ABOUT PRESCRIBING BUPRENORPHINE: AN INTRODUCTION TO THE TRAINING PROGRAM AND PROCESS

WELCOME TO THE BUPPRACTICE TRAINING ACTIVITY!

On behalf of the American Society of Addiction Medicine, we are glad you have chosen to complete your training with us. This training prepares any practicing physician, nurse practitioner, or physician assistant having a DEA number to prescribe buprenorphine to patients experiencing the more common problems associated with opioid use disorder.

This training activity does not assume that you have expertise in addiction, nor does it claim to prepare you to treat ANY patient with opioid addiction. If you are not an addiction specialist, some patients will need to be referred to an addiction specialist for treatment.

Buprenorphine can offer a successful and viable treatment option for opioid-addicted patients. Treatment can change lives.

Disclaimer
This content is for educational purposes only, and medical decisions should not be based solely on its content. This site, its authors, and its consultants do not assume liability for errors or omissions.

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SAMHSA/CSAT’s Buprenorphine Waiver Information

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Summary
ABOUT PRESCRIBING BUPRENORPHINE

Goal
To introduce providers to office-based opioid treatment with buprenorphine, including its importance, effectiveness, approach, and training requirement.

After completing this module, participants will be able to:

• Recognize the need for opioid use disorder treatment given its prevalence
• Apply a patient-centered approach in a buprenorphine practice
• Describe buprenorphine’s status as a controlled substance and the laws governing the prescribing of this medication
• Describe the requirements to receive a waiver to prescribe buprenorphine
• Explain the process of becoming certified to prescribe buprenorphine for patients with opioid use disorder

Professional Practice Gaps
The Substance Abuse and Mental Health Services Administration (SAMHSA), based on National Survey on the 2013 Drug Use and Health survey, found the following evidence of a continuing opioid epidemic and need for additional treatment among Americans age 12 and over. The total number of outpatient prescription purchases of opioids rose drastically between 2002 and 2012, going from 85.9 to 143.9 million, an increase of 67.5 percent:

Current use:
• 289,000 or 0.1 percent current users of heroin (similar to 2008 to 2012)
• 4.5 million or 1.7% current users of non-medical use of pain relievers (similar to 2011 and 2012).

New initiates:
• 169,000 new initiates to heroin (similar to estimates from 2007 to 2012)
• 1.5 million new initiates to nonmedical use of pain relievers (lower than 2002 to 2012, which was 1.9 million to 2.5 million).

Receiving treatment: Only a small fraction of users needing treatment for an opioid use disorder receive it, especially for prescription pain relievers, but the numbers increased in 2013:
• Past year receipt of treatment for heroin users rose from 277,000 persons in 2002 to 526,000 persons in 2013
• Past year receipt of treatment for nonmedical users of prescription pain relievers increased from 360,000 in 2002 to 746,000 in 2013.

Buprenorphine is a safe and effective treatment for opioid use disorder that offers patients a more widely available, accessible, convenient treatment option as compared to traditional opioid treatment programs (OTP). The Drug Addiction Treatment Act (DATA) of 2000—an amendment to the Controlled Substances Act — allowed physicians who are not part of an OTP to prescribe buprenorphine with additional training and a waiver to the Controlled Substances Act. The Comprehensive Addiction and Recovery Act of 2016 (CARA) added nurse practitioners and physician assistants to the list of providers who can train to prescribe buprenorphine and become waivered.
The law requires physicians to complete an 8-hour buprenorphine training conducted by an approved organization in order to prescribe it; the required training for nurse practitioners and physician assistants is 24 hours. While buprenorphine is relatively safe, there are risks of overdose and death due to buprenorphine, and there is a risk of diversion\(^3\), which, in addition to skills needed to prescribe the medication effectively for each individual, are among the reasons for the mandatory training.

This buprenorphine training activity prepares providers to prescribe buprenorphine safely and effectively to address the needs of the millions of Americans with opioid use problems. The activity has been developed to meet the DATA 2000 training guidelines as defined in Public Law 106-310-106th Congress as well as the Comprehensive Addiction and Recovery Act of 2016 (S 524, Title III, Section 303-114th Congress) and is endorsed by the American Society of Addiction Medicine, one of the approved training organizations named in DATA 2000. The activity content was initially based upon SAMHSA's 2004 publication Treatment Improvement Protocol (TIP) #40: Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction and follow the Model Policy on DATA 2000 and Treatment of Opioid Addiction in the Medical Office\(^3\). The activity is updated to SAMHSA's Sublingual and Transmucosal Buprenorphine for Opioid Use Disorder - Review and Update (2016), ASAM's National Practice Guideline For the Use of Medication in the Treatment of Addiction Involving Opioid Use (2015), and the CDC's guidelines on opioid treatment\(^4\) as well as CARA 2016. The courses are regularly reviewed and updated by ASAM members who are experts in the field of addiction medicine and buprenorphine treatment.

ABOUT THIS TRAINING ACTIVITY

Regarding This Buprenorphine Training and Federal Law
1. Federal law describes which healthcare providers can prescribe buprenorphine in an office setting and the number of hours of training required:
   - DATA 2000 law allows physicians to complete an **8-hour** equivalent training activity to become qualified to prescribe buprenorphine. This activity meets that requirement.
   - As of the 2016 CARA law, nurse practitioners and physician assistants can complete a 24-hour program. This 10 module activity is Part 1 of a 24-hour program.

Be prepared to spend the equivalent of 8 hours of classroom time learning and thinking about this material. PLEASE NOTE that if you spend insufficient time/pages viewed in the activity, your name will NOT be forwarded to SAMHSA as having met the training requirement and you will be contacted by email.

2. You must take and pass a post-test, and complete a post-survey after finishing the training. The post-test and post-survey are reached from the Activity page (where the modules are listed). You may take the post-test more than once, but we suggest you review the material again before a second attempt.
   - In-module quiz scores do not count toward completion of the activity but do help prepare the learner for the post-test.

3. After you complete the modules thoughtfully, pass the post-test, and complete the survey, you will be able to request up to 9 hours of CME (AMA PRA Category 1 Credits\(^{™}\)) / Florida Academy of Physician Assistants (FAPA) / DC Board of Nursing (DCBN). Please request an amount of credit commensurate with your effort.
4. The required online waiver request form can be reached from the Activity Homepage AFTER you have completed the post-test. It may take up to 45 days for SAMHSA to process the request.

5. You will be able to get copies of your continuing education and training certificates or review the material and resources, at any time in the future.

Source
This content was originally adapted from the Substance Abuse and Mental Health Services Administration's (SAMHSA's) Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction (TIP 40) (2004). Because it is the basis for the content, we do not cite the TIP 40 source in the text.

The content has been updated, as noted by citations, according to SAMHSA's (2016) Sublingual and Transmucosal Buprenorphine for Opioid Use Disorder – Review and Update, expert review, and other subsequent literature including The ASAM National Practice Guideline For the Use of Medication in the Treatment of Addiction Involving Opioid Use (2015).

BupPractice was created using NO pharmaceutical or other industry support.

MEETING A NEED

Provider training in office-based opioid treatment with buprenorphine, such as the activity you are starting, addresses an important, continuing need. Survey evidence shows opioid use disorder continues to be prevalent in the U.S. In 2016, of people aged 12 or older, an estimated:

- 1.8 million had pain reliever use disorder (0.7 percent of this age group)
- 626,000 had heroin disorder (0.2 percent of this age group)\(^5\)

Opioid misuse is more common. The National Drug Use and Health survey of 2016\(^5\), found the following rates of opioid misuse among Americans age 12 and over in the past year:

- 11.8 million or 4.4% of the American population misused prescription pain reliever (includes any non-medically supervised use).
  - Approximately 62.3% of this group said that their opioid misuse was to relieve pain.
- 948,000 people used heroin in the past year.

The opioid epidemic is complicated by the legitimate need for opioid treatment for many individuals suffering from chronic pain: 11.2% of adults in the United States experience chronic pain and 6.4% have severe pain\(^6\).

The rate of overdose deaths is also steadily increasing. In 2015, over 22,000 deaths involved prescription opioids, an increase from 19,000 in 2014, which is nearly a 16% increase\(^7\). In 2016, 63,600 drug overdose deaths involved an opioid, either prescription or heroin\(^8\). There have been three waves in the increase of opioid deaths:

1. First, opioid overdose deaths rose in parallel with an increase in opioid prescribing in the 1990s. Increases in opioid prescribing appear to be related to increases in opioid use disorder. Survey data shows that treatment for opioid use disorder increased steadily in parallel to sales of opioid pain relievers from 1999 to 2009\(^9,10\)
2. An increase in heroin overdose deaths starting around 2010
3. An increase in deaths from synthetic opioid overdose, especially fentanyl, starting around 2013. Office-based opioid treatment is critical to help meet the significant need for treatment of opioid use disorder and help decrease the rate of overdose deaths.

In the modules of this activity, you will learn to recognize signs of opioid misuse and the criteria for opioid use disorder as well as to initiate treatment and maintain patients on buprenorphine.

**TREATMENT NEED**

**Large and Unmet Need for Substance Use Treatment**

2.4 million people age 12 or older had an opioid use disorder in 2016. Many of these patients could be treated in office-based opioid treatment, which is a treatment option that many people not having advanced needs prefer. However, currently, only 48,745 providers are waivered to provide this treatment.

There is a large and largely unmet need for substance abuse treatment. The National Survey on Drug Use and Health (NSDUH) identifies people who need substance use treatment (alcohol or illicit drugs) in the past year.

- In 2016, the NSDUH survey found that approximately 21 million people age 12 or older needed substance use treatment. That's approximately 1 in 13 people in this age group.
- If treatment is defined as any kind of treatment including 12-step groups, of the people who ever received treatment, 3.8 million people or 1.4 percent of those age 12 or older received treatment in the past year.

In 2016, of people aged 12 or older, an estimated 626,000 had heroin disorder (0.2 percent of this age group), and 0.9 million received treatment for any illicit drugs. Similar information is not available from this survey for the 1.8 million people who had pain reliever use disorder in 2016, because the NSDUH survey only asks about treatment for illicit drug use, so the extent of any treatment deficit is not clear from this source.

2.4 million people age 12 or older had opioid disorder in 2016. Many of these patients could be treated in office-based opioid treatment. However, currently, only 48,745 providers are waivered to provide this treatment.

**POLL: APPROXIMATELY WHAT PERCENTAGE OF YOUR PATIENTS ARE ON CHRONIC OPIOID THERAPY AND/OR HAVE OPIOID USE DISORDER, TREATED OR UNTREATED?**

**Poll Responses:**
1. 0 to 5%
   - 17% (757 votes)
2. 6 to 15%
   - 32% (1444 votes)
3. 16 to 30%
   - 18% (847 votes)
4. 31 to 60%
   - 10% (454 votes)
MEDICATION-ASSISTED TREATMENT FOR OPIOID USE DISORDER

What is Medication-Assisted Treatment for Opioid Use Disorder?
The FDA has approved three medications for use in medication-assisted treatment (MAT) of opioid use disorder:

- buprenorphine
- methadone
- naltrexone

The first two medications, buprenorphine and methadone, can be used for the initial process of quitting opioids (first stage of treatment - detoxification) and help reduce the need for inpatient care at this stage\(^\text{12-14}\). Buprenorphine and methadone also help in managing withdrawal from opioids by relieving withdrawal symptoms and psychological cravings. These medications typically need to be continued indefinitely, because withdrawal symptoms from their discontinuation can be severe and prolonged even with a taper\(^\text{13}\).

Buprenorphine and methadone work via the opioid receptors, the same receptors that are responsible for problematic dependence on opioids\(^\text{15}\). They have weaker effects and/or slower onset, so the individual does not feel "high" from taking them. Naltrexone has a different mechanism. It blocks opioid receptors, that is, it acts as an antagonist. Methadone and buprenorphine are much less addicting than other opioids that have more rapid onset or potent effects that lead to addiction; naltrexone is non-addicting.

These medications can be used to support long-term maintenance of being free from dependence on opioids (other than those being used in treatment) as they can be taken safely for years. Additionally, MAT has a higher rate of success than medication-free treatment. Whether or not medication-assisted treatment is chosen, however, psychosocial treatment is an important component of treatment and should be integrated into the overall treatment plan for your patients.

How Is the Treatment Chosen?
The provider and patient work together to select the best treatment considering:

- Whether the patient is open to taking a medication to assist with treatment, including an understanding of the physical dependence they will have on methadone or buprenorphine
- Efficacy, requirements/costs, side effects, and risks of each medication
- Patient preference among the choices
- Past experience with treatment
FYI: MAT and Alcohol Use Disorder
The FDA has also approved two additional medications for medication assisted treatment, and both are for treating alcohol use disorder:

- Disulfiram is used to treat chronic alcoholism. It acts by creating metabolic products that cause a negative reaction and nausea, thus motivating the individual to not drink and thus avoid having this experience.
- Acamprosate is used to treat chronic alcoholism. It acts by normalizing the brain neurochemistry, reducing cravings.

Neither drug is a narcotic; they do not require a waiver to prescribe them.

Note that naltrexone also may be used to treat alcohol use disorder.

Introduction to Buprenorphine
Buprenorphine is an opioid partial agonist used in the treatment of opioid use disorder. As a Schedule III drug, it:

- Has potential for abuse, but less than Schedule I and II drugs.
- Has a currently accepted medical use.
- May lead to moderate or low physical dependence or high psychological dependence if abused.

Other characteristics of buprenorphine. It is:

- Combined with naloxone in its most commonly prescribed form for treatment of opioid use disorder.
- Administered by either:
  - Slowly dissolving it sublingually or through the buccal mucosa, depending upon the product used.
  - Inserting subdermal implants
  - Injecting subcutaneously a formulation for that purpose.
- Has low bio-availability if swallowed, decreasing potential for diversion.
- Treats opioid use disorder from prescription opioids or heroin.
- Has milder withdrawal symptoms than full agonists, such as heroin, due to being a partial-agonist.
- As effective as methadone treatment for reducing opioid use in addicted individuals.
- Is effective at markedly reducing relapse rate when taken long-term.

Physicians reported that 68 to 81% of patients were “very satisfied” with buprenorphine treatment.

INDICATIONS FOR BUPRENORPHINE AND EFFICACY

Indicated Use
Buprenorphine is used for withdrawal and maintenance treatment for opioid use disorder. Buprenorphine is primarily prescribed to patients who currently meet the DSM 5 criteria for opioid use disorder but may be used for patients who are at risk of relapsing to opioid use disorder.
Buprenorphine Efficacy
Buprenorphine (16 mg/day of sublingual tablets or equivalent) has been shown in multiple research studies to be effective in suppressing opioid misuse\textsuperscript{13}. Many studies have shown that, in addition to being effective in opioid treatment programs, buprenorphine is effective when used in a qualified practitioner’s office\textsuperscript{19–21} Subsequent formulations showed similar efficacy before being FDA approved.\textsuperscript{22,23}

Comparison to Methadone
In research settings, buprenorphine maintenance (16 mg/day, sublingual tablets) is described as being as effective as methadone treatment (60 mg/day) for reducing opioid use in addicted persons\textsuperscript{24}. However, research shows methadone (or perhaps the clinic structure) has better patient retention\textsuperscript{13}. Furthermore, individual patients may respond better to one medication or the other.

- Like methadone, buprenorphine suppresses cravings for opioids and prevents withdrawal.
- Unlike methadone, which can only be prescribed by specially accredited opioid treatment programs, buprenorphine can be prescribed by physicians and qualifying physician assistants and nurse practitioners in their practices. Essentially, any physician addiction specialist or any physician, nurse practitioner, or physician assistant with a DEA license to prescribe and a DATA 2000 waiver is permitted to prescribe buprenorphine.
- Some patients may do better with office-based treatment, for example, if they had trouble getting to the clinic every day to pick up their methadone dose. Other patients may need the structure and high doses provided by a methadone program and may do poorly in less regimented, office-based buprenorphine treatment.

QUIZ: ABOUT BUPRENORPHINE
Question: Which of the following is true about buprenorphine:

1. For opioid-addicted individuals, buprenorphine is less effective than methadone treatment for reducing opioid use disorder.
   - Feedback: Incorrect. This is not a true statement about buprenorphine. It is as effective as methadone for treatment of opioid use disorder.
2. Buprenorphine has the potential for drug abuse.
   - Feedback: Correct! This is the one statement in this list that is true. Buprenorphine DOES have potential for abuse, but less than schedule I and II drugs.
3. Buprenorphine can be prescribed for treating opioid use disorder by any licensed provider with a DEA number.
   - Feedback: Incorrect. This is not a true statement about buprenorphine. While having a DEA number is a requirement to prescribe buprenorphine to treat opioid use disorder, it is not enough. You must also have a Data 2000/CARA 2016 waiver to prescribe buprenorphine for this purpose.
4. Buprenorphine has harsher withdrawal symptoms than full agonists, such as heroin, which helps motivate patients to stay on the medication.
   - Feedback: Incorrect. This is not a true statement about buprenorphine. It has milder symptoms of withdrawal due to buprenorphine being a partial-agonist.
METHADONE DETOXIFICATION AND MAINTENANCE

History
Methadone has been used to treat opioid dependence successfully in the U.S. since the 1960s\textsuperscript{12,25}. It comes in three forms (liquid, pill, or wafer) and is taken daily. This medication is still widely used as a safe and effective treatment for opioid dependence, and has been shown to provide longer-term treatment program retention among patients when taken in higher doses as well\textsuperscript{14}. It is also sometimes used in pain management, alleviating pain symptoms for 4-8 hours\textsuperscript{14}.

Efficacy
Methadone (60 mg/day) is about as effective as buprenorphine (16 mg/day) at maintaining opioid abstinence\textsuperscript{24}. In comparison to buprenorphine, methadone has better patient retention\textsuperscript{13}. Long-term maintenance appears to be necessary for success, as relapse rates are high among patients who drop out of treatment. However, misperception of long-term methadone treatment as simply "replacing one addictive drug with another” has led to some opposition to its use and discrimination against patients using it.

Treatment Settings
Currently, methadone maintenance treatment for opioid dependence can be administered only by a federal and state licensed opioid treatment program (OTP) by a licensed physician\textsuperscript{12}. Office-based administration of methadone is not permitted by law, unlike office-based buprenorphine treatment.

PHARMACOLOGY OF METHADONE

Biological Mechanisms and Pharmacokinetics
When taken daily, methadone (a synthetic analgesic) achieves its therapeutic effects by attaching itself to neuronal mu receptor sites in the brain\textsuperscript{15}. Although methadone-maintained patients will develop physical dependence, the mechanisms by which methadone achieves its therapeutic effects are different from those of heroin and other illicit opioids as it is slower acting. It is also a full agonist, unlike buprenorphine which is a partial agonist, and it is, therefore, more likely to cause physiological dependence\textsuperscript{12}. At therapeutic doses, methadone does not produce the heroin-like rush or sedation, and its slow onset and long duration of action prevent withdrawal symptoms and drug cravings. With a half-life of 22 to 24 hours, methadone stays in the system longer than heroin and other opioids and produces an extended period of physiologic homeostasis without withdrawal.

Dosing
Methadone must be taken daily and is traditionally distributed to patients one dose at a time in a methadone clinic. However, federal regulations allow methadone programs to prescribe take-home doses for well-stabilized patients with low risk for diversion\textsuperscript{12}. Effective daily maintenance doses vary, but the typical effective dose, one that reduces both withdrawal and cravings, is usually between 60 and 120 mg/day. At an adequate dose, methadone prevents withdrawal symptoms, drug craving, and reduces relapse to opioid misuse. Because of the long half-life, and the risk for overdose, it is important to avoid rapid increases in dose.

Side Effects
Daily, long-term methadone use is safe, with infrequent side effects. However, some side effects are potentially serious and warrant emergency treatment\textsuperscript{14}:

- Breathing difficulties or shallow breathing
• Feeling faint or light-headed
• Hives, rash, swelling of face, mouth, or throat
• Chest pain
• Rapid or pounding heartbeat
• Hallucinations, confusion

Complications
There are potential interactions with other drugs (especially sedating drugs, hypnotics, or anxiolytics) and alcohol, which can cause life-threatening respiratory depression. Chronic, heavy alcohol use can either inhibit or accelerate the rate of methadone metabolism, depending on alcohol blood levels and resulting effects on liver enzymes. Some prescription medications (including tricyclic antidepressants) can also affect the speed at which methadone is metabolized, and dosing must be adjusted accordingly.

Precautions
Patients having opioid use disorder often have co-occurring alcohol use disorder or other substance use disorder, and so they would be at risk for potentially dangerous interactions. Clinicians should observe patients for signs of intoxication and withdrawal.

There is also a risk for prolongation of the QTc interval and other arrhythmias; the risk increases as the methadone dose increases.

NALTREXONE
Naltrexone (Vivitrol®) is given as an injection for the treatment of opioid use disorder and other addictions, most often to prevent relapse. It is sometimes used after detoxification, as an alternative to methadone or buprenorphine maintenance, although there must first be a period without buprenorphine or other opioids. For example, a large study of naltrexone use after enforced abstinence while in prison found that released former prisoners had better success rates with naltrexone plus counseling and community treatment programs than controls having only counseling and community programs. At long-term follow-up, abstinence rates were similar to the other FDA-approved medication-assisted treatments for opioid use disorder, buprenorphine, and methadone.

Naltrexone costs $12,000 to $14,400 per year compared to $4 to 5,000 per year for daily buprenorphine, which makes it more cost prohibitive to many patients.

Similarities with buprenorphine include:
• Like buprenorphine, naltrexone can be administered through an office setting.
• Like buprenorphine, naltrexone blocks use of illicit opioids.

Advantages over buprenorphine include:
• Naltrexone injections are given only once per month. However, long-acting forms of buprenorphine are available and appropriate for some patients.
• Naltrexone does not cause a physical dependence as does buprenorphine.
• Naltrexone can be prescribed by any clinician who can prescribe medications and does not require a waiver to prescribe.

Challenges and risks of naltrexone include:
• Warning about transfer from buprenorphine to naltrexone: To reduce the patient's dependence on buprenorphine and avoid triggering precipitated withdrawal, patients should be tapered to
discontinue buprenorphine and then abstain from buprenorphine 7–14 days, before starting naltrexone. The medication, lofexidine, a non-opioid medication that is FDA approved to treat physical symptoms of opioid withdrawal and available around August 2018, may be employed to help reduce symptoms during opioid detoxification before starting naltrexone.

- Greater risk for overdose if opioids are used, especially near the time for a new dose of naltrexone and after being on naltrexone for a while. Patients should be educated that they will have lost any tolerance they built up for higher dose opioids and relapsing and using their old dose could be dangerous.
- Side effects are experienced by some patients, for example, nausea, dizziness, and injection site complications. Patients often feel poorly in the first month of treatment.
- Patients taking naltrexone will require non-opioid pain management for chronic pain. They should wear bracelets or carry wallet information about their medication so that an anesthesiologist can adjust analgesia when in hospital.
- Poor medication adherence is fairly common with naltrexone, and so it is primarily used when adherence can be enforced. Using the extended-release injectable formulation helps to some extent with medication adherence.
- Naltrexone is not as effective as buprenorphine or methadone at decreasing opioid cravings.

**Dosing:** Oral dosing can be daily or every three days. Injections of extended-release naltrexone are deep IM in the dorsogluteal muscle every 4 weeks. Patients must be cleared of buprenorphine or any opioid for 7 to 14 days before starting naltrexone in order to avoid precipitated withdrawal. Adjunctive medications (clonidine, clonazepam, trazodone) can be given to manage opioid withdrawal symptoms if needed during the interim period. The starting protocol involves use of the COWS to assess withdrawal symptoms and test dose(s), as described in the step-by-step clinical guide for XR Naltrexone available in the related resources section of this module.

**FYI**

Naltrexone may also be used to treat alcohol use disorder. It does help diminish alcohol cravings to some extent.

**OFFICE-BASED TREATMENT**

**An Opportunity for Treatment in Nontraditional Settings**

Making treatment available in nontraditional settings represents a tremendous opportunity for reaching more people and improving general public health.

Incorporating treatment for opioid use disorder into primary care settings addressed three important public health needs:

**Increased Availability**

It allowed treatment to reach more people.

**Increased Accessibility**

It allowed treatment to occur in places other than specialized clinics.

**Better Overall Treatment**
It allowed simultaneous and improved treatment for other commonly co-occurring medical conditions, such as hepatitis C and HIV. Individuals treated in opioid treatment centers that do not have medical facilities must be referred for such treatment.

**Current Number of Providers Prescribing Buprenorphine Through a Waiver**

Approximately 36,000 providers were waivered to prescribe buprenorphine at the end of 2016\(^5\), which is only around 6% of the physicians and surgeons in the United States\(^31\). A smaller number are actively prescribing buprenorphine through a waiver\(^17\), but the percentage of active prescribers may increase now that prescribers can eventually apply to treat up to 275 patients. A little over 7% of waivered prescribers had such approval at the end of 2016\(^5\).

**PRACTICE TIP**

The following are considered when determining whether a patient is better served in office-based treatment or an opioid treatment center\(^12\):

- Psychosocial factors
- Co-occurring disorders
- Likelihood of treatment retention
- Risk of diversion

**THE OPPORTUNITY**

**Potential To Make A Difference**

Primary care providers have a golden opportunity to recognize and treat patients who have substance abuse problems. Consider the following:

Approximately 20% of all primary care patients have a substance use problem\(^32\). This means that approximately 1 in 5 patients that you see in a day could benefit from screening, intervention, and treatment.

The Advantages of Addiction Treatment in Primary Care

- Primary care is more accessible than specialist treatment.
- There may be an existing therapeutic relationship; whereas an addiction specialist would be starting from scratch in building that relationship.
- Patients with substance use disorders are more likely to present to a PCP for any one of a number of other health reasons than they are to visit an addiction specialist.
- In primary care, addiction can be seen in the context of patients' daily lives, and continuity of care can be assured.
- Patients with substance use disorder are also more likely to return to the provider's office for follow-up visits\(^33\).

FYI: Receiving primary medical care is associated with decreased illicit drug use and improved outcomes among patients with substance use problems\(^32\).
PATIENT-CENTERED SKILLS

BupPractice Is Patient-Centered
The BupPractice training activity highlights ways to collaborate and communicate effectively with your patients. A patient-centered approach is taken, which includes information sharing, respect, support, and patient empowerment.

PATIENT-CENTERED: "Providing care that is respectful of and responsive to individual patient preferences, needs, and values, and ensuring that patient values guide all clinical decisions.”

Why is this important in a buprenorphine practice?

- Buprenorphine is a long-term treatment, so it is important to establish rapport and a collaborative relationship with your patients in what could be a long relationship.
- Patients who are engaged in their own treatment are more likely to pay attention to and follow important instructions regarding treatment.
- An accepting and supportive atmosphere will help patients return to treatment if they relapse, a point at which many patients are tempted to leave treatment.
- Patients who need it will be more likely to accept a high level of treatment structure, such as frequent drug screens, in an egalitarian, supportive atmosphere.

BupPractice Is Clinical Skills-Focused
BupPractice training takes the following approach to provide you with essential clinical skills:

- Challenging, realistic patient cases to advance your confidence and expertise
- Quizzes that call for clinical decision-making that applies what you just learned
- Practice tips for starting buprenorphine practice
- Highlighted "Caution" boxes draw your attention to many of the steps in buprenorphine practice requiring particular caution

CASE PREVIEW

Example Patient Dialogue
People from all walks of life can become addicted to opioids.

Example: Ms. Copeland has come to your office for a check-up and reports long-term Vicodin® use that was initially prescribed for severe menstrual cramps. However, she has continued opioid use despite a hysterectomy two years ago.

Provider: I see from your chart that you are still taking Vicodin®. Do you still have pain?

Mrs. Copeland: No, and I'm trying to wean myself off the Vicodin, but it's been hard. I take about ten pills a day, but when I try to reduce that dosage I have trouble sleeping, and I feel anxious. I get diarrhea off and on, too. So I haven't been able to stop taking it.
With the high rate of opioid addiction, chances are that there is someone in your practice who could benefit from buprenorphine treatment.

DEFINITIONS

Defining Common Terms
The following terms are used throughout this buprenorphine training activity:

- **ADDICTION** – The use of the term "addiction" has seen a number of changes. It was not used as a diagnosis in the DSM-IV but is back again in the DSM 5, not as a diagnosis, but as a Chapter heading: "Substance-Related and Addictive Disorders." A widely used definition: A primary, chronic, neurobiological disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include the following: impaired control over drug use, craving, compulsive use, and continued use despite harm.

- **CUES** – The term "cue" is often used to describe things that trigger or remind an individual with a substance use disorder to use the substances they misuse. These may include direct cues, such as drug paraphernalia; environments, such as the place where they often used the drug or purchased it; people, such as other people with substance use disorder. Even certain smells can serve as a cue. When counseling patients who are trying to quit drug abuse, help them think about their personal cues that might remind them of using or bring back the desire to use the drug they are trying to quit and then counsel them to avoid these cues.

- **OBOT** – The acronym OBOT stands for Office-Based Opioid Therapy and is used throughout this activity.

- **OPIOID MISUSE** – "Uses of a prescription medication other than [as] directed by a [provider] and [other than] used by a patient within the law and the requirements of good medical practice."  

- **OPIOID USE DISORDER** – The current DSM 5 diagnosis. It combines the older "opioid abuse" and "opioid dependence" diagnoses that were in the DSM-IV. Previously, a diagnosis of "opioid dependence" was needed before prescribing buprenorphine.

- **SUBSTANCE MISUSE** – "The use of any substance in a manner, situation, amount, or frequency that can cause harm to users or to those around them."  

- **SUBSTANCE USE DISORDER** – "A medical illness caused by repeated misuse of a substance or substances...characterized by clinically significant impairments in health, social function, and impaired control over substance use and are diagnosed through assessing cognitive, behavioral, and psychological symptoms."  

- **WAIVER** – Authorization which allows qualified providers an exemption from rules for opioid treatment providers, thus permitting them to treat opioid addiction in their offices using buprenorphine.

FEDERAL LAW – DATA 2000, CARA 2016, SPCA 2018

There are three major federal laws that, among other provisions, permit the prescribing of buprenorphine in the office-based setting and describe the requirements and limitations:

- The Drug Addiction Treatment Act (DATA 2000)
- The Comprehensive Addiction and Recovery Act of 2016 (CARA)
- The Support for Patients and Communities Act (SPCA, 2018)
DATA 2000 An Amendment to the Controlled Substances Act
The Drug Addiction Treatment Act (DATA 2000) was an amendment to the Controlled Substances Act signed into law in 2000. DATA made it possible for qualified physicians to prescribe buprenorphine for opioid detoxification and maintenance therapy. The law allowed physicians to be granted a waiver from the special registration requirements of that act, which allows them to prescribe, dispense, or administer buprenorphine to patients in their office, greatly expanding the availability and accessibility of opioid addiction treatment. It also described regulations that govern this prescribing. The waiver applies to Schedule III, IV, or V medications approved by the FDA for treating opioid use disorder, however, this currently only applies to buprenorphine products.

DATA 2000 in Nontraditional Settings: Under DATA 2000, treatment for opioid use disorder can take place in nontraditional settings, such as primary care offices. An advantage is that, in the past, some patients may have avoided treatment at substance abuse clinics due to worries about stigma and confidentiality.

- DATA described specific guidelines that physicians must follow before starting to prescribe buprenorphine. These include an 8-hour equivalent training.
- DATA does not include methadone—only a licensed opioid treatment program can prescribe methadone.

Some provisions of the DATA 2000 act were revised by CARA 2016, which is described in the following pages.

POLL: FAMILIARITY WITH DATA 2000
Poll Question: BEFORE THIS TRAINING, WERE YOU FAMILIAR WITH THE DATA 2000 REQUIREMENTS FOR PRESCRIBING BUPRENORPHINE?

Poll Responses:
1. Fully familiar with all the requirements
   - 7% (327 votes)
2. Partially familiar with the requirements
   - 45% (2249 votes)
3. Not familiar with the requirements
   - 49% (2435 votes)

FEDERAL LAW – CARA 2016
The Comprehensive Addiction and Recovery Act of 2016 (CARA): Law Updates
The Comprehensive Addiction and Recovery Act (CARA) was signed into law on July 22, 2016. This broad purposed bill aims to address the opioid epidemic through prevention, expanded access to treatment, increasing use of overdose reversal medication, expanding recovery support, and specifically targeting specific needs, such as those of pregnant and postpartum women, or those affected most, for example, via the criminal justice system and law enforcement.
Relevance to Office-Based Opioid Addiction Treatment
Among the provisions of CARA, are changes that affect office-based opioid addiction treatment with buprenorphine:

• **Professions that can be waivered.** Physician assistants and nurse practitioners (PAs and NPs) with DEA numbers, who previously were not permitted to prescribe buprenorphine under the 2000 law (DATA 2000), are permitted to prescribe according to changes in the Controlled Substance Act made by CARA 2016, which was signed into law on July 22, 2016. This change has no time limitation as of the Support for Patients and Communities Act (SPCA) (October, 2018). The original DATA 2000 law only allowed physicians completing the training or meeting certain other specific qualifications to prescribe buprenorphine. CARA, provides for PAs and NPs who can prescribe schedule III, IV, or V medications for pain to prescribe buprenorphine within limits set by their respective states. The SPCA added that clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives are qualified to obtain a waiver as of October 1, 2018 through October 1, 2023. In contrast to the 8-hour training required of physicians, a 24-hour training is required for these providers.

• **Patient limits.** This law also raised the upper limit of the number of patients a provider can treat using buprenorphine from 100 to 275. The initial limit is still 30 for the first year, however, unless you have specified additional training in addiction ("additional credentialing in addiction medicine or addiction psychiatry from a specialty medical board and/or professional society, or practice in a qualified setting"). Each step up in the maximum number of patients allowed (from 30 to 100 patients, from 100 to 275 patients) requires a year of experience at the previous limit and a waiver for the new limit.

Other Details Affecting Buprenorphine Treatment

• Expansion of NP and PA prescribing privileges is for 5 years (until October 1, 2021).
• The HHS Secretary was granted authority to exclude patients who are given their medication directly from the patient limit.
• The patient limit may be changed every 3 years based on a review of opioid addiction services in the U.S.
• States may lower the patient limit, but not below 30, or add practice setting, education, or reporting requirements.
• State Demonstration Grants for Comprehensive Opioid Abuse Response are authorized and may be available for prevention or to improve prescription drug monitoring programs, expand education, or expanding treatment.
• Consolidation of pain management best-practices.

PUBLIC HEALTH INITIATIVES OF CARA 2016 AND SPCA 2018
Other provisions of CARA 2016 aim to address the opioid epidemic by 1) expanding access to treatment and overdose reversal medication, and 2) addressing the problem within the criminal justice system and law enforcement. These initiatives include:

• Authorization of the HHS Secretary to award grants to state agencies and governments to make buprenorphine and other medication-assisted treatment more available in areas hardest hit by the opioid epidemic.
• Improvement of access to overdose treatment and related education via authorization for grants to buprenorphine prescribers and others to establish a naloxone co-prescribing program (prescribe naloxone to reduce overdose at the same time you prescribe an opioid) which would include training for providers, purchasing naloxone, reaching out to patients who have overdosed. Patients targeted include those being treated for opioid use disorders. There also is a training initiative for pharmacists who will also develop naloxone training for the public.
• Increase in public awareness of prescription opioid misuse and provide education.
• Authorization of a plan for safe prescribing and dispensing of drugs often abused or diverted, targeting at-risk Medicare prescription drug plan beneficiaries.
• Improving treatment for pregnant and postpartum women by reinstituting a grant program for their residential treatment and pilot studies for non-residential treatment.
• Support for states to make prescription drug monitoring plans (PDMPs) interoperable via reauthorization of the National All Schedules Prescription Electronic Reporting Act (NASPER). Requires states to share data with at least one adjacent state.
• Miscellaneous other grants for education for providers and providers in training, expanding the availability of treatment, enhancing efforts to prevent overdose, and improving law enforcement and criminal justice system efforts related to substance use disorders.

TRAINING TOPICS REQUIRED BY CARA

The topics specified in CARA (2016) as a requirement for training to obtain a waiver are all covered in this BupPractice training activity. They consist of:

TOPICS REQUIRED FOR TRAINING

• Opioid maintenance and detoxification
• Appropriate clinical use of all drugs approved by the Food and Drug Administration 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 Secretary of Health and Human Services

FEDERAL PROVIDER REQUIREMENTS

The Requirements to Prescribe Buprenorphine

To prescribe buprenorphine, DATA 2000 requirements include that the provider must:

• Be licensed in the state.
• Have a valid Drug Enforcement Administration (DEA) registration and identification number for controlled substances and obtain a DATA 2000 identification number (which begins with the prefix X).
• Comply with federal and state regulations for controlled substances.
Hold a current waiver.

Requirements to Obtain a Waiver
According to DATA regulations, providers were required to meet three requirements to apply for a waiver to prescribe buprenorphine to patients with opioid use disorder. CARA (2016) modifies these requirements slightly and adds several additional requirements:

Requirements from DATA 2000 and CARA (2016) that providers must fulfill in order to be waivered are that they must:

- Be a qualifying provider, i.e., have completed Data 2000/CARA training and received a waiver. Physicians were qualified by DATA 2000 and nurse practitioners, and physician assistants were qualified by provisions in CARA (2016).
- Have the capacity to provide the following for patients directly or by referral:
  - All FDA-approved drugs "for treatment of opioid use disorder, including for maintenance, detoxification, overdose reversal, and relapse prevention."
  - "Appropriate counseling and other appropriate ancillary services."
- Adhere to patient prescribing limits. Providers can treat 30 patients concurrently initially, apply to treat up to 100 patients concurrently after one year from initial notification and apply to treat 275 patients a year or more after notification of treating 100. Certain specialists may qualify to treat 275 patients from the start.

Many further public health initiative were signed into law with the SPCA of 2018 that include Medicaid, Medicare, and other health provisions to address the opioid crisis—so many that it is beyond the scope of this training. The reader is referred to the HR 6 SPCA resource at the end of this module for a summary of these changes. Those that are specific to this training have been added to the modules where relevant.

PRACTICE TIP
Note that insurance companies often ask whether counseling is offered in conjunction with buprenorphine treatment, in order to pay under the pharmacy benefit.

FYI
Over 29,000 U.S. providers were certified to prescribe buprenorphine for treatment of opioid use disorder as of 2015.

QUALIFYING TO PRESCRIBE
Qualify by Professional Credentials and Completing Buprenorphine Training or Addiction Certification
To be considered a qualifying practitioner, the DATA 2000 and CARA laws require the following. Practitioners must:

- Be a licensed physician, nurse practitioner, physician assistant, nurse anesthetist, nurse midwife, or clinical nurse specialist. Furthermore,
• Physicians must possess sufficient training or experience to show the ability to treat and manage opioid use disorder as determined by the medical licensing board of the physician's state.

• Nurse practitioners, physician assistants, nurse anesthetists, nurse midwives, and clinical nurse specialists must be licensed by their state to prescribe schedule III, IV, or V medications for the treatment of pain, and be supervised or collaborate in this work with a qualifying physician if required by their state.

• Be a licensed physician who graduated from medical school in the past 5 years and 44:
  • Graduated in “good standing from an accredited school of allopathic medicine or osteopathic medicine in the United States during the 5-year period immediately preceding the date on which the physician submits to the Secretary a written notification”
  • To qualify, recent graduates must have completed a comprehensive curriculum or an accredited medical residency that offered at least 8 hours of training on treating/managing opioid-dependent patients that included the training required for others or trainings on certain other pain and opioid-related topics also specified in detail in the law (see the law itself for specifics).

• Possess sufficient training or experience in the treatment of opioid use disorder as determined by the Secretary of Health and Human Services. This can be achieved by one of the following:
  • Completing an approved training on the treatment and management of opioid-dependent patients — such as this training activity lasting at least:
    • 8 hours for physicians
    • 24 hours for nurse practitioner or physician assistants
  • Being a physician who is an addiction specialist through one of the following:\n    • Board certification in addiction psychiatry or addiction medicine from the American Board of Medical Specialties.
    • Addiction certification or board certification from the American Society of Addiction Medicine or the American Board of Addiction Medicine.
    • Subspecialty board certification in addiction medicine from the American Osteopathic Association.
    • Participate as an investigator in at least one clinical trial leading to the approval of a Schedule III, IV, or V narcotic drug used for detoxification or maintenance treatment.

Certain providers with additional training in addiction may obtain this waiver (those with "additional credentialing in addiction medicine or addiction psychiatry from a specialty medical board and/or professional society, or practice in a qualified setting as described in the rule.") Specialists with these qualifications may qualify to treat 275 patients without going through the steps of treating smaller numbers of patients if they meet several additional requirements, available in Section 303(g)(2)(G)(ii) of the Controlled Substances Act (21 U.S.C. 823(g)(2)(G)(ii)).

The number of patients you are qualified to see is determined when you submit the Buprenorphine Waiver Notification form. Raising your limit requires an application be filed with the DEA to extend waived capacity. The online waiver application used for the initial application can be used for this purpose.
Limits for Group Practice: For waivered providers in group practices, the patient limits apply to individual practitioners, not the group, according to an amendment to the DATA 2000 law enacted in 2005. For instance, a group practice with 4 qualified waivered providers could treat 120 total patients (30 patients per provider) concurrently during the first year that the providers are certified, and a total of 400 at any given time in each year thereafter. Patients who are prescribed buprenorphine purely for pain treatment do not need to be counted.45

PRESCRIBING LIMITS

Adhere to Patient Prescribing Limits
Providers who obtain their buprenorphine waiver can treat up to 30 patients concurrently (including both detoxification and maintenance) during their first year prescribing it. Exceptions allowing the treatment of 100 patients are described below.

Higher Prescribing Limits: Providers who have a limit of 30 patients in their first year and want to treat more than 30 patients after their first year must submit a second notification form to the DEA to increase the limit to 100 patients being treated concurrently.

The Support for Patients and Communities Act (SPCA) signed into law October 24, 2018, also allows the following providers to see 100 patients initially44:

- Having additional credentialing of board certification in addiction medicine or addiction psychiatry by the American Board of Addiction Medicine, the American Board of Medical Specialties, or the American Osteopathic Association or certification by the American Board of Addiction Medicine, or the American Society of Addiction Medicine.
- Buprenorphine is provided in a qualified practice setting (described in section 8.615 of title 42, Code of Federal Regulations):
  - Provides coverage for patient medical emergencies when closed
  - Provides case-management services
  - Uses health information technology, e.g. electronic health records
  - Uses the state prescription drug monitoring program
  - Accepts third-party payment

Based on provisions in the Comprehensive Addiction and Recovery Act of 2016 (CARA) and SPCA of 2018, prescribers who have been waivered to prescribe for 100 patients at one time, can apply to treat as many as 275 patients if they meet several additional requirements43,44,46.

For details, view the SPCA and Title 42 › Chapter I › Subchapter A › Part 8 › Subpart F › Section 8 and following, which are both available in the External Resources at the end of this module.

WAIVER PROGRAM SUCCESS

The US Department of Health and Human Services (USDHHS) and Substance Abuse and Mental Health Administration (SAMHSA) concluded the following from a three-year evaluation of the Buprenorphine Waiver Program47:
• Office-based buprenorphine treatment appears to be clinically effective and well-accepted by patients.
• The availability of medication-assisted treatment for opioid addiction seems to have increased as a result of the waiver program.

In a nutshell, office-based buprenorphine treatment is effective!

Adverse effects, such as diversion, clinical events, and public health consequences, initially were considered to have been minimal. However, experience has since revealed significant problems with diversion and misuse of buprenorphine. This training activity will help you acquire skills to reduce these risks.

Further studies and evaluations are underway to determine

• The cost-effectiveness of Office-Based Opioid Therapy (OBOT)
• The effect of perceived barriers upon patient access to treatment

As more providers are training to prescribe, and more patients have access to treatment, the problem of opioid use disorder is being addressed.

HOW TO OBTAIN A WAIVER

Submitting a Waiver Notification Form
Providers who fulfill the requirements may apply for a waiver to prescribe buprenorphine. To apply, providers must complete and submit the online "Buprenorphine Waiver Notification" to CSAT, a department of SAMHSA. You can submit your waiver Notification of Intent form at any time after completing buprenorphine training; there is no time limit.

Providers: A link to the online waiver notification form and more instructions will be provided at the end of this training activity after you request credit.

The DEA Registration Process
CSAT will review your completed Waiver Notification of Intent form, and if it is approved, they will alert the DEA that you are a new buprenorphine prescriber. The DEA will then issue you a separate registration (DEA) number—called an "X" number—that you must write on any buprenorphine prescriptions that you write. There is no additional cost for this "X" number.
Allow 45 days for CSAT to review your waiver notification form. CSAT has 45 days after receipt of a Notification of Intent form to make a decision about an applicant. If 45 days have passed and you have not received confirmation from CSAT, contact CSAT’s Buprenorphine Information Center at 866-BUP-CSAT (866-287-2728) or send an email to infobuprenorphine@samhsa.hhs.gov.

**Exception to the 45-Day Waiting Period**
Under DATA, an exception is made for qualified practitioners who have an immediate need to treat a patient, but who have not received their waiver. These providers should refer to procedures on SAMHSA’s website page on obtaining a waiver for details of the procedures in this "emergency" situation.

**RESOURCES**

**SAMHSA**
The Substance Abuse and Mental Health Services Administration (SAMHSA) within the U.S. Department of Health and Human Services, through their Center for Substance Abuse Treatment (CSAT), includes the mission of promoting community-based substance abuse treatment and recovery services for individuals and families. SAMHSA's goals include improving access, reducing barriers, and promoting high quality, effective treatment and recovery services.

**SAMHSA/CSAT’s Buprenorphine Waiver Information**
The SAMHSA Medication Assisted Treatment webpage, in the section on buprenorphine waivers, provides links to valuable information about buprenorphine, how to become waivered, and the resources you will need. Once you have completed the BupPractice.com training, we will direct you to visit the buprenorphine waiver management section of SAMHSA's medication assisted treatment page [http://www.samhsa.gov/medication-assisted-treatment](http://www.samhsa.gov/medication-assisted-treatment). Follow links to their Center for Substance Abuse Treatment to fill out and submit your waiver notification of intent form. This webpage also provides links to the following:

- Information on how to obtain a waiver
- Buprenorphine Clinical Discussion WebBoard
- Forms for later in your practice, including to update your information or apply to increase the number of patients you see
- The Drug Addiction Treatment Act (DATA) of 2000
- Buprenorphine Treatment Physician Locator and several other resources for patients and families

**PCSS-MAT**
The Provider’s Clinical Support System is a training and mentoring project that partners with several professional societies to provide modules, webinars, resources, and a mentoring program to help providers who provide medication-assisted treatment for opioid use problems.

**QUIZ: DATA 2000**

**Question:** DATA 2000 is best described as:
1. The FDA’s guidelines for training programs in how to prescribe buprenorphine  
   • Feedback: Incorrect.

2. An amendment to the Controlled Substances Act  
   • Feedback: Correct! The Drug Addiction Treatment Act (DATA), signed into effect in 2000, is an amendment to the Controlled Substances Act that permits opioid detoxification and maintenance with buprenorphine in non-traditional settings, such as a clinical office. The Comprehensive Addiction and Recovery Act of 2016 and the Support for Patients and Communities Act of 2018 made some additional changes, including expanding the practitioners who can prescribe buprenorphine to include nurse practitioners, physician assistants, nurse anesthetists, nurse midwives, and clinical nurse specialists and raising the potential limit on the number of patients that can be treated for many providers.

3. A checklist of the DEA’s requirements for prescribing buprenorphine  
   • Feedback: Incorrect.

**SUMMARY**

- Buprenorphine is a partial agonist opioid used in the treatment of opioid addiction.
- A patient-centered approach to prescribing buprenorphine is important to keep patients fully engaged and empowered in their own recovery.
- As a Schedule III drug, buprenorphine has potential for abuse, so a thorough understanding of how to prescribe it effectively and safely is important.
- The Drug Addiction Treatment Act (DATA 2000) and the Comprehensive Addiction and Recovery Act (CARA 2016), amendments to the Controlled Substances Act, makes it possible for qualified physicians, nurse practitioners, physician assistants, and nurse anesthetists, nurse midwives and clinical nurse specialists to prescribe buprenorphine for opioid detoxification and maintenance therapy in their offices.
- These laws require that the provider must:
  - Be licensed in the state
  - Have a valid DEA registration and identification number for controlled substances and obtain an identification number signifying the waiver (which begins with the prefix X)
  - Comply with federal and state regulations for controlled substances
  - Hold a current waiver
- DATA 2000 requires of physicians an 8-hour training or equivalent, CARA 2016, and SPCA 2018 require a 24-hour training for qualified nurse practitioner, physician assistant, nurse anesthetist, nurse midwife, or clinical nurse specialists before applying for a waiver to prescribe buprenorphine.
- Providers who qualify and have completed the training apply for their waiver through the Center for Substance Abuse Treatment (CSAT), a division of SAMHSA, which also provides many resources related to prescribing buprenorphine.

**RESOURCES AVAILABLE THROUGH THIS MODULE:**

- 42 CFR Part 8 – Medication Assisted Treatment for Opioid Use Disorders
• AANP State Practice Environment
  Nurse practice laws and regulations for each state on an interactive map
• AATOD Guidelines for Using Naltrexone (Vivitrol) in OTPs
  Describes alternative treatment for opioid dependence, Vivitrol (long-acting naltrexone).
• ASAM Summary of the Comprehensive Addiction and Recovery Act
  Summarizes key features of CARA 2016.
• Buprenorphine and Buprenorphine plus Naloxone (en Español)
  La buprenorfina sublingual, y la buprenorfina y naloxona. This patient education resource addresses common questions about buprenorphine treatment for opioid dependence.
• Buprenorphine Management - SAMHSA
  Find information for providers on the waiver application and management process to prescribe or dispense buprenorphine for opioid dependency treatment.
• Buprenorphine Waiver Notification Form. 30 Patient Notification
  Slides describe the process of applying to prescribe buprenorphine for 30 patients by submitting a Waiver Notification form to SAMHSA.
• Buprenorphine Waiver Notification Form. 275 Patient Notification
  Slides describe the process of applying to prescribe buprenorphine for 275 patients by submitting a Waiver Notification form to SAMHSA.
• Comprehensive Addiction and Recovery Act of 2016
  The House of Representatives Filing Copy
• DATA 2000
  This page provides links to the full text, summary, and physician waiver requirements under DATA 2000.
• Flowchart of Steps in Applying for DEA Registration
  Steps in Applying for DEA Registration
• H.R.6 - SUPPORT for Patients and Communities Act
• Nurse Practitioners and Physician Assistants Prescribing Buprenorphine
  Describes and interprets the impact of Section 303 of the Comprehensive Addiction and Recovery Act (CARA), signed into law by President Obama on July 22, 2016. One of the changes allows nurse practitioners and physician assistants to prescribe buprenorphine with the appropriate training.
• Provider's Clinical Support System MAT
  Provider's Clinical Support System (PCSS-MAT) is a national training and mentoring project. Offerings include online training modules and webinars, resources, and a mentor program for providers of medication assisted treatment who are getting started or have less experience.
• SAMHSA's Buprenorphine Physician and Treatment Program Locator
  A directory of treatment programs and physicians authorized to treat patients with buprenorphine.
• SAMHSA/CSAT Evaluation of the Buprenorphine Waiver Program
  Webpage that reports how SAMHSA evaluates the buprenorphine waiver program. Includes "Evaluation of the Buprenorphine Waiver Program" and "Number of DATA-Certified Physicians."
• SAMHSA Medication Assisted Treatment Website
  Created by SAMHSA, this website section provides information about buprenorphine, including resources, the waiving process, DATA 2000, and the latest news.
• SAMHSA Provider Waiver Qualifications
Information from the CSAT Buprenorphine Information Center on the criteria required to receive waiver under DATA 2000.

- **Schedule of Opioids**
  A table showing the schedule of opioids.

- **The ASAM National Practice Guideline (Medication Assisted Treatment)**
  This document outlines the 2015 guidelines for assessment and pharmacological treatment of patients with opioid use disorder.

- **VIDEO: Patient Mike's Story**
  View three short webisodes that share Mike's buprenorphine success story. This story was taken from The National Alliance of Advocates for Buprenorphine Treatment (NAABT.org). Mike is an average middle-class American, a business owner, and a loving husband, father, and grandfather. While remodeling his restaurant, he hurt himself, and slowly became addicted to prescription opioid painkillers. A medication called buprenorphine, in addition to counseling and support, would allow him to get back on a productive path.

- **XR-Naltrexone: A Step-by-Step Guide**
  This step-by-step guide provides medical professionals a clear clinical plan from patient history intake to follow-up visit after administering XR-Naltrexone injections.

**REFERENCES USED IN THIS MODULE:**

5. SAMHSA. *Key Substance Use and Mental Health Indicators in the United States: Results from the 2016 National Survey on Drug Use and Health*. *SAMHSA.gov*. 2017.
12. ASAM. The ASAM National Practice Guideline For the Use of Medications in the Treatment of Addiction Involving Opioid Use. June 1, 2015.


28. Volkow N. NIDA-supported science leads to first FDA-approved medication for opioid withdrawal. NIDA. 2018.

29. PCSS. Vivitrol: How important is this piece of the treatment puzzle?. 2015.


37. SAMHSA. Treatments for Substance Use Disorders. 2015.

38. USDHHS. Medication Assisted Treatment for Opioid Use Disorders Reporting Requirements. 2016.

