

# Initiating Office-Based Opioid Therapy

## Important Information for Physicians

Frequently Asked Questions

SUBOXONE<sup>®</sup>  
(buprenorphine and naloxone) sublingual tablet CIII

## **I. Introduction**

The purpose of this brochure is to provide information about the Risk Evaluation and Mitigation Strategy (REMS) to prescribers of SUBOXONE<sup>®</sup> (buprenorphine and naloxone) sublingual tablet CIII who are certified to treat opioid dependence under the Drug Addiction Treatment Act of 2000 (DATA 2000; See Appendix A)

This brochure summarizes important safety issues and messages needed to counsel patients about safe use of SUBOXONE.

*This REMS does not apply to SUBOXONE tablet dispensed to patients admitted to Opioid Treatment Programs under 42 CFR Part 8 because the care of these patients is subject to specific requirements under those regulations.*

### **What is SUBOXONE sublingual tablet?**

SUBOXONE sublingual tablet is indicated for the maintenance treatment of opioid dependence and should be used as part of a complete treatment plan to include counseling and psychosocial support.

SUBOXONE contains the active ingredient buprenorphine HCl. The sublingual tablet formulation is administered sublingually as a single daily dose. SUBOXONE is intended to be part of a treatment plan that includes counseling and/or behavioral therapy.

SUBOXONE includes a second active ingredient, naloxone HCl, at a ratio of 4:1 buprenorphine/naloxone (ratio of free bases). Naloxone is included in the SUBOXONE formulation, and is intended to deter individuals from abusing it by the intravenous route.

### **How is SUBOXONE sublingual tablet different from the film formulation?**

The primary difference is the delivery mechanism of the sublingual formulation. SUBOXONE sublingual tablet contains buprenorphine and naloxone, similar to the film formulation. The dosage strengths for SUBOXONE tablet are the same as the film formulation: 2/0.5 mg and 8/2 mg.

## **II. REMS – Risk Evaluation and Mitigation Strategy**

### **What is a Risk Evaluation and Mitigation Strategy (REMS)?**

A REMS is a strategy to manage a known or potential risk associated with a drug. A REMS can include, among other strategies, a Medication Guide, a communication plan, and elements to assure safe use.

### **Is there a REMS for SUBOXONE?**

Yes, a REMS has been implemented as part of the FDA requirements to ensure that the benefits of treatment with SUBOXONE outweigh the potential risks, particularly risks of accidental overdose, misuse, and abuse.

### **What are the goals of the SUBOXONE REMS?**

The goals of the REMS for SUBOXONE are to:

1. Mitigate the risks of accidental overdose, misuse, and abuse
2. Inform physicians, pharmacists, and patients of the serious risks associated with the use of SUBOXONE

### **What is my role with regard to the REMS for SUBOXONE?**

To meet the requirements of the REMS and to ensure the benefits of prescribing SUBOXONE to a patient outweigh the risks of accidental overdose, misuse, and abuse, physicians should take the following measures and document actions taken with each patient to ensure safe use conditions.

- Verify patient meets diagnostic criteria for opioid dependence
- Discuss the risks associated with SUBOXONE, including those described in the Medication Guide
- Provide induction doses under appropriate supervision
- Prescribe a limited amount of medication during the initial stages of treatment
- Explain how to safely store the medication
- Schedule patient appointments commensurate with patient stability (weekly or more frequent visits recommended for the first month)
- Consider pill count/dose reconciliation
- Assess whether patient is receiving counseling/psychosocial support considered necessary for treatment
- Assess whether patient is making progress toward treatment goals (including, as appropriate, urine toxicology testing)
- Continually assess appropriateness of maintenance dose
- Continually assess whether or not benefits of treatment outweigh the risks

As part of the REMS, physicians prescribing SUBOXONE for opioid dependence will be provided with an 'Appropriate Use Checklist' to document safe use conditions and clinical monitoring of each patient. This can be retained in the records of each patient.

*This REMS does not apply to SUBOXONE tablet dispensed to patients admitted to Opioid Treatment Programs under 42 CFR Part 8 because the care of these patients is subject to specific requirements under those regulations.*

### **III. Highlighted Important Safety Information for SUBOXONE sublingual tablet**

This section of the brochure highlights important safety information to consider when prescribing SUBOXONE sublingual tablet. **Refer to the prescribing information (PI) for detailed safety-related information for SUBOXONE sublingual tablet.**

#### ***Abuse Potential for SUBOXONE***

**Is SUBOXONE abusable?**

Buprenorphine, like morphine and other opioids, has the potential for being abused and is subject to criminal diversion. This should be considered when prescribing or dispensing buprenorphine in situations when the clinician is concerned about an increased risk of misuse, abuse, or diversion. Healthcare professionals should contact their state professional licensing board or state controlled substances authority for information on how to prevent and detect abuse, misuse, or diversion of this product.

Patients who continue to misuse, abuse, or divert buprenorphine products or other opioids should be provided with, or referred to, more intensive and structured treatment.

Abuse of buprenorphine poses a risk of overdose and death. This risk is increased with the abuse of buprenorphine and alcohol and other substances, especially benzodiazepines.

The physician may be able to more easily detect misuse or diversion by maintaining records of medication prescribed including date, dose, quantity, frequency of refills, and renewal request of medication prescribed.

Proper assessment of the patient, proper prescribing practices, periodic re-evaluation of therapy, and proper handling and storage of the medication are appropriate measures that help to limit abuse of opioid drugs.

Because it contains naloxone, SUBOXONE is highly likely to produce marked and intense withdrawal signs and symptoms if misused parenterally by individuals dependent on full opioid agonists such as heroin, morphine, or methadone. SUBUTEX<sup>®\*</sup> (buprenorphine) sublingual tablet (CIII) does not contain a naloxone component. Therefore, to discourage misuse or abuse, it is highly recommended that SUBOXONE is prescribed whenever feasible.

Clinicians should also be aware that some opioid-dependent persons, particularly those with a low level of full mu-opioid physical dependence or those whose opioid physical dependence is predominantly to buprenorphine, abuse buprenorphine/naloxone combinations by the intravenous or intranasal route.

Because of the partial agonist properties of buprenorphine, SUBOXONE may precipitate opioid withdrawal signs and symptoms in such persons if administered sublingually before the agonist effects of the opioid have subsided.

\*SUBUTEX full Prescribing Information can be found at [www.suboxone.com](http://www.suboxone.com)

### **Can SUBOXONE cause dependence?**

Buprenorphine, the active ingredient in SUBOXONE, is a partial agonist at the mu-opioid receptor. Chronic administration produces dependence of the opioid type, characterized by withdrawal upon abrupt discontinuation or rapid taper. The withdrawal syndrome is milder than seen with full agonists, and may be delayed in onset. Buprenorphine can be abused in a manner similar to other opioids, legal or illicit. This should be considered when prescribing or dispensing buprenorphine in situations where there is an increased concern about the possibility of misuse, diversion, or abuse.

## **What precautions should I take in my practice to prevent diversion and abuse?**

You should consider the following suggestions:

- Initiate treatment with supervised administration, progressing to unsupervised administration as your patient's clinical stability permits
- Limit the use of buprenorphine-only products, such as buprenorphine sublingual tablets to supervised use, wherever possible. Point out to the patient that SUBOXONE products contain naloxone. The naloxone in SUBOXONE is likely to precipitate withdrawal signs and symptoms when injected by individuals dependent on heroin, morphine, or other full opiate agonists. It is strongly recommended that SUBOXONE be used whenever unsupervised administration is planned
- As your patients progress beyond induction to a stabilized dose, consider a longer-term prescription of SUBOXONE to be taken at home. When determining the quantity of SUBOXONE to be prescribed, you should consider your patient's level of stability, the security of his or her home situation, and other factors likely to affect the ability to manage supplies of medication in an unsupervised environment
- Have plans in place to deal with patient requests for replacement of prescriptions or supplies of medication that are described as lost or stolen
- Keep tight control of your prescription pads. Never leave them in the examination room, even inside a desk drawer. Never sign an incomplete prescription blank
- Write all numbers (quantity and strength) in both numbers and letters - like you would write a personal check
- Establish a relationship with the pharmacies you expect to be filling your prescriptions. Discuss potential diversion problems and controls with them
- Maintain copies of photo (or other) I.D. and Social Security numbers in patients' records
- If you suspect an attempt to divert prescription medications, unsupervised administration privileges should be reevaluated. Carefully consider options such as random drug testing or a callback to verify adherence to program rules. In a callback, the patient receives an unannounced phone call and must show up at the physician's office within a reasonable period (e.g., 24 to 36 hours) with all prescribed medications. In this case, the number of tablets remaining must correspond to the number expected based on prescribed dosing. If this program is implemented, physicians should clearly state their policy to patients in advance

*Buprenorphine, like morphine and other opioids, has the potential for being abused and is subject to criminal diversion.* Patients who continue to misuse, abuse, or divert buprenorphine products or other opioids should be provided or referred for more intensive and structured treatment.

## **What is an appropriate medical response to overdose on SUBOXONE?**

*In the case of overdose, the primary management should be the re-establishment of adequate ventilation with mechanical assistance of respiration, if required.*

Naloxone hydrochloride may be of value for the management of buprenorphine overdose. Higher than normal doses and repeated administration may be necessary.

### ***Contraindications***

- Hypersensitivity to buprenorphine or naloxone

### ***Warnings and Precautions***

- Buprenorphine can be abused in a similar manner to other opioids. Clinical monitoring appropriate to the patient's level of stability is essential. Multiple refills should not be prescribed early in treatment or without appropriate patient follow-up visits
- Significant respiratory depression and death have occurred in association with buprenorphine, particularly when taken by the intravenous (IV) route in combination with benzodiazepines or other CNS depressants (including alcohol)
- Consider dose reduction of CNS depressants, SUBOXONE sublingual tablet, or both in situations of concomitant prescription
- Store SUBOXONE sublingual tablet safely out of the sight and reach of children. Buprenorphine can cause severe, possibly fatal, respiratory depression in children
- Chronic administration produces opioid-type physical dependence. Abrupt discontinuation or rapid dose taper may result in opioid withdrawal syndrome
- Monitor liver function tests prior to initiation and during treatment and evaluate suspected hepatic events
- Do not administer SUBOXONE sublingual tablet to patients with known hypersensitivity to buprenorphine or naloxone
- A marked and intense opioid withdrawal syndrome is highly likely to occur with parenteral misuse of SUBOXONE sublingual tablet by individuals physically dependent on full opioid agonists or by sublingual administration before the agonist effects of other opioids have subsided
- Neonatal withdrawal has been reported following use of buprenorphine by the mother during pregnancy
- SUBOXONE sublingual tablet is not appropriate as an analgesic. There have been reported deaths of opioid naïve individuals who received a 2 mg sublingual dose
- Caution patients about the risk of driving or operating hazardous machinery

### ***Adverse Reactions***

- Adverse events most commonly observed with the sublingual administration of the SUBOXONE sublingual tablet during clinical trials and post-marketing experience are headache, nausea, vomiting, hyperhidrosis, constipation, signs and symptoms of withdrawal, insomnia, pain, and peripheral edema
- To report SUSPECTED ADVERSE REACTIONS, contact Reckitt Benckiser Pharmaceuticals Inc. at 1-877-SUBOXONE (1-877-782-6966), FDA at 1-800-FDA-1088, or [www.fda.gov/medwatch](http://www.fda.gov/medwatch)

## ***Drug Interactions***

- Monitor patients starting or ending CYP3A4 inhibitors or inducers for potential over or under dosing
- Use caution in prescribing SUBOXONE sublingual tablet for patients receiving benzodiazepines or other CNS depressants and warn patients against concomitant self-administration/misuse

## ***Use in Specific Populations***

- SUBOXONE sublingual tablet is not indicated for use during pregnancy unless potential benefit justifies potential risk
- Buprenorphine passes into the mother's milk. Breast-feeding is not advised while taking SUBOXONE sublingual tablet
- Safety and effectiveness of SUBOXONE sublingual tablet in patients below the age of 16 has not been established
- Administer SUBOXONE sublingual tablet with caution to elderly or debilitated patients
- Administer SUBOXONE sublingual tablet with caution in patients with liver dysfunction

## ***Prescribing SUBOXONE sublingual tablet***

### **When should SUBOXONE sublingual tablet be prescribed?**

SUBOXONE sublingual tablet, which includes naloxone, is indicated for maintenance treatment of opioid dependence and is preferred for unsupervised administration.

### **What is the proper protocol for induction?**

SUBUTEX tablets are preferred for use during induction. Prior to induction, consideration should be given to the type of opioid dependence, the time since last opioid use, and the degree or level of opioid dependence (see package insert for complete instructions).

To avoid inadvertently precipitating opioid withdrawal, induction should be undertaken when clear and obvious signs of withdrawal are evident. A clinical tool to assess withdrawal should be used. For example, the Clinical Opioid Withdrawal Scale (COWS) can be used. A score of >12 should be recorded on the COWS before the first dose is administered.

In some studies, gradual induction over several days led to a high rate of drop-out of buprenorphine patients during the induction period. Therefore, it is recommended that an adequate maintenance dose, titrated to clinical effectiveness, should be achieved as rapidly as possible to prevent undue opioid withdrawal signs and symptoms.

### **How should I schedule office visits: how much involvement should I have?**

During the induction period, it is recommended that the initial dose(s) be provided under supervision and that no more than 1 to 2 days of SUBUTEX for take-home use be provided on each of the 2 to 3 daily visits during the first week of treatment.

Patients should be seen at reasonable intervals (e.g., at least weekly during the first month of treatment) based upon the individual circumstances of the patient. SUBOXONE should be prescribed in consideration of the frequency of visits. Provision of multiple refills is not advised early in treatment or without appropriate patient follow-up visits. Periodic assessment is necessary to determine compliance with the dosing regimen, effectiveness of the treatment plan, and overall patient assessment.

Once a stable dosage has been achieved and toxicological tests do not indicate illicit drug use, less frequent follow-up visits may be appropriate. A once-monthly visit schedule may be reasonable for patients on a stable dosage of SUBOXONE who are making progress toward the treatment objectives. Continuation or modification of pharmacotherapy should be based on the physician's evaluation of treatment outcomes and objectives such as:

1. Absence of SUBOXONE toxicity
2. Absence of medical or behavioral adverse effects
3. Responsible handling of SUBOXONE by the patient
4. Patient's compliance with all elements of the treatment plan (including recovery-oriented activities, psychotherapy, and/or other psychosocial modalities)
5. Abstinence from illicit drug use (including problematic alcohol and/or benzodiazepine use)

If treatment goals are not being achieved, the physician should reevaluate the appropriateness of continued treatment. Patients who continue to misuse, abuse or divert buprenorphine products or other opioids should be provided with, or referred to, more intensive and structured treatment.

### **How do I manage in-office induction doses without maintaining a supply in my office?**

For those physicians who do not wish to maintain a supply of SUBUTEX in their offices, it is important to develop a good working relationship with your local pharmacies. To ensure that you will be able to exchange information with the pharmacist, such as confirming the validity of your induction prescriptions, it is recommended that you have the patient sign a release of information at the time of the initial office visit. A sample consent form with all the elements required under 42 CFR Part 2.31 is included with this booklet (see page 20).

On the day of induction, write a prescription **only** for the induction day's dosage. Instruct your patient (or, if available, a trustworthy family member accompanying the patient) to take the prescription to the pharmacy, have it filled and bring it back to your office for dosing.

It is recommended that you call or fax ahead to the pharmacy to ensure availability of the medication and to reduce patient waiting time. You should instruct the patient not to take the dose until he or she returns to the office. The induction dose will be administered, and he or she will be monitored, in your office. The pharmacist should reiterate this instruction upon filling the prescription.

Note that it is illegal for a physician to hold medication in the office that is prescribed for a specific patient. Therefore, you should limit the prescription to one day's dose, and repeat this method for the first several days of treatment before providing a prescription for several days' supply at one time.

Further information is available by calling the toll-free SUBOXONE Help Line at 1-877-SUBOXONE (1-877-782-6966) or by logging onto **www.suboxone.com**.

**Will prescriptions be valid at any pharmacy, or will I need to refer patients to a specific location?**

Prescriptions specifying SUBOXONE will be valid at any pharmacy. However, prior to prescribing SUBOXONE it is essential that you establish a relationship with one or more specific pharmacies in your area that will be in a position to provide your patients with initial doses, as well as instructions for returning to your office for induction and the follow-up prescription.

Generally, a pharmacy near your office is recommended for patient convenience. To reduce patient waiting time, it is recommended that you avail yourself of any call-in or fax-in prescription services offered. Please call the toll-free SUBOXONE Help Line at 1-877-SUBOXONE (1-877-782-6966) or visit **www.suboxone.com** for more information or assistance.

**Are there special confidentiality issues I should consider?**

Remember that you may be communicating with the pharmacist to verify prescriptions for a particular patient. As you may know, there are special federal regulations concerning the confidentiality of substance abuse treatment records (42 CFR Part 2), and the privacy of health records (Health Insurance Portability and Accountability Act [HIPAA]). To ensure that you will be able to exchange information with the pharmacist, such as confirming the validity of a SUBOXONE prescription, it is recommended that you have the patient sign a release of information at the time of the initial office visit. A sample consent form with all the elements required under 42 CFR Part 2.31 is included with this booklet (see page 20). It is particularly important to obtain the patient's consent if you elect to phone or fax in prescriptions, as this constitutes disclosure of the patient's treatment. When the prescription is directly transmitted by the physician, there are also prohibitions on the further redisclosure of patient identifying information by the pharmacist. 42 CFR Part 2.31 does not apply when it is the patient who delivers the prescription to the pharmacist, without direct communication from the physician to the pharmacist.

To learn more about these regulations, visit the SAMHSA website, [www.hipaa.samhsa.gov](http://www.hipaa.samhsa.gov), or call 1-866-BUP-CSAT (1-866-287-2728).

### ***Dosing and Administration of SUBOXONE sublingual tablet***

#### **How do I maintain clinically effective dosing for stabilized patients?**

The recommended target dose of SUBOXONE is 16 mg/day. Clinical studies have shown that this is a clinically effective dose. Although doses as low as 12 mg may be effective in some patients, for most patients, a 16 mg dose should alleviate withdrawal symptoms and block or attenuate the effects of other opioid agonists for at least 24 hours.

The upper limit of the recommended daily dosage of buprenorphine is 24 mg. The reported lack of significant increase in brain mu-receptor occupancy between doses of 16 mg and 32 mg would imply that there should be little difference in clinical effectiveness at doses between 16 mg and 24 mg in most patients. When a patient expresses a need for a higher dose, consider the possible causes (e.g., environmental stressors or psychosocial issues that increase cravings or possible drug interactions). Before increasing the patient's dose, explore other alternatives. Also consider the possibility that the patient may be exaggerating symptoms to obtain additional medication for diversion.

#### **How should SUBOXONE sublingual tablets be administered?**

SUBOXONE is administered sublingually.

SUBOXONE sublingual tablet should be placed under the tongue until it is dissolved. For doses requiring the use of more than 2 tablets, patients are advised to either place all the tablets at once or alternatively (if they cannot fit in more than 2 tablets comfortably), place 2 tablets at a time under the tongue. Either way, the patients should continue to hold the tablets under the tongue until they dissolve; swallowing the tablets reduces the bioavailability of the drug. To ensure consistency in bioavailability, patients should follow the same manner of dosing with continued use of the product.

#### **How should I manage patients who are not compliant with therapy?**

Physicians will need to decide when they cannot appropriately provide further management for particular patients. For example, some patients may be abusing or dependent on various drugs, or unresponsive to psychosocial intervention, such that the physician does not feel that he or she has the expertise to manage the patient. In such cases, the physician may want to assess whether to refer the patient to a specialist and/or more intensive behavioral treatment environment. Decisions should be based on a treatment plan established and agreed upon with the patient at the beginning of treatment.

### ***Discontinuing SUBOXONE Therapy***

#### **What can I tell patients who wish to discontinue treatment?**

Patients should be advised not to change the dose of SUBOXONE without consulting their physician.

Patients seeking to discontinue treatment with SUBOXONE for opioid dependence should be apprised of the potential to relapse to illicit drug use associated with discontinuation of opioid agonist medication-assisted treatment.

If a dependent patient abruptly discontinues use of SUBOXONE, an opioid abstinence or withdrawal syndrome may develop. If cessation of therapy is indicated, it may be appropriate to taper the SUBOXONE dose, rather than abruptly discontinue it. The physician can provide a dose schedule to accomplish a gradual discontinuation of the medication.

## **IV. Psychosocial Support and Other Patient Counseling**

### **How important is counseling for my patients and my practice?**

Pharmacotherapy is only one aspect of treatment. Psychosocial counseling is an essential component of treatment for opioid dependence. Because it is such a crucial element, DATA 2000 requires that physicians seeking to obtain the certification to prescribe SUBOXONE must be able to provide or refer patients for counseling.

In addition to services typically provided by physicians, counseling may incorporate such elements as motivational enhancement therapy, cognitive behavioral therapy, prevention education, and intervention in case of relapse.

If counseling is provided by an individual other than the prescribing physician, it is essential that the counselor partner with the physician in providing care. The counselor can provide an additional measure of monitoring for adherence and treatment response.

### **What safety conditions need to be communicated to patients about SUBOXONE sublingual tablets?**

Review the contents of the Medication Guide, in its entirety, with each patient, including the following:

- Warn patients that it is extremely dangerous to self-administer non-prescribed benzodiazepines or other CNS depressants (including alcohol) while taking SUBOXONE. Patients prescribed benzodiazepines or other CNS depressants should be cautioned to use them only as directed by their physician
- Advise patients that SUBOXONE contains an opioid that can be a target for people who abuse prescription medications or street drugs. Patients should be cautioned to keep their tablets in a safe place, and to protect them from theft
- Instruct patients to keep SUBOXONE in a secure place, out of the sight and reach of children. Accidental or deliberate ingestion by a child may cause respiratory depression that can result in death. Patients should be advised that if a child is exposed to SUBOXONE, medical attention should be sought immediately
- Advise patients never to give SUBOXONE to anyone else, even if he or she has the same signs and symptoms. It may cause harm or death
- Advise patients that selling or giving away SUBOXONE is against the law

- Caution patients that SUBOXONE may impair the mental or physical abilities required for the performance of potentially dangerous tasks, such as driving or operating machinery. Caution should be taken especially during induction and dose adjustments and until patients are reasonably certain that SUBOXONE therapy does not adversely affect their ability to engage in such activities
- Advise patients not to change the dose of SUBOXONE without consulting their physician
- Advise patients to take SUBOXONE once a day as directed
- Inform patients that SUBOXONE can cause drug dependence of the opioid type. Withdrawal signs and symptoms may occur when the medication is discontinued
- Advise patients seeking to discontinue treatment with SUBOXONE for opioid dependence to work closely with their physician on a tapering schedule and apprise them of the potential to relapse to illicit drug use associated with discontinuation of opioid agonist/partial agonist medication-assisted treatment
- Caution patients that, like other opioids, SUBOXONE may produce orthostatic hypotension in ambulatory individuals
- Ask patients if other prescription medications, over-the-counter medications, or herbal preparations are prescribed or currently being used
- Advise patients that women of childbearing potential, who become pregnant, or are planning to become pregnant, should consult their physician regarding the possible effects of using SUBOXONE during pregnancy
- Warn patients that buprenorphine passes into breast milk and breast-feeding is therefore not advised in mothers treated with SUBOXONE
- Ask patients to inform their family members or other appropriate individuals that, in the event of emergency, the treating physician or emergency department staff should be informed that the patient is physically dependent on an opioid and that the patient is being treated with SUBOXONE
- Instruct patients to dispose of unused SUBOXONE tablets by flushing the tablets down the toilet

## **V. Where Can I Get More Information on Treating Patients with SUBOXONE sublingual tablets?**

Refer to the package insert for full Prescribing Information. Additional recommendations may be found in treatment guidelines available free from the Center for Substance Abuse Treatment (CSAT) at the Substance Abuse and Mental Health Services Administration. Additional information is also available on the CSAT website at [www.csat.samhsa.gov](http://www.csat.samhsa.gov).

## Appendix A

### *Obtaining Eligibility to Prescribe SUBOXONE*

#### *The Drug Addiction Treatment Act of 2000 (DATA 2000)*

This act enables *qualifying physicians* to receive a *waiver* from the special registration requirements in the Controlled Substances Act for the provision of medication-assisted opioid therapy. This waiver allows qualifying physicians to practice medication-assisted opioid addiction therapy with Schedule III, IV, or V narcotic medications specifically approved by the **Food and Drug Administration (FDA)**. SUBOXONE sublingual tablet is a medication that may be used in medication-assisted therapy under the provisions of DATA 2000.

The **Drug Enforcement Administration (DEA)** assigns the physician a special identification number. DEA regulations require this ID number to be included on all buprenorphine prescriptions for opioid addiction therapy, along with the physician's regular DEA registration number.

#### **Who is qualified to obtain a waiver to prescribe SUBOXONE?**

Physicians who:

- Hold a current State Medical License
- Hold a valid DEA registration number
- Meet one or more of the following training requirements:
  - Hold a subspecialty board certification in addiction psychiatry from the American Board of Medical Specialties
  - Hold an addiction certification from the American Society of Addiction Medicine
  - Hold a subspecialty board certification in addiction medicine from the American Osteopathic Association
  - Have completed not less than 8 hours of authorized training on the treatment or management of opioid-dependent patients. This training may include classroom situations, seminars at professional society meetings, electronic communications, or other media. The American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic Association, and the American Psychiatric Association are all authorized to provide this training. Details and website addresses can be found on page 14

AND meet the following criteria:

- Have the capacity to provide or to refer patients for necessary ancillary services, such as psychological therapy

- Agree to limit the number of patients they have in treatment at any one time to the following:
  - 30 patients for the first year
  - 100 patients after the first year

**How do I obtain the necessary training to become qualified for the waiver?**

The Substance Abuse and Mental Health Services Administration (SAMHSA) also maintains a web page listing of upcoming DATA 2000-qualifying training events and web-based training, which can be found at <http://buprenorphine.samhsa.gov/pls/bwns/training>.

Each of the following organizations has scheduled training sessions. You may contact them directly at the addresses below, or visit their websites.

Additionally, you can call the toll-free SUBOXONE Help Line at 1-877-SUBOXONE (1-877-782-6966) or log on to our website **www.suboxone.com**.

American Academy of Addiction Psychiatry

345 Blackstone Boulevard  
1st Floor—Weld  
Providence, RI 02906  
Telephone: 1-401-524-3076  
E-mail: [information@aaap.org](mailto:information@aaap.org)  
Website: [www2.aaap.org](http://www2.aaap.org)

American Society of Addiction Medicine

4601 North Park Ave, Upper Arcade #101  
Chevy Chase, MD 20815  
Telephone: 1-301-656-3920  
E-mail: [email@asam.org](mailto:email@asam.org)  
Website: [www.asam.org](http://www.asam.org)

American Psychiatric Association

1000 Wilson Boulevard, Suite 1825  
Arlington, VA 22209-3901  
Telephone: 1-888-357-7924  
E-mail: [apa@psych.org](mailto:apa@psych.org)  
Website: [www.psych.org](http://www.psych.org)

American Osteopathic Association

142 East Ontario Street  
Chicago, IL 60611  
Telephone: 1-800-621-1773  
E-mail: [info@osteotech.org](mailto:info@osteotech.org)  
Website: [www.osteopathic.org](http://www.osteopathic.org)

### **How do I obtain the waiver?**

To receive a waiver to practice opioid addiction therapy with approved Schedule III, IV, or V narcotics, a physician must notify the **Center for Substance Abuse Treatment (CSAT, a component of SAMHSA)** of his or her intent to begin dispensing or prescribing this treatment. This Notification of Intent must be submitted to CSAT before the initial dispensing or prescribing of opioid therapy.

Physicians can complete and submit a Waiver Notification Form (SMA-167) online, via fax, or by traditional mail. It is not mandatory to use the SMA-167 form to submit a waiver notification; however, CSAT does recommend the use of this form, either online or in hard copy, as it contains all the data items necessary to expedite the timely processing of waiver notifications.

The Notification of Intent can be submitted online at <http://buprenorphine.samhsa.gov/howto.html>, or via ground mail or fax.

#### Substance Abuse and Mental Health Services Administration

Division of Pharmacologic Therapies (DPT)  
Attn: Opioid Treatment Waiver Program  
One Choke Cherry Road, Room 2-1063  
Rockville, MD 20857  
Telephone: 1-866-BUP-CSAT (1-866-287-2728)  
Fax: 1-240-276-1630

Call CSAT/DPT if you have any questions about the notification process or need help completing the form. They can be reached at 1-240-276-2700.

### **What happens after my notification is sent to CSAT?**

CSAT will communicate with the DEA, review your notification, and then notify the DEA that you are qualified as required by DATA 2000. DATA 2000 allows 45 days for this review process. No later than at the end of that 45-day period, the DEA will issue a unique identification number indicating that you are a qualifying physician under DATA 2000. **DEA regulations require that this number, along with your existing DEA registration number, be included on all prescriptions issued for the treatment of opioid dependence under DATA 2000. You must include these numbers when you write prescriptions for SUBOXONE for the treatment of opioid dependence.** CSAT will send you a letter notifying you of the new DEA identification number that will be assigned. You will subsequently receive a revised DEA registration certificate (showing both numbers).

### **Do I have to wait 45 days before treating patients?**

DATA 2000 envisions physicians notifying CSAT as soon as they are qualified, but makes provisions for those who find themselves in the position of being qualified and needing to treat a patient, but not having notified CSAT. In this case, you must first notify CSAT and the DEA of your intent before treating the patient; this can be done

electronically on the Internet by checking the appropriate box or by faxing the form included in this booklet to CSAT at 1-240-276-1630.

**Once I have been treating patients for a year, how do I arrange to increase my patient limit to 100 patients?**

If you meet the following conditions, you may have your patient limit increased to 100 patients.

1. Physicians must currently be authorized under DATA 2000
2. Physicians must have submitted the notification for initial authorization at least 1 year ago
3. Physicians must submit a second notification that conveys the need and intent to treat up to 100 patients and certifies their necessary qualifying criteria and their capacity to refer patients for appropriate counseling and other appropriate ancillary services

You can submit your second notification online at

[http://buprenorphine.samhsa.gov/pls/bwns/additional\\_notification\\_form?prefilled\\_or\\_online=ONLINE](http://buprenorphine.samhsa.gov/pls/bwns/additional_notification_form?prefilled_or_online=ONLINE)

Or print a copy from <http://buprenorphine.samhsa.gov/federal.html> and mail or fax it to SAMHSA.

SAMHSA/CSAT will formally acknowledge your submission of the second notification by letter; however, unless you are notified of the contrary, the “good faith” submission of the second notification permits treatment of up to 100 patients.

**How do I get SUBOXONE for use in the office?**

State laws vary regarding ordering, storing, and dispensing of controlled substances. If you have a routine supplier of products such as vaccines, or injectable products that you use in your office, that supplier will be able to provide you with SUBOXONE in 2 mg buprenorphine/0.5 mg naloxone and 8 mg buprenorphine/2 mg naloxone strengths.

**What storage and record-keeping requirements are associated with maintenance of a supply of SUBOXONE in my office?**

You will be required to keep the medications in a secure environment. According to federal requirement, they must be kept in a securely locked, substantially constructed cabinet. You will also be required to maintain a written record of the disposition of all doses. Usually this can be done with the maintenance of a logbook in which you record all incoming doses and account for each dispensed dose as it is used. This record must be kept current at all times. Additional requirements may be in place in your state. You are also required to take an inventory every 2 years, and to keep records of all receipts.

In addition, physicians prescribing SUBOXONE should keep accurate and complete records for each patient that include:

1. The medical history and physical examination

2. Diagnostic, therapeutic, and laboratory results
3. Evaluations and consultations
4. Treatment objectives
5. Discussion of risks and benefits
6. All treatments that the patient is receiving
7. Medications (including date, type, dosage, and quantity prescribed and/or dispensed to each patient)
8. A physical inventory of all Schedule III, IV, and V controlled substances on hand that are dispensed by the physician in the course of maintenance or detoxification treatment of an individual
9. Instructions and agreements
10. Periodic reviews

Records should remain current and be maintained in an accessible manner and readily available for review. Physicians must adhere to the special confidentiality requirements of 42 CFR Part 2, which apply to the treatment of patients for drug and alcohol addiction (see page 20).

SUBOXONE<sup>®</sup> is a registered trademark of Reckitt Benckiser Healthcare (UK) Ltd.

Form SMA-167 – Notification of Intent to Use Schedule III, IV, or V Opioid Drugs for Maintenance and Detoxification Treatment of Opiate Addiction under 21 USC §823(g)(2)

<b>Notification of Intent to Use Schedule III, IV, or V Opioid Drugs for the Maintenance and Detoxification Treatment of Opiate Addiction under 21 USC § 823(g)(2)</b>		Form Approved: 0930-0234 Expiration Date: 05/31/2012 See OMB Statement on Reverse
		DATE OF SUBMISSION
Note: Notification is required by § 303(g)(2), Controlled Substances Act (21 USC § 823(g)(2)). See instructions on reverse. <b>For second notifications, you must complete items 6, 8, 9, 10, and sign and date the form (item 12).</b>		
<b>1a. NAME OF PRACTITIONER</b>  b. State Medical License Number _____ c. DEA Registration Number _____		
<b>2. ADDRESS OF PRIMARY LOCATION (Include Zip Code) (See instruction below)</b>		<b>3. TELEPHONE NUMBER (Include Area Code)</b>  <b>4. FAX NUMBER (Include Area Code)</b>  <b>5. EMAIL ADDRESS (Optional)</b>
<b>6. PURPOSE OF NOTIFICATION (See instruction below)</b> <input type="checkbox"/> New Notification <input type="checkbox"/> New Notification, with the intent to immediately facilitate treatment of an individual (one) patient. <input type="checkbox"/> Second Notification of need and intent to treat up to 100 patients		
<b>7. CERTIFICATION OF USE OF NARCOTIC DRUGS UNDER THIS NOTIFICATION</b> <input type="checkbox"/> I certify that I will only use Schedule III, IV, or V drugs or combinations of drugs that have been approved by the FDA for use in maintenance or detoxification treatment and that have not been the subject of an adverse determination.		
<b>8. CERTIFICATION OF QUALIFYING CRITERIA</b> I certify that I meet at least one of the following criteria and am therefore a qualifying physician (Check and provide copies of documentation for all that apply): <ul style="list-style-type: none"> <li><input type="checkbox"/> Subspecialty board certification in addiction psychiatry from the American Board of Medical Specialties</li> <li><input type="checkbox"/> Addiction certification from the American Society of Addiction Medicine</li> <li><input type="checkbox"/> Subspecialty board certification in addiction medicine from the American Osteopathic Association</li> </ul> Completion of not less than eight hours of training for the treatment and management of opioid-dependent patients provided by the following organization(s): _____ Date and location of training: _____ <ul style="list-style-type: none"> <li><input type="checkbox"/> American Society of Addiction Medicine _____</li> <li><input type="checkbox"/> American Academy of Addiction Psychiatry _____</li> <li><input type="checkbox"/> American Medical Association _____</li> <li><input type="checkbox"/> American Osteopathic Association _____</li> <li><input type="checkbox"/> American Psychiatric Association _____</li> <li><input type="checkbox"/> Other (Specify, include date and location) _____</li> </ul> <input type="checkbox"/> Participation as an investigator in one or more clinical trials leading to the approval of a Schedule III, IV, or V narcotic drug for maintenance or detoxification treatment <input type="checkbox"/> State medical licensing board-approved experience or training in the treatment and management of opioid-dependent patients <input type="checkbox"/> OTHER (Specify) _____		
<input type="checkbox"/> <b>For Second Notifications</b> - I certified qualifications in my initial notification and these qualifications have not changed.		
<b>9. CERTIFICATION OF CAPACITY</b> <input type="checkbox"/> I certify that I have the capacity to refer patients for appropriate counseling and other appropriate ancillary services.		
<b>10. CERTIFICATION OF MAXIMUM PATIENT LOAD</b> <input type="checkbox"/> I certify that I will not exceed 30 patients for maintenance or detoxification treatment at one time. <input type="checkbox"/> Second Notification - I need to treat up to 100 patients and I certify that I will not exceed 100 patients for maintenance or detoxification treatment at one time.		

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<p><b>11. CONSENT TO RELEASE IDENTIFYING INFORMATION TO SAMHSA BUPRENORPHINE PHYSICIAN AND TREATMENT PROGRAM LOCATOR WEB SITE</b> <i>(Read instruction 11 below before answering)</i></p> <p><input type="checkbox"/> I consent to the release of my name, primary address, and phone number to the SAMHSA Buprenorphine Physician and Treatment Program Locator Web site.</p> <p><input type="checkbox"/> I do not consent to the release of my name, primary address, and phone number to the SAMHSA Buprenorphine Physician and Treatment Program Locator Web site.</p>	
<p>12. I certify that the information presented above is true and correct to the best of my knowledge. I certify that I will notify SAMHSA at the address below if any of the information contained on this form changes. Note: Any false, fictitious, or fraudulent statements or information presented above or misrepresentations relative thereto may violate Federal laws and could subject you to prosecution, and/or monetary penalties, and or denial, revocation, or suspension of DEA registration. (See 18 USC § 1001; 31 USC §§ 3801-3812; 21 USC § 824.)</p>	
Signature _____	Date _____
<p><i>Please send the completed form to:</i>                  Substance Abuse and Mental Health Services Administration                  Division of Pharmacologic Therapies                  Attention: Opioid Treatment Waiver Program                  One Choke Cherry Road, Rm 2-1063                  Rockville, MD 20857                  Fax 240-276-1630                  Phone 1-866-287-2728 (1-866-BUP-CSAT)</p>	
<p>This form is intended to facilitate the implementation of the provisions of 21 USC § 823(g)(2). The Secretary of DHHS will use the information provided to determine whether practitioners meet the qualifications for waivers from the separate registration requirements under the Controlled Substances Act (21 USC § 823(g)(1)). The Drug Enforcement Administration will assign an identification number to qualifying practitioners and the number will be included in the practitioner's registration under 21 USC § 823(f).</p>	
<p>This form may be completed and submitted electronically (including facsimile) to facilitate processing.</p>	
<p>1. The practitioner must identify the DEA registration number issued under 21 USC § 823(f) to prescribe substances controlled in Schedules III, IV, or V.</p>	<p>2. Only one address should be specified. For the practitioner to dispense the narcotic drugs or combinations to be used under this notification, the primary address listed here must be the same primary address listed in the practitioner's registration under § 823(f).</p>
<p><b>6. Purpose of notification:</b></p> <p><b>New Notification</b> - an initial notification for a waiver submitted for the purpose of obtaining an identification number from DEA for inclusion in the registration under 21 USC § 823(f).</p> <p><b>New Notification, with the intent to immediately facilitate treatment of an individual (one) patient</b> - an initial notification submitted for the purpose described above, with the additional purpose of notifying the Secretary and the Attorney General of the intent to provide immediate opiate addiction treatment for an individual (one) patient pending processing of this waiver notification.</p> <p><b>Second Notification</b> - For physicians who submitted a new notification not less than one year ago and intend and need to treat up to 100 patients. (See Office of National Drug Control Policy Reauthorization Act of 2006.)</p>	
<p>11. The SAMHSA Buprenorphine Physician and Treatment Program Locator Web site is publicly accessible at <a href="http://buprenorphine.samhsa.gov/bwns_locator/">http://buprenorphine.samhsa.gov/bwns_locator/</a>. The Locator Web site lists the names and practice contact information of physicians with DATA waivers who agree to be listed on the site. The Locator Web site is used by the treatment-seeking public and health care professionals to find physicians with DATA waivers. The Locator Web site additionally provides links to many other sources of information on substance abuse. No physician listings on the SAMHSA Buprenorphine Physician and Treatment Program Locator Web site will be made without the express consent of the physician.</p>	
<p><b>PRIVACY ACT INFORMATION</b></p>	
<p>Authority: Section 303 of the Controlled Substances Act of 1970 (21 USC § 823(g)(2)).                  Purpose: To obtain information required to determine whether a practitioner meets the requirements of 21 USC § 823(g)(2).                  Routine Uses: Disclosures of information from this system are made to the following categories of users for the purposes stated:                  A. Medical specialty societies to verify practitioner qualifications.                  B. Other federal law enforcement and regulatory agencies for law enforcement and regulatory purposes.                  C. State and local law enforcement and regulatory agencies for law enforcement and regulatory purposes.                  D. Persons registered under the Controlled Substance Act (PL 91-513) for the purpose of verifying the registration of customers and practitioners.</p> <p>Effect: This form was created to facilitate the submission and review of waivers under 21 USC § 823(g)(2). This does not preclude other forms of notification.</p>	
<p><b>Paperwork Reduction Act Statement</b></p>	
<p>Public reporting burden for completing this form is estimated to average 4 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the completed form. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this project is 0930-0234. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to SAMHSA Reports Clearance Officer; Paperwork Reduction Project (0930-0234); Room 71-1044, One Choke Cherry Road, Rockville, MD 20857</p>	

### Sample 42 CFR Part 2.31 Consent Form

1. I (name of patient) \_\_\_\_\_
2. Authorize Dr. \_\_\_\_\_
3. To disclose any information needed to confirm the validity of my prescription and for submission for payment for the prescription.
4. To the dispensing pharmacy to whom I present my prescription or to whom my prescription is called/sent/faxed, as well as to third party payors.
5. For the purpose of assuring the pharmacy of the validity of the prescription, so it can be legally dispensed, and for payment purposes.
6. Date (on which this consent is signed)  
\_\_\_\_\_
7. Signature of patient  
\_\_\_\_\_
8. Signature of parent or guardian (where required)  
\_\_\_\_\_
9. Signature of person authorized to sign in lieu of the patient (where required)
10. This consent is subject to revocation at any time except to the extent that the program which is to make the disclosure has already taken action in reliance on it. If not previously revoked, this consent will terminate upon: (specify date, event, or condition, i.e. termination of treatment)

#### Notice to accompany disclosure:

Each disclosure made with the patient's written consent must be accompanied by the following written statement:

This information has been disclosed to you from records protected by Federal confidentiality rules (42 CFR Part 2). The Federal rules prohibit you from making any further disclosure of this information unless further disclosure is expressly permitted by the written consent of the person to whom it pertains or as otherwise permitted by 42 CFR Part 2. A general authorization for the release of medical or other information is NOT sufficient for this purpose. The Federal rules restrict any use of the information to criminally investigate or prosecute any alcohol or drug abuse patient.

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