

**DEPARTMENT OF VERMONT HEALTH ACCESS
MANAGED CARE ENTITY
VERMONT BUPRENORPHINE PRACTICE
GUIDELINES**

December 2012

DEPARTMENT OF VERMONT HEALTH ACCESS MANAGED CARE ENTITY
VERMONT BUPRENORPHINE PRACTICE GUIDELINES

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INTRODUCTION

Purpose/Disclaimer

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* attempt to balance the need for expanding treatment capacity for opioid addicted patients with the need to prevent the inappropriate, unwise or illegal prescribing of opioids. Since the introduction of buprenorphine as an option in the treatment of opioid-dependent patients, it has become clear that buprenorphine itself has some degree of abuse potential and must be prescribed and monitored carefully.

These *Guidelines* are not intended as absolute requirements for practitioners. They should not be considered as medical advice for individual patients.

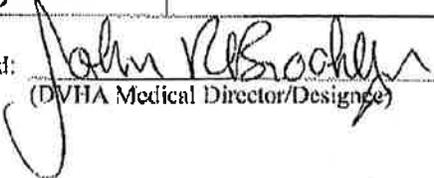
Acknowledgements

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

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OVERVIEW

Legislation

On October 17, 2000, “The Children’s Health Act of 2000” (HR 4365) was signed into federal law. Section 3502 of that act set forth “Drug Addiction Treatment Act of 2000 (DATA). This legislation provided significant changes in the oversight of the medical treatment of opioid addiction by allowing physicians to provide treatment with opioid medications in office-based settings under certain restrictions. This new treatment modality made it possible for physicians to treat patients for opioid addiction with Schedules III–V narcotic controlled substances specifically approved by the FDA for addiction treatment in physician offices instead of referring patients to specialized opioid treatment programs (OTPs), as previously required under federal law. To date, Suboxone[®] sublingual film and sublingual tablet and buprenorphine mono sublingual tablet are the only approved options for use in an office-based setting.

Physicians who consider providing office-based treatment of opioid addiction 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 under and in accordance with the 2000 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 (HHS).

The Vermont Board of Medical Practice

The Vermont Board of Medical Practice is obligated under the laws of the state of Vermont to protect the public health and safety of its citizens. It recognizes that the prevalence of addiction to heroin and other opioids, especially prescription opioids, has risen sharply in the United States, and that Vermont residents should have access to modern, appropriate and effective addiction treatment. The appropriate application of up-to-date knowledge and treatment modalities can successfully treat patients and reduce the morbidity, mortality and costs associated with opioid addiction, as well as with public health problems such as HIV, HBV, HCV and other infectious diseases, including sexually transmitted diseases.

Physician Waiver Requirements

The Drug Enforcement Administration (DEA) assigns the physician a special identification number. DEA regulations require this ID number to be included on all buprenorphine prescriptions for opioid addiction therapy, along with the physician's regular DEA registration number. Prescribing buprenorphine for opioid addiction without this ID number is a legal violation.

To qualify for a waiver under DATA 2000, a licensed physician (MD or DO) must meet any one or more of the following criteria:

- The physician holds a subspecialty board certification in addiction psychiatry from the American Board of Medical Specialties.
- The physician holds an addiction certification from the American Society of Addiction Medicine (ASAM).
- The physician holds a subspecialty board certification in addiction medicine from the American Osteopathic Association (AOA).
- The physician has, with respect to the treatment and management of opioid-addicted patients, completed eight (8) hours of training provided by one of the following organizations or other designated organizations:
 1. American Society of Addiction Medicine (ASAM).
 2. American Academy of Addiction Psychiatry (AAAP), www.aaap.org (click on *Buprenorphine*, then *Web-Based Training*).
- The physician has participated as an investigator in one or more clinical trials leading to the approval of a narcotic drug in schedule III, IV, or V for maintenance or detoxification treatment, as demonstrated by a statement submitted to the Secretary of Health and Human Services (HHS) by the sponsor of such approved drug.
- The physician has such other training or experience as the state medical licensing board (of the state in which the physician will provide maintenance or detoxification treatment) considers adequate for demonstrating the ability of the physician to treat and manage opioid-addicted patients.
- Additional qualification criteria may be added through legislative enactment.

Once a physician has completed training, the physician registers at SAMHSA (<http://buprenorphine.samhsa.gov/howto.html>) to obtain a waiver, and a certificate is sent to the physician with the special DEA license number amendment.

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

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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.

BUPRENORPHINE TREATMENT

The use of agonist treatment, either methadone or the partial agonist buprenorphine, offers physicians an opportunity to move away from abstinence-based treatments and into the use of empirically-supported therapies. Abstinence-based treatments for opioid 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 opioids. It has been found safe and effective in minimizing withdrawal symptoms, as well as blocking the effects of illicit opioids. 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.

Unlike morphine or other full agonists, buprenorphine effects are not linear with increasing doses; buprenorphine exhibits a “ceiling on its agonist effects” with respect to the respiratory system, making a lethal overdose unlikely. This property also means that buprenorphine may not be appropriate for everyone. Individuals with very high levels of opioid dependence may be better suited for methadone.

Note: Buprenorphine’s ceiling effect and elevated safety profile are diminished when it is combined with a variety of others drugs, particularly sedating drugs such as alcohol and benzodiazepines, especially if injected. In addition, 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 actions to take if a child comes in contact with any buprenorphine preparation (Boyer, McCance-Katz, & Marcus, 2009).

The physician must also have the capacity to refer patients for appropriate counseling and other services (e.g., family planning) that are usually needed in conjunction with opioid treatment. These services include but are not limited to the following:

- Different levels of chemical dependency treatment services.
 - 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 G**).
- Psychiatric consultation.
- Consultation for medical co-morbidities.
 - Medical co-morbidities that may affect use of buprenorphine:
 1. Hepatitis B, C. Buprenorphine inhibits hepatic mitochondrial function at high concentrations.

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- Buprenorphine may cause elevation of transaminases, but no documentation of fulminant liver failure due solely to buprenorphine.
- Patients must be advised not to use buprenorphine IV.

2. Renal Failure

- Few studies available.
- No significant difference in kinetics of buprenorphine in patients with renal failure vs. controls.

3. Medication Interactions

- Increased buprenorphine levels (e.g., Delavirdine® and Atazanavir®)
- Increased sedation – benzodiazepine, Xanax® (alprazolam) associated with fatalities.
- Decreased buprenorphine levels - St. John's Wort and rifampin.

Note: There are remarkably few drug interactions, although many drugs have not been studied.

- 12-Step Programs

In addition, a waived physician may provide the following:

- Observed random urinalysis screening for buprenorphine patients, either onsite or in conjunction with a certified laboratory.
- Call-backs for confirmation of remaining buprenorphine prescription supply (“pill counts”).
- Waivered physicians must provide staff and patient education/training programs (see section of *Guidelines on Provider Information and Supports, Resources for Staff and Patient Education*).

1. Staff Education

- Treating patient with substance abuse disorders
- The disorder of opioid 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

2. Patient Information

- Informed consent (see **Appendix F-III**)
- Treatment agreements (see **Appendix F-IV**)

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- Waivered physicians must provide office policies, procedures and coverage with knowledge and experience using buprenorphine.
- Waivered physicians must provide medication security and storage if dispensing buprenorphine onsite.

Preauthorization for Vermont Medicaid

Vermont Medicaid insurance requires medication precertification prior to starting a patient on buprenorphine (see **Appendix C-I** for the *DVHA Clinical Criteria for Suboxone®/Buprenorphine Prior Approval* and **Appendix C-II** for the *DVHA Buprenorphine Prior Authorization Request Form*).

Available Buprenorphine Preparations

Buprenorphine for treatment of opioid addiction is administered sublingually and is available in three formulations:

- *Buprenorphine* (generic) tablets (formerly available as brand Subutex®) – mono-therapy containing only buprenorphine.
- *Suboxone*® is available in both film and tablet and is a combination therapy, containing both buprenorphine and naloxone. Suboxone® film is the preferred dosage form for the DVHA. Naloxone has been added to help minimize diversion and intravenous abuse. Suboxone® is the recommended preparation for induction, maintenance, and, if necessary, supervised withdrawal (detoxification).

Treatment Settings

Rules were enacted by Vermont statute in 2012 that apply to physicians who treat thirty (30) or more patients with buprenorphine and to all of the Opioid Treatment Programs (OTPs). Please refer to the *Vermont Department of Health Medication Assisted Treatment for Opioid Dependence Rules* at:

http://healthvermont.gov/regs/documents/opioid_dependence_rule.pdf

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 and medical specialists. Some practitioners may be able to provide all services on their own (e.g., an addictions psychiatrist with buprenorphine training).

Opioid Treatment Programs (OTPs) may provide buprenorphine mono or Suboxone® following the same regulations that exist for methadone treatment (42 CFR Part 8: *Code of*

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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=ff035bdee995442682f5b832c9e2480b;rgn=div5;view=text;node=42%3A1.0.1.1.10;idno=42;cc=ecfr>, including a take-home schedule in which buprenorphine is dispensed from the window without giving a prescription. Only OTPs (aside from pharmacies that can dispense buprenorphine mono or Suboxone[®]) are allowed to *dispense* approved pharmacological treatments for opioid addiction. Due to the long-acting pharmacodynamic profile of buprenorphine, multiple-day dosing can occur two to three times per week. Buprenorphine is part of the OTP's DEA registration, not that of an individual physician; 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 and 100 patient limits.

Practices planning to provide buprenorphine in a clinic setting for more than 30 patients should review the Federal Guidelines for methadone clinics and consider issues such as “no drive” and “impairment” assessments.

Urine Drug Testing

Urine drug testing (UDT) encompasses a variety of assays that can be incorporated into the patient's care. It can be used to document adherence to the treatment plan (urine buprenorphine and buprenorphine metabolites) and guide both the clinician and patient through the next course of action that may need to take place. A consistent clinical approach in performing UDT can optimize the use of this type of technology for both the patient and practitioner. Observed specimen collection is recommended.

The *Vermont Department of Health Medication Assisted Therapy for Opiate Dependence Rules*, revised October 5, 2011, recommends that when UDT is initiated, each program/provider will:

- Use random drug and alcohol testing as aids in monitoring and evaluating a patient's progress in treatment.
- Ensure that treatment personnel in a medication-assisted treatment program understand the benefits and the limitations of urine toxicology testing procedures.
- Collect all urine or other toxicological specimens in the context of the patient's treatment.
- Determine the drug-testing regimen by analyzing community drug-use patterns, scientific guidelines and individual medical indications.
- Address results of toxicology testing with patients promptly. Programs must document in the patient record both the results of toxicology tests and follow-up therapeutic interventions.
- Ensure that, following the patient's admission toxicology screening, clinicians determine the frequency of toxicological testing by evaluating the clinical

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appropriateness for each patient in relation to the patient's stage in treatment. For patients receiving services from multiple providers, attention to coordinating/sharing toxicology results is expected.

- Ensure that clinicians consider confirming the results of drug screening tests with additional testing (e.g., gas chromatography–mass spectrometry). Treatment programs will establish procedures for addressing potential false-positive and false-negative urines or other toxicology test results following principles outlined in TIP 43, *Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs* (CSAT 2005, Chapter 9).
- Ensure compliance with all federal regulations related to urine toxicology results, 42 CFR § 8.12(f) *Drug abuse testing services*.

Urine Drug Testing Negative for Buprenorphine

Monitoring for the presence of buprenorphine plays an important role in the determination of possible nonadherence and/or diversion. It is very important that a negative buprenorphine test result be managed in a timely manner, including an immediate meeting between the patient and physician to discuss the result. Presence of buprenorphine but absence of buprenorphine metabolites (primarily norbuprenorphine) usually indicates the patient is not ingesting buprenorphine. It is important to note, however, that a negative reading does not necessarily mean that the beneficiary is diverting buprenorphine. Low to absent levels of urine buprenorphine metabolites in the presence of urine buprenorphine may reflect that:

- Patient did not take a recently-scheduled dose or may not be taking the full daily prescribed dose.
- Patient ingested buprenorphine only on the day of urine drug screening.
- Patient has recently ingested a large enough amount of water or other liquids to dilute the urine sample and render it invalid or the patient is using a urine sample from someone else.
- Patient is not taking buprenorphine at all.

All incidents that involve a negative result should be handled on a case by case basis and discussed with the patient. If there is continued suspicion of diversion, discontinuing buprenorphine treatment should be considered and, as deemed medically necessary, assistance provided to transition to another program, likely one that provides agonist maintenance combined with greater clinical oversight.

Pharmacy Home

The use of a single pharmacy for all prescriptions, called a *Pharmacy Home*, is required for DVHA buprenorphine patients (and is encouraged for all patients receiving buprenorphine treatment). This practice discourages the use of interacting medications and additional drugs of abuse and the pharmacist is then available as an additional partner and support resource.

Primary Therapy and Continuing Care

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, or Dialectical Behavioral Therapy. Research has shown comprehensive and sustained substance abuse treatment:

- Is as effective as treatments for other chronic conditions, including diabetes and asthma;
- Can help individuals reduce or stop using illegal or dangerous drugs, thereby greatly improving their functioning in the family, at work, and in society.

Research also has demonstrated that there are effective approaches to substance abuse treatment that can help people achieve long-term success. Some key points to consider are:

- Treatment should be readily available to individuals who need it without undue delays and especially immediately available after opioid detoxification in a therapeutic treatment setting.
- Individuals need to be engaged in treatment for an adequate period of time.
- Recovery is a long-term effort, often requiring multiple episodes of treatment.
- Addiction often co-occurs with multiple disorders and the treatment plan must take those into consideration.
- Treatment programs/providers work better if they are individually tailored to the patient's needs. One size does not fit all and no single type of treatment is appropriate for everyone.
- Treatment must be reassessed periodically and adjusted as needed.

Provider Education and Training Requirements

Comprehensive education and training requirements must be established, including relevant aspects of behavioral therapy and pharmacological treatment, for physicians, pharmacists, and certified or licensed alcohol and drug abuse/behavioral health counselors affiliated with an approved treatment program. (For technical assistance identifying specific training options, please contact the Vermont Department of Health, Division of Alcohol and Drug Abuse Programs.)

Buprenorphine During Pregnancy and Breast-Feeding

Although no buprenorphine preparations have been FDA approved for use during pregnancy, buprenorphine-mono has been used for medication assisted therapy (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

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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 also may contact John Brooklyn, MD, at the Howard Center Chittenden Clinic, c/o University Health Care, 1 South Prospect Street, Burlington, VT 05401, 802-488-6452 or 800-413-2272. It is expected that once delivery has occurred the mother will be transitioned back to Suboxone®.

Research demonstrates that buprenorphine has been used successfully in breastfeeding mothers. In situations where the baby is showing signs of opioid withdrawal and is being actively treated with either methadone or morphine, buprenorphine-mono may be prescribed. The naloxone contained in *Suboxone*® is negligibly absorbed when administered sublingually and therefore significant amounts are unlikely to reach the baby; however, prescribing buprenorphine-mono removes any concern of confounding factors in assessment of the baby's withdrawal symptoms.

Adolescent Treatment Services (Under 18)

42 CFR 8.12, Federal Opiate Treatment standards in OTPs, requires that persons under the age of 18 who are receiving maintenance treatment have had two documented unsuccessful attempts at short term detoxification or drug free treatment within a 12-month period to be eligible. No person under 18 years of age may be admitted to maintenance treatment unless a parent, legal guardian, or responsible adult designated by the relevant state authority consents in writing to such treatment.

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.

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However, the Department of Corrections has reported that buprenorphine is one of the 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. Furthermore, many patients in treatment with buprenorphine or *Suboxone*® “snort” or inject the tablets or film to produce a drug “high” despite the addition of naloxone to *Suboxone*®.

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 patient review through the Vermont Prescription Monitoring Program (VPMS) to monitor for opioid prescriptions or other medication that may be abused.
- Random toxicology screens with minimal advance notice.
- Film/tablet call backs (for counting), also ideally administered randomly with minimal prior notice.

Bubble packing of prescriptions is no longer recommended.

Vermont Prescription Monitoring Program

In our current health care system, patients often visit multiple providers and can receive multiple prescriptions in an uncoordinated fashion. Reports continue to indicate that, at both the state and national levels, the abuse of pharmaceutical drugs is the fastest growing area of substance abuse.

The Vermont Prescription Monitoring Program (VPMS) is a web-based application designed for both prescribers and pharmacists to use as a tool to provide better care for the patient and reduce the danger of abuse, diversion or overdose. VPMS collects prescription data for schedule II – IV drugs dispensed by pharmacies licensed by Vermont. VPMS tracks the prescribing and dispensing of controlled substances with the goal of providing timely and useful information for providers to assist them in the proper treatment of their patients. Please note that many pharmacies in bordering states are not licensed in Vermont and so prescription activity in border towns may not be reflected in the VPMS.

PHASES OF BUPRENORPHINE TREATMENT

Determining a Patient's Motivation and Readiness (Stages of Change)

The ability to understand a patient's motivation to engage in treatment is very important during the initial assessment phase. Prochaska and DiClemente have developed the "Stages of Change" model that addresses an individual's readiness. There are five stages, as follows:

- *Pre-contemplation:* Individual shows no evidence of intent to change or is unaware the behavior is a problem.
- *Contemplation:* Individual is considering changing his or her behavior.
- *Preparation:* Individual is ready to change in both attitude and behavior.
- *Action:* The change in behavior has begun.
- *Maintenance:* Individual now strengthens and sustains the changes made.

Patients may be at different stages of change depending on the substance being discussed. For example, the patient may want to discontinue the use of narcotics but may not feel that nicotine or marijuana use is problematic for them. This variation will be important in formulating treatment strategies/planning based on the patient's perception of the issues.

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 a patient's appropriateness for office-based treatment), and include the following:

1. Medical history with attention to liver, renal, cardiac status, current prescribed and non-prescribed medication and psychiatric history with attention to current compliance with all prescribed medications.
2. Psychiatric history with attention to treatment adherence, including medications and counseling.
3. Substance abuse and treatment history to identify whether patient was ever on buprenorphine, methadone, or other medications for opioid addiction and to ensure patient meets criteria for opioid dependence and is not currently on methadone (see **Appendix A, 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. Complete physical exam including a mental status exam.

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6. Lab screening for ALT, AST, creatinine, Hepatitis B and C, HIV, gonorrhea, Chlamydia, syphilis, TB.
7. Urine screen (collected under observation) with attention to opioids and other illicit drugs, including methadone, buprenorphine, and benzodiazepines.
8. If urine specimen is negative for opioids (which may occur with synthetic opioids), 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 D**). The urine specimen can also be sent to an outside laboratory for more sensitive measures for detecting commonly-abused synthetic opioids.
9. In some cases, dependence may be confirmed 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®) should not be used due to the protracted withdrawal syndrome it causes.
10. Sometimes a patient previously detoxed from opioids will present for treatment due to high risk of returning to opioid use. Examples include individuals recently released from prison or other restrictive environments who may not demonstrate evidence of withdrawal but still may be appropriate for treatment with buprenorphine. Physicians are encouraged to consult with a substance abuse counselor or addiction specialist in these cases.
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).

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/Contract* (see **Appendices F-II, F-III** and **F-IV** for sample *Patient Information, Consent for Treatment, and Buprenorphine Treatment Agreement* forms). One copy goes in the patient chart and one goes to the patient. A copy of the contract also should be sent to the pharmacy.

Release of Information forms should be completed for the substance abuse counselor and any other individuals or agencies, such as the psychiatrist, VNA, Family Services Division of the Department for Children and Families, referring treatment center, etc. Signed releases should be placed in the patient chart (see **Appendix F-I** for sample *Release of Information* forms).

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

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Appendices B-I and B-II for criteria and *Treatment Needs Questionnaire* for assessing candidacy). Some factors to consider include the following:

- High level of dependence on opioids, benzodiazepines, alcohol, or other CNS depressants;
- Significant particularly active psychiatric co-morbidity;
- Active or chronic suicidal or homicidal ideation or attempts;
- Multiple previous treatments and relapses during opioid agonist maintenance;
- Non-response to buprenorphine in the past;
- High relapse risk;
- Pregnancy;
- Current medical conditions that could complicate treatment;
- Severe psychosocial instability (e.g., poor support systems, unstable housing);
- Patient needs cannot be addressed with existing office-based resources.

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** or other long-acting opioids as buprenorphine may precipitate withdrawal if it too closely follows long-acting opioids. (If patient is on methadone, see below protocol for long-acting opioids.)
5. Day 1: Give the patient a prescription for #2 2 mg Suboxone® film/tablets.
6. Patient takes the prescription to the pharmacy and returns to the office with the medication.
7. Patient takes the film and lets it dissolve under the tongue for 5 minutes (or 10 minutes if using the tablet) with no talking, drinking, or swallowing.
8. Target buprenorphine dose range should be 6 mg to 12 mg per day, with a recommended maximum of 16mg daily.
9. If more than an 8 mg dose is needed, gradually increase the dose in 2mg increments over the next several days.

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10. The patient's condition before the next scheduled dosing time is one of the best ways to assess adequacy of the dose. (Refer to **Appendix E**, *Clinical Opiate Withdrawal Scale (COWS)*, for assessing withdrawal symptoms before the first dose is given and before each subsequent dose 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:
 - 2 mg sublingual buprenorphine.
 - Monitor for 2+ hours and consider 2 mg 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: 2 mg sublingual Suboxone® (combination therapy) with direct observation after 5 minutes for film (ten minutes for tablet) to confirm that the medication is dissolved.
3. Monitor the patient in the office for up to 2 hours to ensure no vomiting and/or intolerance of the dose.
4. Send patient home with the additional 2 mg dose and re-dose 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 patient shows signs of withdrawal based on *CINA Scale* and/or *Clinical Opiate Withdrawal Scale*, prescribe #4 2 mg film/tablets, have patient go to pharmacy, return to office with medication and take 3 film/tablets in front of nurse; wait 5 minutes and then send home and re-dose 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 film for 3 days and send 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 is 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.

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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 recommended dose: 16 mg.

NOTE: If a patient has an insurance co-pay, consider writing a prescription for #16 film/tablets of 2 mg for a minimum of 4 days of induction. The patient can bring the film/tablets 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 CAN HELP MINIMIZE RISK OF POTENTIAL DIVERSION LATER ON.

Specific recommendations for patients dependent on LONG ACTING opioids:

1. Doses of methadone should be decreased to a stable state of 30 mg 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.

Sublingual Administration

All patients should in general be instructed on the proper procedure for taking buprenorphine when they first enter treatment. After each administration, nursing staff should visually inspect the patient's mouth to ensure the tablet/film has been fully dissolved. The same manner is followed each time.

- Buprenorphine tablet or film is placed under tongue.
- Patient should not eat, drink, chew gum, suck on candy or talk for at least five minutes in order to ensure adequate absorption thru the buccal mucosa into the blood stream.
- Observation by the nursing staff is necessary to ensure that the patient follows these procedures.

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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.

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 their treatment status.
3. Write 7 days' worth of medication at a time for 2 months.

Maintenance and Follow Up

1. Once patient has remained compliant with counseling and physician visits, has not had any mishaps with the Suboxone®, and feels ready to do so, the physician can extend the prescriptions to 14 days for the next 2 months.
2. 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 an OTP.
3. After a period of time that varies with each patient but should reflect compliance with treatment, a prescription for 14 days may be written. Film or pill counts may be a useful monitoring tool at this point.
4. Urine drug testing is now available for determining the presence of the buprenorphine metabolite. Presence of buprenorphine but absence of buprenorphine metabolites (primarily norbuprenorphine) usually indicates the patient is not ingesting buprenorphine.

Dosing Frequency

Buprenorphine is generally recommended to be administered once daily. Dosing multiple times per day should not be necessary to adequately treat withdrawal symptoms. Patients who feel the need for multiple times per day buprenorphine are most probably in need of a potential dose increase as well as more intense counseling to deal with “cravings.”

Tapering Patients off a Stable Buprenorphine Dose

There may be a subset of patients who desire to discontinue buprenorphine maintenance. There is scientific evidence that some patients, particularly the most stable opioid-dependent patients, may succeed with a brief but carefully-crafted outpatient buprenorphine taper. However, the scientific evidence suggests that duration or speed of dose reductions during opioid detoxification significantly affects treatment outcome and are consistent with prior studies showing more favorable outcomes with longer- vs. briefer-duration opioid tapers (Amass et al., 1994; Dunn, Sigmon et al., 2011; Fudala et al., 1990; Gossop et al., 1989;

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Kosten & Kleber, 1988; Nosyk et al., 2012; Senay et al., 1977; Sigmon et al., 2012; Sigmon et al., submitted). A 4-week taper duration at present has most of the support in the scientific literature. The below table *Suboxone® Taper Regimen* provides one example of a dose-tapering schedule for a 4-week buprenorphine detoxification.

Also worth noting is that, while a meaningful subset of opioid-dependent patients may do well with a carefully-implemented buprenorphine taper, it is also the case that ongoing support with antagonist therapy and other psychosocial services will likely be important for good long-term outcomes. As one example, naltrexone can help prevent relapse to opioids post-taper and should be considered following detoxification. Additionally, the recent development of sustained-release naltrexone formulations may provide an additional way to provide ongoing pharmacological support in the weeks and months following opioid taper (Sigmon et al., 2012).

SUBOXONE® TAPER REGIMEN

(*dose noted is the dose of buprenorphine)

| | 28-Day Taper Period | | |
|-------------------------|------------------------|-------|-------|
| *Stabilization Dose: | 8 mg | 16 mg | 24 mg |
| Study Day | | | |
| 1 | 8 | 16 | 24 |
| 2 | 8 | 16 | 24 |
| 3 | 6 | 12 | 20 |
| 4 | 6 | 12 | 20 |
| 5 | 6 | 12 | 20 |
| 6 | 6 | 10 | 16 |
| 7 | 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 |

Ling, W., et al., Buprenorphine Tapering Schedule and Illicit Opioid Use, *Addiction*, 104, 2009.

Detoxification

Rapid detox: Three days or less

- Low doses of buprenorphine given 2-3 times daily.
- More effective in suppressing withdrawal than clonidine.

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- Long term efficacy not well documented.
- Not recommended due to potential for adverse events and 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 opioids 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 (Sigmon et al., 2012).

GUIDE FOR DOSE TARGETS

| <u>Buprenorphine</u> <u>Doses</u> | <u>Oxycodone</u> | <u>Morphine</u> | <u>Heroin</u> | <u>Methadone</u> |
|--|-------------------------|------------------------|----------------------|-------------------------|
| 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 |

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 scenario. Although there are some published articles, no approach has been rigorously tested. Buprenorphine blocks opioid receptors, making them unavailable for further opioid analgesic effects. The dose of buprenorphine predicts how many of the receptors are blocked; generally, any buprenorphine dose above 10 mg will block opioid 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

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remaining amount of buprenorphine is converted to short acting opiates. (Refer to the above *Guide for Dose Targets* 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 four hours for three 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 four times a day for three days would be provided to make up the opioid debt from the 8 mg of buprenorphine that has been stopped. In addition, post operatively the patient would take 10 mg of oxycodone every four hours for the three post operative days.

After the end of the three 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-opioid 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.

For some patients who require analgesia short term for an intervening illness, procedure, or surgery, increasing the buprenorphine dose for several days may be an alternative to prescribing short acting opioids, especially for patients who have problems using short term opioids or have significant risks for diversion.

Special Note: Research comparing opioid dependent women and non-opioid dependent women for treatment of pain during labor and delivery indicates that women maintained on either buprenorphine or methadone have similar analgesic needs as non-opioid dependent women do during labor. However, opioid dependent women maintained on either medication experience greater post partum pain and also require more opioid analgesic following cesarean delivery (see Meyer, M., Paranya, G., Norris, A.K., & Howard, D., 2010, and Meyer, M., Wagner, K., Benvenuto, A., Plante, D., & Howard, D., 2007).

PROVIDER INFORMATION AND SUPPORTS

Physician Clinical Support System (PCSS-B)

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

SAMHSA Websites

Substance Abuse and Mental Health Services Administration (SAMHSA)—www.samhsa.gov and <http://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) — <http://www.samhsa.gov/about/csat.aspx> . 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.

Staff and Patient Education Resources

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.

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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.

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 .

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 .

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APPENDIX A

DSM-IV DIAGNOSIS OF OPIOID 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.

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APPENDIX B-I

TEN FACTOR OFFICE-BASED CRITERIA CHECK LIST

In general, ten (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 | yes | no |
|--|-----|----|
| 1. Does the patient have a <i>diagnosis of opioid dependence</i> ? | | |
| 2. Is the patient <i>interested in office-based buprenorphine treatment</i> ? | | |
| 3. Is the patient <i>aware of the other treatment options</i> ? | | |
| 4. Does the patient understand the <i>risks and benefits</i> of buprenorphine treatment and that it will address some aspects of the substance abuse, but not all aspects? | | |
| 5. Is the patient expected to be <i>reasonably compliant</i> ? | | |
| 6. Is the patient expected to <i>follow safety procedures</i> ? | | |
| 7. Is the patient <i>psychiatrically stable</i> ? | | |
| 8. Are the <i>psychosocial circumstances</i> of the patient stable and supportive? | | |
| 9. Are <i>resources available in the office</i> 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? | | |
| 10. Is the patient <i>taking other medications that may interact</i> with buprenorphine, such as naltrexone, benzodiazepines, or other sedative-hypnotics? | | |

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

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APPENDIX B-II
TREATMENT NEEDS QUESTIONNAIRE

The following questionnaire will help in considering whether the candidate needs a service in either a lower-intensity/office-based setting or a higher-intensity/clinic-based treatment setting. The questions assume the person *is* opioid dependent.

Patient Name/ID: _____

Date: _____

Staff Name/ID: _____

| Ask patient each question, <u>circle</u> answer for each: | | |
|---|-----|----|
| Questions | Yes | No |
| 1. Are you employed? | 0 | 1 |
| 2. Do you have 2 or more <u>close</u> friends or family members who <u>do not</u> use alcohol or drugs? | 0 | 1 |
| 3. Do you have a partner that uses drugs or alcohol? | 1 | 0 |
| 4. Is your housing stable? | 0 | 1 |
| 5. Do you have legal issues (e.g., charges pending, probation/parole, etc.)? | 1 | 0 |
| 6. Have you ever been charged (not necessarily convicted) with drug dealing? | 1 | 0 |
| 7. Are you on probation? | 1 | 0 |
| 8. Do you have any psychiatric problems (e.g., major depression, bipolar, severe anxiety, PTSD, schizophrenia, personality subtype of antisocial, borderline, or sociopathy)? | 1 | 0 |
| 9. Do you have a chronic pain issue that needs treatment? | 2 | 0 |
| 10. Do you have access to reliable transportation? | 0 | 1 |
| 11. Do you have a reliable phone number? | 0 | 1 |
| 12. If you have ever been on medication assisted treatment (e.g., methadone, buprenorphine) before, were you successful? | 0 | 2 |
| 13. Do you have a problem with alcohol, have you ever been told that you have a problem with alcohol, or have you ever gotten a DWI/DUI? | 2 | 0 |
| 14. Do you ever use cocaine, even occasionally? | 2 | 0 |
| 15. Do you ever use benzodiazepines, even occasionally? | 2 | 0 |
| 16. Are you motivated for treatment? | 0 | 1 |
| 17. Are you currently going to any counseling, AA, or NA? | 0 | 1 |
| 18. Do you have any significant medical problems (e.g., hepatitis, HIV, diabetes)? | 1 | 0 |
| 19. Have you ever used a drug intravenously (IV)? | 2 | 0 |
| 20. Did you receive a high school diploma (e.g., did you complete at least 12 years of education)? | 0 | 1 |
| Calculate total points. | | |

Provided by John R. Brooklyn, MD, and Stacey C. Sigmon, PhD, 2012.

Scoring Key: (Total possible points = 26)

Score: 0-13 - Consider as a candidate for lower-intensity/office-based treatment, with movement toward more intensive treatment if patient destabilizes.

Score: 14-26 - Consider as candidate for higher-intensity/clinic-based treatment, followed by a potential reduction in intensity contingent upon documented treatment success.

APPENDIX C-I

**DVHA CLINICAL CRITERIA FOR SUBOXONE®/BUPRENORPHINE
PRIOR APPROVAL**

Opiate Dependency: Suboxone®, Buprenorphine

- Diagnosis of opiate dependence confirmed (will not be approved for alleviation of pain).

AND

- Prescriber has a DATA 2000 waiver ID number (“X-DEA license”) in order to prescribe.

AND

- A *Pharmacy Home* for all prescriptions has been selected (pharmacy located or licensed in VT).

AND

- Patients new to Suboxone® (no claims in last 60 days) will be prescribed Suboxone® film (not SL tablet).

AND

- Patients new to Suboxone® (no claims in last 60 days) will be subject to a quantity limit of 16 mg/day.

AND

- Requests for Suboxone® SL tablet after documented intolerance of Suboxone® film must include a completed MedWatch form that will be submitted by DVHA to the FDA.

AND

- If buprenorphine (formerly Subutex®) is being requested:
 - Patient is either pregnant and history (copy of positive pregnancy test, results of pelvic ultrasound confirm pregnancy, positive findings on physical exam, other imaging test confirming pregnancy) has been submitted [duration of PA will be one (1) month post anticipated delivery date].

OR

- Patient is breastfeeding a methadone or morphine dependent baby and history from the neonatologist or pediatrician has been submitted.

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APPENDIX C-II



Department of Vermont Health Access
312 Hurricane Lane, Suite 201
Williston, Vermont 05495

Agency of Human Services

~BUPRENORPHINE ~
Prior Authorization Request Form

Vermont Medicaid has established criteria for prior authorization of buprenorphine/naloxone or buprenorphine mono. These criteria are based on concerns about safety and the potential for abuse and diversion. All requests must be submitted using this fax form.

Submit request via Fax (only): 1-866-767-2649

Prescribing physician:

Name: _____
Phone #: _____
Fax #: _____
Address: _____

Beneficiary:

Name: _____
Medicaid ID #: _____
Date of Birth: _____ Sex: _____

Contact Person at Office: _____

► Please 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 |
| Has the prescriber queried the VPMS (Vermont Prescription Monitoring System) to review patient's scheduled II-IV medication history? | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not signed up |
| A "Pharmacy Home" for ALL prescriptions has been selected AND discussed with patient? (Pharmacy must be located/licensed in VT) Pharmacy Name: _____ Pharmacy Phone #: _____ | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| Has patient filled a Suboxone RX in last 60 days | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know |
| Request is for the following medication: Sublingual FILM | <input type="checkbox"/> Suboxone® (buprenorphine/naloxone) |
| Request is for the following medication: Sublingual TABLET | <input type="checkbox"/> Suboxone® (buprenorphine/naloxone) <input type="checkbox"/> Buprenorphine (formerly Subutex®) |
| Anticipated maintenance dose/frequency: (target dose of no more than 16 mg/day) (maximum 14 day supply per prescription fill) | |
| Dose: _____ | Frequency: _____ (recommended once daily) |

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|---|--|
| <p>If this request is for Buprenorphine (formerly Subutex[®]), please answer the following questions:</p> <p>Is the member pregnant? (please provide positive pregnancy test, results of pelvic ultrasound confirm pregnancy, positive findings on physical exam, other imaging test confirming pregnancy) has been submitted (duration of PA will be one month post anticipated delivery date)</p> <p>If yes, anticipated date of delivery: _____</p> <p>Is the member breastfeeding a methadone or morphine dependent baby? (please provide history from neonatologist or pediatrician)</p> | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| <p>Would you have referred your patient to a methadone clinic if this option was conveniently located and available?</p> | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| <p>Additional clinical information to support PA request:</p> | |

Prescriber Signature: _____ **(stamps not acceptable)**

Prescriber X-DEA License #: _____ **Date of request:** _____

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APPENDIX D

**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 | FINDINGS | POINTS |
|--|---|---------------|
| <i>Parameters based on Questions and Observation:</i> | | |
| (1) Abdominal changes: Do you have any pains in your abdomen? | No abdominal complaints, normal bowel sound. Reports waves of cramps abdominal pain. Cramp abdominal pain, diarrhea, active bowel sounds. | 0 1 2 |
| (2) Changes in temperature: Do you feel hot or cold? | None reported. Reports feeling cold, hands cold and clammy to touch. Uncontrolled shivering. | 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 |
| <i>Parameters based on Observation Alone:</i> | | |
| (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 |

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|--------------------|--|---------|
| (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., & Lei, H., (1988). Assessment of opioid dependence with naloxone. *British Journal of Addiction*, 83(2):193–201, 1988. Reprinted with permission from Blackwell Publishing, Ltd.

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APPENDIX E

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 5 unable to sit still for more than a few seconds | | | |
| Pupil Size: <i>Observation during assessment.</i> 0 pupils pinned or normal size for room light 1 pupils possibly larger than normal for room light 2 pupils moderately dilated 5 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 | | | |

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| | | | |
|---|--|--|--|
| 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 Moderate Moderately Severe Severe Withdrawal
 5-12 13-24 25-36 More than 36

APPENDIX F- I

PATIENT CONSENT FOR RELEASE OF INFORMATION

-- Sample 1 --

I, _____, born on _____
(patient name) (patient birth date)

SSN _____, authorize _____ to
(patient social security #) (clinic or 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.

I understand that my records are protected under the Federal regulations and cannot be disclosed without my written consent unless otherwise provided for in the regulations. I also understand that I may revoke this consent at any time except to the extent that action has been taken in reliance on it.

Signature of patient _____ Dated _____

Signature of witness _____ Dated _____

**ATTENTION RECIPIENT:
Notice Prohibiting Redisclosure**

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

APPENDIX F- I

RELEASE OF INFORMATION FORM

-- Sample 2 --

a) *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.

(b) *Sample consent form.* The following form complies with paragraph (a) of this section, but other elements may be added.

1. I (name of patient) 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):

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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)
(Approved by the Office of Management and Budget under control number 0930-0099)

APPENDIX F-II

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) film has been developed for treatment of addiction.

Buprenorphine/naloxone (Suboxone®) film also contains 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. However, it is important to note that this safety is lost when combined with certain other medications. These are some of the unusual qualities of this medication that 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?

In order to 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 opioid 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

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(Suboxone) to detoxify from heroin or prescription narcotics, instead of other detoxification treatments (methadone, clonidine, etc). Despite the effectiveness of buprenorphine detoxification, all opioid-dependent patients are at high risk for relapse and should consider the benefits of maintenance treatment.

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 film or 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 alcohol excessively, or take any of these sedating drugs, either by prescription or on your own, buprenorphine may not be a good treatment for you.

APPENDIX F-III

PATIENT CONSENT FOR BUPRENORPHINE TREATMENT

-- Sample --

Consent for Treatment with Suboxone® (Buprenorphine/Naloxone)

Suboxone® (a film or 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 opioids – any opioids - **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 opioid 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 can experience drowsiness until the correct dose is determined for them.

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 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 opioid blocker (naloxone) in a 4 to 1 ratio (4 mg of buprenorphine to 1 mg naloxone). **Buprenorphine will maintain physical dependence on opioids**, and if you discontinue it suddenly, you will likely experience withdrawal. If you are not already dependent, you should not take buprenorphine, as it could eventually cause physical dependence.

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Buprenorphine/naloxone film or 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 film or 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 60 mg 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 methadone dose has to be tapered until you have been **below 30 mg 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.

Signed _____ Date _____

Witness _____ Date _____

APPENDIX F-IV

BUPRENORPHINE TREATMENT AGREEMENT

-- Sample 1 --

Agreement for Treatment with Buprenorphine/Naloxone

Patient Name: _____

I am requesting that my doctor provide buprenorphine/naloxone treatment for opioid
_____ addiction. I freely and voluntarily agree to accept this treatment
_____ list drug(s)
agreement, as follows:

1. I agree to keep, and be on time to, all my scheduled appointments with the doctor and his/her assistant.
2. I agree to conduct myself in a courteous manner in the physician's or clinic's office.
3. I agree to pay all office fees for this treatment at the time of my visits. I will be given a receipt that I can use to get reimbursement from my insurance company if this treatment is a covered service. I understand that this medication will cost between \$5 to \$10 a day just for medication and that the office visits are a separate charge.
4. I agree not to arrive at the office intoxicated or under the influence of drugs. If I do, the staff will not see me and I will not be given any medication until my next scheduled appointment.
5. I agree not to sell, share, or give any of my medication to another person. I understand that such mishandling of my medication is a serious violation of this agreement and would result in my treatment being terminated without recourse for appeal.
6. I understand that the use of buprenorphine/naloxone (Suboxone®) by someone who is addicted to opioids could cause them to experience severe withdrawal.
7. I agree not to deal, steal, or conduct any other illegal or disruptive activities in or in the vicinity of the doctor's office.
8. I agree that my medication (or prescriptions) can only be given to me at my regular office visits. Any missed office visits will result in my not being able to get medication until the next scheduled visit.

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9. I agree that the medication I receive is my responsibility and that I will keep it in a safe, secure place. I agree that lost medication will not be replaced regardless of the reasons for such loss.

10. I agree not to obtain medications from any physicians, pharmacists, or other sources without informing my treating physician. I understand that mixing buprenorphine/naloxone (Suboxone®) with other medications, especially benzodiazepines, such as Valium® (diazepam), Xanax® (alprazolam), Librium® (chlordiazepoxide), Ativan® (lorazepam), and/or other drugs of abuse including alcohol, can be dangerous. I also understand that a number of deaths have been reported in persons mixing buprenorphine with benzodiazepines. I also understand that I should not drink alcohol while taking this medication as the combination could produce excessive sedation or impaired thinking or other medically dangerous events.

11. I agree to take my medication as the doctor and his/her assistant has instructed, and not to alter the way I take my medication without first consulting the doctor.

12. I understand that medication alone is not sufficient treatment for my disease and I agree to participate in the recommended patient education and relapse prevention program, to assist me in my treatment.

13. I understand that my buprenorphine/naloxone (Suboxone®) treatment may be discontinued and I may be discharged from the clinic if I violate this agreement.

14. I understand that there are alternatives to buprenorphine/naloxone (Suboxone®) treatment for opioid addiction including:
 - medical withdrawal and drug-free treatment
 - naltrexone treatment
 - methadone treatment

My doctor will discuss these with me and provide a referral if I request this.

Patient's Signature

Date

Witness Signature

Date

APPENDIX F-IV

BUPRENORPHINE TREATMENT AGREEMENT

-- Sample 2 --

Agreement for Treatment with Suboxone®

| | | |
|------------------------------|-----------------------------|--|
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | I understand that Suboxone® is a medication to treat opioid addiction (for example: heroin, prescription opiates such as oxycodone, hydrocodone, methadone). Suboxone® contains the opioid narcotic analgesic medication buprenorphine, and the opioid antagonist drug naloxone, in a 4 to1 (buprenorphine to naloxone) ratio. The naloxone is present in the film or tablet to prevent diversion to injected abuse of this medication. Injection of Suboxone® by a person who is addicted to opioids will produce severe 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. |

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| | | |
|------------------------------|-----------------------------|--|
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <p>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®.</p> |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <p>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 opioid withdrawal.</p> |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <p>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®.</p> |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <p>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.</p> |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <p>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.</p> |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <p>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.</p> |

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| | | |
|------------------------------|-----------------------------|--|
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | 10. I agree to bring my supply 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. |
| <input type="checkbox"/> Yes | <input type="checkbox"/> 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. |
| <input type="checkbox"/> Yes | <input type="checkbox"/> 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. |
| <input type="checkbox"/> Yes | <input type="checkbox"/> 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. |
| <input type="checkbox"/> Yes | <input type="checkbox"/> 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. |
| <input type="checkbox"/> Yes | <input type="checkbox"/> 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 opioid dependence, not addiction to other classes of drugs. |
| <input type="checkbox"/> Yes | <input type="checkbox"/> 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®. |
| <input type="checkbox"/> Yes | <input type="checkbox"/> 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. |

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| | | |
|------------------------------|-----------------------------|--|
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | 19. I agree to participate in a regular program of peer/self-help while being treated with Suboxone®. |
| <input type="checkbox"/> Yes | <input type="checkbox"/> 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. |
| <input type="checkbox"/> Yes | <input type="checkbox"/> 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. |
| <input type="checkbox"/> Yes | <input type="checkbox"/> 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 <i>has</i> occurred -- <i>before</i> a drug test result shows it. |
| <input type="checkbox"/> Yes | <input type="checkbox"/> 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: _____

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APPENDIX G

ASAM ADULT ADMISSION CROSSWALK

| Dimensions | Level I Outpatient | Level III.1 Intensive Outpatient | Level II.5 Partial | III.1 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.1. | 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. |

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| Dimensions (continued) | Level I Outpatient (continued) | Level II.I Intensive Outpatient (continued) | Level II.5 Partial (continued) | III.1 Clinically Managed Low Intensity Residential (continued) | III.3 Clinically Managed Medium Intensity Residential (continued) | III.5 Clinically Managed High Intensity Residential (continued) | III.7 Medically Monitored Intensive Inpatient (continued) | IV Medically Managed Intensive Inpatient (continued) |
|---|--|--|--|---|--|---|--|--|
| 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 addiction 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.I; 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 imminently 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. |
| Dimension 6 Recovery Environment | Recovery environment is supportive and/or patient has skills to cope. | Recovery environment is not supportive but patient can cope given structure and supports. | Recovery environment not supportive but with structure, support and relief from home, patient can cope. | Environment is dangerous but recovery is achievable if this level is available. | Environment is dangerous and patient needs 24 hour structure to learn to cope. | Environment is dangerous and patient lacks skills to cope outside of a highly structured 24 hour setting. | Environment is dangerous and patient lacks skills to cope outside of a highly structured 24 hour setting. | Problems in this dimension do not qualify for Level IV services. |
| <i>ASAM Patient Placement Criteria, Second Edition-Revised (adapted by T. W. Mandell, MD, 2002. NOT approved by ASAM)</i> | | | | | | | | |