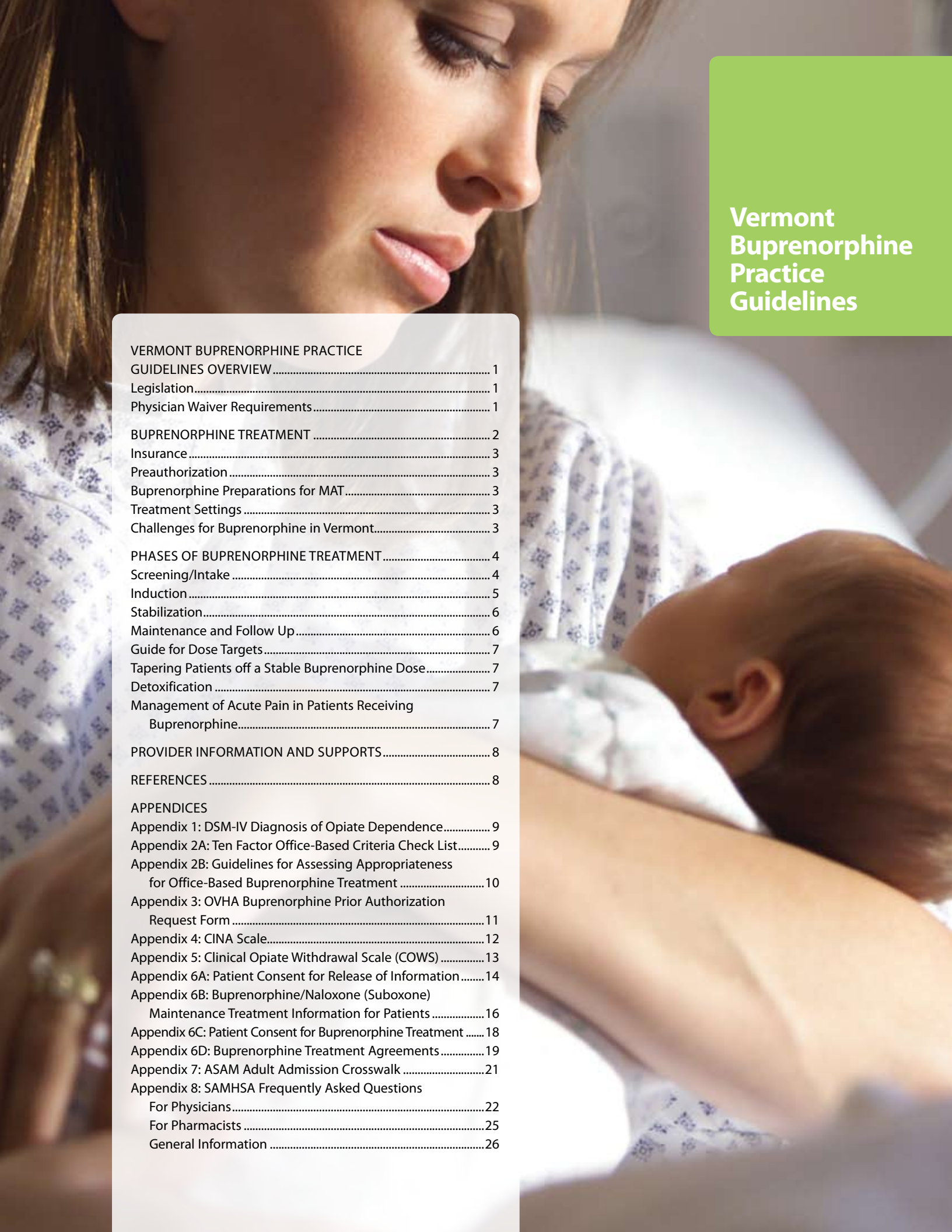




**Vermont
Buprenorphine
Practice
Guidelines**



Vermont Buprenorphine Practice Guidelines

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ACKNOWLEDGEMENTS

The *Vermont Buprenorphine Practice Guidelines* are a collaborative effort of the Vermont Department of Health, Division of Alcohol and Drug Abuse Programs (VDH/ADAP) and the Department of Vermont Health Access (DVHA), with guidance from local treatment providers. Many people contributed to developing these Guidelines. Special thanks go to the following individuals:

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Vermont Buprenorphine Practice Guidelines Overview

The *Vermont Buprenorphine Practice Guidelines* were created to provide Vermont practitioners with a consolidated set of recommendations and best practices for the management of opioid dependence in an office-based setting. The content of these *Guidelines* is intended to complement information presented in online and live trainings on this subject, as well as other resources available through SAMHSA/CSAT and other national organizations. These *Guidelines* are not intended as requirements for practitioners. They should not be considered as medical advice.

LEGISLATION

Section 3502 of The Children's Health Act of 2000 (HR 4365) set forth the Drug Addiction Treatment Act of 2000 (DATA). This legislation provided significant changes in the oversight of the medical treatment of opioid addiction, allowing physicians to treat opioid addiction with opioid medications in office-based settings under certain restrictions. Whereas physicians previously were required to refer patients to specialized opioid treatment programs (OTPs), the DATA 2000 enabled physicians to treat patients in their offices for opioid addiction with Schedules III, IV and V narcotic controlled substances specifically approved by the FDA for addiction treatment.



For physicians to provide office-based treatment of opioid addiction, they must be able to recognize the condition of drug or opioid addiction and be knowledgeable about the appropriate use of opioid-agonist, antagonist, and partial agonist medications. Physicians must also demonstrate required qualifications as defined in the DATA (Public Law 106-310, Title XXXV, Sections 3501 and 3502) and obtain a waiver from the Substance Abuse and Mental Health Services Administration (SAMHSA), as authorized by the Secretary of Health and Human Services.

The Vermont Board of Medical Practice is obligated under the laws of the state of Vermont to protect the public health and safety. The Board recognizes that inappropriate prescribing of controlled substances, including opioids, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Physicians must be diligent in preventing the diversion of drugs for illegitimate and non-medical uses.

PHYSICIAN WAIVER REQUIREMENTS

Training requirements for providers of office-based buprenorphine treatment are much more extensive than those needed to prescribe other medications, such as new antidepressants, other psychotropic medications, or antihypertensives.

To apply for a *DATA 2000* waiver to provide office-based treatment to patients with opioid addiction in Vermont, physicians must be licensed in the state of Vermont and must meet at least one of the following requirements:

- ABPN Added Qualification in Addiction Psychiatry
- Certified in Addiction Medicine by the American Society of Addiction Medicine (ASAM)
- Certified in Addiction Medicine by the American Osteopathic Association (AOA)
- Investigator in buprenorphine clinical trials
- Completed eight (8) hours of training provided by one of the following organizations or other designated organizations:

1. American Society of Addiction Medicine (ASAM), www.asam.org/CMEOnline.html (click on Buprenorphine and Office-Based Treatment of Opioid Dependence)
 2. American Academy of Addiction Psychiatry (AAAP), www.aaap.org (click on Buprenorphine, then Web-Based Training)
- Training/experience as determined by state medical licensing board
 - Other criteria established through regulation by the Secretary of Health and Human Services
- Physicians seeing patients under the DEA number of an Opiate Treatment Program (OTP) do not have to apply individually for the waiver and are not required to take the eight hour training course.

Following training, the physician registers at SAMHSA (<http://buprenorphine.samhsa.gov/howto.html>) to obtain a waiver. The physician will then receive an amended DEA number which must be used on all prescriptions for buprenorphine in the treatment of opioid dependence. Failure to use this amended number is a legal violation.

To qualify for a waiver, the physician must have the capacity to refer patients for appropriate counseling and other services that might be needed in conjunction with buprenorphine treatment. These services include, but are not limited to, the following:

- Different levels of chemical dependency treatment services¹
- Psychiatric consultation
- Consultation for medical co-morbidities²
- 12 Step program

Physicians should expect that clinicians to whom they refer their buprenorphine treated patients will have been trained in evidence-based therapies such as Cognitive Behavioral Therapy, Motivation Enhancement Therapy, Dialectical Behavioral Therapy, etc. Patients unfamiliar with these therapeutic approaches may not accept them without

the clinician providing some education about their benefits. Please contact the Alcohol and Drug Abuse Programs (ADAP) office at 802-651-1550 or vtadap@vdh.state.vt.us, as well as the SAMHSA website, for additional assistance for this training.

In addition, a waived physician must be able to provide the following:

- Random urine screening for buprenorphine patients, either on site or in conjunction with a certified laboratory
- Staff and patient education/training program³
- Office policies, procedures and coverage with knowledge and experience using buprenorphine
- Medication security and storage

DATA 2000, as amended in 2006, places limits on the number of patients a physician may treat with buprenorphine. During a waived physician's first year, a maximum of 30 patients may be treated at any one time. One year from the date on which the physician submitted the initial notification to apply for a waiver, the physician may submit a second notification of the need and intent to treat up to 100 patients (<http://buprenorphine.samhsa.gov/howto.html>).

BUPRENORPHINE TREATMENT

The use of agonist treatment, either methadone or buprenorphine, offers physicians an opportunity to move away from abstinence-based treatments and into the use of research grounded therapies. Abstinence-based treatments for opiate dependence are in many ways not compatible with agonist treatment.

Buprenorphine is used for both long-term maintenance and for medically supervised withdrawal/detoxification from opiates. It has been found safe and effective in minimizing withdrawal symptoms, as well as blocking the effects of illicit opiates. It is a partial opioid-agonist: at low doses, it acts as an agonist and at high doses as either an agonist or antagonist depending on the circumstance.

- 1 Levels of care range from ambulatory 1:1 substance abuse counseling in conjunction with 12 Step or other community-based recovery support (least restrictive), to inpatient, medically managed acute treatment (most restrictive). (See ASAM level of care placement guidelines and Appendix 7.)
- 2 Medical co-morbidities that may affect use of buprenorphine:

HEPATITIS B, C

- Buprenorphine inhibits hepatic mitochondrial function at high concentrations
- May cause elevation of transaminases, but no documentation of fulminant liver failure due solely to buprenorphine
- Monitor liver enzymes levels in patients with Hepatitis, especially those on Buprenorphine/NALOXONE
- Warn patients not to use Buprenorphine IV
- Renal Failure
- Few studies available
- No significant difference in kinetics of buprenorphine in patients with renal failure vs. controls
- No significant side effects in patients with renal failure

MEDICATION INTERACTIONS

- Cytochrome P450 3A4 Interactions:
 - (1) 3A4 Inhibitors may raise Buprenorphine levels [e.g., Fluoxetine (Prozac), Fluvoxamine (Luvox), nefazodone (Serzone), cimetidine (Tagamet), and possibly antiretrovirals (e.g., ritonavir)]
 - (2) 3A4 Substrates may raise Buprenorphine levels [e.g., trazodone

- (Desyrel), alprazolam (Xanax), diazepam (Valium), buspirone (Buspar), zolpidem (Ambien), caffeine, haloperidol (Haldol), pimozide (Orap), erythromycin, nifedipine, oral contraceptives]
- (3) 3A4 Inducers may lower buprenorphine levels [e.g., crabamazepine, phenobarbital, phenytoin, barbiturates, primidone, St. John's Wort, rifampin protease inhibitors (nelfinavir, lopinavir) non-nucleoside Rtiis (nevirapine, efavirenz)]
- For a complete list of substrates, inhibitors and inducers: www.drugs.com

- 3 Staff and patient education/training programs (see section of Guidelines on Provider Information and Supports, Resources for Staff and Patient Education)

STAFF EDUCATION

- Treating patient with substance abuse disorders
- The disorder of opiate dependence
- Role and importance of medication in treatment of opioid dependence
- Maintenance of confidentiality
- Treatment philosophy
- Providing medication
- Role of non-pharmacological treatments
- Universal precautions

PATIENT INFORMATION

- Informed consent (see Appendix 6C)
- Treatment agreements (see Appendix 6D)

Unlike morphine or other full agonists, buprenorphine's effects are not linear with increasing doses; it exhibits a "ceiling effect" with respect to the respiratory system, making a lethal overdose unlikely. This property also means that buprenorphine is not right for everyone. Individuals with high opiate needs are better suited for methadone.

Note: The ceiling effect and its potential safety margin are eliminated when buprenorphine is combined with alcohol or a variety of other drugs, such as benzodiazepines, especially if injected. There have been reports of disastrous consequences when small children are exposed even briefly to buprenorphine as the "ceiling effect" does not appear to hold for this population. Providers should educate all patients on the importance of safe medication storage and what to do if a child comes in contact with any of the buprenorphine preparations. (Boyer EW, McCance-Katz E, Marcus, S., Methadone and Buprenorphine Toxicity in Children The American Journal on Addictions, 19: 89–95, 2009)

Insurance

Please consult your patient's health insurance carrier for preauthorization information.

Preauthorization

A medication preauthorization is required prior to starting a patient on buprenorphine. See *Appendix 3* for the Preauthorization Form for the Department of Vermont Health Access (DVHA), available at <http://dvha.vermont.gov/for-providers/buprenorphine-prior-auth-form-2009-11.pdf>.

Buprenorphine Preparations for MAT

Two sublingually dissolved buprenorphine preparations are currently available.

1. SUBUTEX is a mono-therapy containing only buprenorphine. It is available from a pharmaceutical house in small supply to be kept in physicians' offices. This preparation is more easily diverted and should be judiciously used.
2. SUBOXONE is a combination therapy, containing both buprenorphine and naloxone. Naloxone has been added to avoid diversion and intravenous abuse. Suboxone is the recommended preparation for induction, maintenance, and, if necessary, supervised withdrawal (detoxification).

To minimize diversion of buprenorphine, especially the mono-therapy product, it is recommended that Subutex only be used during the management of pregnant, opioid dependent women or in the extremely rare occurrence of allergy or intolerance to Suboxone (not just because the patient does not like the taste of Suboxone). Allergy or intolerance to Suboxone should be fully documented, including but not limited to witnessing by the treating provider.

BUPRENORPHINE DURING PREGNANCY. Although neither preparation has been approved for use during pregnancy, Subutex has been used for medically assisted treatment (MAT) during pregnancy. In addition, although the mono-product is preferred, women have conceived and delivered on the

combination-therapy product. For more information about treatment of opioid dependence during pregnancy, please contact Marjorie Meyer, MD, at Fletcher Allen Health Care/ University of Vermont at Marjorie.meyer@uvm.edu. To refer a patient directly for treatment, contact the Comprehensive Obstetrics and Gynecology Service at Fletcher Allen Health Care at 802-847-1400. You may also contact John Brooklyn, MD, at the Howard Center Chittenden Clinic, c/o University Health Care, 1 South Prospect Street, Burlington, VT 05401, 802-656-3700 or 800-413-2272.

Treatment Settings

OFFICE-BASED PRACTICE CARE may be provided by a solo practitioner or a group practice with the required training and ability to provide clinical evaluation, buprenorphine induction, maintenance and follow up. The practitioner or group also must be able to provide consultation and referrals as needed with primary care providers, medical specialists and counseling services. Some practitioners may be able to provide all services on their own (e.g., an addictions psychiatrist with buprenorphine training).

OPIATE TREATMENT PROGRAMS (OTPs) may provide Subutex or Suboxone following the same regulations that exist for methadone treatment (42 CFR Part 8: Code of Federal Regulations, Title 42: Public Health, Part 8–Certification of Opioid Treatment Programs, <http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr;sid=d5f2d13f11085410f289dd08209805f4;rgn=div5;view=text;node=42%3A1.0.1.1.9;idno=42;cc=ecfr>), including a take-home schedule in which buprenorphine is dispensed from the window without giving a prescription. Due to the long-acting nature of buprenorphine, multiple day dosing can occur two to three times per week. Buprenorphine is part of the OTP's DEA registration, not an individual physician's; consequently, physicians working in OTPs do not have to seek a waiver or complete the eight hour training. In addition, these programs are exempt from the 30 patient limit.

Practices planning to provide buprenorphine in an office-based setting for more than 30 patients should review the Federal Guidelines for methadone clinics and consider issues such as "no drive" and "impairment" assessments.

Challenges with Buprenorphine Treatment in Vermont

BROADER POPULATION THAN ANTICIPATED. Office-based treatment of opioid dependence with buprenorphine was originally intended for a rather circumscribed population with existing community supports and relatively shorter addiction histories. However, demand for opioid replacement therapy in Vermont, along with insufficient availability of methadone programs, has resulted in a broader use of buprenorphine services than originally anticipated. Examples of some unexpected difficulties include:

- Patients are more time consuming than expected
- Counseling resources are not readily available
- Reports of diversion and injection have increased

Nevertheless, many physicians treat patients with excellent results and successful integration into their practices. Patient selection criteria are important.

DIVERSION of both the mono and combination buprenorphine preparations present additional challenges; most reports suggest these primarily are “lateral” or “addict to addict” diversions to help bridge the gap while awaiting treatment or when street drug supplies are limited. However, the Department of Corrections has reported that buprenorphine is one of their most frequently found contraband items among inmates, and many inmates who are not recorded as being prescribed buprenorphine are testing positive for it on random toxicology screens.

Physicians must inform patients that diversion is a reportable criminal offense, and indicate how suspicions or evidence of diversion will be handled clinically by the practice. Practices should have clinical procedures in place for minimizing diversion risk to ensure appropriate addiction treatment, such as the following:

- Routine toxicology screens
- Pill call backs (for counting)
- Bubble packing of prescriptions

Physicians also should make use of the Vermont Prescription Drug Monitoring System (VPMS), established by the Vermont Department of Health to provide health care professionals with as much information as possible to guide their prescribing practices. The VPMS may be accessed online by registered prescribers and pharmacists at <http://healthvermont.gov/adap/VPMS.aspx>. Additional information is available through the Alcohol and Drug Abuse Programs (ADAP) office at 802-652-4147.

All these concerns underscore the need for integrated and coordinated services for buprenorphine patients, with associated challenges regarding confidentiality and sharing necessary information to ensure all treatment providers are aware of the proposed treatment plan and specific patient issues. All information sharing must conform to current 42 CFR Part 2 (Code of Federal Regulations, Title 42: Public Health, Part 2 – Confidentiality of Alcohol & Drug Abuse Patient Records, <http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=d5f2d13f11085410f289dd08209805f4&rgn=div5&view=text&node=42:1.0.1.1.2&idno=42>) and HIPAA standards for release of information forms (see *Appendix 6A* for sample Consent for Release of Information forms).

PHASES OF BUPRENORPHINE TREATMENT

Screening/Intake

Initial screening for opioid addiction should consist of a combination of interviews, objective screening instruments and laboratory evaluations (see *Appendices B I* and *B II* for examples of screening and assessment tools that may help determine how appropriate a patient is for office-based treatment), and include the following:

1. Medical history with attention paid to liver and cardiac

status and medications.

2. Psychiatric history with attention to treatment adherence including medications and counseling.
3. Substance abuse history and treatment history to identify whether patient was ever on buprenorphine and to insure patient is not currently on methadone but meets criteria for Opiate Dependence (see *Appendix 1*, DSM-IV Diagnosis of Opiate Dependence). If a patient reports they have been using buprenorphine obtained on the street, and even provides the dose they have been taking, they still should go through the induction process to determine the appropriate clinical dose.
4. Social, work, and family circumstances history.
5. Physical exam, mental status exam.
6. Lab screening for ALT, AST, Hep B and C, HIV, Gonorrhea, Chlamydia, Syphilis, TB test.
7. Urine screen (witnessed) with attention to opiates, including methadone and buprenorphine, and benzodiazepines.
8. If urine is negative for opiates (which may occur with synthetic opiates), evidence of IV puncture marks on the skin and evidence of withdrawal symptoms, such as runny eyes, sniffing, yawning, tremor, sweating, gooseflesh, vomiting, abdominal cramps, muscle aches, pupil dilation. The *CINA Scale (Clinical Institute for Narcotic Assessment Scale for Withdrawal Symptoms)* can be very useful (see *Appendix 4*).
9. In some cases, dependence may be diagnosed through the use of 1 cc of naloxone (Narcan) (0.4 mg/ml) injected subcutaneously followed by observing the patient for up to 30 minutes for evidence of precipitated withdrawal. Naltrexone (ReVia) would not be used due to the protracted withdrawal syndrome it causes. (Narcan Challenge)
10. Patients who have recently been released from prison or other restrictive, drug-free environments, may not demonstrate evidence of withdrawal. They may still be appropriate for treatment with buprenorphine to avoid relapse.
11. Women using illicit opioids may experience menstrual cycle irregularity and infertility. Unplanned pregnancy can occur as women recover and improve their health status. As opioid-agonist therapy is initiated, the potential for pregnancy should be addressed and a plan for contraception developed. If pregnancy is desired, women should receive a prescription for prenatal vitamins (for additional folic acid).

POSSIBLE INDICATIONS OF LESS APPROPRIATE CANDIDACY.

Certain factors may suggest a patient is LESS likely to be an appropriate candidate for office-based buprenorphine treatment (see *Appendices B I* and *B II* for criteria and guidelines for assessing candidacy). Some factors to consider include the following:

- Dependence on high doses of benzodiazepines, alcohol, or other CNS depressants
- Significant psychiatric co-morbidity
- Active or chronic suicidal or homicidal ideation or attempts
- Multiple previous treatments and relapses
- Non-response to buprenorphine in the past

- High level of physical dependence (risk for severe withdrawal)
- High relapse risk
- Pregnancy
- Current medical conditions that could complicate treatment
- Poor support systems
- Patient needs cannot be addressed with existing office-based resources

PATIENT CONSENT, TREATMENT AGREEMENTS, AND RELEASE OF INFORMATION FORMS. Once all screening information has been evaluated, both physician and patient review and sign a Consent for Treatment form and a Treatment Agreement (see *Appendices 6B, 6C and 6D* for sample Patient Information, Consent for Treatment and Buprenorphine Treatment Agreement forms). One copy is kept in the medical record and one goes to the patient. A copy of the agreement also should be sent to the pharmacy.

Release of Information forms should be completed for the substance abuse counselor and the pharmacy that will be dispensing the medication. Any other individuals or agencies, such as the psychiatrist, VNA, Family Services Division of the Department for Children and Families, referring treatment center, etc., should also have releases signed and placed in the patient chart (see *Appendix 6A* for sample Release of Information forms).

Induction

Induction onto buprenorphine is considered to be an ambulatory procedure not requiring an inpatient admission unless there are medical complications or other extenuating circumstances. The induction steps listed below are guidelines intended to ensure close monitoring during the initial phases of treatment. Dosing guidelines based on reported drug use can be helpful in targeting eventual final buprenorphine doses. (See Guide for Dose Targets, end of this section.)

General Guidelines for patients physically dependent on opioids:

1. Begin induction early in the week.
2. Plan on 3-5 days for stable dosing.
3. Patient's last reported use should have been at least 6 hours prior to induction.
4. MAKE SURE THE PATIENT IS NOT ON METHADONE as buprenorphine may cause an acute withdrawal syndrome; if patient is on methadone, see below protocol for long acting opiates.
5. Day 1: Give the patient a prescription for #2 2mg Suboxone tablets.
6. Patient takes the prescription to the pharmacy and returns to the office with the medication.
7. Patient takes the tablet and lets it dissolve under the tongue for 5 minutes with no talking, drinking, or swallowing.

8. Target buprenorphine dose range should be 12mg to 16mg per day, with a recommended maximum of 16mg daily.
9. If more than 8mg are needed, gradually increase the dose in 2mg increments over the next several days.
10. The patient's condition before dosing time is one of the best ways to assess adequacy of the dose. (Refer to *Appendix 5*, Clinical Opiate Withdrawal Scale (COWS), for assessing withdrawal symptoms before the first dose is given and throughout the Induction period.

Guidelines for patients NOT physically dependent on opioids (e.g., coming out of incarceration or otherwise high-risk for relapse):

First dose: 2mg sublingual buprenorphine.

Monitor for 2+ hours and consider 2mg incremental dosage increases over the next several days.

Specific recommendations for patients dependent on Short-acting opioids:

1. Instruct patient to abstain from any opioid use for a minimum of 6-12 hours so they are in mild withdrawal at time of first buprenorphine dose. Note: If patient is not in withdrawal, have them wait and reassess their use or abstinence over past 12-24 hours or return another day.
2. Week 1, Day 1: First dose: 2mg sublingual Suboxone (combination therapy) with direct observation after 5 minutes that the medication is dissolved.
3. Monitor in office for up to 2 hours to insure no vomiting and tolerance of the dose.
4. Send patient home with the additional 2 mg dose and redose in 2-4 hours if withdrawal subsides, then reappears. Maximum dose for first day: 4 mg.
5. Day 2: Patient returns to office. If looks well, renew same dose of 4 mg for the next 2 days. If shows signs of withdrawal based on CINA Scale and/or Clinical Opiate Withdrawal Scale, prescribe #4 2 mg tabs, have patient go to pharmacy, return to office with medication and take 3 pills in front of nurse; wait 5 minutes and then send home and redose later in the day if needed. Maximum dose for second day: 8 mg.
6. Day 3: If patient needed the dose adjustment on Day 2, have them return for direct observation pre-dose and if looks well, give prescription for 8 mg tabs for 3 days and send them home. Have patient return for follow-up in 2 days. If showing signs of withdrawal on CINA score, give a prescription for 10 mg to take for the next 3 days.
7. Day 4: If patient stable on 4 mg on Day 2, make sure they are well and give one week's supply to take at home. If dose needs adjustment, increase to 6 mg and give one week's supply to take at home.
8. Day 5: If patient from Day 3 shows any signs of withdrawal, give an additional 2 mg dose per day and give a week's supply. Maximum dose: 12 mg.
9. Week 2: Before renewing the week's supply, have patient come in pre-dose to assess whether any adjustment in dose is needed; if needed, adjust by 2-4 mg. Maximum dose: 16 mg.

NOTE: If a patient has insurance co-pay, consider writing prescription for #16 pills of 2 mg for a minimum of 4 days of induction. The patient can bring the pills in each day for directly observed dosing to make sure they are taking them. **The most critical thing is making sure the patient is taking the correct dose. Doing this early will reduce diversion later on.**

Specific recommendations for patients dependent on LONG ACTING opioids:

1. Doses of methadone should be decreased to a stable state of 30mg of methadone or equivalent.
2. The following dose equivalents are target doses, not starting doses:
Methadone 40 mg = Buprenorphine 8 mg
Methadone 60 mg = Buprenorphine 12 mg
Methadone 80 mg = Buprenorphine 16 mg
3. Begin Induction 24 hours after last methadone. No additional methadone given after Induction begins.
4. Follow same protocol for short-acting opioids, but faster dose adjustments may be needed daily for the first week.

Stabilization

Patient should receive daily dose until stabilized.

An option is to shift to alternate day dosing, by increasing the amount on the dosing day by the amount not received on the intervening days (see #5 below).

1. Urine screens should be done once a week.
2. Non-attendance for counseling for more than two

consecutive sessions should trigger an automatic call from the counselor. The physician should schedule an office visit with the patient to make sure the patient understands that failure to follow through with counseling jeopardizes treatment and puts them outside of “good standing.”

3. Write 7 days’ worth of medication at a time for 2 months and appropriateness of treatment in an office-based setting will be re-evaluated.

Maintenance and Follow Up

4. Once patient has remained compliant with counseling and physician visits, has not had any mishaps with the Suboxone, and feels ready to do so, extend the prescriptions to 14 days for the next 2 months.
5. A patient may choose to take Suboxone every 2 or 3 days. The dose is doubled or tripled, depending on the time frame, and taken all at once. This is very effective in controlled settings, such as dispensing by a family member or clinic, but may be done for patient preference only.
6. After an agreed upon period of treatment adherence, prescriptions for 30 days may be written. Random pill counts may be useful at this point.
7. Urine drug testing is now available for determining the presence of the buprenorphine metabolite and this may be used as a clinical tool to encourage success in treatment, as well as a precautionary measure for avoiding diversion.

SUBOXONE TAPER REGIMEN FOR TWO STUDY TAPER GROUPS

| Stabilization*Dose | Study Day | 7-Day Taper Period | | | 28-Day Taper Period | | |
|--------------------|-----------|--------------------|-------|-------|---------------------|-------|-------|
| | | 8 mg | 16 mg | 24 mg | 8 mg | 16 mg | 24 mg |
| | 1 | 8 | 16 | 24 | 8 | 16 | 24 |
| | 2 | 6 | 12 | 20 | 8 | 16 | 24 |
| | 3 | 6 | 10 | 17 | 6 | 12 | 20 |
| | 4 | 4 | 8 | 12 | 6 | 12 | 20 |
| | 5 | 4 | 4 | 8 | 6 | 12 | 20 |
| | 6 | 2 | 2 | 4 | 6 | 10 | 16 |
| | 7 | 2 | 2 | 2 | 6 | 10 | 16 |
| | 8 | | | | 6 | 10 | 16 |
| | 9-11 | | | | 6 | 8 | 12 |
| | 12-14 | | | | 4 | 8 | 10 |
| | 15-16 | | | | 4 | 6 | 8 |
| | 17-19 | | | | 4 | 4 | 6 |
| | 20-22 | | | | 2 | 4 | 4 |
| | 23-25 | | | | 2 | 2 | 2 |
| | 26-28 | | | | 2 | 2 | 2 |

*dose noted is the dose of buprenorphine
Ling, W., et al., Buprenorphine Tapering Schedule and Illicit Opioid Use, Addiction, 104, 2009.

GUIDE FOR DOSE TARGETS

| Buprenorphine Doses | Oxycodone | Morphine | Heroin | Methadone |
|---------------------|-----------|----------|----------|-----------|
| 2 mg | 30 mg | 60 mg | 1-2 bags | 10 mg |
| 4 mg | 60 mg | 120 mg | 3 bags | 20 mg |
| 6 mg | 90 mg | 180 mg | 4 bags | 30 mg |
| 8 mg | 120 mg | 240 mg | 6 bags | 40 mg |
| 12 mg | 180 mg | 360 mg | 8 bags | 60 mg |
| 16 mg | 240 mg | 480 mg | 10 bags | 80 mg |

Tapering Patients Off a Stable Buprenorphine Dose

There may be well-stabilized patients who desire to be withdrawn from buprenorphine medication. There is evidence a relatively quick taper from buprenorphine may be advantageous and will not result in relapse at greater rates than for patients weaned more slowly. Research comparing relatively shorter taper periods (7-days) with relatively longer ones (28-days) found a higher percentage of patients in the 7-day taper group were opioid free at the end of the taper, and both self-reports and physician observation of withdrawal symptoms and craving were no different between the two groups. In addition, no differences between the two groups were found in the rate of relapse to illicit opioid use three months after the taper period ended. The following table provides taper schedules for both taper periods.

Detoxification

Rapid detox: Three days or less

- Low doses of buprenorphine given 2-3 times daily
- More effective in suppressing withdrawal than clonidine
- Long term efficacy not well documented
- Not recommended due to poor outcomes and should only be done when there is a compelling reason for patient to be detoxed quickly (e.g., out of country travel, imminent incarceration)

Moderate detox: 30 days or less

- Raise dose daily over 4 days to equal opiates taken, then decrease by 2 mg every 1-2 days until weaned
- Better tolerated than clonidine
- Few studies of buprenorphine for this time period

Long detox: more than 30 days

- Raise dose daily over 4 days to equal opiates taken, then reduce by 2 mg weekly until weaned
- Not well studied but some evidence suggests this approach is more efficacious than briefer ones, especially if naltrexone is started after an appropriate wash out period

Management of Acute Pain in Patients Receiving Buprenorphine

Management of acute pain in patients receiving buprenorphine products (either mono therapy or combination buprenorphine/naloxone) is a common clinical challenge. While no approach to this has been rigorously tested, commonly accepted principles have developed over the years. The following article also may be of interest: www.pcsmmentor.org/pcss/documents2/PCSS_AcutePain_052307.pdf

Buprenorphine blocks opiate receptors, making them unavailable for further opiate analgesic effects. The dose of buprenorphine predicts how many of the receptors are blocked; generally, any buprenorphine dose above 10 mg will block opiate analgesics for pain.

As a general rule, a patient who will experience acute pain from surgery or a recent injury should have the dose of buprenorphine reduced to 8 mg; to make up the opiate debt, the remaining amount of buprenorphine is converted to short-acting opiates. (Refer to the chart on page 18 of these Guidelines for reasonable equal-analgesic doses of oxycodone and morphine.)

For example, carpal tunnel release surgery is planned for a patient taking 16 mg of buprenorphine. The typical post operative treatment for this surgery is 10 mg of oxycodone every 4 hours for 3 days. Therefore, the patient would stop taking one of the 8 mg buprenorphine tablets the day of surgery. A prescription for 30 mg of oxycodone to be taken 4 times a day for 3 days would be provided to MAKE UP THE OPIATE DEBT FROM THE 8 MG OF BUPRENORPHINE that has been stopped. In addition, post operatively the patient would take 10 mg of oxycodone every 4 hours for the 3 post operative days.

After the end of the 3 day post operative period, the patient resumes taking the 8 mg of buprenorphine that had been stopped, discontinues the replacement oxycodone, and begins using non-opiate analgesics. Of course, in cases with persistent pain the above regimen could be continued for a longer period of time, and for some procedures several weeks might be needed. Seeing the patient every 3-5 days to manage their pain is most effective as it provides the patient with stability and prevents relapse and misuse of opiates.

PROVIDER INFORMATION AND SUPPORTS

Vermont Opioid Treatment Provider List Serve

This is a provider-only list serve hosted by the Vermont Medical Society that serves as a venue for buprenorphine providers to obtain support from other Vermont providers. The email address is: opiatetreatment@vtmd.org. To register with the list serve and receive information, please contact Stephanie Winters at swinters@vtmd.org.

Physician Clinical Support System (PCSS)

The SAMHSA-funded PCSS is designed to assist practicing physicians, in accordance with the Drug Addiction Treatment Act of 2000 (DATA 2000), with incorporating buprenorphine treatment of prescription opioid and heroin dependent patients into their practices. Physicians may use this resource for assistance with obtaining a mentor for beginning an office-based practice. The PCSS service is available, at no cost, to interested physicians and staff. <http://pcssmentor.org>. Phone: 877-630-8812

SAMHSA Websites

Substance Abuse and Mental Health Services Administration (SAMHSA): www.samhsa.gov and www.buprenorphine.samhsa.gov. Provides information on the *DATA 2000*, physician waiver qualifications, how to request a waiver form, buprenorphine trainings, and other information.

Center for Substance Abuse Treatment (CSAT): csat.samhsa.gov. Phone: 866-BUP-CSAT

National Clearinghouse for Alcohol and Drug Information (NCADI) – a Department of Health and Human Services and SAMHSA website: www.health.org

Resources for Staff and Patient Education

Medication-Assisted Treatment For Opioid Addiction in Opioid Treatment Programs Inservice Training, based on Treatment Improvement Protocol 43. http://buprenorphine.samhsa.gov/bwns/tip43_curriculum.pdf

Buprenorphine: A Guide for Nurses http://buprenorphine.samhsa.gov/bwns/TAP_30_Certified.pdf

Note: Guides for Counselors and Pharmacists will be made available in the near future through SAMHSA. For questions: info@buprenorphine.samhsa.gov

Responsible Opioid Prescribing: A Physician's Guide. Scott Fishman, MD. Waterford Life Sciences, Washington, DC, 2007.

Universal Precautions: A Matter of Mutual Trust and Responsibility. Pain Medicine. Gourlay, D., and Heit, H. March-April 2006, 7(2):210-211, author reply, 212.

Other Substance Abuse-Related Web Sites

American Academy of Addiction Psychiatry (AAAP). Web-based training, information on live training, news, governmental agency links: www.aaap.org/buprenorphine/buprenorphine.html. Phone: 401-524-3076

Food and Drug Administration. Provides talk paper, drug label, patient leaflet, physician information, pharmacist information, Q&A about Subutex and Suboxone: www.fda.gov/cder/drug/infopage/subutex_suboxone/default.htm

Addiction Treatment Watchdog (ATW): www.atwatchdog.org

AL-ANON and ALATEEN: www.al-anon.alateen.org

American Association for the Treatment of Opioid Dependence (AATOD) – formerly the American Methadone Treatment Association, Inc: www.aatod.org

Join Together Online – Take Action Against Substance Abuse and Gun Violence: www.jointogether.org

Narcotics Anonymous: www.na.org

National Alliance of Methadone Advocates (NAMA): www.methadone.org

Project Cork, Authoritative Information on Substance Abuse, Dartmouth Medical School: www.projectcork.org

REFERENCES

Buprenorphine Clinical Practice Guidelines Field Review Draft, November 17, 2000.

Buprenorphine in the Treatment of Opioid Dependence. American Academy of Addiction Psychiatry. Eric Strain, MD and Jeff Novey, MPH.

Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction. SAMHSA/CSAT Treatment Improvement Protocols, TIP 40. Laura McNicholas, MD, PhD, Consensus Panel Chair.

Confidentiality of Patient Records for Alcohol and Other Drug Treatment. Center for Substance Abuse Treatment, Technical Assistance Publication (TAP) Series, Number 13. Rockville, MD: Center for Substance Abuse Treatment, 1994.

Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV).

Drug Addiction Treatment Act of 2000 (DATA 2000).

Patient Placement Criteria. American Society of Addiction Medicine.

PCSS Guidance – Treatment of Acute Pain in Patients Receiving Buprenorphine/Naloxone. David Fiellin, MD. Physician Clinical Support System, November 10, 2005.

Use of Buprenorphine in Pharmacologic Management of Opioid Dependence. Elinore F. McCance-Katz, MD, PhD, course director. Medical College of Virginia.

Appendix 1: DSM-IV Diagnosis of Opiate Dependence

Maladaptive pattern of use, leading to significant impairment or distress, as manifested by 3 or more of the following, occurring at any time in the same 12-month period:

1. Tolerance, as defined by decreased effect with same amount or increased amount needed to achieve same effect.
2. Withdrawal, as defined by characteristic syndrome for the substance when withdrawn or closely related substance taken to relieve the syndrome.
3. An increase in the amount or the duration from what was intended.
4. Persistent desire or unsuccessful attempts to cut down or control use.
5. Spending a great deal of time in activities needed to obtain or use the substance or recover from the effects of it.
6. Giving up social, occupational, or recreational activities because of use.
7. Continuing the use despite knowing that it is causing or worsening a persistent or recurrent psychological or physical problem.

Appendix 2A: Ten Factor Office-Based Criteria Check List

In general, 10 factors help determine whether a patient is appropriate for office-based buprenorphine treatment. This checklist may be useful during the screening process. Check “yes” or “no” next to each factor.

FACTOR

1. Does the patient have a diagnosis of opioid dependence? Yes No
2. Is the patient interested in office-based buprenorphine treatment? Yes No
3. Is the patient aware of the other treatment options? Yes No
4. Does the patient understand the risks and benefits of buprenorphine treatment and that it will address some aspects of the substance abuse, but not all aspects? Yes No
5. Is the patient expected to be reasonably compliant? Yes No
6. Is the patient expected to follow safety procedures? Yes No
7. Is the patient psychiatrically stable? Yes No
8. Are the psychosocial circumstances of the patient stable and supportive? Yes No
9. Are resources available in the office to provide appropriate treatment?
Are there other physicians in the group practice?
Are treatment programs available that will accept referral for more intensive levels of service? Yes No
10. Is the patient taking other medications that may interact with buprenorphine, such as naltrexone, benzodiazepines, or other sedative-hypnotics? Yes No

Source: Based on the CSAT-funded curriculum *Use of Buprenorphine in the Pharmacologic Management of Opioid Dependence*. American Academy of Addiction Psychiatry on line training. Eric Strain, MD and Jeff Novey, MPH. Course revised by Elinore F. McCance-Katz, MD, Ph.D., 2004.

Appendix 2B: Guidelines for Assessing Appropriateness for Office-Based Buprenorphine Treatment*

The following guidelines will help in deciding whether to treat with buprenorphine in the office. They assume the person is opioid dependent.

SCORING KEY

- 0-5: Excellent candidate for office-based treatment.
- 6-10: Good candidate for office-based treatment.
- 11-15: Good candidate, but only with tightly structured program providing supervised dosing and on site counseling.
- 16-20: Candidate for office-based treatment by board certified addiction physician in a tightly structured program or hub induction with follow-up by office-based provider or methadone clinic referral.
- 21-25: Candidate for methadone program only.

For each answer check YES or NO and add points for YES and NO below.

| Questions | Points: | Yes | No | Possible |
|--|---------------------|----------------------------|----------------------------|----------------------------|
| Is the person employed? | | <input type="checkbox"/> | <input type="checkbox"/> 1 | <input type="checkbox"/> 1 |
| Is the family intact? | | <input type="checkbox"/> | <input type="checkbox"/> 1 | <input type="checkbox"/> 1 |
| Does the person have a partner who uses drugs or alcohol? | | <input type="checkbox"/> 1 | <input type="checkbox"/> | <input type="checkbox"/> 1 |
| Is the person's housing stable? | | <input type="checkbox"/> | <input type="checkbox"/> 1 | <input type="checkbox"/> 1 |
| Does the person have legal issues? | | <input type="checkbox"/> | <input type="checkbox"/> 1 | <input type="checkbox"/> 1 |
| Does the person have any convictions for drug dealing? | | <input type="checkbox"/> 2 | <input type="checkbox"/> | <input type="checkbox"/> 2 |
| Is the person on probation? | | <input type="checkbox"/> 1 | <input type="checkbox"/> | <input type="checkbox"/> 1 |
| Does the person have psychiatric problems, e.g., major depression, bipolar, severe anxiety, PTSD, schizophrenia, personality subtype of antisocial, borderline, or sociopathy? | | <input type="checkbox"/> 2 | <input type="checkbox"/> | <input type="checkbox"/> 2 |
| Does the person have a chronic pain syndrome that needs treatment? | | <input type="checkbox"/> 2 | <input type="checkbox"/> | <input type="checkbox"/> 2 |
| Does the person have reliable transportation? | | <input type="checkbox"/> | <input type="checkbox"/> 1 | <input type="checkbox"/> 1 |
| Does the person have a reliable phone number? | | <input type="checkbox"/> | <input type="checkbox"/> 1 | <input type="checkbox"/> 1 |
| Has the person been on medicated assisted treatment before? | | <input type="checkbox"/> | <input type="checkbox"/> 1 | <input type="checkbox"/> 1 |
| Was the medicated assisted treatment successful? | | <input type="checkbox"/> | <input type="checkbox"/> 2 | <input type="checkbox"/> 2 |
| Does the person have a problem with alcohol? | | <input type="checkbox"/> 2 | <input type="checkbox"/> | <input type="checkbox"/> 2 |
| Does the person have a problem with cocaine? | | <input type="checkbox"/> 1 | <input type="checkbox"/> | <input type="checkbox"/> 1 |
| Does the person have a problem with benzodiazepines? | | <input type="checkbox"/> 2 | <input type="checkbox"/> | <input type="checkbox"/> 2 |
| Is the person motivated for treatment in the office? | | <input type="checkbox"/> | <input type="checkbox"/> 1 | <input type="checkbox"/> 1 |
| Is the person currently going to counseling, AA, or NA? | | <input type="checkbox"/> | <input type="checkbox"/> 2 | <input type="checkbox"/> 2 |
| Total points possible: 25 | Total each column: | | | |
| | Total both columns: | | | |

Provided by John R. Brooklyn, MD, May 21, 2009

Appendix 3: DVHA Buprenorphine Prior Authorization Request Form



Office of Vermont Health Access Agency of Human Services, 312 Hurricane Lane, Suite 201, Williston, VT 05495

BUPRENORPHINE PRIOR AUTHORIZATION REQUEST FORM

Vermont Medicaid has established criteria for prior authorization of buprenorphine (Suboxone®, Subutex®). These criteria are based on concerns about safety and the potential for abuse and diversion. For beneficiaries to receive coverage for Suboxone® or Subutex®, it will be necessary for the prescriber to telephone or complete and fax this form to MedMetrics Health Partners. Please complete this form in its entirety and sign and date below. Incomplete requests will be returned for additional information.

Submit request via: Fax: 1-866-767-2649 or Phone: 1-800-918-7549

Prescribing physician:

Beneficiary:

NAME _____
 PHONE _____
 FAX _____
 ADDRESS _____

NAME _____
 MEDICAID ID NO. _____
 DATE OF BIRTH _____
 DIAGNOSIS _____

CONTACT PERSON AT OFFICE _____

PHARMACY _____

PHONE _____

FAX _____

Qualifications:

| | |
|----------|--|
| MD/DO | Prescribers must have a DATA 2000 waiver ID (X-DEA license) in order to prescribe. |
| Patients | Patients must have a diagnosis of opiate dependence confirmed. |

Process: Answer the following questions.

| | |
|--|--|
| Is buprenorphine being prescribed for opiate dependency? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| Does the prescriber signing this form have a DATA 2000 waiver ID number (X-DEA license)? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| Request is for the following medication: <input type="checkbox"/> Suboxone® (buprenorphine/naloxone) <input type="checkbox"/> Subutex® (buprenorphine) | |
| Anticipated maintenance dose/frequency: Dose _____ Frequency: _____ | |
| If this request is for Subutex®, please answer the following questions: | |
| Is the member pregnant? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| If yes, anticipated date of delivery: _____ | |
| Does the member have a documented allergic reaction to naloxone that has been witnessed by a health care professional? | |
| If yes, please provide medical records documenting the allergic reaction. | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| Additional clinical information to support PA request: | |

PRESCRIBER SIGNATURE _____

DATE _____

Appendix 4: Clinical Institute Narcotic Assessment (CINA) Scale for Withdrawal Symptoms

The Clinical Institute Narcotic Assessment (CINA) Scale measures 11 signs and symptoms commonly seen in patients during narcotic withdrawal. This can help to gauge the severity of the symptoms and to monitor changes in the clinical status over time.

| Parameters Based on Questions and Observation | Findings | Points |
|--|---|---------|
| 1 Abdominal changes: Do you have any pains in your abdomen? Crampy abdominal pain, diarrhea, active bowel sounds. | No abdominal complaints, normal bowel sound. Reports waves of crampy abdominal pain. | 0 1 2 |
| 2 Changes in temperature: Do you feel hot or cold? clammy to touch. Uncontrolled shivering. | None reported. Reports feeling cold, hands cold and | 0 1 2 |
| 3 Nausea and vomiting: Do you feel sick in your stomach? Have you vomited? | No nausea or vomiting. Mild nausea; no retching or vomiting. Intermittent nausea with dry heaves. Constant nausea; frequent dry heaves and/or vomiting. | 0 2 4 6 |
| 4 Muscle aches: Do you have any muscle cramps? | No muscle aching reported, arm and neck muscles soft at rest. Mild muscle pains. Reports severe muscle pains, muscles in legs, arms or neck in constant state of contraction. | 0 1 3 |
| Parameters based on Observation Alone | Findings | Points |
| 5 Goose flesh | None visible. Occasional goose flesh but not elicited by touch; not permanent. Prominent goose flesh in waves and elicited by touch. Constant goose flesh over face and arms. | 0 1 2 3 |
| 6 Nasal congestion | No nasal congestion or sniffing. Frequent sniffing. Constant sniffing, watery discharge. | 0 1 2 |
| 7 Restlessness | Normal activity. Somewhat more than normal activity; moves legs up and down; shifts position occasionally. Moderately fidgety and restless; shifting position frequently. Gross movement most of the time or constantly thrashes about. | 0 1 2 3 |
| 8 Tremor | None. Not visible but can be felt fingertip to fingertip. Moderate with patient's arm extended. Severe even if arms not extended. | 0 1 2 3 |
| 9 Lacrimation | None. Eyes watering; tears at corners of eyes. Profuse tearing from eyes over face. | 0 1 2 |
| 10 Sweating | No sweat visible. Barely perceptible sweating; palms moist. Beads of sweat obvious on forehead. Drenching sweats over face and chest. | 0 1 2 3 |
| 11 Yawning | None. Frequent yawning. Constant uncontrolled yawning. | 0 1 2 |
| TOTAL SCORE | Sum of points for all 11 parameters | |

Minimum score = 0, Maximum score = 31. The higher the score, the more severe the withdrawal syndrome.
Percent of maximal withdrawal symptoms = total score/31 x 100%.

Source: Adapted from Peachey, J.E., and Lei, H. Assessment of opioid dependence with naloxone. *British Journal of Addiction* 83(2):193–201, 1988.
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Appendix 5: Clinical Opiate Withdrawal Scale (COWS)

For Suboxone (Buprenorphine/naloxone) induction: Enter scores at time zero, 1-2 hours after first dose, and at additional times Suboxone is given over the induction period.

| | Date/Time | Date/Time | Date/Time |
|--|-----------|-----------|-----------|
| Resting Pulse Rate: (record beats per minute) <i>Measured after patient is sitting/lying for one minute.</i> 0 pulse rate 80 or below 1 pulse rate 81-100 2 pulse rate 101-120 4 pulse rate greater than 120 | | | |
| Sweating: <i>Over past ½ hour not accounted for by room temperature or patient activity.</i> 0 no report of chills or flushing 1 one subjective report of chills or flushing 2 flushed or observable moistness on face 3 beads of sweat on brow or face 4 sweat streaming off face | | | |
| Restlessness: <i>Observation during assessment.</i> 0 able to sit still 1 reports difficulty sitting still, but is able to do so 3 frequent shifting or extraneous movements of legs/arms 2 unable to sit still for more than a few seconds | | | |
| Pupil Size: 0 pupils pinned or normal size for room light 1 pupils possibly larger than normal for room light 2 pupils moderately dilated 2 pupils so dilated that only rim of the iris is visible | | | |
| Bone or Joint Aches: <i>If patient was having pains previously, only the additional component attributed to opiate withdrawal is scored.</i> 0 not present 1 mild diffuse discomfort 2 patient reports severe diffuse aching of joints/muscles 4 patient is rubbing joints or muscles and is unable to sit still because of discomfort | | | |
| Runny Nose or Tearing: <i>Not accounted for by cold symptoms or allergies.</i> 0 not present 1 nasal stuffiness or unusually moist eyes 2 nose running or tearing 4 nose constantly running or tears streaming down cheeks | | | |
| GI Upset: <i>Over last ½ hour.</i> 0 no GI symptoms 1 stomach cramps 2 nausea or loose stools 3 vomiting or diarrhea 5 multiple episodes of diarrhea or vomiting | | | |
| Tremor: <i>Observation of outstretched hands.</i> 0 no tremor 1 tremor can be felt, but not observed 2 slight tremor observable 4 gross tremor or muscle twitching | | | |
| Yawning: <i>Observation during assessment.</i> 0 no yawning 1 yawning once or twice during assessment 2 yawning three or more times during assessment 4 yawning several times/minute | | | |
| Anxiety or Irritability 0 none 1 patient reports increasing irritability or anxiousness 2 patient obviously irritable, anxious 4 patient so irritable or anxious that participation in the assessment is difficult | | | |
| Gooseflesh Skin 0 skin is smooth 3 piloerection of skin can be felt or hairs standing up on arms 5 prominent piloerection | | | |
| Total Score | | | |
| Observer's Initials | | | |
| Blood Pressure/Pulse | | | |
| Dose of Suboxone Given | | | |

SCORE Mild: 5-12 Moderate: 13-24 Moderately Severe: 25-36 Severe Withdrawal: More than 36

Appendix 6A: Patient Consent for Release of Information

SAMPLE 1

I, _____, born on _____
PATIENT NAME PATIENT BIRTH DATE

SSN _____, authorize _____ to _____
PATIENT SOCIAL SECURITY NO. CLINIC /DOCTOR'S NAME

disclose to _____
NAME AND LOCATION OF PERSON/ORGANIZATION TO RECEIVE INFORMATION

the following information: _____

The purpose of this disclosure is: _____

This authorization expires on: _____, or

whenever _____ is no longer providing me with services.

Appendix 6A: Release of Information Form

SAMPLE 2

Required elements:

A written consent to a disclosure under these regulations must include:

1. The specific name or general designation of the program or person permitted to make the disclosure.
2. The name or title of the individual or the name of the organization to which disclosure is to be made.
3. The name of the patient.
4. The purpose of the disclosure.
5. How much and what kind of information is to be disclosed.
6. The signature of the patient and, when required for a patient who is a minor, the signature of a person authorized to give consent under §2.14; or, when required for a patient who is incompetent or deceased, the signature of a person authorized to sign under §2.15 in lieu of the patient.
7. The date on which the consent is signed.
8. A statement that the consent is subject to revocation at any time except to the extent that the program or person which is to make the disclosure has already acted in reliance on it. Acting in reliance includes the provision of treatment services in reliance on a valid consent to disclose information to a third party payer.
9. The date, event, or condition upon which the consent will expire if not revoked before. This date, event, or condition must insure that the consent will last no longer than reasonably necessary to serve the purpose for which it is given.

Sample consent form:

The following form complies with the required elements above, but other elements may be added.

1. I (patient name) Request Authorize: _____
2. Name or general designation of program which is to make the disclosure: _____
3. To disclose (kind and amount of information to be disclosed): _____
4. To: (name or title of the person or organization to which disclosure is to be made): _____
5. For (purpose of the disclosure): _____
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): _____

Appendix 6B: Buprenorphine/Naloxone (Suboxone) Maintenance Treatment Information for Patients

BUPRENORPHINE/NALOXONE (SUBOXONE) TREATMENT FOR OPIOID ADDICTION

Buprenorphine is an opioid medication which has been used as an injection for treatment of pain while patients are hospitalized, for example for surgical patients. It is a long acting medication, and binds for a long time to the “mu” opioid receptor.

Buprenorphine/naloxone or Suboxone is a combination medication that can be used to treat opioid dependence (addiction). Patients only need to take medication once daily and some will be able to take this medication less frequently (every other day or every third day). Buprenorphine is not absorbed very well orally (by swallowing) – so a sublingual (dissolve under the tongue) tablet has been developed for treatment of addiction. Buprenorphine/naloxone (Suboxone) tablets also contain a small amount of naloxone (Narcan) which is an opioid antagonist. Naloxone is poorly absorbed from under the tongue, but if Suboxone is injected, the naloxone will cause withdrawal symptoms. The reason that naloxone is combined with the buprenorphine in Suboxone is to help discourage abuse of this drug by injection.

Aside from being mixed with naloxone to discourage needle use, buprenorphine itself has a “ceiling” for narcotic effects (it is termed a “partial agonist”) which makes it safer in case of overdose. This means that by itself, even in large doses, it doesn’t suppress breathing to the point of death in the same way that heroin, methadone and other opioids could do in huge doses. These are some of the unusual qualities of this medication which make it safer to use outside of the usual strict methadone regulations at a clinic and, after stabilization, most patients would be able to take home up to two-four weeks worth of buprenorphine/naloxone (Suboxone) at a time.

Will Buprenorphine/Naloxone (Suboxone) be Useful for Patients on Methadone?

Methadone maintenance patients may be interested in whether this medication might help them. Unfortunately, because of the partial agonist nature of the medication, it is not equivalent in maintenance strength to methadone. In order to even try buprenorphine/naloxone (Suboxone) without going into major withdrawal, a methadone-maintained patient would have to taper down to 30 mg of methadone

daily or lower. In some cases, buprenorphine may not be strong enough for patients used to high doses of methadone and may lead to increased cravings and the risk of a relapse to opiate use. If you are methadone-maintained and decide to try buprenorphine, please be aware of this risk, and keep the door open for resuming methadone immediately if necessary.

There are also some studies which show that detoxification from buprenorphine/naloxone (Suboxone) is effective. Some patients may decide to use buprenorphine/naloxone (Suboxone) to detoxify from heroin or prescription narcotics, instead of other detoxification treatments (methadone, clonidine, etc). Despite the effectiveness of buprenorphine detoxification, all narcotic addicts are at high-risk for relapse and should consider the benefits of maintenance treatment. One issue with buprenorphine/naloxone treatment is that not all insurers will pay for treatment with this medication. Many doctors are requiring patients to pay for treatment and get reimbursed by their insurance company if possible.

Remember the Following Tips:

- If you are offered Suboxone by a “friend” and you are taking methadone or are addicted to prescription opioids, the buprenorphine in Suboxone will push the other opioids off the receptor site, and you may be in withdrawal and very uncomfortable.
- If you dissolve and inject the buprenorphine-naloxone (Suboxone) sublingual tablet it may induce severe withdrawal because of the naloxone, which is an antagonist.
- If you are on methadone treatment and wish to transfer to buprenorphine/naloxone (Suboxone), your dose has to be at or below 30 mg daily.
- There have been deaths reported when buprenorphine is injected in combination with high doses of benzodiazepines. (This family of drugs includes Klonopin, Ativan, Halcion, Valium, Xanax, Librium, etc.) There is a risk of overdose when any narcotic drug is taken in combination with alcohol and/or other sedative drugs. If you drink excessively, or take any of these drugs, either by prescription or on your own, buprenorphine may not be a good treatment for you.

Appendix 6C: Patient Consent for Buprenorphine Treatment

SAMPLE 1

Consent for Treatment with Suboxone (Buprenorphine/Naloxone)

Buprenorphine is a medication approved by the Food and Drug Administration (FDA) for treatment of people with opioid dependence. Buprenorphine can be used for detoxification or for maintenance therapy. Maintenance therapy can continue as long as medically necessary.

Buprenorphine itself is an opioid, but it is not as strong an opioid as heroin or morphine. Buprenorphine treatment can result in physical dependence of the opiate type.

Buprenorphine withdrawal is generally less intense than with heroin or methadone. If buprenorphine is suddenly discontinued, some patients have no withdrawal symptoms; others have symptoms such as muscle aches, stomach cramps, or diarrhea lasting several days. To minimize the possibility of opiate withdrawal, buprenorphine should be discontinued gradually, usually over several weeks or more.

If you are dependent on opiates (heroin or prescription opioids such as Lortab or Lorcet, Percodan or Percocet, Oxycontin, Dilaudid, methadone, morphine, MS Contin), you should be in as much withdrawal as possible when you take the first dose of buprenorphine. If you are not in withdrawal, buprenorphine may cause significant opioid withdrawal. For that reason, you should take the first dose in the office and remain in the office for observation. Within a few days, you will have a prescription for buprenorphine that will be filled in a pharmacy.

Some patients find that it takes several days to get used to the transition from the opioid they had been using to buprenorphine. During that time, any use of other opioids may cause an increase in symptoms. After you become stabilized on buprenorphine, it is expected that other opioids will have less effect. Attempts to override the buprenorphine by taking more opioids could result in an

opioid overdose. You should not take any other medication without discussing it with your doctor first.

Combining buprenorphine with alcohol or some other medications may also be hazardous. The combination of buprenorphine with medication such as Valium, Librium, Ativan has resulted in deaths.

The form of buprenorphine (Suboxone) you will be taking is a combination of buprenorphine with a short-acting opiate blocker (Naloxone). If the Suboxone tablet were dissolved and injected by someone taking heroin or another strong opioid, it could cause severe opiate withdrawal.

Buprenorphine tablets must be held under the tongue until they dissolve completely. Buprenorphine is then absorbed over the next 30 to 120 minutes from the tissue under the tongue. Buprenorphine will not be absorbed from the stomach if it is swallowed.

Buprenorphine will cost \$10+/day just for the medication. If you have medical insurance, you should find out whether or not buprenorphine is a benefit. In any case, office fees must be kept current or you will not be able to continue receiving this treatment from this program.

Alternatives to Buprenorphine

Some hospitals that have specialized drug abuse treatment units can provide detoxification and intensive counseling for drug abuse. Some outpatient drug abuse treatment services also provide individual and group therapy, which may emphasize treatment that does not include maintenance on buprenorphine or other opiate-like medications. Other forms of opioid maintenance therapy include methadone maintenance. Some opioid treatment programs use naltrexone, a medication that blocks the effects of opioids, but has no opioid effects of its own.

SIGNATURE

DATE

PRINT NAME

WITNESS

Appendix 6C: Patient Consent for Buprenorphine Treatment

SAMPLE 2

Consent for Treatment with Suboxone (Buprenorphine/Naloxone)

Suboxone® (a tablet with buprenorphine and naloxone) is an FDA approved medication for treatment of people with heroin or other opioid addiction. Buprenorphine can be used for detoxification or for maintenance therapy. Maintenance therapy can continue as long as medically necessary. There are other treatments for opiate addiction, including methadone, naltrexone, and some treatments without medications that include counseling, groups and meetings.

If you are dependent on opiates – any opiates – **you should be in as much withdrawal as possible when you take the first dose of buprenorphine. It you are not in withdrawal, buprenorphine can cause severe opiate withdrawal.** For that reason, you should take the first dose in the office and remain in the office for at least 2 hours. We recommend that you arrange not to drive after your first dose, because some patients get drowsy until the correct dose is determined for them.

Some patients find that it takes several days to get used to the transition from the opiate they had been using to buprenorphine. During that time, any use of other opiates may cause an increase in symptoms. After you become stabilized on buprenorphine, it is expected that other opiates will have less effect. Attempts to override the buprenorphine by taking more opiates could result in an opiate overdose. You should not take any other medication without discussing it with the physician first.

Combining buprenorphine with alcohol or other sedating medications is dangerous. The combination of buprenorphine with benzodiazepines (such as Valium®, Librium®, Ativan®, Xanax®, Klonopin®, etc.) has resulted in deaths.

Although sublingual buprenorphine has not been shown to be liver-damaging, your doctor will monitor your liver tests while you are taking buprenorphine. (This is a blood test.)

The form of buprenorphine (Suboxone®) you will be

taking is a combination of buprenorphine with a short-acting opiate blocker (naloxone) in a 4 to 1 ratio (4 mg of buprenorphine to 1 mg naloxone). **It will maintain physical dependence**, and if you discontinue it suddenly, you will likely experience withdrawal. If you are not already dependent, you should not take buprenorphine; it could eventually cause physical dependence.

Buprenorphine/naloxone tablets must be held under the tongue until they dissolve completely. You will be given your first dose at the clinic, and you will have to wait as it dissolves, and for two hours after it dissolves, to see how you react. **It is important not to talk or swallow until the tablet dissolves.** This takes up to ten minutes. Buprenorphine is then absorbed over the next 30 to 120 minutes from the tissue under the tongue. Buprenorphine is poorly absorbed from the stomach. **If you swallow the tablet, you will not have the important benefits of the medication, and it may not relieve your withdrawal.**

Most patients end up at a daily dose of 12/3-16/4 mg of buprenorphine. (This is roughly equivalent to 60mg of methadone maintenance). Beyond that dose, the effects of buprenorphine plateau, so there may not be any more benefit to increase in dose. It may take several weeks to determine just the right dose for you. The first dose is usually 2/0.5-4/1 mg.

If you are transferring to Suboxone® from methadone maintenance, your dose has to be tapered until you have been **below 30mg for at least a week.** There must be **at least 24 hours** (preferably longer) between the time you take your last methadone dose and the time you are given your first dose of buprenorphine. Your doctor will examine you for clear signs of withdrawal, and you will not be given buprenorphine until you are in withdrawal.

I have read and understand these details about buprenorphine treatment. I wish to be treated with buprenorphine.

SIGNATURE

DATE

WITNESS

Appendix 6D: Buprenorphine Treatment Agreement

SAMPLE 2: AGREEMENT FOR TREATMENT WITH SUBOXONE®

I understand that Suboxone is a medication to treat opiate addiction (for example: heroin, prescription opiates such as oxycodone, hydrocodone, methadone). Suboxone contains the opiate narcotic analgesic medication buprenorphine, and the opiate antagonist drug naloxone, in a 4 to 1 (buprenorphine to naloxone) ratio. The naloxone is present in the tablet to prevent diversion to injected abuse of this medication. Injection of Suboxone by a person who is addicted to opiates will produce severe opiate withdrawal.

| | | |
|------------------------------|-----------------------------|---|
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | 1. I agree to keep appointments and let appropriate staff know if I will be unable to show up as scheduled. |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | 2. I agree to report my history and my symptoms honestly to my physician, nurses, and counselors involved in my care. I also agree to inform staff of all other physicians and dentists I am seeing, of all prescription and non-prescription drugs I am taking, of any alcohol or street drugs I have recently been using, and whether I have become pregnant or have developed hepatitis. |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | 3. I agree to cooperate with witnessed urine drug testing whenever requested by medical staff, to confirm if I have been using any alcohol, prescription drugs, or street drugs. |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | 4. I have been informed that buprenorphine, as found in Suboxone, is a narcotic analgesic, and thus it can produce a 'high'; I know that taking Suboxone regularly can lead to physical dependence and addiction and that if I were to abruptly stop taking Suboxone after a period of regular use, I could experience symptoms of opiate withdrawal. I also understand that combining Suboxone with benzodiazepine medications (including but not limited to Valium, Klonopin, Ativan, Xanax, Librium, Serax) has been associated with severe adverse events and even death. I also understand that I should not drink alcohol with Suboxone since it could possibly interact with Suboxone to produce medical adverse events such as reduced breathing or impaired thinking. I agree not to use benzodiazepine medications or to drink alcohol while taking Suboxone. |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | 5. I have been informed that Suboxone is to be placed under the tongue for it to dissolve and be absorbed, and that it should never be injected. I have been informed that injecting Suboxone after taking Suboxone or any other opiate regularly could lead to sudden and severe opiate withdrawal. |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | 6. I have been informed that Suboxone is a powerful drug and that supplies of it must be protected from theft or unauthorized use, since persons who want to get high by using it or who want to sell it for profit may be motivated to steal my take-home prescription supplies of Suboxone. |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | 7. I have a means to store take-home prescription supplies of Suboxone safely, where it cannot be taken accidentally by children or pets, or stolen by unauthorized users. I agree that if my Suboxone pills are swallowed by anyone besides me, I will call 911 or Poison Control at 1-800-222-1222 immediately. |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | 8. I agree that if my doctor recommends that my home supplies of Suboxone should be kept in the care of a responsible member of my family or another third party, I will abide by such recommendations. |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | 9. I will be careful with my take-home prescription supplies of Suboxone, and agree that I have been informed that if I report that my supplies have been lost or stolen, my doctors will not be requested or expected to provide me with make-up supplies. This means that if I run out of my medication supplies it could result in my experiencing symptoms of opiate withdrawal. Also, I agree that if there has been a theft of my medications, I will report this to the police and will bring a copy of the police report to my next visit. |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | 10. I agree to bring my bottle of Suboxone in with me for every appointment with my doctor so that remaining supplies can be counted. |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | 11. I agree to take my Suboxone as prescribed, to not skip doses, and that I will not adjust the dose without talking with my doctor about this so that changes in orders can be properly communicated to my pharmacy. |

- Yes No 12. I agree that I will not drive a motor vehicle or use power tools or other dangerous machinery during my first days of taking Suboxone, to make sure that I can tolerate taking it without becoming sleepy or clumsy as a side-effect of taking it.
- Yes No 13. I agree that I will arrange transportation to and from the treatment facility during my first days of taking Suboxone so that I do not have to drive myself to and from the clinic or hospital
- Yes No 14. I have been informed that it can be dangerous to mix Suboxone with alcohol or another sedative drug such as Valium, Ativan, Xanax, Klonopin or any other benzodiazepine drug--so dangerous that it could result in accidental overdose, over-sedation, coma, or death. I agree to use no alcoholic beverages and to take no sedative drugs at any time while being treated with Suboxone. I have been informed that my doctor will almost certainly discontinue my buprenorphine treatment with Suboxone if I violate this agreement.
- Yes No 15. If a female, I am not pregnant, and will not attempt to become pregnant. I will not have unprotected sex while I am taking Suboxone, because of the unknown safety of buprenorphine during pregnancy. I will tell my doctor if I become pregnant so that other treatment options can be discussed with me.
- Yes No 16. I want to be in recovery from addiction to all drugs, and I have been informed that any active addiction to other drugs besides heroin and other opiates must be treated by counseling and other methods. I have been informed that buprenorphine, as found in Suboxone, is a treatment designed to treat opiate dependence, not addiction to other classes of drugs.
- Yes No 17. I agree that medication management of addiction with buprenorphine, as found in Suboxone, is only one part of the treatment of my addiction, and I agree to participate in a regular program of professional counseling while being treated with Suboxone.
- Yes No 18. I agree that professional counseling for addiction has the best results when patients also are open to support from peers who are also pursuing recovery.
- Yes No 19. I agree to participate in a regular program of peer/self-help while being treated with Suboxone.
- Yes No 20. I agree that the support of loved ones is an important part of recovery, and I agree to invite significant persons in my life to participate in my treatment.
- Yes No 21. I agree that a network of support, and communication among persons in that network, is an important part of my recovery. I will be asked for my authorization, if required (which it almost always is) to allow telephone, email, or face-to-face contact, as appropriate, between my treatment team and outside parties, including physicians, therapists, probation and parole officers, and other parties, when the staff has decided that open communication about my case, on my behalf, is necessary.
- Yes No 22. I agree that I will be open and honest with my counselors and inform staff about cravings, potential for relapse to the extent that I am aware of such, and specifically about any relapse which has occurred --before a drug test result shows it.
- Yes No 23. I have been given a copy of clinic procedures, including hours of operation, the clinic phone number, and responsibilities to me as a recipient of addiction treatment services, including buprenorphine treatment with Suboxone.

PATIENT SIGNATURE

DATE

STAFF SIGNATURE

TITLE

DATE

Appendix 7: ASAM Adult Admission Crosswalk

| Dimensions | Level I Outpatient | Level II.I Intensive Outpatient | Level II.5 Partial | III.I Clinically Managed Low Intensity Residential | III.3 Clinically Managed High-Intensity Residential Treatment | III.5 Clinically Managed Medium Intensity Residential | III.7 Medically Monitored High Intensity Residential/ Inpatient | IV. Medically Managed Intensive Inpatient |
|--|---|---|---|---|--|--|--|--|
| Dimension 1 Alcohol Intoxication and/or Withdrawal Potential | No significant withdrawal or at minimal risk for severe withdrawal. | Minimal risk of severe withdrawal. | Moderate risk of severe withdrawal. | Not at risk of withdrawal or experiencing minimal or stable withdrawal. | Not at risk of severe withdrawal. | Minimal risk of severe withdrawal at III.3 or III.5 If withdrawal is present, it meets Level III.2-D. | High risk of withdrawal, but manageable at Level III.7-D and not requiring full licensed hospital resources. | High risk of withdrawal requiring full licensed hospital services. |
| Dimension 2 Biomedical Conditions and Complications | None or very stable, or patient is receiving concurrent medical monitoring. | None or not a distraction from treatment, i.e. manageable at Level II.I. | None or not sufficient to distract from treatment, i.e. manageable at II.5. | None or stable, or patient is receiving concurrent medical monitoring. | None or stable, or patient is receiving concurrent medical monitoring. | None or stable, or patient is receiving concurrent medical monitoring. | Needs 24-hour medical monitoring but not intensive treatment. | Requires 24-hour medical and RN care. |
| Dimension 3 Emotional, Behavioral or Cognitive Conditions and Complications | None or very stable, or patient is receiving concurrent mental health monitoring. | Mild severity, with potential to distract from recovery; patient needs monitoring. | Mild to moderate severity, with potential to distract from recovery. Patient needs stabilization. | None or minimal; not distracting to recovery. | Mild to moderate severity; patient needs structure to focus on recovery. | Patient demonstrates repeated inability to control impulses or personality disorder requires structure to shape behavior. | Moderate severity; patient needs 24-hour structured setting. | Severe and unstable problems; requires 24-hour psychiatric care with concomitant addictions treatment. |
| Dimension 4 Readiness to Change | Patient is ready for recovery but needs motivating and monitoring strategies to strengthen readiness. Or, high severity in this but not other dimensions. | Variable engagement in treatment, ambivalence or lack of awareness of the substance use or mental health problem. Requires structured program several times a week to promote progress. | Poor engagement in treatment, ambivalence or lack of awareness of CD or mental health problems; requires near-daily structured program or intensive engagement. | Patient open to recovery, but needs structured environment to maintain therapeutic gains. | Little awareness and needs interventions only available at Level III.3 to engage and stay in treatment or High severity in this dimension but not in others. | Marked difficulty with or opposition to treatment with dangerous consequences, or high severity in this dimension but not in others. | High resistance and poor impulse control, despite negative consequences. Needs motivating strategies only available in a 24-hour structured setting. | Problems in this dimension do not qualify for Level IV services. |
| Dimension 5 Relapse, Continued Use or Continued Problem Potential | Able to maintain abstinence or control use and pursue recovery or motivational goals with minimal support. | Intensification of addition or mental health symptoms indicate high likelihood of continued problems/use without close monitoring and support several times weekly. | Intensification of addiction or mental health symptoms despite active participation in Level I or II.; high likelihood of relapse, continued use or problems without near-daily monitoring and support. | Patient understands relapse but needs structure to maintain therapeutic gains. | Little awareness and needs interventions available only at Level III.3 to prevent continued use, with imminent dangerous consequences due to cognitive deficits or comparable dysfunction. | No recognition of the skills needed to prevent continued use with imminent dangerous consequences. | Unable to control use, with imminently dangerous consequences despite active participation at less intensive levels of care. | Problems in this dimension do not qualify for Level IV services. |

ASAM Patient Placement Criteria, Second Edition-Revised (adapted by T. W. Mandell, MD, 2002. NOT approved by ASAM)

Appendix 8: SAMHSA Frequently Asked Questions

FOR PHYSICIANS

Can Buprenex[®], or any other medications besides Subutex[®] and Suboxone[®], be prescribed/dispensed for opioid addiction treatment in practice settings other than Opioid Treatment Programs (OTPs) (e.g., methadone clinics)?

No. At the present time Subutex[®] and Suboxone[®] are the only Schedule III, IV, or V substances to have received Food and Drug Administration approval for opioid addiction treatment. Thus, they are the only opioid medications that may be prescribed or dispensed for this indication outside the OTP setting. The approval of Subutex[®] and Suboxone[®] does not affect the status of any other medications. Buprenex[®] is not approved for treatment of opioid addiction. The status of methadone and LAAM are also unchanged. They still can be only dispensed, not prescribed, for opioid addiction, and only at Federally regulated OTPs.

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 us, 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, we 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 us, and it has been more than two months since you submitted your notification, OR if you submitted a notification and you did not receive an acknowledgment from us that it had been received, please call 1-866-BUP-CSAT (1-866-287-2728) or e-mail info@buprenorphine.samhsa.gov. Please be prepared to provide the date when you submitted your original notification and other identifying information.

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 with requests to change Locator listings. There is also a new online form for physicians to request changes to their contact information. Click on Update Physician Contact

Information and use the State Medical License Number and DEA Registration Number that we currently have on file to locate and change your information.

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. Or you may use our new online form to submit changes to your contact information. Click on Update Physician Contact Information and use the State Medical License Number and DEA Registration Number that we currently have on file to locate and change your information. 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 www.dea.gov.

With a DATA 2000 waiver, can I prescribe Subutex[®] or Suboxone[®] for opioid addiction in more than one practice location? Can I dispense Subutex[®] or Suboxone[®] from more than one location?

Physicians with DATA 2000 waivers may prescribe Subutex[®] or Suboxone[®] 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 Subutex[®] or Suboxone[®] (or any other controlled substances) only at the practice address(es) 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.

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 Subutex[®] and Suboxone[®] to treat opioid addiction only in the office-based setting?

No. Treatment of opioid addiction under the authority of a DATA 2000 waiver is not confined to the office-based setting. Physicians with DATA 2000 waivers may treat opioid addiction with Subutex[®] and Suboxone[®] 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, health department).

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 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 (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, as well as 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, DEA suggests that practitioners could 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, DEA will only review those records related to controlled substances prescribed and dispensed for maintenance or detoxification treatment for physicians maintaining separate records.

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

The physician group practice limit was eliminated by Public Law 109-56, which became effective August 2, 2005.

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

Yes. DATA 2000, as amended in December 2006, specifies that an individual physician may have a maximum of 30 patients on opioid therapy at any one time for the first year. 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.

Can an Opioid Treatment Program (i.e., methadone clinic or OTP) dispense Subutex® and Suboxone® to patients admitted to the program? If so, is there a limit on the number of patients who can be treated with Subutex® and Suboxone® 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 ORLAAM®. These regulations enable OTPs that are certified by SAMHSA to use Subutex® and Suboxone® for opioid maintenance or detoxification treatment. Follow this link to read the text of the Federal regulation (PDF, 43 kb).

The provision of opioid addiction treatment with Subutex® and Suboxone® 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 Subutex® or Suboxone® 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 Subutex® and Suboxone® 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 Subutex® and Suboxone®, 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. The completed letter can be either faxed to Ms. Ghana Giles at 202-353-1125 or mailed to Ms. Giles at: DEA, Registration Unit – OPRR, Washington, DC, 20537. In addition, OTPs can access the DEA registration Web site for more information.

Once the registration has been modified, OTPs can order Subutex® and Suboxone® directly from Reckitt Benckiser, the product manufacturer, by calling 1-877-782-6966.

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 Subutex® or Suboxone® for addiction treatment 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.

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.

May physicians in residency training programs obtain DATA waivers?

The DATA legislation does not specify that a physician in a residency training program who otherwise meets the qualifications for a DATA waiver is ineligible to apply for and obtain a waiver. Therefore, SAMHSA has granted DATA waivers to physicians in residency training who have unrestricted licenses and the appropriate DEA registration. Individual States may have laws with more restrictive rules regarding who may prescribe or dispense Schedule III narcotic drugs for detoxification or maintenance treatment.

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.

Can physicians begin immediately treating 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 only one of 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 that, first, 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). Second, the physician must check "Immediate" on the waiver. Third, 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. Pharmacists may contact the Buprenorphine Information Center if additional information is needed.

How do I increase my patient limits?

To increase your patient limits, visit <http://buprenorphine.smdi.com/federal.html>.

FOR PHARMACISTS

Are Subutex® and Suboxone® available in pharmacies?

Subutex® and Suboxone® are 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.

Do pharmacies need waivers to dispense buprenorphine?

No. Physicians are required to obtain DATA 2000 waivers to prescribe and dispense buprenorphine (Subutex® and Suboxone®) 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.

How can a pharmacist verify if a physician has a waiver to prescribe buprenorphine (Subutex® or Suboxone®) for the treatment of opioid addiction?

Effective July 25, 2005, physicians must include their DATA 2000 waiver ID number on prescriptions for opioid addiction treatment medications. The practitioner's DEA registration number and the unique identification number (DATA 2000 waiver ID number or "X" number) must be on the prescription 21 CFR 1306.05(a). The identification number is not in lieu of the DEA registration number, it is an addition. If the prescription is telephoned to the pharmacy, the pharmacist must have both of these numbers on the prescription record so the physician can provide the numbers or the pharmacist may have them on file.

The SAMHSA Buprenorphine Physician Locator Web site lists the physicians in each state who have DATA 2000 waivers. A physician listed on the site can be considered to have a valid DATA 2000 waiver. Note, however, that the site does not list every physician with a valid waiver, only those who have agreed to be listed on the site. Physicians with valid waivers may choose not to be listed on the site.

A pharmacist desiring to verify that a physician who is not listed on the site has a valid DATA 2000 waiver can contact SAMHSA by phone at 1-866-BUP-CSAT (1-866-287-2728) or by e-mail at info@buprenorphine.samhsa.gov. Pharmacists should convey their DEA registration number with these requests.

Can Subutex® or Suboxone® be prescribed for conditions other than opioid addiction, e.g., pain control?

Subutex® and Suboxone® have received FDA approval only for the treatment of opioid addiction. However, once approved, a drug product may be prescribed by a licensed physician for any use that, based on the physician's professional opinion, is deemed to be appropriate. Neither the FDA nor the Federal government regulates the practice of medicine. Any approved product may be used by a licensed practitioner for uses other than those stated in the product label. Off-label use is not illegal, but it means that the data to support that use has not been independently reviewed by the FDA. Information on FDA policy regarding off-label use of pharmaceuticals is available on the FDA Web site, www.fda.gov/cder/cancer/tour.htm, or www.fda.gov/cder/present/diamontreal/regappr/index.htm

Physicians and other practitioners who are authorized to prescribe Schedule III controlled narcotic medications under Federal and State laws are eligible and the unique identifier under the Drug Addiction Treatment Act is not required

GENERAL INFORMATION

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.

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.

Can physicians begin immediately treating 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 only one of 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 that, first, 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). Second, the physician must check “Immediate” on the waiver. Third, 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. Pharmacists may contact the Buprenorphine Information Center if additional information is needed.

Where can I get a copy of the Buprenorphine Clinical Practice Guidelines?

Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction, Treatment Improvement Protocol (TIP) 40, is available via SAMHSA’s National Clearinghouse for Alcohol and Drug Information (NCADI), or by calling 1-800-729-6686. It will also be available in the near future from the National Library of Medicine (NLM), or by calling 1-888-346-3656.

Are there exceptions when Subutex and Suboxone may 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 program 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 (72-hour) emergency exception cannot be renewed or extended. Because this is a Drug Enforcement Administration (DEA) rule, for further details consult DEA. This information may be found at www.deadiversion.usdoj.gov/drugreg/faq.htm.

What is buprenorphine's safety profile? Some sources indicate that the medications Suboxone® and Subutex® are safer and less abusable than methadone. Other information indicates that these medications have been associated with diversion, abuse, and overdose deaths, including over 100 associated deaths tied to Subutex® in France.

The Food and Drug Administration (FDA) approved the buprenorphine products Subutex® and Suboxone® in October 2002. At the same time, the Drug Enforcement Administration (DEA) placed buprenorphine in Schedule III of the Controlled Substances Act. Schedule III substances have a potential for abuse that is less than substances in Schedule II (methadone, morphine, oxycodone, hydrocodone, cocaine, etc.); however, the abuse of Schedule III substances may still lead to moderate or low physical dependence or high psychological dependence.

The use of Suboxone® and Subutex® has increased steadily since their introduction in early 2003. In 2007 alone, over 2 million prescriptions were issued to 300,000 patients.

Almost 14,000 physicians have been authorized to prescribe buprenorphine for addiction treatment. When patients and physicians were surveyed by SAMHSA about the effectiveness of buprenorphine, they reported over 80% reductions in illicit opioid use, along with significant increases in employment, and other indices of recovery.

Suboxone® and Subutex® are also diverted and abused. A recent series of articles in the Baltimore Sun in late 2007 and early 2008 describe increasing levels of diversion and abuse in Baltimore itself, Maryland, Massachusetts, and other parts of the United States. Information from SAMHSA's Drug Abuse Warning Network (DAWN) indicates an increase in buprenorphine reports from hospital emergency departments over the last 3 years. Recent publications^{1,2} indicate a period of experimentation and increased reports of abuse to substance abuse treatment centers in the United States. Buprenorphine products are diverted, misused, and injected. In some cases, this misuse has been associated with overdose deaths.

There have been many references to the French buprenorphine experience. Subutex®, the only product marketed initially in that country, was subject to misuse and many overdose deaths when co-injected with benzodiazepines. In France, however, buprenorphine remains widely available. Physicians are not subject to mandatory training/qualifications as they are in the United States, nor are French physicians subject to patient limits, as in the United States. Pharmacies in France, however, do have additional responsibilities to limit dispensing and report misuse and diversion back to prescribing physicians.

In February 2008, SAMHSA convened a special summit on buprenorphine. The meeting examined the state of buprenorphine treatment and what steps could be considered to improve office-based opioid treatment with buprenorphine and to reduce the risk of diversion and abuse. Buprenorphine is an extremely valuable treatment medication with recognized potential for abuse and diversion.

1 Cicero, T. J., Surratt, H. L., & Inciardi, J. (2007). Use and misuse of buprenorphine in the management of opioid addiction. *Journal of Opioid Management*, 3(6), 302–308.

2 Cicero, T. J., Surratt, H., Inciardi, J. A., & Munoz, A. (2007). Relationship between therapeutic use and abuse of opioid analgesics in rural, suburban, and urban locations in the United States. *Pharmacoepidemiology and Drug Safety*, 16, 827–840.

In addition to this Web site, you can visit the Food and Drug Administration's buprenorphine pages at www.fda.gov/cder/drug/infopage/subutex_suboxone/default.htm, and the manufacturer's Web site at www.suboxone.com. Additionally, you can contact the SAMHSA Buprenorphine Information Center toll-free at 1-866-BUP-CSAT (1-866-287-2728), or by e-mail at info@buprenorphine.samhsa.gov.