What is the benefit of obtaining a DATA 2000 Waiver?

A Drug Addiction Treatment Act (DATA) 2000 Waiver allows practitioners to prescribe buprenorphine. Buprenorphine is a type of medication used in MAT to help people recover from opioid use disorders. Unlike methadone, which can only be administered in an opioid treatment program such as a Narcotic Treatment Program (NTP) or Medication Unit (MU), buprenorphine can be prescribed and dispensed to clients by qualified practitioners in other health care settings. Prescribers include physicians, nurse practitioners, and physician assistants that have

received a DATA 2000 Waiver.

With the passage of the SUP-PORT for Patients and Communities Act in 2018, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives are also qualified practitioners.¹

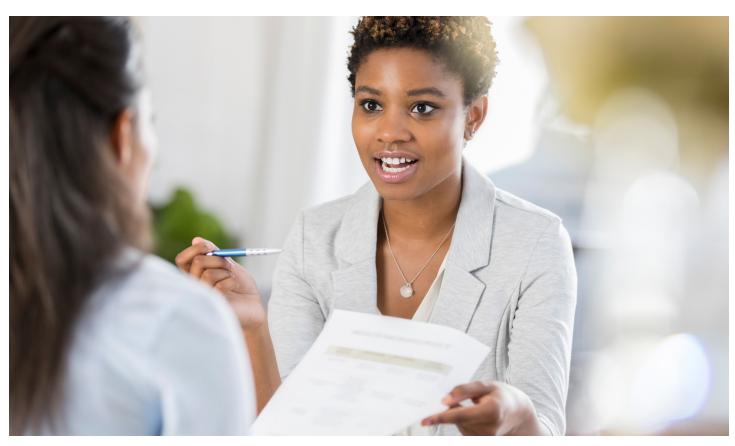
The Drug Addiction Treatment Act of 2000 allows these practitioners to prescribe buprenorphine and other Schedule III, IV, and V narcotic medications outside of opioid treatment program settings, including medical offices, emergency rooms, hospitals, and other settings.

DATA 2000 WAIVER

Allows providers to prescribe buprenorphine outside of opioid treatment programs.



This resource was created by Harbage Consulting with support from the California Health Care Foundation.



What steps must physicians take to obtain a DATA 2000 Waiver?^{2, 3}

MEET THE CRITERIA TO QUALIFY

Physicians must be qualified to apply for the waiver. DATA 2000 defines a "qualifying physician" as one who is:

- Licensed under state law.
- Registered with the Drug **Enforcement Administration** (DEA) to dispense controlled substances.
- Required to treat no more than 30 patients at a time within the first year and may treat up to 100 or 275 at a time (if certain qualifications are met) after the first year.4
- Capable of referring patients to counseling services.
- Completes training and/or certification requirements.
- Additionally, physicians must either be board-certified in addiction medicine, or complete required 8-hour training for the treatment and management of patients with opioid use disorders. Many of these trainings are available free and online.



COMPLETE TRAINING AND CERTIFICATION REQUIREMENTS

Under the DATA 2000 requirements, physicians must complete an 8-hour training to qualify for a waiver to prescribe and dispense buprenorphine. The Substance Abuse and Mental Health Services Administration (SAMHSA) maintains a list of supported continuing medical education (CME) courses that can help physicians qualify to prescribe buprenorphine in an office setting. See the "Where Can I Find More Information" section on Page 5 for more details.

APPLY FOR THE WAIVER

Physicians can take the following steps to apply for a DATA 2000 Waiver:

Ensure you meet and have documentation showing you are a qualifying physician.

Complete the required 8-hour training to prescribe and dispense buprenorphine.

Fill out the SAMHSA Buprenorphine Waiver Notification form: bit.ly/20j0A0D.

Send SAMHSA all supporting documentation, including an 8-hour training certificate, via email to infobuprenorphine@ samhsa.hhs.gov or via fax to (301) 576-5237.

⁴The first year cap of 30 patients may be increased up to 100 in the first year for physicians who are certified in addiction medicine or addiction psychiatry, or that work in an approved MAT facility. SUPPORT for Patients and Communities Act, H.R.6, Sec. 3201, available at bit.ly/2QeY98A.

² Substance Abuse and Mental Health Services Administration, "Buprenorphine Waiver Management," available at bit.ly/2L2vulh.

³ Substance Abuse and Mental Health Services Administration, "Qualify for a Physician Waiver," available at bit.ly/2ngA8xS.

CONTINUED: WHAT STEPS MUST PHYSICIANS TAKE TO OBTAIN A DATA 2000 WAIVER?



WAIT FOR APPROVAL

SAMHSA conducts an application review within 45 days of receipt. Once the application process is approved, SAMHSA will email a letter to the applicant that confirms their waiver and includes a prescribing identification number for the physician to use.

EXPEDITED APPLICATIONS

Physicians may also request to provide treatment while their waiver application ('notification') is under review. To do this:

Check the box "New Notification, with the intent to immediately facilitate treatment of an individual (one) patient" on the SAMHSA Buprenorphine Waiver Notification form.

Meet criteria for obtaining a waiver (i.e., valid medical license, valid DEA registration number, completed training requirements).

Contact the SAMHSA Center for Substance Abuse Treatment (CSAT)'s Buprenorphine Information Center (866)-BUP-CSAT to verify that the notification has been received and inform CSAT of your intention to begin treatment for one patient.



WAIVER RESTRICTIONS FOR PHYSICIANS

Once a physician has been granted a waiver to prescribe buprenorphine, they may have a maximum of 30 patients in opioid dependence treatment at a time for the first year. This cap can be increased to 100 in the first year for physicians who are certified in addiction medicine or addiction psychiatry, or who work in an approved MAT facility.5 One year after the initial notification is submitted, the physician may submit a second notification of the need and intent to treat up to 100 patients at a time. Physicians with board certification in addiction medicine, or those meeting certain requirements (24/7 call coverage, electronic health record use, access to case management services, prescription drug monitoring programs (PDMP) registration, and acceptance of third-party insurance payment) may apply to treat 275 patients at a time.6

⁵ SUPPORT for Patients and Communities Act, H.R.6, Sec. 3201, available at bit.ly/2QeY98A.

⁶ More information on requirements for providers treating up to 275 patients are available at bit.ly/2LL5yMw.

What steps must NPs & PAs take to obtain a DATA 2000 Waiver?

COMPLETE TRAINING AND CERTIFICATION REQUIREMENTS

The Comprehensive Addiction and Recovery Act (CARA) requires that nurse practitioners (NPs) and physician assistants (PAs) complete at least 24 hours of initial training to be eligible for a prescribing waiver for up to 30 patients. The 24 hours of initial training must cover each of the following topics:8

- Opioid maintenance and detoxification
- Appropriate clinical use of all drugs approved by the FDA for the treatment of opioid use disorder
- 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
- Other best practices, as identified by the U.S. Secretary of Health and Human Services

SAMHSA also requires that the 24 hours of initial training is provided by one of the following organizations:

- The American Society of Addiction Medicine
- American Academy of Addiction Psychiatry
- American Medical Association
- American Osteopathic Association
- American Nurses Credentialina Center
- American Psychiatric Association
- American Association of Nurse Practitioners
- American Academy of Physician Assistants
- Any other organization that the U.S. Secretary of Health and Human Services determines is appropriate.

In addition, NPs and PAs may take the following training courses:

- An 8-hour training to qualify for a waiver to prescribe and dispense buprenorphine. SAMHSA maintains a list of supported CME courses that can help providers qualify to prescribe buprenorphine in an office setting. See "Where Can I Find More Information" section for more details.
- An additional 16 hours of free training offered by SAMHSA through the Providers' Clinical Support System for Medication Assisted Treatment (PCSS-MAT), See the "Where Can I Find More Information" section on Page 5 for more details.

⁷ Substance Abuse and Mental Health Services Administration, "Qualify for Nurse Practitioners (NPs) and Physician Assistants (PAs) Waiver," available at bit.ly/2JmTDmq.

⁸²¹ USC 823(g)(2)(G)(ii)(IV).

CONTINUED: WHAT STEPS MUST NPs & PAs TAKE TO OBTAIN A DATA 2000 WAIVER?

APPLY FOR THE WAIVER

NPs and PAs can take these steps to apply for a DATA 2000 waiver for up to 30 patients at a time:

Complete the 24-hour training to become an eligible prescriber.

Fill out the SAMHSA Buprenorphine Waiver Notification form: bit.ly/2oj0A0D.

Send SAMHSA all supporting documentation via email to infobuprenorphine@samhsa. hhs.gov or fax to (301) 576-5237.

WAIT FOR APPROVAL

SAMHSA conducts an application review within 45 days of receipt. Once the application process is approved, SAMHSA will email a letter to the applicant that confirms their waiver and includes a prescribing identification number for the NP or PA to use.

NP and PA waiver applications are forwarded to the Drug Enforcement Administration (DEA) and assigned a special identifi-



cation number. DEA regulations require both this number and the NP or PA's regular DEA registration number to be included on all buprenorphine prescriptions for opioid dependency treatment.

NOTE: Expedited applications are not available for NPs and PAs.

Where can I find more information?

For more information, please reference the following resources:

- Part 1: Basic Overview of MAT - To learn more about MAT and the positive impact it can have on clients.
- Part 2: MAT in Residential Facilities – To learn more about how MAT can be offered in a residential treatment facility setting.
- Free Online DATA Waiver Training Course for Physicians: bit.ly/2QCwEdn

OTHER RESOURCES

Supported CME Course: bit.ly/2vBqVAq.

NP and PA MAT Waiver Training: bit.ly/2PTxORy.

SAMHSA MAT of OUD Pocket Guide: bit.ly/2Dluisl.

SAMHSA MAT App: bit.ly/2QMAkq1.

California Health Care Foundation Opioid Safety Network: bit.ly/2qTVt6l.

Clinical Guidelines & Research:

Clinical Use of Extended-

Release Injectable Naltrexone in the Treatment of Opioid Use Disorder: A Brief Guide: bit.ly/2K5tQjk.

- General Principles for the Use of Pharmacological Agents to Treat Individuals with Co-Occurring Mental and Substance Use Disorders: bit.ly/2rcWTZB.
- Sublingual and Transmucosal Buprenorphine for Opioid Use Disorder: Review and Update: bit.ly/2RqTfGW.
- The ASAM Standards of Care for the Addiction Specialist Physician: bit.ly/2DjmmrD.