



**California Medication Assisted Treatment Expansion Project  
Prescriber Toolkit  
Revised July 2018**

## **Background**

The Drug Addiction Treatment Act of 2000 (DATA 2000) **permits qualified physicians to prescribe buprenorphine (and other Schedule III, IV, and V narcotic medications) in settings other than opioid treatment programs.** DATA 2000 reduces the regulatory burden on physicians who choose to practice opioid dependency treatment by allowing them to apply for waivers of the special registration requirements defined in the Controlled Substances Act.

On July 22, 2016, President Obama signed the Comprehensive Addiction and Recovery Act (CARA) into law as [Public Law 114-198](#). Among CARA's provisions is the **expansion of the prescribing privileges for buprenorphine in office-based settings to qualifying nurse practitioners (NPs) and physician assistants (PAs)** until October 1, 2021.

## **Physician Requirements for DATA 2000 Waiver**

### **Qualifying for a Physician Waiver**

A "qualifying physician" is specifically defined in DATA 2000 as one who is:

- Licensed under state law;
- Registered with the Drug Enforcement Administration (DEA) to dispense controlled substances;
- Capable of referring patients to counseling services; and
- Qualified by training and/or certification.

### **DATA 2000 Physician Criteria**

Physicians are considered qualified for a DATA 2000 Waiver if they meet **one or more** of the following criteria, with supporting documentation:

- Hold a subspecialty board certification in addiction psychiatry from the American Board of Medical Specialties.
- Hold an addiction certification from the American Society of Addiction Medicine (ASAM).
- Hold a subspecialty board certification in addiction medicine from the American Osteopathic Association.
- Have completed required training for the treatment and management of patients with opioid use disorders. This involves, at minimum, eight hours of training through classroom situations, seminars at professional society meetings, electronic communications, or training otherwise provided by ASAM and other organizations.

- Have participated as an investigator in one or more clinical trials leading to the approval of a narcotic medication in Schedule III, IV, or V for maintenance or detoxification treatment. The physician’s participation should be confirmed in a statement by the sponsor of the approved medication to Department of Health and Human Services (HHS). [Drug scheduling](#) definitions are available from the DEA for scheduled medications.
- Have other training or experience that the state medical licensing board (of the state in which the physician will provide maintenance or detoxification treatment) considers a demonstration of the physician’s ability to treat and manage patients with opioid dependency.
- Have completed other training or experience that HHS considers a demonstration of the physician’s ability to treat and manage patients with an opioid dependency. The criteria of HHS for this training or experience will be established by regulation.

**Waiver Training**

Under the DATA 2000 requirements, physicians must complete an eight-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. These courses may require registration and include fees.

**Application Process**

Follow these steps to apply:

1.	Ensure you meet and have documentation showing you are a qualifying physician.
2.	Complete the required 8-hours of training to prescribe and dispense buprenorphine.
3.	Fill out the <a href="#">Waiver Notification Form</a> .
4.	Send SAMHSA all supporting documentation, including the 8-hour training certificate, via email to <a href="mailto:infobuprenorphine@samsha.hhs.gov">infobuprenorphine@samsha.hhs.gov</a> or fax to (301) 576-5237.

**Expedited Application**

To receive permission to provide treatment while your waiver application (‘notification’) is under review:

1.	Check the box “New Notification, with the intent to immediately facilitate treatment of an individual (one) patient” on the notification form.
2.	Meet the criteria for obtaining a Waiver (i.e., having a valid medical license, valid DEA registration, completed eight hours of qualifying training).

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

### **Review Process**

SAMHSA reviews waiver applications within 45 days of receipt. If approved, physicians receive a letter via email that confirms their waiver and includes their prescribing identification number.

### **Waiver Restrictions**

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. 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.

## **Nurse Practitioner (NP) and Physician Assistant (PA) Requirements for DATA 2000 Waiver**

### **Waiver Training**

Under the DATA 2000 requirements, NPs and PAs must complete an eight-hour training to qualify for a DATA 2000 Waiver to prescribe and dispense buprenorphine. SAMHSA maintains a [list of supported continuing medical education \(CME\) courses](#) can help providers qualify to prescribe buprenorphine in an office setting (courses may require registration and include fees).

### **Application Requirements**

CARA requires that NPs and PAs complete, at minimum:

- 24 hours of training to be eligible for a prescribing waiver. The 24 hours of initial training must cover each of the following topics (21 USC 823(g)(2)(G)(ii)(IV))<sup>1</sup>:
  - Opioid maintenance and detoxification;
  - Appropriate clinical use of all drugs approved by the Food and Drug Administration (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; and
  - Other best practices, as identified by the Secretary of Health and Human Services.
- An 8-hour DATA-waiver course; and

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<sup>1</sup> The training must be provided by one of the following organizations: ASAM, 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 of Health and Human Services determines is appropriate.

- An additional 16-hours of free training offered SAMHSA through the [Providers' Clinical Support System for Medication Assisted Treatment \(PCSS-MAT\)](#)

### **Application Process**

1.	Complete the 24-hour training to become an eligible prescriber.
2.	Complete the required 8-hours training to prescribe and dispense buprenorphine.
3.	Complete the additional 16-hour training from SAMHSA.
4.	Fill out the <a href="#">Waiver Notification Form</a> .
5.	Send SAMHSA all supporting documentation, including 8-hour training certificate, via email to <a href="mailto:infobuprenorphine@samhsa.hhs.gov">infobuprenorphine@samhsa.hhs.gov</a> or fax to (301) 576-5237.

### **Review Process**

NP and PA Waiver applications are forwarded to the DEA and assigned a special identification 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.

SAMHSA reviews the waiver applications within 45 days of receipt. If approved, NPs and PAs receive a letter via email that confirms their waiver and includes a unique prescribing identification number.

### **Resources for Prescribers**

There are several helpful resources available to support subscribers once they receive a waiver. Below are a few examples, including a pocket guide, an app, research, and an opioid safety support network.

- **App:** [SAMHSA MATx Mobile App to support Medication Assisted Treatment of Opioid Use Disorder](#)
- **Clinical Guidelines and Research:**
  - [Clinical Use of Extended-Release Injectable Naltrexone in the Treatment of Opioid Use Disorder: A Brief Guide](#) (SAMHSA)
  - [General Principles for the Use of Pharmacological Agents to Treat Individuals with Co-Occurring Mental and Substance Use Disorders](#) (SAMHSA)
  - [Sublingual and Transmucosal Buprenorphine for Opioid Use Disorder: Review and Update](#) (SAMHSA)
  - [The ASAM Standards of Care for the Addiction Specialist Physician](#)
- **Pocket Guide:** [SAMHSA Medication- Assisted Treatment of Opioid Use Disorder Pocket Guide](#)

- Available for free in hard copy or via download.
- **Other**
  - [California Health Care Foundation Opioid Safety Network](#)