

# BUPRENORPHINE RESOURCE GUIDE

## **Purpose:**

This guide introduces the office-based treatment of opioid dependence using buprenorphine to VA health care providers.

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## **Introduction**

### *The problem of treatment for opioid dependence in the VA*

Opioid dependence is a chronic, relapsing medical disorder that afflicts several million individuals in the United States, including at least 30,200 veterans enrolled in the Veterans Health Administration (VHA). Untreated or ineffectively treated opioid dependence significantly contributes to premature mortality and increased utilization of health care and social services. Furthermore, illicit opioid use contributes to increased use of alcohol and other drugs, criminal activity, and incidence of and morbidity from psychiatric and other medical disorders, including human immunodeficiency virus (HIV) and hepatitis C. In the VHA, as many as 65% of veterans diagnosed with opioid dependence do not receive specialized care for it, and over a twelve-month period, only 21% of veterans with opioid dependence had six or more visits with a VA opioid agonist therapy program (OATP) (e.g., methadone program).

### *Efforts to solve the problem*

In an effort to expand access to opioid agonist therapy beyond traditional opioid agonist therapy programs, Congress made an amendment to the Drug Addiction Treatment Act (DATA 2000), signed in 2002, which allows qualified physicians to prescribe and dispense approved buprenorphine (Subutex) and buprenorphine/naloxone (Suboxone) sublingual tablets (hereafter collectively termed 'buprenorphine') in office-based practices.

Buprenorphine has been shown to be a safe and effective treatment of opioid dependence in non-specialized, outpatient, office-based settings, including VA environments. Furthermore, buprenorphine's availability has encouraged opioid-dependent patients who would not otherwise present themselves to an OATP to access treatment. In 2003, after an evidence-based literature review and consultation with topic experts, the VHA established non-formulary guidelines for buprenorphine use, and in 2006, [formulary guidelines](#) were established. This permitted the use of buprenorphine sublingual tablets for the treatment of opioid dependence in the VA.

These are links to important VA information regarding buprenorphine use:

- [VA Formulary Guidelines for Use](http://vawww.apps.cmop.va.gov/PBMIntranetWEbSiteArchive/criteria/Buprenorphine.pdf)  
<http://vawww.apps.cmop.va.gov/PBMIntranetWEbSiteArchive/criteria/Buprenorphine.pdf>
- [VA Buprenorphine Drug Monograph](http://vawww.pbm.va.gov/drugmonograph/BuprenorphineDrugMonograph.pdf)  
<http://vawww.pbm.va.gov/drugmonograph/BuprenorphineDrugMonograph.pdf>
- [VA Buprenorphine Pharmacy Information](http://vawww.pbm.va.gov/drugmonograph/BUP%20PHARMACIST%20INFO%20(Rav%20070103).pdf)  
[http://vawww.pbm.va.gov/drugmonograph/BUP%20PHARMACIST%20INFO%20\(Rav%20070103\).pdf](http://vawww.pbm.va.gov/drugmonograph/BUP%20PHARMACIST%20INFO%20(Rav%20070103).pdf)

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### **Buprenorphine’s properties and merits as a treatment for opioid dependence**

-- Buprenorphine is a partial opioid agonist. Since it is a partial agonist, it helps to treat opioid dependence by activating mu-opioid receptors enough to prevent withdrawal symptoms but not enough to induce a high (though it does so in opioid-naïve individuals).

-- Buprenorphine has a ceiling effect, meaning that beyond a certain dose (generally considered to be 32mg), no further effect is achieved. Thus, the risk of respiratory depression is lower than full agonists such as methadone, and an overdose is far less likely to have serious consequences.

-- Buprenorphine has a higher affinity for the mu-opioid receptor than other opioids. If another opioid is taken concurrently, it will have no effect since buprenorphine blocks the receptor site.

-- Buprenorphine has a half-life of 24 to 36 hours. This makes daily or every-other-day dosing possible.

-- Buprenorphine can be prescribed in an office setting on an outpatient basis just like medications for any other chronic disease.

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## **First steps in making buprenorphine available at your facility**

Examine the VA web-based information (listed above). A common barrier is simply the lack of knowledge at the administrative level that use of buprenorphine has been mandated in the VA, and these resources may be helpful in overcoming this.

At least one prescribing physician needs to be waived to provide buprenorphine (though it is good for more than one to be waived for back-up). Only physicians can prescribe buprenorphine. Before a physician may prescribe buprenorphine, he or she must meet eligibility by being trained and then applying for a DEA waiver to prescribe buprenorphine. The training consists of either a one-day, 8-hour training course approved by the Drug Addiction and Treatment Act of 2000 (DATA-2000) or an online version certified by the American Psychiatric Association, American Academy of Addiction Psychiatry, or the American Society of Addiction Medicine (ASAM). Physicians who hold board certification in addiction medicine from ASAM, the American Osteopathic Association, or in addiction psychiatry from the American Board of Medical Specialties are exempt from the training course. A waiver to prescribe buprenorphine can then be filed with the Center for Substance Abuse Treatment (CSAT) online, or via mail or fax. After a 45-day waiting period, the DEA will issue the prescribing physician a DEA number granting permission to initiate buprenorphine utilization. During the first year of holding the waiver, a physician can prescribe buprenorphine to a maximum of 30 patients at any one time. One year after the date on which a physician submitted the initial notification, he or she may submit a second notification of the need and intent to treat up to 100 patients.

Wherever buprenorphine is prescribed, non-pharmacologic treatments for addiction should be available and offered to patients who are considering buprenorphine. Unlike prescribing methadone in OATPs, the only regulation in prescribing buprenorphine in an office-based practice is the one dictating the maximum number of patients being treated by a waived physician at any given time.

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## Web-Based Resources

- Buprenorphine SAMHSA website:
  - <http://www.buprenorphine.samhsa.gov/>
- Buprenorphine Information:
  - [http://www.csam-asam.org/resources-buprenorphine\\_info.vp.html](http://www.csam-asam.org/resources-buprenorphine_info.vp.html)
- Clinical Guidelines:
  - <http://www.csam-asam.org/TIP40.vp.html>
- Physician & treatment program locator:
  - [http://buprenorphine.samhsa.gov/bwns\\_locator/index.html](http://buprenorphine.samhsa.gov/bwns_locator/index.html)
- Upcoming trainings:
  - <http://buprenorphine.samhsa.gov./training.html>
- Online waiver to prescribe buprenorphine:
  - <http://buprenorphine.samhsa.gov./pls/bwns/waiver>
- Print waiver to prescribe buprenorphine:
  - <http://buprenorphine.samhsa.gov/howto.html>
- Mentors for physicians treating opioid dependence:
  - <http://www.pcssmentor.org/>
- American Academy of Addiction Psychiatry (AAAP):
  - <http://www.aaap.org>
- American Society of Addiction Medicine (ASAM):
  - <http://www.asam.org>
- Center for Substance Abuse Treatment (CSAT):
  - <http://www.csat.samhsa.gov/>
- The College on Problems of Drug Dependence:
  - <http://www.cpdd.vcu.edu/>
- The National Association of Alcoholism and Drug Abuse Counselors:
  - <http://naadac.org>
- The National Clearinghouse for Drug and Alcohol Information catalog:
  - <http://www.health.org/catalog/catalog.htm>
- National Institute on Alcohol Abuse and Alcoholism (NIAAA):
  - <http://www.niaaa.nih.gov/>
- National Institute on Drug Abuse (NIDA):
  - <http://www.nida.nih.gov/>
- Office of National Drug Control Policy:
  - <http://www.whitehousedrugpolicy.gov>

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## Frequently Asked Questions (FAQ)

The following FAQ and responses have been reproduced from [buprenorphine.samhsa.gov](http://buprenorphine.samhsa.gov), other web-based resources, and best available evidence and expert opinions. Most of this information is covered in the training course that allows providers to receive a waiver to prescribe buprenorphine.

The questions are linked to their answers in this document.

### Waiver issues

1. [As a physician employed by the Federal Government \(Veterans Administration, Indian Health Service, Federal Department of Corrections, etc.\) practicing in a Federal Government installation, am I eligible for a DATA 2000 waiver?](#)
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3. [May buprenorphine ever be administered by a practitioner without the DATA 2000 waiver?](#)
4. [I submitted my waiver notification to SAMHSA a few weeks ago and received an acknowledgment letter, but I haven’t heard anything since. How can I check on the status of my waiver?](#)
5. [I’ve heard this new model for the treatment of opioid addiction referred to as “office-based opioid therapy.” Does that mean that physicians with DATA 2000 waivers can use buprenorphine to treat opioid addiction only in an office-based setting?](#)
6. [With a DATA 2000 waiver, can I prescribe buprenorphine for opioid addiction in more than one practice location? Can I dispense it from more than one location?](#)
7. [I am a waived physician, and I’ve moved my practice location since receiving my waiver. Do I need to notify SAMHSA or DEA of my new practice address?](#)
8. [I am a waived physician and would like to add, change, or remove my listing on the SAMHSA Buprenorphine Physician Locator Web site. How do I do this?](#)

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### Opioid dependence and prescribing issues

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2. [What is the clinical use of buprenorphine for opioid addiction therapy?](#)
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5. [Do you follow the same rules for dispensing buprenorphine as you would for dispensing methadone through a methadone clinic \(e.g. labeling, take home doses\)?](#)
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8. [Is buprenorphine safe for use during pregnancy?](#)
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10. [Is it safe to drive or operate machinery while on buprenorphine?](#)
11. [Is it required that a patient fail a trial of methadone prior to being prescribed buprenorphine?](#)
12. [If a patient has been on greater than 60mg of methadone at any time in the past, do you consider that to be a contraindication for buprenorphine induction?](#)
13. [Is it acceptable to start patients on buprenorphine while they are inpatients?](#)
14. [What are the guidelines for continuing buprenorphine treatment on patients who are using illicit drugs \(e.g. marijuana\)?](#)
15. [Is use of benzodiazepines a contraindication to buprenorphine treatment?](#)
16. [Should a patient be experiencing withdrawal symptoms when starting the induction phase of buprenorphine?](#)
17. [Is it acceptable to induce patients who are not in current withdrawal?](#)
18. [How long do patients stay on buprenorphine?](#)
19. [Are SARRTPs allowing patients taking buprenorphine to stay in the domiciliary?](#)
20. [I practice both in the VA and outside of it. Do my VA patients count toward my patient limit?](#)

### **Pharmacy and cost issues**

1. [Do pharmacies need waivers to dispense buprenorphine?](#)
2. [Is buprenorphine available in pharmacies?](#)
3. [How much will a dose of buprenorphine cost a consumer?](#)
4. [Will buprenorphine be available in treatment programs for indigent patients and patients who don't have Medicaid or Medicare?](#)

## **Administrative issues**

1. [What job description should be used in describing the physician and non-physician positions that were funded under the buprenorphine initiative?](#)
2. [Are there specific federal record-keeping requirements for office-based opioid therapy?](#)
3. [Can an opioid treatment program \(i.e., methadone clinic\) dispense buprenorphine to patients admitted to the program? If so, is there a limit on the number of patients who can be treated with buprenorphine for opioid addiction treatment in an OTP? Is a DATA 2000 waiver required?](#)
4. [Are providers with an X-number required to keep a copy of their license in the pharmacy?](#)
5. [Is there a specific stop code for providing buprenorphine treatment?](#)
6. [How do physicians obtain buprenorphine for patients' induction?](#)
7. [Are patients able to take home supplies of these medicines?](#)
8. [Does DATA 2000 limit the number of patients who may be treated for opioid addiction at any one time by a physician group practice?](#)
9. [Is there a limit on the number of patients a practitioner may treat with buprenorphine at any one time?](#)
10. [What should be done when a clinic wants to keep buprenorphine on site?](#)
11. [Can physicians and other authorized hospital staff administer buprenorphine to a patient who is addicted to opioids but who is admitted to a hospital for a condition other than opioid addiction?](#)
12. [Can physician assistants or nurse practitioners prescribe buprenorphine for opioid addiction treatment in states that permit them to prescribe schedule III, IV, or V medications?](#)
13. [What can physician assistants and nurse practitioners do?](#)
14. [May physicians in residency training programs obtain DATA waivers?](#)
15. [Should our facility implement maintenance instead of detoxification with buprenorphine or both programs?](#)
16. [How do you get patients?](#)
17. [What type of clinical work-up do you do prior to admission to the program?](#)
18. [Is there a special group therapy guide for this population?](#)



19. [Can the medical personnel in correctional facilities dispense \(or administer\) buprenorphine to incarcerated individuals?](#)

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## WAIVER ISSUES

1. **As a physician employed by the Federal Government (Veterans Administration, Indian Health Service, Federal Department of Corrections, etc.) practicing in a Federal Government installation, am I eligible for a DATA 2000 waiver?**

Yes. Physicians employed by an agency of the Federal Government are eligible for DATA 2000 waivers. In order to be eligible for a waiver under DATA 2000, a physician must have a valid, individually assigned DEA registration number (in addition to a license to practice medicine and the credentialing/training discussed elsewhere). A physician who is directly employed by the Federal Government may obtain a DEA number free of charge without being licensed in the state where the Federal facility is located (the physician must have a valid state license in one of the 50 states, the District of Columbia, Virgin Islands or Puerto Rico). In order to receive a DEA number under this program, each physician must complete a DEA registration application that includes the physician's official business address and the name and phone number of the certifying official who can verify the physicians' eligibility for this program. This DEA registration number may only be used for practice within the Federal Government installation and may not be used for practice outside this setting. ([Return](#))

2. **Can physicians immediately treat patients if they have checked “Immediate” on the waiver notification form?**

A place to check “Immediate” is included on the form to address a provision in the Drug Addiction Treatment Act to permit treatment while a notification is under review. Checking “Immediate” is one of the three requirements that a physician must meet in order to start a patient on treatment, and treatment is limited to ONE patient per form submitted. (Each form must have a different submission date.) The three requirements are: 1) the physician must “in good faith” meet the criteria for obtaining a waiver (i.e., valid medical license, valid DEA registration, credentialing, or 8 hours of qualifying training), 2) the physician must check “Immediate” on the waiver, and 3) the physician must contact the Buprenorphine Information Center at 1-866-BUP-CSAT to verify that the notification form has been received and to notify CSAT of his/her intent to begin treating ONE patient.

Since the physician will not have the unique identifying number, pharmacists may question prescriptions received under this provision and contact the Buprenorphine Information Center if additional information is needed. ([Return](#))

3. **May buprenorphine ever be administered by a practitioner without the DATA 2000 waiver?**

Under the Narcotic Addiction Treatment Act of 1974, all practitioners who use narcotic drugs for treating opiate addiction must obtain a separate registration under 21 U.S.C.

Section 823(g)(1) or a DATA 2000 Waiver under 21 U.S.C. Section 823(g)(2). However, according to the Drug Enforcement Administration (DEA), an exception to the registration requirement known as the "three-day rule" (Title 21, Code of Federal Regulations, Part 1306.07(b)) allows a practitioner who is not separately registered as a narcotic treatment provider or certified as a "waivered DATA 2000 physician" to administer (but not prescribe) narcotic drugs to a patient for the purpose of relieving acute withdrawal symptoms while arranging for the patient's referral for treatment under the following conditions: 1) not more than one day's medication may be administered or given to a patient at one time, 2) this treatment may not be carried out for more than 72 hours, and 3) this 72-hour period cannot be renewed or extended.

The intent of 21 CFR 1306.07(b) is to provide practitioner flexibility in emergency situations where he or she may be confronted with a patient undergoing withdrawal. In such emergencies, it is impractical to require practitioners to obtain a separate registration. The 72-hour exception offers an opioid-dependent individual relief from experiencing acute withdrawal symptoms, while the physician arranges placement in a maintenance/detoxification treatment program. This provision was established to augment, not to circumvent, the separate registration requirement. The three-day emergency exception cannot be renewed or extended. For further details, consult DEA at <http://www.deadiversion.usdoj.gov/drugreg/faq.htm>. [\(Return\)](#)

**4. I submitted my waiver notification to SAMHSA a few weeks ago and received an acknowledgment letter, but I haven't heard anything since. How can I check on the status of my waiver?**

If you have submitted a notification and received an acknowledgment letter (or e-mail) from SAMHSA, then your notification is under active review. It is SAMHSA's intent to complete the review of notifications within 45 days of receipt. When processing of your notification is complete, they will mail you a letter confirming your waiver and containing your prescribing identification number.

If you have submitted a notification and received an acknowledgment from SAMHSA and it has been more than 2 months since you submitted your notification, or if you submitted a notification and you did not receive an acknowledgment that it had been received, please call 1-866-BUP-CSAT (1-866-287-2728) or e-mail [info@buprenorphine.samhsa.gov](mailto:info@buprenorphine.samhsa.gov). Please be prepared to provide the date when you submitted your original notification and other identifying information. [\(Return\)](#)

**5. I've heard this new model for the treatment of opioid addiction referred to as "office-based opioid therapy." Does that mean that physicians with DATA 2000 waivers can use buprenorphine to treat opioid addiction only in an office setting?**

No. Treatment of opioid addiction under the authority of a DATA 2000 waiver is not confined to the office setting. Physicians with DATA 2000 waivers may treat opioid addiction with buprenorphine in any practice settings in which they are otherwise credentialed to practice and in which such treatment would be medically appropriate (e.g., office, community hospital). [\(Return\)](#)

**6. With a DATA 2000 waiver, can I prescribe buprenorphine for opioid addiction in more than one practice location? Can I dispense it from more**

### **than one location?**

Physicians with DATA 2000 waivers may prescribe buprenorphine for opioid addiction in any appropriate practice setting in which they are otherwise credentialed to practice (e.g., office, hospital). However, they may store and dispense buprenorphine (or any other controlled substances) only at the practice address or addresses that they have registered with the DEA. Only one DATA-waiver unique identification number will be issued for each DATA-waived physician, no matter how many practice locations or DEA registrations a physician may have.

Additionally, a physician may have a total of 30 (or 100) patients on buprenorphine under his or her care, not 30 or 100 at each practice location. ([Return](#))

#### **7. I am a waived physician, and I've moved my practice location since receiving my waiver. Do I need to notify SAMHSA or DEA of my new practice address?**

Waived physicians who change the primary practice address at which they intend to treat opioid addiction under the authority of their DATA 2000 waiver must notify SAMHSA by calling 1-866-BUP-CSAT (1-866-287-2728) or via e-mail at [info@buprenorphine.samhsa.gov](mailto:info@buprenorphine.samhsa.gov). The Drug Enforcement Administration must also be notified. Call the DEA Office of Diversion Control at 1-800-882-9539. Phone numbers for local DEA offices can be found on the DEA Web site at <http://www.dea.gov>. ([Return](#))

#### **8. I am a waived physician and would like to add, change, or remove my listing on the SAMHSA Buprenorphine Physician Locator Web site. How do I do this?**

Waived physicians may call 1-866-BUP-CSAT (1-866-287-2728) or e-mail [info@buprenorphine.samhsa.gov](mailto:info@buprenorphine.samhsa.gov) with requests to change locator listings. ([Return](#))

## **OPIOID DEPENDENCE AND PRESCRIBING ISSUES**

### **1. How is opioid dependence diagnosed?**

A diagnosis of opioid dependence is based on the DSM-IV Criteria for Substance-Related Disorders. According to these criteria, a person is considered opioid-dependent when he or she manifests 3 or more of the following within a 12-month period:

- Tolerance (defined as a need for substantially greater amounts of an opioid to achieve the desired effect or a substantially reduced effect with continued use of the same amount of the opioid).
- Withdrawal (which, for opioid dependence, is characterized by certain symptoms that appear when heavy or prolonged use of the opioid ceases or when an opioid antagonist is taken after a period of opioid use).
- Frequent use of larger amounts of the opioid than planned or use of it over a longer period of time than planned.
- Persistent desire to cut down or control use of the opioid or trying unsuccessfully to do so .
- Devotion of a great deal of time toward obtaining the opioid, using it, or recovering from its effects.

- Surrendering or reduction of important social, occupational, or recreational activities because of the use of the opioid.
- Continued use of the opioid despite knowing that one has a persistent or recurrent physical or psychological problem probably caused or made worse by the opioid. ([Return](#))

## 2. What is the clinical use of buprenorphine for opioid addiction therapy?

Ideal candidates for opioid addiction treatment with buprenorphine are individuals who have been objectively diagnosed with opioid addiction, are willing to follow safety precautions for treatment, can be expected to comply with the treatment, have no contraindications to buprenorphine therapy, and who agree to buprenorphine treatment after a review of treatment options.

There are three phases of buprenorphine maintenance therapy: induction, stabilization, and maintenance.

**The induction phase** is the medically monitored start-up of buprenorphine therapy. Buprenorphine for induction therapy is administered when an opioid-addicted individual has abstained from using opioids for 12–24 hours and is in the early stages of opioid withdrawal. If the patient is not in the early stages of withdrawal (i.e., if he or she has other opioids in the bloodstream), then the buprenorphine dose could precipitate acute withdrawal. Induction is typically initiated as observed therapy in the physician’s office.

**The stabilization phase** has begun when a patient has discontinued or greatly reduced the use of his or her drug of abuse, no longer has cravings, and is experiencing few or no side effects. The buprenorphine dose may need to be adjusted during the stabilization phase. Because of the long half-life of buprenorphine, it is sometimes possible to switch patients to alternate-day dosing once stabilization has been achieved.

**The maintenance phase** is reached when the patient is doing well on a steady dose of buprenorphine. The length of the maintenance phase is different for each patient and in fact may be indefinite.

If both doctor and patient agree that buprenorphine treatment may be ceased, then the dose is gradually tapered until the phase called **medically supervised withdrawal**. This takes the place of what was formerly called “detoxification.” ([Return](#))

## 3. How is buprenorphine different from the current treatment options for opioid dependence such as methadone?

Currently, opiate dependence treatments like methadone can be dispensed only in a limited number of clinics that specialize in addiction treatment. There are not enough addiction treatment centers to help all patients seeking treatment. Buprenorphine is the first narcotic drug available under the Drug Abuse Treatment Act (DATA) of 2000 that can be prescribed in a doctor’s office for the treatment of opioid dependence. This provides more patients the opportunity to access treatment. ([Return](#))

## 4. Can a person currently being treated with methadone switch to buprenorphine without suffering withdrawal symptoms?

Patients can switch from methadone to buprenorphine treatment, but because the two drugs are very different, patients are not always satisfied with the results. A number of factors affect whether buprenorphine is a good choice for someone who is currently receiving methadone.

It is also possible for patients receiving buprenorphine to be switched to methadone. Patients interested in finding out more about the possibility of switching treatment should discuss this with their prescribing physician. ([Return](#))

**5. Do you follow the same rules for dispensing buprenorphine as you would for dispensing methadone through a methadone clinic (e.g. labeling, take home doses)?**

Yes, but only when used in a methadone program; it requires the same dosing schedule/take homes. When outside of a methadone program, it is prescribed just like any other medication without special regulations. ([Return](#))

**6. What are the side effects of buprenorphine?**

*(This is **NOT** a complete list of side effects reported with buprenorphine. Please refer to the package insert for a complete list of side effects.)*

The most common reported side effects include:

- cold or flu-like symptoms
- headaches
- sweating
- sleeping difficulties
- nausea
- mood swings

Like other opioids, buprenorphine has been associated with respiratory depression, especially when combined with other depressants. ([Return](#))

**7. Is it feasible to treat patients who are homeless with buprenorphine?**

Yes. This is the conclusion from a pertinent study:

*“Despite homeless opioid dependent patients' social instability, greater comorbidities, and more chronic drug use, office-based opioid treatment with buprenorphine was effectively implemented in this population comparable to outcomes in housed patients with respect to treatment failure, illicit opioid use, and utilization of substance abuse treatment.”*

Alford, DP, et al. Treating Homeless Opioid Dependent Patients with Buprenorphine in an Office-Based Setting. *J Gen Intern Med.* 2007 Feb;22(2):171-176. ([Return](#))

**8. Is buprenorphine safe for use during pregnancy?**

Buprenorphine is classified as Pregnancy Category C. There are no adequate and well-controlled studies of buprenorphine in pregnant women. Naloxone is strongly contraindicated as it can cause seizures in the newborn infant, so the buprenorphine monotherapy (Subutex) is preferred if the mother is unable or unwilling to switch to methadone for the duration of the pregnancy. ([Return](#))

**9. Is buprenorphine safe for use with breastfeeding mothers?**

Small amounts of buprenorphine and naloxone pass into the milk, but since there has been so little research regarding the effect this may have on the child, buprenorphine is not recommended for breastfeeding mothers. ([Return](#))

**10. Is it safe to drive or operate machinery while on buprenorphine?**

Buprenorphine can cause drowsiness and slow reaction times. This may occur more often in the first few weeks of treatment when the dose is being changed, but it can also occur when alcohol or other sedative drugs are taken concurrently. Caution should be exercised when driving cars or operating machinery. ([Return](#))

**11. Is it required that a patient fail a trial of methadone prior to being prescribed buprenorphine?**

(This does not apply to those sites that do not have methadone available to patients.)

If methadone treatment is available, the VA pharmacy buprenorphine formulary criteria are fairly clear on this point. If a methadone maintenance program is available, methadone should be used first unless it is not feasible (e.g., methadone clinic is too far away). ([Return](#))

**12. If a patient has been on greater than 60mg of methadone at any time in the past, do you consider that to be a contraindication for buprenorphine induction?**

No, there is no contraindication. Patients who have taken doses greater than 60mg of methadone (or dose equivalent on other medications) can be successful on buprenorphine. The transition from methadone opioid agonist therapy (OAT) to buprenorphine OAT can be tricky. It is important to make sure the patient is motivated to make the switch, is stable and can remain stable on buprenorphine, and has tapered down to a lower dose of methadone for some time (e.g., no more than 30mg for at least week). ([Return](#))

**13. Is it acceptable to start patients on buprenorphine while they are inpatients?**

Yes. Many buprenorphine-approved and -credentialed physicians find that an inpatient setting is an acceptable location to start patients on buprenorphine treatment. Physicians may opt to use buprenorphine for “detoxification” or “induction” to maintenance therapy. Once begun in an inpatient setting, arrangements for outpatient maintenance using buprenorphine should be arranged with the patient. In general, physicians start buprenorphine treatment the same way as in outpatient settings. It is important to remember that once the treatment is started, patients should not be prescribed opioid medications. ([Return](#))

**14. What are the guidelines for continuing buprenorphine treatment on patients who are using illicit drugs (e.g. marijuana)?**

Opioid dependence is a chronic relapsing medical illness. Buprenorphine is a treatment for opioid dependence. Some studies indicate that when treatment for opioid dependence occurs, use of other substances decreases. It is up to individual programs to define their requirements for abstinence of illicit or diverted substances when on buprenorphine. Evidence suggests that non-pharmacologic treatment is helpful for patients with opioid dependence and illicit and diverted substance use. Please refer to the VA/DoD formulary guidelines for buprenorphine [here](#) [PDF file]. [\(Return\)](#)

**15. Is benzodiazepine use a contraindication to buprenorphine treatment?**

No. Benzodiazepine *abuse* is a contraindication. When patients take benzodiazepines as prescribed, problems do not usually occur.

Using buprenorphine intravenously in combination with illegal use of benzodiazepines or other CNS depressants has been associated with respiratory depression and death. [\(Return\)](#)

**16. Should a patient be experiencing withdrawal symptoms when starting the induction phase of buprenorphine?**

Yes, it is very important that patients are experiencing withdrawal symptoms before inducing. If patient is not experiencing withdrawal when inducted, buprenorphine can cause immediate severe withdrawal. The Clinical Opioid Withdrawal Scale (COWS) may be used to objectively determine how severe the patient's withdrawal is. A score of 12-13 is a good time to begin the induction. [\(Return\)](#)

**17. Is it acceptable to induct patients who are not in current withdrawal?**

Yes, as long as they have no opioids in their system. This is applicable to patients who have been recently released from prison and have not used during that time, patients who use infrequently, and patients who have recently completed a detoxification program. The average dose to start these particular patients on during the induction phase is 2-4mg of buprenorphine. [\(Return\)](#)

**18. How long do patients stay on buprenorphine?**

As with other chronic medical diseases, the evidence indicates that duration of treatment should be decided on a case-by-case basis, and it varies widely by patients' support systems, clinic setting, practice resources, and site. [\(Return\)](#)

**19. Are SARRTPs allowing patients taking buprenorphine to stay in the domiciliary?**

This decision seems to differ facility by facility, but there is no regulation to preclude it. However, the domiciliary patients cannot have more than a week's supply of a controlled substance, so the prescriptions will have to be rewritten every 7 days. [\(Return\)](#)

**20. I practice both in the VA and outside of it. Do my VA patients count toward my patient limit?**

Yes. Each physician may have a total of 30 (or 100, if waiver requested after first year of prescribing) patients under his or her care with buprenorphine at any one time, regardless of the practice locations.

There is a caveat: a physician working in a methadone program treating patients under that program's DEA/VA license may treat another sample of patients you can treat up to 30 (or 100) under his or her own DEA x number. ([Return](#))

## PHARMACY AND COST ISSUES

### 1. Do pharmacies need waivers to dispense buprenorphine?

No. Physicians are required to obtain DATA 2000 waivers to prescribe and dispense buprenorphine for opioid addiction, but pharmacists and pharmacies are not required to have any special credentials for dispensing these medications above and beyond those for other Schedule III medications. Certain Federal laws and regulations, however, do affect pharmacy practice with regard to opioid addiction treatment prescriptions. ([Return](#))

### 2. Is buprenorphine available in pharmacies?

Buprenorphine is available in pharmacies throughout the United States. Pharmacies and physicians can obtain the medications by contacting a pharmaceutical wholesaler directly, or by contacting the drug manufacturer, Reckitt Benckiser, at 1-877-782-6966. Consumers may also call the same toll-free number for additional information. ([Return](#))

### 3. How much will a dose of buprenorphine cost a consumer?

The relative cost of buprenorphine compared to methadone may have been a significant barrier for its non-formulary use. Some VISN committees may have been reluctant to add buprenorphine to regional formularies based on a medication-to-medication cost comparison. Based on typical doses (12 to 16 mg per day), the average drug acquisition cost per day of buprenorphine/naloxone in the VA is between \$9.48 and \$10.10 (Goodman et al, 2006). The average daily cost for methadone (60 to 80 mg per day) in the VA is only \$0.36 to \$0.48; however, methadone is not approved for use outside of OATPs. Due to reduced regulatory burdens, lack of need for OATPs support infrastructure and salary costs, non-pharmacy costs are likely considerably lower for buprenorphine than for methadone. In prior research, VA investigators have concluded that sublingual buprenorphine use is cost-effective at the current costs accrued by VA, especially if its adoption does not lead to a net decline in methadone use through OATPs (Barnett, 2009). ([Return](#))

### 4. Will Medicare and Medicaid cover substance abuse treatment and buprenorphine?

Medicare – Substance abuse treatment may be covered under Medicare if it is determined to be medically necessary and it is provided in an inpatient or outpatient treatment center that is Medicare-certified according to the HHS. Medicare does not generally cover prescription drugs that are prescribed or dispensed to individuals on an



outpatient basis. If buprenorphine is administered by a Medicare-certified facility as a component of inpatient or emergency treatment such as detoxification or early stage stabilization treatment, rather than being a separate outpatient prescription, the medication's cost could be covered during that episode of care, just as the cost for any other medication used in the treatment process is covered when administered within a certified program/facility. However, this reimbursement would only occur if the Medicare-certified facility had buprenorphine on its list of eligible drugs and if the patient received the treatment at the facility.

There is currently no Medicare fee-for-service coverage for buprenorphine prescribed by a physician during an outpatient office visit, whether for outpatient detoxification, early stabilization, or maintenance. However, if a person is covered by a Medicare HMO that has a substance abuse and a pharmacy benefit, buprenorphine could be covered if it is on that particular plan's formulary and is determined to be medically necessary under the plan's coverage policies. Additionally, some Medicare beneficiaries have Medicare supplementary or Medi-gap insurance that covers some pharmaceutical benefits. Again, however, even under a supplementary plan, there may or may not be benefits for substance abuse treatment or for buprenorphine if it is not on the supplementary insurer's formulary. Medicare HMO members should read their coverage bulletins or call their plans to determine whether they have coverage for buprenorphine and for substance abuse treatment. Many HMOs do not cover outpatient substance abuse treatment except on an emergency basis required by law.

Medicaid – Medicaid coverage of substance abuse treatment and medication such as buprenorphine varies considerably by state and by whether or not the state's Medicaid plan is offered under managed care/HMO arrangements. Coverage of buprenorphine and/or substance abuse treatment connected with buprenorphine under Medicaid benefits will not only be a state-by-state decision, but will also be subject in most states to rules about prior authorization and medical necessity. In addition, in many states, Medicaid programs operate with a preferred drug list on which buprenorphine must be placed before it can be reimbursed. State Medicaid programs administered by HMOs may have an additional level of formulary and treatment authorization that affects whether buprenorphine and treatment connected to it are covered. ([Return](#))

#### **5. Will buprenorphine be available in treatment programs for indigent patients and patients who don't have Medicaid or Medicare?**

Community health centers, clinics, and hospitals offering free care to indigent individuals may or may not make buprenorphine available. Availability will depend on whether that health center or hospital offers substance abuse treatment or emergency care of addictions and whether buprenorphine is available on its formulary, as well as whether there is a staff/attending physician associated with the hospital who is qualified to administer the drug and whether the medication is determined to be medically necessary.

Individuals not eligible for Medicaid or Medicare who are not indigent fall into two categories: those who have commercial insurance coverage and those who do not. If an individual has insurance coverage outside of Medicare and Medicaid, the individual's insurance plan may or may not cover all or part of buprenorphine medication, depending on medical necessity, whether pharmaceuticals are covered, whether there is a required co-payment, and whether buprenorphine is on the plan's approved drug list. Individuals

who are not insured but who are neither indigent nor eligible for Medicaid or Medicare will have to pay themselves for buprenorphine and any treatment associated with it.

[\(Return\)](#)

## ADMINISTRATIVE ISSUES

### 1. **What job description should be used in describing the physician and non-physician positions that were funded under the buprenorphine initiative?**

Position descriptions can be different than typical physicians, counselors, or affiliated staff members at individual VA sites, but buprenorphine originally was intended legislatively to be a regular medication provided by regular physicians in regular settings. The provision of care should be similar to other addictive disorders. In other words, the counseling for buprenorphine and the provision of care for buprenorphine is not dissimilar to what many programs or providers do today on a regular basis.

Some sites have incorporated buprenorphine with general and specialty psychiatric settings and primary care settings using the position descriptions of existing or hired staff as a template. It has worked well. To accomplish this, use existing position descriptions at your facility as a template. [\(Return\)](#)

### 2. **Are there specific federal record-keeping requirements for office-based opioid therapy?**

DEA record-keeping requirements for office-based opioid therapy go beyond the Schedule III record keeping requirements. According to the DEA:

“Practitioners must keep records (including an inventory that accounts for amounts received and amounts dispensed) for all controlled substances dispensed, including Subutex and Suboxone [(buprenorphine)] (21 PART 1304.03[b]). In some cases, patients return to the prescribing physician with their filled Subutex or Suboxone prescriptions so that the practitioner can monitor the induction process. While it is acceptable for the patient to return to the practitioner with their filled prescription supplies, practitioners shall not store and dispense controlled substances that are the result of filled patient prescriptions.

“Practitioners must keep records for controlled substances prescribed and dispensed to patients for maintenance or detoxification treatment (21 CFR Section 1304.03[c]). Many practitioners comply with this requirement by creating a log that identifies the patient (an ID number may be used instead of name), the name of the drug prescribed or dispensed, the strength and quantity, and date of issuance or dispensing. Some physicians comply with this requirement by keeping a copy of the prescription in the patient record.”

Alternatively, the DEA suggests that practitioners keep separate records for controlled substances prescribed and dispensed for maintenance or detoxification treatment to facilitate the record reviews during physician inspections for DATA compliance. This way, the DEA will only review those records related to controlled substances prescribed and dispensed for maintenance or detoxification treatment for physicians maintaining separate records.

Additionally, individual physicians are ultimately responsible for keeping track of the number of patients for whom s/he is currently prescribing buprenorphine. ([Return](#))

**3. Can an opioid treatment program (i.e., methadone clinic) dispense buprenorphine to patients admitted to the program? If so, is there a limit on the number of patients who can be treated with buprenorphine for opioid addiction treatment in an OTP? Is a DATA 2000 waiver required?**

New SAMHSA regulations permit OTPs serving persons addicted to prescription opioids or heroin to offer buprenorphine treatment along with methadone and LAAM. These regulations enable OTPs that are certified by SAMHSA to use buprenorphine for opioid maintenance or detoxification treatment. The text of the federal regulations is found [here](#) (PDF, 43 kb).

The provision of opioid addiction treatment with buprenorphine in OTPs certified by SAMHSA/CSAT does not require a DATA 2000 waiver. Additionally, such treatment is not subject to the patient limits that apply to individual physicians providing opioid addiction treatment outside the OTP system under the authority of a DATA 2000 waiver. The provision of opioid addiction treatment with buprenorphine in treatment settings other than OTPs, even by physicians who are licensed to practice in OTPs, does require a DATA 2000 waiver and is subject to the patient limits for individual physicians.

OTPs providing buprenorphine for opioid maintenance or detoxification treatment must conform to the federal opioid treatment standards set forth under 42 C.F.R. § 8.12. These regulations require that OTPs provide medical, counseling, drug abuse testing, and other services to patients admitted to treatment. To offer buprenorphine, OTPs will need to review their state licensing laws and regulations and to modify their registration with the DEA to add schedule III narcotics to their registration certificates. Opioid treatment programs can initiate this streamlined process by fax or letter. The letter should include the OTP's DEA registration number and request that the registration be amended to list schedule III narcotic drugs. The letter must be signed by the program sponsor (program director) or medical director. For more information, visit the DEA's Office of Diversion Control [website](#).

Once the registration has been modified, OTPs can order buprenorphine directly from Reckitt Benckiser, the product manufacturer, by calling 1-877-782-6966. ([Return](#))

**4. Are providers with an X-number required to keep a copy of their license in the pharmacy?**

It is fine for physicians employed outside of the VA to keep their license in their own files, but VA-employed physicians should keep a copy of their license with the pharmacy. As a general rule, local policies should always be followed. ([Return](#))

**5. Is there a specific stop code for providing buprenorphine treatment?**

Providers should use the same stop code for providing buprenorphine treatment as they do for providing other care. If buprenorphine is being provided in primary care, the stop code would be 323. If it is provided in a licensed methadone clinic, the stop code would be 523. If in infectious disease, the stop code would be 310, and so forth.

A procedure code can be used to differentiate buprenorphine care for your monitoring.

In substance abuse treatment clinics, the stop codes are as follows:

- Substance Abuse – Individual: 523
- Substance Abuse Disorder/PTSD Teams: 519
- Opioid Substitution: 523
- Intensive Substance Abuse Treatment – Group: 547 ([Return](#))

## **6. How do physicians obtain buprenorphine for patients' induction?**

Some physicians obtain limited supplies through their distributor and store them at their offices.

Other physicians write prescriptions for induction doses to be picked up at local pharmacies by the patients themselves. Patients may be in the early stages of withdrawal when they pick up their induction prescription, so some physicians may send patients' family members or close friends to pick up the induction doses

A prescribing physician may call or fax in the induction prescription to request delivery (if your pharmacy provides this service) or to ensure that the prescription is ready in advance of the patient's arrival.

The physician must also send a signed copy of a consent form giving permission for the doctor to disclose the patient's treatment to the pharmacy.

During the induction phase, it is common for prescriptions to be written for 1- to 3-day quantities instead of 30-day supplies. ([Return](#))

## **7. Are patients able to take home supplies of these medicines?**

Yes. Buprenorphine is less tightly controlled than methadone because it has a lower potential for abuse and is less dangerous in an overdose. As patients progress on therapy, their doctor may write a prescription for increasingly longer take-home supplies of the medication. ([Return](#))

## **8. Does DATA 2000 limit the number of patients who may be treated for opioid addiction at any one time by a physician group practice?**

Not anymore. The physician group practice limit was eliminated by Public Law 109-56, which became effective August 2, 2005. ([Return](#))

## **9. Is there a limit on the number of patients a practitioner may treat with buprenorphine at any one time?**

Yes. DATA 2000 specifies that an individual physician may have a maximum of 30 patients on opioid therapy at any one time for the first year of holding the waiver. One year after the date on which a physician submitted the initial notification, the physician may submit a second notification of the need and intent to treat up to 100 patients. ([Return](#))

## **10. What should be done when a clinic wants to keep buprenorphine on site?**

The medication should be kept in a locked cabinet in a locked room. ([Return](#))

**11. Can physicians and other authorized hospital staff administer buprenorphine to a patient who is addicted to opioids but who is admitted to a hospital for a condition other than opioid addiction?**

Neither the Controlled Substances Act (as amended by the Drug Addiction Treatment Act of 2000) nor DEA implementing regulations (21 CFR 1306.07(c)) impose any limitations on a physician or other authorized hospital staff to maintain or detoxify a person with an opioid treatment drug like buprenorphine as an incidental adjunct to medical or surgical conditions other than opioid addiction.

Thus, a patient with opioid addiction who is admitted to a hospital for a primary medical problem other than opioid addiction (e.g., myocardial infarction) may be administered opioid agonist medications (e.g., methadone, buprenorphine) to prevent opioid withdrawal that would complicate the primary medical problem. A DATA 2000 waiver is not required for practitioners in order to administer or dispense buprenorphine (or methadone) in this circumstance. It is good practice for the admitting physician to consult with the patient's addiction treatment provider, when possible, to obtain treatment history. ([Return](#))

**12. Can physician assistants or nurse practitioners prescribe buprenorphine for opioid addiction treatment in states that permit them to prescribe schedule III, IV, or V medications?**

No. Under DATA 2000, waivers to permit the prescription of Schedule III, IV, or V medications for opioid addiction treatment are available only to "qualifying physicians." The term "qualifying physician" is specifically defined in DATA 2000 as a "physician who is licensed under state law," has DEA registration to dispense controlled substances, has the capacity to refer patients for counseling and ancillary services, will treat no more than 30 such patients at any one time, and is qualified by certification, training, and/or experience to treat opioid addiction. ([Return](#))

**13. What can physician assistants and nurse practitioners do?**

The short answer is: Everything except actually write the prescription.

Under the close supervision of a physician who holds an x-designation, a PA or NP may give counsel, administer buprenorphine, and follow patients on through the maintenance phase. The physician must be the only prescriber at all points in the process (induction, maintenance, etc.). X numbers cannot be given to non-physicians even if the NP/PA has his or her own DEA license. ([Return](#))

**14. May physicians in residency training programs obtain DATA waivers?**

Yes, however, individual states may have laws with more restrictive rules regarding who may prescribe or dispense schedule III narcotic drugs for detoxification or maintenance treatment. ([Return](#))

**15. Should our facility implement maintenance instead of detoxification with buprenorphine or both programs?**

Each site should aim to provide maintenance treatment of opioid dependence using buprenorphine. Maintenance treatment using buprenorphine is an effective treatment for opioid dependence. Detoxification is generally considered a medical procedure (to reduce medical risk when a patient must discontinue opioid use) and not a treatment for substance use disorders. However, detoxification using buprenorphine may provide safer and enhanced outcomes over detoxification of opioids using other medications. In addition, detoxification may provide a bridge to maintenance therapy for many programs. ([Return](#))

**16. How do you get patients?**

There are over 20,000 veterans nationally who have opioid dependence. Many patients are unknown to providers. One strategy to initiate buprenorphine at your site is to indicate to inpatient wards and outpatient clinics that buprenorphine is available. Once the clinic or program is established, patients new and old to the VA may self-refer and refer others to the clinic or program. ([Return](#))

**17. What type of clinical work-up do you do prior to admission to the program?**

A complete history should be taken, patient should be given a physical exam, lab testing should be completed, mental status exam given, and a psychiatric evaluation completed if indicated. The eight-hour training program provides a good synopsis of what medical and psychiatric evaluation should occur. ([Return](#))

**18. Is there a special group therapy guide for this population?**

There is no known evidence-based group therapy specifically designed for buprenorphine patients. Any evidence-based group therapy for substance use disorders would be appropriate. ([Return](#))

**19. Can the medical personnel in correctional facilities dispense (or administer) buprenorphine to incarcerated individuals?**

Qualified physicians who have obtained a DATA 2000 waiver can dispense or prescribe buprenorphine in any practice setting, including in correctional facilities. Currently, state laws and policies vary considerably regarding opioid-assisted (methadone) treatment within correctional facilities. It is assumed that this same variation will occur with the use of buprenorphine in this setting. The patient limits per waived physician as stated in the DATA 2000 legislation also apply to the prescribing or dispensing of this treatment in correctional facilities. ([Return](#))