The <u>Drug Addiction Treatment Act of 2000 (DATA 2000)</u> and the <u>Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities or SUPPORT for Patients and Communities Act of 2018 (SUPPORT Act)</u> expands the use of medication-assisted treatment using buprenorphine to additional practitioners in various settings.

To receive a practitioner waiver to administer, dispense, and prescribe buprenorphine practitioners must notify <u>SAMHSA's Center for Substance Abuse Treatment (CSAT)</u>, <u>Division of Pharmacologic Therapies (DPT)</u> of their intent to practice this form of medication-assisted treatment (MAT). The notification of intent (NOI) must be submitted to SAMHSA before the initial dispensing or prescribing of OUD treatment medication.

Qualified practitioners include physicians, Nurse Practitioners (NPs), Physician Assistants (PAs), Clinical Nurse Specialists (CNSs), Certified Registered Nurse Anesthetist (CRNAs), and Certified Nurse-Midwifes (CNMs).

Recent <u>Practice Guidelines</u> have allowed for an alternative NOI for those seeking to treat **up to 30 patients**: The customary NOI requires eligible providers to undertake required training activities prior to their application to prescribe Buprenorphine; the alternative type of NOI allows those providers who wish to treat up to 30 patients to forego the training requirement, as well as certification to counseling and other ancillary services (i.e., psychosocial services). Practitioners utilizing this training exemption are limited to treating no more than 30 patients at any one time (time spent practicing under this exemption will not qualify the practitioner for a higher patient limit). This exemption applies only to the prescription of Schedule III, IV, and V drugs or combinations of such drugs, covered under the CSA, such as buprenorphine.

Qualified practitioners who undertake required training can treat up to 100 patients using buprenorphine for the treatment of opioid use disorder (OUD) in the first year if they possess a waiver under 21 U.S.C. § 823(g)(2) (i.e., a DATA 2000 waiver) and meet certain conditions.

One of two conditions must be satisfied for qualified practitioners to treat 100 patients in their first year:

- 1. The physician holds a board certification in addiction medicine or addiction psychiatry by the American Board of Preventive Medicine or the American Board of Psychiatry and Neurology
- 2. The practitioner provides medication-assisted treatment (MAT) in a "qualified practice setting." A qualified practice setting is a practice setting that:
 - provides professional coverage for patient medical emergencies during hours when the practitioner's practice is closed;

- provides access to case-management services for patients including referral and follow-up services for programs that provide, or financially support, the provision of services such as medical, behavioral, social, housing, employment, educational, or other related services;
- uses health information technology systems such as electronic health records;
- is registered for their State prescription drug monitoring program (PDMP) where operational and in accordance with Federal and State law; and
- accepts third-party payment for costs in providing health services, including written billing, credit, and collection policies and procedures, or federal health benefits.

After one year at the 100-patient limit, qualifying practitioners who meet the above criteria can apply to increase their patient limit to 275. In addition, <u>42 CFR 8.655</u> defines circumstances in which qualifying practitioners may request a temporary increase to treat up to 275 patients to address emergency situations for six months. <u>Apply for a patient waiver</u>.

Buprenorphine Waiver Notification of Intent (NOI)

The waiver form contains all the data items necessary to complete the processing of the buprenorphine waiver notification. The NOI must contain information on the practitioner's qualifying credentials and additional certifications. It must also confirm that the practitioner will not have more than the approved number of patients at any one time, regardless of the number of practice locations.

To apply, mid-level practitioners (APRNs and PAs) should check SAMHSA's Providers Clinical Support System (PCSS) in "CERTIFICATION OF QUALIFYING CRITERIA," then enter "practice guidelines" in the text box for the date.

Physicians should select "Other" in "CERTIFICATION OF QUALIFYING CRITERIA," then enter "practice guidelines" in the text box for the city of the training. The training date should be the application date.

Practitioners who wish to increase their 30-patient limit after the first year must also must upload their training certificate after completing the waiver form to show that they have completed the required training to prescribe and dispense buprenorphine. The recent Practice Guidelines exempts eligible physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives from the certification requirements related to training, counseling and other ancillary services (i.e., psychosocial services) under 21 U.S.C. § 823(g)(2)(B)(i)-(ii) of the Controlled Substances Act (CSA).

Practitioners utilizing this exemption are limited to treating no more than 30 patients at any one time (time spent practicing under this exemption will not qualify the practitioner for a higher patient limit). This exemption applies only to the prescription of Schedule III, IV, and V drugs or combinations of such drugs, covered under the CSA, such as buprenorphine.

Complete the Online Request for a New Waiver or Patient Limit Increase.

SAMHSA reviews applications within 45 days of receipt. Once the application process is complete and the application is approved, SAMHSA will email an approval letter to the practitioner indicating their waiver level with certification date, and informing them they will receive their x-designation from the DEA within seven to ten business days.

If it has been more than 45 days since a practitioner has submitted an application or if a practitioner submitted an application and did not receive an acknowledgement of receipt, contact CSAT's Buprenorphine Information Center at 866-BUP-CSAT (866-287-2728) or send an email to infobuprenorphine@samhsa.hhs.gov.

Apply to Begin Treatment with Buprenorphine Immediately

Several federal laws and regulations permit physicians and other qualifying practitioner to administer medications approved by the Food and Drug Administration (FDA) for the treatment of OUD under special circumstances without a buprenorphine waiver. Learn about these <u>special circumstances</u>.

To receive permission to provide treatment while a waiver notification is under review, check the box "New Notification, with the intent to immediately facilitate treatment of an individual (one) patient" on the <u>waiver notification form</u>. Checking the "immediate" box is only one of three requirements a practitioner must meet in order to start a patient on treatment, and immediate treatment is limited to one patient per form submitted. Each form must have a different submission date. Practitioners must address the additional following requirements:

- Meet "in good faith" the criteria for obtaining a waiver such as having a valid medical license, valid Drug
 Enforcement Administration (DEA) registration, and proof of completion of 8 hours of qualified training for
 physicians and 24 hours for other qualified practitioners (For those applying for the 30 patient limit, proof of
 qualified training is no longer required, but still encouraged).
- Contact CSAT's Buprenorphine Information Center at 1-866-BUP-CSAT (1-866-287-2728) or send an email to infobuprenorphine@samhsa.hhs.gov to verify that the notification form has been received and to notify CSAT of the practitioner's intent to begin treating one patient.
- After reviewing the practitioners immediate to treat request, CSAT's Buprenorphine Information Center will send an email to the practitioner approving their intent to treat one patient immediately.

Since the practitioner will not have a unique identifying number, pharmacists may question prescriptions received under this provision. Pharmacists should contact CSAT's Buprenorphine Information Center for additional information at 1-866-BUP-CSAT (1-866-287-2728) or send an email to infobuprenorphine@samhsa.hhs.gov.

Annual Reporting Requirements to Treat Up to 275 Patients

Every year, per <u>42 CFR 8.635</u>, qualified practitioners approved to treat up to 275 patients must <u>submit information</u> about their practice to SAMHSA for purposes of monitoring regulatory compliance. The goal of the reporting requirement is to ensure that practitioners are providing buprenorphine treatment in compliance with the final rule Medication Assisted Treatment for Opioid Use Disorders (81 FR 44711).

Training

For those providers who wish to treat more than 30 patients after their first year of certification, SAMHSA funds the Providers' Clinical Support System (PCSS) to provide practitioner training in the evidence-based prevention and treatment of OUD and offers the required trainings (PCSS) to provide practitioner training in the evidence-based prevention and treatment of OUD and offers the required training (PCSS) to provide practitioner training in the evidence-based prevention and treatment of OUD and offers the required training (PCSS) to provide practitioner training in the evidence-based prevention and treatment of OUD and offers the required training (PCSS) to provide practitioner training in the evidence-based prevention and treatment of OUD and offers the required training (PCSS) (PCSS) (PCSS) to provide practitioner training trainin

- Physician Buprenorphine Waiver Training 🗹 8-hour training
- Nurses Buprenorphine Waiver Training [(NPs, CNSs, CRNAs, CNMs) 24-hour training
- Physician Assistant Buprenorphine Waiver Training 🗹 24-hour training

SAMHSA offers tools, training, and technical assistance to practitioners in the fields of mental and substance use disorders. Find information on SAMHSA <u>training and resources</u>. SAMHSA has developed a <u>Buprenorphine Quick Start Guide (PDF | 1.4 MB)</u> and <u>pocket guide (PDF | 200 KB)</u> for all practitioners seeking to prescribe buprenorphine.

Learn more about <u>buprenorphine</u>.

For those practitioners who wish to prescribe under the 30-patient limit, without subsequent increases in this cap, the training requirement is no longer required. This has been implemented to reduced barriers in access to Buprenorphine. If a prescriber wishes to treat more than 30 individual patients in a given year, the prescriber must submit the required training documentation in a new Notice of Intent.

Last Updated: 05/14/2021

Medications to Treat OPIOID ADDICTION

Methadone

Naltrexone

Buprenorphine





Contact Us

For information on buprenorphine waiver processing, contact the SAMHSA Center for Substance Abuse Treatment (CSAT) at 866-BUP-CSAT (866-287-2728) or infobuprenorphine@samhsa.hhs.gov.

For information about other medication-assisted treatment (MAT) or the certification of opioid treatment programs (OTPs), contact the SAMHSA Division of Pharmacologic Therapies at <u>240-276-2700</u>.

DPT@SAMHSA.HHS.Gov.

For assistance with the Opioid Treatment Program Extranet, contact the OTP helpdesk at <u>OTP-Help@jbsinternational.com</u> or <u>1-866-348-5741</u>.

Contact SAMHSA's regional <u>OTP Compliance Officers</u> to determine if an OTP is qualified to provide treatment for substance use disorders.

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SAMHSA's mission is to reduce the impact of substance abuse and mental illness on America's communities.

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