Physician Information

Answers to Frequently Asked Questions

Who is qualified to prescribe SUBOXONE or SUBUTEX?

Physicians who:

- 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 in the section below.
- AND meet both of the following criteria:
  - Have the capacity to provide or to refer patients for necessary ancillary services, such as psychosocial therapy.
  - Agree to treat no more than 30 patients at any one time in their individual or group practice

When and where are training sessions being held?

Each of the above organizations has scheduled training sessions. You may contact them directly at the addresses below, or visit their web sites. Additionally, you can call the toll-free SUBOXONE help line at 1-877-SUBOXONE (1-877-782-6966) or log on to our Web site www.suboxone.com.

The American Academy of Addiction Psychiatry
7301 Mission Road, Suite 252
Prairie Village, KS 66208
Telephone: (913) 262-6161
E-mail: info@aaap.org
Web site: www.aaap.org

The American Society of Addiction Medicine
4601 North Park Ave. Arcade Suite 101
Chevy Chase, MD 20815
Telephone (301) 656-3920
E-mail: email@asam.org
Web site http://asam.org

The American Psychiatric Association
1400 K Street N.W.
Washington, DC 20005
Telephone (888) 357-7924
E-mail: apa@psych.org
Web site: http://www.psych.org

American Osteopathic Association
142 East Ontario Street
Chicago, IL 60611
Telephone (800) 621-1773
E-mail: info@aoa-net.org
Web site: http://www.aoa-net.org/

I am already qualified. What do I do next?

The Drug Addiction Treatment Act (DATA) requires that before you begin prescribing SUBOXONE or SUBUTEX you must notify the Secretary of Health and Human Services of your intent to treat patients with these products. The agency within the Department of Health and Human Services to be notified is the Substance Abuse and Mental Health Services Administration (SAMHSA). Notification is handled within SAMHSA by the Division of Pharmacologic Therapies (DPT) within the Center for Substance Abuse

Treatment (CSAT). For convenience CSAT has developed a form that may be used for your notification. A copy is enclosed in this package
You may complete the notification form online or download the form by visiting CSAT's web site at www.dpt.samhsa.gov. The form may also be downloaded from www.suboxone.com. If you prefer, you may also notify by letter if you include all of the required information.
All forms (or letters) should be mailed or faxed to:

Substance Abuse and Mental Health Services Administration
Center for Substance Abuse Treatment
Division of Pharmacologic Therapies
Attn. Opioid Treatment Waiver Program
5600 Fishers Lane, Rm. 12-105
Rockville, MD 20857
FAX: (301) 443-3994

Call CSAT/DPT if you have any questions about the notification process or need help completing the form. They can be reached at (301) 443-7745.

What happens after my notification is sent to CSAT?

CSAT will communicate with the Drug Enforcement Administration (DEA), review your notification and then notify DEA that you are qualified as required by the DATA. The DATA allows 45 days for this review process. No later than at the end of that 45-day period, DEA will issue a unique identification number indicating that you are a qualifying physician under the DATA. DEA is developing regulations that will require this number along with your existing DEA registration number to be included on all prescriptions issued for the treatment of opioid dependence under the DATA; therefore it is strongly recommended that you include this number when you write prescriptions for Subutex and 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?

The DATA envisions physicians notifying CSAT as soon as they are qualified, but makes provision 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 DEA of your intent before treating the patient; this can be done electronically on the internet by checking the appropriate box, or by faxing in the form included in this package to CSAT at: (301) 443-3994

During the training sessions, as well as in the product information and CSAT Guidelines, it is recommended that patients be given initial doses under supervision. It is not my normal practice to keep a stock of controlled substances in my office. How do I get SUBOXONE or SUBUTEX for use in the office?

State laws vary regarding stocking of controlled substances. Information on State requirements can be found on our website, 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 and SUBUTEX. If you do not have a normal supplier of such products we will facilitate the establishment of a relationship with a supplier. Please complete the enclosed pre-addressed request form and mail it to us. Alternately, you may call our toll-free SUBOXONE Help Line at 1 877 SUBOXONE (1-877-782-6966) or log on to our Web site www.suboxone.com. In those States where permitted, we will provide you with an initial supply of SUBOXONE or SUBUTEX for induction use.

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

For a full listing of requirements for a specific State you may call our toll-free SUBOXONE Help Line at 1 877 SUBOXONE (1-877-782-6966) or log on to our Web site www.suboxone.com. Generally, you will be required to keep the medications in a secure environment. They should be kept in a locked compartment with limited access. 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.

While I appreciate the convenience of maintaining a supply of SUBOXONE and SUBUTEX in my office for induction purposes, the situation at our office precludes such an arrangement. How do I manage supervised induction doses without maintaining such a supply in my office?

For those physicians who do not wish to maintain a supply of SUBOXONE or SUBUTEX in their offices, where State law and regulation allows, we will provide coupons for you to provide to your patient for their initial doses. In this circumstance, you would write a prescription only for the initial dose of SUBOXONE or SUBUTEX. If pharmacy delivery services are available, you may choose to arrange to have the dose delivered to your office; if not give the prescription, and a coupon, to the patient (or, if available, to a trustworthy family member accompanying the patient) with instructions that the prescription is to be taken to the pharmacy, filled, and brought back to your office for dosing. It is recommended that you call or fax ahead to ensure

availability of the medication and to reduce patient waiting time. You should instruct the patient that on his or her return to the office the induction dose will be administered, and that he or she will be monitored in your office. The pharmacist should reiterate this instruction upon filling the prescription. You may wish to limit the prescription to one days' dose, and repeat this method (with or without the coupon) for the first several days of treatment before providing a prescription for several days' supply at one time. Further information regarding this program and a supply of coupons is available by calling our toll-free SUBOXONE Help Line at 1 877 SUBOXONE (1-877-782-6966) or log on to our Web site www.suboxone.com.

Will these coupons and prescriptions be valid at any pharmacy, or will I need to refer patients to a specific store?

The coupons and prescriptions will be valid at any pharmacy. However, prior to prescribing SUBOXONE or SUBUTEX, if you do not maintain a supply of tablets for induction dosing in your office, it is essential that you establish a relationship with one or more specific pharmacies in your area who 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. (Such a relationship is also recommended if you intend to maintain initial dosing supplies in your office.) Generally, a pharmacy near your office is recommended for patient convenience. If possible, it is advisable to identify a pharmacy that will deliver initial doses to your office, so that patients do not have to leave and return for induction dosing. Alternatively, it is recommended that you avail yourself of any call-in or fax-in prescription services provided, to reduce patient waiting time. If you do not currently have a commercial or professional relationship with a pharmacy in your area, we will be pleased to assist in facilitating the establishment of such an arrangement, and to help identify pharmacies with delivery service. Please call our toll-free SUBOXONE Help Line at 1 877 SUBOXONE (1-877-782-6966) or log on to our Web site www.suboxone.com.

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 (HIPAA). To ensure that you will be able to communicate with the pharmacist to confirm the validity of a SUBOXONE or SUBUTEX prescription, it is recommended that you have the patient sign a release of information at the time of the office visit. A sample consent form with all the elements required under 42CFR Part 2 is included with this booklet as an attachment. 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. 42CFR Part 2 does not apply when it is the patient who delivers the presciption 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, or call 1-866-BUP-CSAT

I'm familiar with general principles of addiction treatment, but this is my first experience with office-based prescription of this type of medication. 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 Subutex to supervised use, wherever possible. Recall that the Suboxone product contains naloxone, which Subutex does not. The naloxone in Suboxone is likely to precipitate withdrawal symptoms when injected by individuals dependent on heroin, morphine, or other full opiate agonists. Therefore, it is expected that Suboxone will be less attractive to "street addicts" and less likely to be diverted. Therefore, it is strongly recommended that Suboxone be used whenever unsupervised administration is planned.

- As your patients progress, and you consider prescribing Suboxone for take-home use; when determining the size of the prescription you write, 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 take-home medication.

- 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 write your checks.

- Establish a relationship with the pharmacies you expect to be filling your prescriptions for SUBOXONE or SUBUTEX and discuss potential diversion problems and controls with them.

- Request photo (or other) I.D. and Social Security number and maintain copies in patient's record.

- If you suspect an attempt to divert prescription medications, call your local police department.

Where can I get more information on treating patients with Subutex and Suboxone?

- Refer to the physician package insert for prescribing information. Additional recommendations may be found in treatment guidelines available for free from the Center for Substance Abuse Treatment at the Substance Abuse and Mental Health Services Administration. To obtain a copy please call our toll-free SUBOXONE Help Line at 1 877 SUBOXONE (1-877-782-6966) or log on to our Web site www.suboxone.com. Additional information is also available on the CSAT web site at www.dpt.samhsa.gov

- Refer to the package insert for full information on the adverse events seen during the clinical trials using buprenorphine for opiate addiction treatment. Note the important precautions and warnings to share with patients, such as the risk of fatal respiratory depression when buprenorphine is combined with other depressants. Also note other important safety issues such as the fact that buprenorphine should be administered with caution in the elderly or debilitated patient, and those with severe impairment of hepatic, pulmonary or renal function; and that buprenorphine may impair the mental or physical abilities required for the performance of potentially dangerous tasks such as driving a car or operating machinery, especially during drug induction and dose adjustment

- General information on the treatment of addiction is available through;

  The American Academy of Addiction Psychiatry

7301 Mission Road, Suite 252
Prairie Village, KS 66208
Telephone: (913) 262-6161
E-mail: info@aaap.org
Web site: www.aaap.org

The American Society of Addiction Medicine
4601 North Park Ave. Arcade Suite 101
Chevy Chase, MD 20815
Telephone (301) 656-3920
E-mail: email@asam.org
Web site http://asam.org

Substance Abuse and Mental Health
Services Administration
Office of Pharmacologic and Alternative Therapies
CSAT, Rockwall II Building, Suite 740
5600 Fishers Lane
Rockville, MD 20857
Web site: www.dpt.samhsa.gov

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)	Form Approved: 0930- 0234 Expiration Date: 10/31/2002 See OMB Statement on Reverse
	DATE OF SUBMISSION

Note: Notification is required by Sec. 303(g)(2), Controlled Substances Act (21 USC § 823(g)(2)). See instructions on reverse.

1a. **NAME OF PRACTITIONER**

b. State Medical License Number **c. DEA Registration Number**

2. ADDRESS OF PRIMARY LOCATION (*Include Zip Code*)	**3. TELEPHONE NUMBER** (*Include Area Code*) **4. FAX NUMBER** (*Include Area Code)* **5. EMAIL ADDRESS (***optional***)**
6. NAME AND ADDRESS OF GROUP PRACTICE **7. GROUP PRACTICE EMPLOYER IDENTIFICATION NUMBER**	**8. PURPOSE OF NOTIFICATION** (Check all that apply) New Immediate

9. GROUP PRACTITIONERS

NAME _____ **DEA Registration Number**

NAME _____ **DEA Registration Number**

(Include additional pages as necessary to identify each group practice member.)

10. CERTIFICATION OF USE OF NARCOTIC DRUGS UNDER THIS NOTIFICATION

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.

11. CERTIFICATION OF QUALIFYING CRITERIA (*Check each appropriate source and provide documentation.*) **I certify that I meet at least one of the following criteria and am therefore a qualifying physician (check and provide documentation for all that apply):**

Subspecialty board certification in addiction psychiatry from the American Board of Medical Specialties
Addiction certification from the American Society of Addiction Medicine
Subspecialty board certification in addiction medicine from the American Osteopathic Association
Completion of not less than eight hours of training for the treatment and management of opiate-dependent patients provided by the following organization(s): Date and location of training
American Society of Addiction Medicine
American Academy of Addiction Psychiatry
American Medical Association
American Osteopathic Association
American Psychiatric Association
Other (specify, include date and location)
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
State medical licensing board-approved experience or training in the treatment and management of opiate-dependent patients.
OTHER *(Specify)*

12. CERTIFICATION OF CAPACITY

I certify that I have the capacity to refer patients for appropriate counseling and other appropriate ancillary services.

13. CERTIFICATION OF MAXIMUM PATIENT LOAD

I certify that I or my group practice will not exceed 30 patients for maintenance or detoxification treatment at one time. SMA-167

14. CONSENT TO RELEASE IDENTIFYING INFORMATION TO SAMHSA TREATMENT FACILITY LOCATOR

I consent to the release of my name, address, and phone number to the SAMHSA Treatment Facility Locator.

I do not consent to the release of my name, address, and phone number to the SAMHSA Treatment Facility Locator.

15. 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 U.S.C.§1001; 31 U.S.C.§§3801-3812; 21 U.S.C.§824.)

Signature **Date**

Please send the completed form to:
Substance Abuse and Mental Health Services Administration
Office of Pharmacologic and Alternative Therapies
Attention: Opioid Treatment Waiver Program
CSAT, Rockwall II Building, Suite 740
5600 Fishers Lane
Rockville, MD 20857
Fax 301-443-3994
Phone 301-443-7745

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).

This form may be completed and submitted electronically (including facsimile) to facilitate processing.

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.	**2. The address should be the primary address listed in the practitioner's registration under § 823(f). Only one address should be specified. If the narcotic drugs or combinations to be used under this notification are to be dispensed by the practitioner then the address must reflect the site where the medication will be dispensed.**

6. Group practice is defined under section 1877(h)(4) of the Social Security Act. **14. The SAMHSA Treatment Facility Locator is freely accessible on the World Wide Web (http://findtreatment.samhsa.gov) and is widely used by the members of the treatment seeking public and referring professionals. It lists more than 11,000 facilities that offer specialized drug and alcohol abuse treatment programs and provides links to many other sources of information on substance abuse. The information on physicians will be retrieved by a geographical search of a separate category within the locator. No disclosures to the SAMHSA Treatment Facility Locator will be made in the absence of express consent.**	**8. Purpose of notification:** **New - an initial notification for a waiver submitted for the purpose of obtaining an identification number from DEA for inclusion in the registration under 21 U.S.C. §823(f).** **Immediate - a notification submitted for the purpose of notifying the Secretary and the Attorney General of the intent to immediately facilitate the treatment of an individual (one) patient.** **Note: It is permissible to submit a new and immediate notification simultaneously.**

PRIVACY ACT INFORMATION

Authority: Section 303 of the Controlled Substances Act of 1970 (21 U.S.C §823(g)(2)).
Purpose: To obtain information required to determine whether a practitioner meets the requirements of 21 U.S.C §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.

Effect: This form was created to facilitate the submission and review of waivers under 21 U.S.C. §823(g)(2). This does not preclude other forms of notification.

Paperwork Reduction Act Statement

Public reporting burden for completing this form is estimated to average 5 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).

SMA-167

Attachment to Physician's Brochure:

SAMPLE 42 CFR Part 2.31 Consent Form

1. I (name of patient) _____{time}
Authorize:
2. Dr._____
3. To disclose: (kind and amount of information to be disclosed)

Any information needed to confirm the validity of my prescription and for submission for payment for the prescription.

_____
4. To: (name or title of the person or organization to which disclosure is to be made)
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 (purpose of the disclosure)
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: (specific date, event, or condition)

Termination of treatment

(c) Expired, deficient, or false consent. A disclosure may not be made on the basis of a consent which: (1) Has expired; (2) On its face substantially fails to conform to any of the requirements set forth in paragraph (a) of this section; (3) Is known to have been revoked; or (4) Is known, or through a reasonable effort could be known, by the person holding the records to be materially false. (Approved by the Office of Management and Budget under control number 0930-0099)

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.

Information for Pharmacists

SUBOXONE® (buprenorphine HCl/naloxone HCl dihydrate, sublingual tablet)

and SUBUTEX® (buprenorphine HCl, sublingual tablet)

What are SUBOXONE and SUBUTEX?

SUBOXONE and SUBUTEX are sublingual tablets indicated for the treatment of opioid dependence. SUBOXONE contains buprenorphine (a partial agonist at the mu-opioid receptor and an antagonist at the kappa-opioid receptor) and naloxone (an antagonist at the mu-opioid receptor). SUBUTEX contains buprenorphine only.

Why is it important for all pharmacists to learn about SUBOXONE and SUBUTEX?

For the first time, pharmacists will play a role in the delivery of opiate addiction treatment. SUBOXONE and SUBUTEX are the first medications approved for office-based treatment of opioid dependence under the Drug Addiction Treatment Act of 2000 (DATA). Prior to the passage of this law, it was illegal for a doctor to prescribe narcotic drugs for the treatment of narcotic dependence. Opioid dependence treatment of this type could only be provided at specially registered clinics. Under the new law, only opiate addiction treatment drugs under Schedule II are confined to use in the clinic setting. Less tightly controlled drugs (Schedules III-V) may be *prescribed* for opiate