

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

August 2015

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INTRODUCTION

Guideline Purpose and Limitations

The Department of Vermont Health Access (DVHA) develops clinical practice guidelines to support the practice of evidence-based medicine. The guidelines are developed from recognized sources, supported by a synthesis of current literature and clinical consensus and are updated biannually. Guidelines may not apply to every patient or clinical situation; some divergence from guidelines is expected. Guidelines are not inflexible protocols for patient care and are not intended to replace the professional judgment of a provider. In addition, guidelines do not determine insurance coverage or health care services or products. Coverage decisions are based on member eligibility, contractual benefits and determination of medical necessity.

Acknowledgements

The *Vermont Buprenorphine Clinical 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

Opioid Addiction and Medication Assisted Treatment

Substance addiction includes a set of cognitive, behavioral and physiological symptoms in which a person continues to use the substance despite significant substance-related problems. The repeated use of opioids results in patterns of tolerance (requiring increasing doses of the substance to achieve effects) and withdrawal (a set of physiological symptoms) for most people. However, in addition to tolerance and withdrawal, individuals with addiction also exhibit compulsive drug taking due to intense feelings of “craving” for the substance. Opioid addiction includes compulsive, prolonged self-administration of opioid substances that are not for a legitimate medical purpose and are used in doses that are greatly in excess of the amount needed for pain relief.

Opioid addiction is a chronic, relapsing illness diagnosed based on the presence of at least two of eleven criteria over a 12-month period (see Appendix B1). Medication Assisted Treatment (MAT) is defined by the Center for Substance Abuse Treatment (CSAT) as “the use of medications, in combination with counseling and behavioral therapies, to provide a whole patient approach to the treatment of substance use disorders.”

In 2006, prescription opiates, including OxyContin, surpassed heroin as the primary source of opioid addiction for people receiving treatment at programs funded by the Division of Alcohol and Drug Abuse Programs (ADAP) at the Vermont Department of Health (VDH). In 2011, Vermont had the second highest per capita rate of all states for admissions to treatment for prescription opiates. The majority (57%) of these admissions were young people 20 to 29 years old. However, heroin use increased by more than 35% in 2012. Furthermore, the number of people seeking and in treatment for addiction to other opiates has continued to increase each year. (Report to the Vermont Legislature, Opiate Addiction Treatment Programs, in accordance with Act 75, 2013, Section 15a; <http://www.leg.state.vt.us/reports/2013ExternalReports/295237.pdf>)

Vermont Medicaid State Plan for Opioid Addiction

In an effort to address the growing opiate addiction issue and need for increased treatment capacity in Vermont, the DVHA and The Vermont Department of Health (VDH) Division of Alcohol and Drug Abuse Programs (ADAP) have worked with our provider network to develop a system of care known as the Hub and Spokes which include the following types of programs:

Office-Based Opioid Treatment Program (OBOT): A solo practitioner or a group practice with the required training and ability to provide clinical evaluation, buprenorphine induction, maintenance prescriptions, and follow up.

Opioid Treatment Programs (OTPs): a specialty opioid addiction treatment center that can also provide buprenorphine mono or buprenorphine/naloxone in addition to methadone. (42 CFR Part 8: *Code of Federal Regulations*, Title 42: Public Health, Part 8 - Certification of Opioid Treatment Programs, <http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr;sid=ff035bdee995442682f5b832c9e2480b;rgn=div5;view=text;node=42%3A1.0.1.1.10;idno=42;cc=ecfr>)

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Opioid Treatment Programs dispense buprenorphine from a window without giving a prescription; though also allow a take-home option per federal rules. Only OTPs (aside from pharmacies that can dispense buprenorphine mono or buprenorphine/naloxone) are allowed to *dispense* approved pharmacological treatments for opioid addiction. Due to the long-acting pharmacodynamics profile of buprenorphine, multiple-day dosing can occur three to four 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.

Beginning on July 1, 2013 the Centers for Medicare and Medicaid Services (CMS) approved a State Plan Amendment for the Vermont Medicaid Program to create a Health Home (see Appendix C) for Vermonters with opioid addiction.

The Health Home is grounded in the principles of Medication Assisted Treatment and:

- *enhances Methadone treatment programs (Hubs)* by augmenting the programming to include Health Home Services to link with the primary care and community services, provide buprenorphine for clinically complex patients, and provide consultation support to primary care and specialists prescribing buprenorphine
- *embeds clinical staff (a nurse and a Master's prepared, licensed clinician) in physician practices that prescribe buprenorphine (Spokes)* to provide Health Home services, including clinical and care coordination supports to individuals receiving buprenorphine.

Medicaid beneficiaries receiving MAT services in either an OTP (Hub) or a OBOT (Spoke) receive the following Health Home services:

- Comprehensive Care Management
- Care Coordination and
- Referral to Community and Support Services
- Care Transitions
- Individual and Family Supports

Any physician prescribing buprenorphine to Medicaid beneficiaries has access to this MAT clinical staff (an RN and licensed addictions mental health counselor) free of charge to the practice and the patients.

Regulatory Background

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. At present, Suboxone® sublingual film, buprenorphine/naloxone

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(formerly Suboxone®) sublingual tablets, and generic buprenorphine (formerly Subutex®) sublingual tablets 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 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.

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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 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.

Rules were re-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 current *Vermont Department of Health Medication Assisted Treatment for Opioid Dependence Rules* at: http://healthvermont.gov/regs/documents/opioid_dependence_rule.pdf

***Please Note:** As of the writing of this document, the state Opioid Rules are in the process of being revised based upon Act 195, Section 14, enacted by the legislature on July 1, 2014. <http://www.leg.state.vt.us/docs/2014/Acts/ACT195.pdf>

Buprenorphine Treatment

Buprenorphine & Naloxone

Buprenorphine is a semi-synthetic opioid that has partial agonist properties and is metabolized in the liver by cytochrome P450. Buprenorphine is used for both long-term maintenance and for medically supervised withdrawal from opioids. It has been found safe and effective in minimizing withdrawal symptoms, as well as blocking the effects of illicit opioids. Buprenorphine has a poor oral bioavailability and moderate sublingual bioavailability. Buprenorphine products are available in the form of sublingual tablets or films.

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 less likely. Naloxone is an opioid antagonist that has poor sublingual bioavailability but good parenteral bioavailability. As buprenorphine is able to be abused due to its opioid agonist effects, naloxone is added to buprenorphine to decrease the likelihood of diversion and abuse of the combination product. (<http://buprenorphine.samhsa.gov/about.html>)

Safety Issues with Buprenorphine

1. Unintended Buprenorphine Exposure in Young Children

Serious adverse effects of buprenorphine exposure in young children have been reported (Pedapati 2011). Buprenorphine exposure in infants and young children produces apnea; miosis and mental-status depression and even a brief exposure to buprenorphine can lead to respiratory depression or arrest.

Individuals receiving buprenorphine on an outpatient basis should be warned of the risk and instructed to keep medications in a secure place.

2. Drug Interactions with Buprenorphine

Concomitant use of benzodiazepines has been reported to be implicated in non-fatal overdose and overdose deaths. It is recommended that concurrent prescribing of buprenorphine with sedative hypnotics be only used when absolutely required for treatment of psychiatric illness unresponsive to other medications and that the administration be closely monitored. In addition, patients starting or stopping CYP3A4 inhibitors or inducers should be monitored for potential under/over dosing.

<http://www.suboxone.com/content/pdfs/prescribing-information.pdf>

Treatment of Opioid Dependence with Buprenorphine

As a waived buprenorphine prescriber, the physician must have the knowledge to refer patients for appropriate counseling and other services (e.g., family planning) that are usually needed in conjunction with opioid addiction 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
- Family Planning services to include counseling for contraceptive options as well as preconceptional counseling which may include a recommendation for a multivitamin containing folic acid for women of childbearing years regardless of an expressed desire to conceive
- Consultation for medical co-morbidities including but not limited to:
 1. Hepatitis B, C. Buprenorphine inhibits hepatic mitochondrial function at high concentrations.
 - Buprenorphine may cause elevation of transaminases, but no documentation of fulminant liver failure due solely to buprenorphine.
 - Liver enzyme levels should be monitored in patients with hepatitis.
 - Patients must be advised not to use buprenorphine IV.
 2. Moderate/Mild hepatic impairments
 3. Medication Interactions
 - Increased buprenorphine levels (e.g., Delavirdine® and Atazanavir®)
 - Increased sedation – benzodiazepine, Xanax® (alprazolam) associated with fatalities.

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- Decreased buprenorphine levels - St. John's Wort and rifampin.

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

- 12-Step Programs

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
- Recognition of patient behaviors indicating misuse or diversion of medication

2. Patient Information

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

Waivered physicians must provide office policies, procedures and away coverage with knowledge and experience using buprenorphine.

Waivered physicians must provide medication security and storage if dispensing buprenorphine onsite.

In addition, a waivered 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”).

Diversion and Abuse of Buprenorphine

The Vermont Department of Corrections reports 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. 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 as it has been noted that some 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*® and generic buprenorphine combination products.

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Diversion can occur for financial gain or to help pay for treatment such as an individual selling half of a prescribed dose. Buprenorphine may also be diverted for use by individuals who are seeking treatment but unable to access it, or are seeking to withdraw from other opioids relatively comfortably such as a member splitting his or her buprenorphine dose with a partner who is not in treatment. Individuals who are selling their buprenorphine for financial gain may be deterred if required to make frequent trips to the office and attend regular meetings with staff and participate in group and/or individual counseling.

Overly high or low doses of buprenorphine can also increase diversion risk. If most individuals stabilize on a dose of 12-16 mg per day, higher doses can increase the likelihood that some of the medication will be diverted and lower doses may increase the likelihood of concurrent use of other opioids.

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 to test for both the presence of substances other than buprenorphine and to test for the presence of buprenorphine. As some individuals may attempt to circumvent tests which detect the presence of buprenorphine, it may be advisable to test for norbuprenorphine, which is a metabolite of buprenorphine.
- Film/tablet call backs (for counting), also ideally administered randomly with minimal prior notice.
 - Film packets are designed with serialized identification numbers

Vermont Prescription Monitoring Program (<http://healthvermont.gov/adap/VPMS.aspx>)

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.

Prescribers must query VPMS in the following circumstances:

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1. At least annually for patients who are receiving ongoing treatment with an opioid Schedule II, III, or IV controlled substance
2. When starting a patient on a Schedule II, III, or IV controlled substance for nonpalliative long-term pain therapy of 90 days or more
3. The first time the provider prescribes an opioid Schedule II, III, or IV controlled substance written to treat chronic pain
4. Prior to writing a replacement prescription for a Schedule II, III, or IV controlled substance

Source: No. 75. An act relating to strengthening Vermont's response to opioid addiction and methamphetamine abuse, Section 3. d., page 14;
<http://www.leg.state.vt.us/DOCS/2014/ACTS/ACT075.PDF>

Special Populations

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. Per the prescribing information for Suboxone, the safety and efficacy of Suboxone® film in patients below the age of 16 has not been established. <http://www.suboxone.com/content/pdfs/prescribing-information.pdf>

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 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, a 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).

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*, **Appendix C-II** for the *DVHA Buprenorphine Spoke (OBOT) Prior Authorization Request Form*, and **Appendix C-III** for the *DVHA Hub (OTP) Buprenorphine Prior Authorization Request Form*).

Vermont Medicaid Preferred Buprenorphine Preparations

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

- *Suboxone®* is available as film and is a sublingually-administered combination therapy, containing both buprenorphine and naloxone. This 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).
- *Buprenorphine/naloxone tablets* (formerly available as brand *Suboxone* tablets) are also a sublingually-administered combination therapy.
- *Buprenorphine* sublingual tablets (formerly available as brand *Subutex®*) – mono-therapy containing only buprenorphine.

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 guide both the clinician and patient through the next course of action that may need to take place. A consistent clinical

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approach in performing UDT can optimize the use of this type of technology for both the patient and practitioner. Per the SAMSHA TIP 43, specimen collection methods should protect patients' dignity and privacy while minimizing opportunities for falsification.

The consensus panel recommends that staff members use their clinical judgment regarding the need for direct observation of urine collection. Temperature strips, adulterant checks, and other methods should be used when possible to ensure test validity. [Moran and colleagues \(1995\)](#) determined that unsupervised urine collection with a temperature indicator and a minimum 50-mL specimen was practical and reliable and ensured individual privacy and dignity.

If not under direct observation then testing procedures should be identified, often including the following:

Before a patient enters a bathroom stall, he or she is asked to leave coat, outer garments, purse, and bags outside the bathroom to prevent falsification of the sample. A patient is asked to wash and dry his or her hands before and after giving samples to prevent urine contamination. Bacterial overgrowth invalidates a urine specimen. To the extent possible, staff members ensure that patients do not conceal falsified urine specimens on their persons, often by asking the patient to empty their pockets of all contents.

The *Vermont Department of Health Medication Assisted Treatment for Opiate Dependence Rules* recommends that when UDT is initiated, each program/provider:

- 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.
- 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.
- Following the patient's admission toxicology screening, clinicians determine the frequency of toxicological testing by evaluating the clinical 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.
- Consider confirming the results of drug screening tests with additional testing (e.g. buprenorphine metabolite). 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).
- When diversion of buprenorphine is suspected clinically, confirmation testing should include buprenorphine and norbuprenorphine
- Ensure compliance with all federal regulations related to urine toxicology results, 42 CFR § 8.12(f) *Drug abuse testing services*.
- Other forms of testing might also be of consideration including oral fluid testing

Urine Drug Testing Negative for Buprenorphine

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Monitoring for the presence of buprenorphine plays an important role in the determination of possible non-adherence 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. 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 is on a sufficiently low dose that may produce urinary levels that are below the cut-off level being used.
- 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 known to have effectiveness in the treatment of substance abuse disorders, for example, such as Cognitive Behavioral Therapy, Motivation Enhancement Therapy, and 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.

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, pulmonary and cardiac status, current prescribed and non-prescribed medication 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 moderate or severe opioid use disorder and is not currently on methadone (see page 540, DSM-5, *Diagnosis of Opioid Use Disorder*). 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. If there is evidence of a

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known previous prescription pattern (through VPMS) or if the initial projected daily dose is to be 8 mg or less then, then a waived physician may begin home based induction.”

4. Social, work, and family circumstances history.
5. Complete physical exam including a mental status exam.
6. Lab screening for ALT, AST, creatinine, Hepatitis B and C, HIV, , syphilis, TB and others as clinically indicated.
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. 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.
10. 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. For any woman of child-bearing age, a prescription for prenatal vitamins (for additional folic acid) should be offered.

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..

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 **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;
- active psychiatric co-morbidity;
- Active or chronic suicidal or homicidal ideation or attempts;
- Multiple previous treatments and relapses during buprenorphine maintenance;
- Non-response to buprenorphine in the past;

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- 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.

Sublingual Administration

All patients should in general be instructed on the proper procedure for taking buprenorphine when they first enter treatment. For observed dosing, after each administration, the patient's mouth should be visually inspected 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 while the tablet/film has been fully dissolving.
- Patient should keep all dissolved liquid in the mouth for the duration of the administration, including saliva
- Observation by the nursing staff is necessary until medication is sufficiently dissolved to eliminate potential for diversion (approximately 5-6 minutes).

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.

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9. If more than an 8 mg dose is needed, gradually increase the dose in 2mg increments over the next several days.
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 the patient return for direct observation pre-dose and if looks well, give prescription for 8 mg film for 3 days and then 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.
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.

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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 consistent with observed withdrawal (at least 24 hours after last methadone)
No additional methadone given after induction begins.
4. Follow same protocol for short acting opioids, but faster dose adjustments may be needed daily for the first week.

Stabilization

If you are unable to stabilize a patient, a referral to a HUB or some other higher level of care where daily dosing and directly observed therapy can be done is highly recommended. Patient should receive daily dose until stabilized. An option is to shift to multiple-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 as clinically indicated but no less than monthly, optimally screens should be done randomly.
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 demonstrated an active recovery process 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.

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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 and this may be used as a clinical tool to encourage success in treatment, as well as a precautionary measure for avoiding diversion.

Dosing Frequency

Buprenorphine is generally recommended to be administered once daily.

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; 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 |

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| | | | |
|-------|---|----|----|
| 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.
- 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, and 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, and 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 (oral administration)

| <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 |

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://pcssmat.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, 2014.

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

Other Substance Abuse-Related Web Sites

American Academy of Addiction Psychiatry (AAAP). Web-based training, information on live training, news, governmental agency links:

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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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Medication Assisted Treatment for Opioid Addiction in Opioid Treatment Programs: A Treatment Improvement Protocol TIP 4. Substance Abuse and Mental Health Services Administration; <http://www.ncbi.nlm.nih.gov/books/NBK64164/>

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Appendix A: DSM-V DIAGNOSIS OF OPIOID USE DISORDER

***Note:** A new version of the DSM, *DSM-5* was released in May 2013, which did away with the separate diagnoses of substance "dependence" and substance "abuse" and replaced them with a single diagnosis, **substance "use disorder"** based on nearly the same criteria combined. A minimum of 2-3 criteria is required for a **mild** substance use disorder diagnosis, while 4-5 is **moderate**, and 6-7 is **severe** (APA, 2013). The other major change was to remove the criterion related to legal problems and to add one related to substance craving.

Source: Buppractice/Data 2000-Qualifying Buprenorphine Training website:
<http://www.buppractice.com/howto/screen/criteria>

| Worksheet for DSM-5 criteria for diagnosis of Opioid Use Disorder | | | |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|----|-------------------------------------|
| Diagnostic Criteria (Opioid Use Disorder requires at least 2 criteria be met within a 12 month period) | Meets criteria? | | Notes/Supporting information |
| | Yes | No | |
| 1. Opioids are often taken in larger amounts or over a longer period of time than intended. | | | |
| 2. There is a persistent desire or unsuccessful efforts to cut down or control opioid use. | | | |
| 3. A great deal of time is spent in activities necessary to obtain the opioid, use the opioid, or recover from its effects. | | | |
| 4. Craving or a strong desire to use opioids. | | | |
| 5. Recurrent opioid use resulting in failure to fulfill major role obligations at work, school or home. | | | |
| 6. Continued opioid use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of opioids. | | | |
| 7. Important social, occupational or recreational activities are given up or reduced because of opioid use. | | | |
| 8. Recurrent opioid use in situations in which it is physically hazardous | | | |
| 9. Continued use despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by opioids. | | | |

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| | | | |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|--|--|
| <p>10. *Tolerance, as defined by either of the following:</p> <p>(a) a need for markedly increased amounts of opioids to achieve intoxication or desired effect</p> <p>(b) markedly diminished effect with continued use of the same amount of an opioid</p> | | | |
| <p>11. *Withdrawal, as manifested by either of the following:</p> <p>(a) the characteristic opioid withdrawal syndrome</p> <p>(b) the same (or a closely related) substance are taken to relieve or avoid withdrawal symptoms</p> | | | |

*This criterion is not considered to be met for those individuals taking opioids solely under appropriate medical supervision.

Criteria from American Psychiatric Association (2013). *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition*. Washington, DC, American Psychiatric Association page 541.

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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 use disorder</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, circle 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: Health Home Services Hub & Spoke

Health Home Services

Medicaid beneficiaries receiving Medication Assisted Treatment for opioid addiction are now eligible for the following services. The services are detailed in the Affordable Care Act (ACA) and are designed to parallel the types of services and supports available in primary care patient centered medical homes. Vermont's Medicaid State Plan Amendment for the Hub and Spoke initiative offers these six Health Home services.

Documentation

Minimum requirement is an “**auditable record**” of at least one health home service per patient each month.” CMS is not requiring services reports. These services must be documented in the clinical record of each Hub program and Spoke practice. The services follow:

Comprehensive Care Management: Activities undertaken to identify patients for Medication Assisted Therapy, conduct initial assessments, and formulate individual plans of care. Also includes activities related to managing and improving the care of the patient population across health, substance abuse and mental health treatment, and social service providers.

Health Home Staff providing Comprehensive Care Management: Spoke Nurse and Spoke Clinician Care Manager; Hub Health Home Program Director, Hub supervising MD, Hub RN Supervisor, Hub Consulting Psychiatrist.

Specific activities include but are not limited to:

- Identification of potential MAT patients via referrals, prior authorizations, VCCI risk stratification, claims and utilization data, judicial referrals for treatment, and outreach to patients lost to contact.
- Assessment of preliminary service needs; treatment plan development; including client goals.
- Assignment of health team roles and responsibilities.
- Developing treatment guidelines and protocols for health teams to use in specific practice settings (primary care, specialty care) for transitions of care, identified health conditions (e.g., opioid dependence with depression or chronic pain), and prevention and management of substance relapse.
- Developing protocols for health home staff to use in collaborating with community partners on behalf of beneficiaries including: housing, vocational services, peer recovery supports, mental health treatment, and economic and health insurance benefits.
- Monitor MAT patient's health status, treatment progress, service use to improve care and address gaps in care.
- Develop and use data to assess use of care guidelines in practice settings, patient outcomes, and patient experience of care.
- Design and implement quality improvement activities to improve the provision of care (learning collaborative, PDSA cycles).

Care Coordination: Implementation of individual plans of care (with active patient involvement) through appropriate linkages, referrals, coordination and follow-up as needed to services and supports

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across treatment and human services settings and providers. The goal is to assure that all services are coordinated across provider settings, which may include medical, social, mental health, substance, corrections, educational, and vocational services.

Health Home Staff providing Care Coordination: Spoke Nurse and Spoke Clinician Care Manager, the Hub Supervising MD, the Hub MA Addictions Counselors, the Hub MA Clinician Case Managers.

Specific activities include but are not limited to:

- Appointment scheduling, outreach to support attendance at scheduled treatment and human services appointments.
- Conducting referrals and follow-up monitoring, participating in discharge planning from hospital, residential, and corrections.
- Communicating with other providers and family members.
- Monitoring treatment progress and implementation of the individual care plan.
- Case management necessary for individuals to access medical, social, vocational, educational, substance abuse and/or mental health treatment supports, and community-based recovery services.
- Coordinating with other providers to monitor individuals' health status and participation in treatment.
- Assessing medication adherence and calculating medication possession rates.
- Identification of all medications being prescribed, communication with prescribers, and medication reconciliation.
- Access to and assistance in maintaining safe and affordable housing.
- Conducting outreach to family members and significant others in order to maintain individual's connection to services and expand their social network.

Health Promotion: Activities that promote patient activation and empowerment for shared decision-making in treatment, healthy behaviors, and self-management of health, mental health, and substance abuse conditions.

Health Home staffs providing Health Promotion Activities are the Spoke Nurse and Spoke Clinician Care Manager, and the Hub MA Addictions Counselors and the MA Clinician Case Managers.

Specific activities include but are not limited to:

- Providing health education specific to a patient's chronic conditions; including medication management.
- Providing of health education specific to opioid dependence and treatment options.
- Identifying health and life goals and development of self-management plans with the patient.
- Motivational interviewing and other behavioral techniques to engage patients in healthy lifestyles and reduce substance abuse.
- Supports for management of chronic pain and depression.
- Supports for smoking cessation and reduction of use of alcohol and other drugs.

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- Providing health promoting lifestyle interventions including but not limited to nutritional counseling, obesity reduction, and increasing physical activity.
- Development of health information materials for patient and family education specific to MAT and common co-occurring conditions.
- Providing support to develop skills for emotional regulation and parenting skills.
- Providing support for improving social networks.

Comprehensive Transitional Care: Care coordination focused on planned, seamless transitions of care through streamlining the movement of patients from one treatment setting to another, between levels of care, and between health and specialty MH/SA service providers. Goals are to reduce hospital readmissions, facilitate timely development of community placements, and coordinate the sharing of necessary treatment information among providers.

Health Home Staff providing Transitional: Spoke Nurse, Spoke Clinician Care Manager, the Hub Health Home Director, the Hub Supervising MD, the Hub RN Supervisor, and the Hub MA Clinician Case Managers.

Specific activities include but are not limited to:

- Developing and maintaining collaborative relationships between health home providers and other entities such as hospital emergency departments, hospital discharge departments, corrections, probation and parole, residential treatment programs, primary care providers, and specialty MH/SA treatment services.
- Developing and implementing referral protocols including standardized clinical treatment information on electronic and paper CCD.
- Developing and using data to identify MAT clients with patterns of frequent ER, hospital, or other relapse-related services utilization and planning systemic changes to reduce use of acute care services.

Individual and Family Support: Assisting individuals to fully participate in treatment, reducing barriers to access to care, supporting age and gender appropriate adult role functioning, and promoting recovery.

Health Home Staff providing Individual and Family Support: Spoke Nurse, Spoke Licensed Clinician Case Manager, the Hub Supervising MD, the Hub MA Addictions Counselors, and the Hub MA Clinician Case Managers.

Specific services include but are not limited to:

- Advocacy.
- Assessing individual and family strengths and needs.
- Providing outreach and supportive counseling to key caregivers.
- Providing information about services and formal and informal resources, and education about health conditions and recommended treatments.
- Providing assistance with navigating the health and human services systems.

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- Providing assistance with obtaining and adhering to prescribed treatments including medications.
- Facilitating participation in ongoing development and revisions to individual plan of care.

The Hub Supervising MD specifically assists with patient education about health conditions and recommended treatments and facilitating ongoing revisions to individual plans of care.

Referral to Community & Social Support Services: Assisting clients obtain and maintain eligibility for formal supports and entitlements (e.g., health care, income support, housing, legal services) and to participate in informal resources to promote community participation and well-being.

Health Home Staff providing Referral to Community Services: Spoke Nurse, Spoke Licensed Clinician Case Manager, the Hub MA Addictions Counselors, and the Hub MA Clinician Case Managers.

Specific services include but are not limited to:

- Developing and maintaining up-to-date local information about formal and informal resources beyond those covered in the Medicaid plan, including peer and community-based programs.
- Assisting and supporting access to community resources based on individual patient needs and goals.
- Assisting patients obtain and maintain eligibility for income support, health insurance, housing subsidies, food assistance.
- Providing information and supporting participation in vocational and employment services to promote economic self-sufficiency.

APPENDIX D-I: DVHA CLINICAL CRITERIA FOR SUBOXONE®/BUPRENORPHINE PRIOR APPROVAL

Opiate Dependency: Suboxone®, Buprenorphine

- Diagnosis of opiate use disorder 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.

- Requests for buprenorphine/naloxone SL tablets 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 has been submitted (duration of PA will be 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 D-II: BUPRENORPHINE Prior Authorization Request Form (Spokes/OBOTS)

In order for beneficiaries to receive Medicaid coverage for medications that require prior authorization, the prescriber must telephone or complete and fax this form to Goold Health Systems. Please complete this form in its entirety and sign and date below. Incomplete requests will be returned for additional information.

Submit request via: Fax: 1-844-679-5366 or Phone: 1-800-679-5363

Prescribing physician:

Beneficiary:

Name: _____
Phone#: _____
Fax#: _____
Address: _____
Contact Person at Office: _____

Name: _____
Medicaid ID#: _____
Date of Birth: _____ Sex: _____
Pharmacy Name _____
Pharmacy Phone: _____ Pharmacy Fax: _____

Anticipated maintenance dose/ frequency (target dose ≤ than 16 mg/day) (maximum 14 day supply per prescription fill)

Dose: _____ Dosage Form (e.g. Film): _____ Frequency : _____ (recommended once daily)

| | |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------|
| Is buprenorphine being prescribed for opiate dependency? | <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 |
| Does the prescriber signing this form have a DATA 2000 waiver ID (“X-DEA license”)? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| A “Pharmacy Home” for ALL prescriptions has been selected AND discussed with the 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 the last 60 days | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don’t know |
| If this request is for Buprenorphine (formerly Subutex®), please answer the following questions: Is the member pregnant? (please provider positive pregnancy test copy) If yes, anticipated date of delivery: _____ Is the member breastfeeding a methadone or morphine dependent baby? (please provider history from neonatologist or pediatrician) | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| Would you have referred your patient to a methadone clinic if this option was conveniently located and available? | <input type="checkbox"/> Yes <input type="checkbox"/> No |

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Additional clinical information to support PA request: (please attach if necessary)

By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is medically necessary, does not exceed the medical needs of the member, and is clinically supported in your medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.

Prescriber Signature: _____ **XDEA License#:** _____ **Date of**

request: _____



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APPENDIX D-III: HUB (OTP) BUPRENORPHINE Prior Authorization Form

All requests for Suboxone® Film > 16MG, Suboxone® Tablets (all doses) and Buprenorphine monotherapy in women who are pregnant or who are breastfeeding a morphine or methadone-dependent baby must be reviewed by the GHS Clinical Call Center. Documentation must accompany this form.

Submit request via Fax (only): (844)-679-5366

Prescribing physician:

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

Beneficiary:

Name: _____
Medicaid ID #: _____
Date of Birth: _____
Diagnosis: _____
Date of Admission to HUB: _____

CHECK HERE IF PATIENT IS ADAP UNINSURED

Request is from the following HUB location: _____ / _____
Name NPI

Contact Person at HUB (OTP): _____

► Please choose the requested formulation, check that you have provided a clinical note/letter, and complete any other required information.

| | |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|
| <input type="checkbox"/> Suboxone® Film > 16 mg Dose per day requested: _____mg | <input type="checkbox"/> Suboxone® Tablets Dose per day requested: _____mg |
| <input type="checkbox"/> Clinical note/letter from prescriber that documents the prescriber's clinical rationale for requesting Suboxone® tablets or Suboxone® Film > 16MG (REQUIRED) is <u>attached</u> . | |

| | |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|
| <input type="checkbox"/> Buprenorphine (mono formulation) – Females Only | Dose per day requested: _____mg |
| <input type="checkbox"/> Pregnancy DUE DATE: _____ | <input type="checkbox"/> Pregnancy test/ultrasound result/lab attached (REQUIRED) |
| <input type="checkbox"/> Breastfeeding a morphine or methadone-dependent baby (baby is being administered morphine or methadone for opiate withdrawal symptoms) | |
| <input type="checkbox"/> Clinical note/letter from a pediatrician/neonatologist that documents that the member is breastfeeding a morphine or methadone dependent baby (REQUIRED) is <u>attached</u> . | |
| <input type="checkbox"/> Using buprenorphine mono to switch from methadone to Suboxone® Dates buprenorphine mono will be administered: _____ | |

Please Note: All requests other than for Suboxone Film <=16mg must be directed to GHS at

Phone: (844)-679-5363 or Fax: (844)-679-5366

Prescriber Signature: _____ (stamps not acceptable) Date of request: _____

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APPENDIX E: 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.

| <u>PARAMETERS</u> | <u>FINDINGS</u> | <u>POINTS</u> |
|------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|
| Parameters based on Questions and Observation: | | |
| (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 |
| Parameters based on Observation Alone: | | |
| (5) Goose flesh | None visible. Occasional goose flesh but not elicited by touch; not permanent. Prominent goose flesh in waves and elicited by touch. Constant goose flesh over face and arms. | 0 1 2 3 |
| (6) Nasal congestion | No nasal congestion or sniffing. Frequent sniffing. Constant sniffing, watery discharge. | 0 1 2 |
| (7) Restlessness | Normal activity. Somewhat more than normal activity; moves legs up and down; shifts position occasionally. Moderately fidgety and restless; shifting position frequently. Gross movement most of the time or constantly thrashes about. | 0 1 2 3 |
| (8) Tremor | None. Not visible but can be felt fingertip to fingertip. Moderate with patient's arm extended. Severe even if arms not extended. | 0 1 2 3 |
| (9) Lacrimation | None. Eyes watering; tears at corners of eyes. Profuse tearing from eyes over face. | 0 1 2 |
| (10) Sweating | No sweat visible. Barely perceptible sweating; palms moist. Beads of sweat obvious on forehead. Drenching sweats over face and chest. | 0 1 2 3 |
| (11) Yawning | None. Frequent yawning. Constant uncontrolled yawning. | 0 1 2 |
| TOTAL SCORE | [Sum of points for all 11 parameters] | |

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

Source: Adapted from Peachey, J.E., & 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 F: 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 | | | |
| 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 | | | |
| | | | |

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| | | | |
|---------------------------------------|--|--|--|
| <i>Total Score</i> | | | |
| <i>Observer's Initials</i> | | | |
| <i>Blood Pressure/Pulse</i> | | | |
| <i>Dose of Suboxone® Given</i> | | | |

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

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APPENDIX G-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 G- 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):
 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 G-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 use disorder (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 blocker. 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 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 (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.

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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 G-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. If 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.

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.**

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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 G-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.
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,

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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 G-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, and 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. |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | 4. I have been informed that buprenorphine, as found in Suboxone®, is a narcotic analgesic, and thus it can produce a 'high'; I know that taking Suboxone® regularly can lead to physical dependence and addiction and that if I were to abruptly stop taking Suboxone® after a period of regular use, I could experience symptoms of opiate withdrawal. I also understand that combining Suboxone® with benzodiazepine medications (including but not limited to Valium®, Klonopin®, Ativan®, Xanax®, Librium®, Serax®) has been associated with severe adverse events and even death. I also understand that I should not drink alcohol with Suboxone® since it could possibly interact with Suboxone® to produce medical adverse events such as reduced breathing or impaired thinking. I agree not to use benzodiazepine medications or to drink alcohol while taking Suboxone®. |

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| <input type="checkbox"/> Yes | <input type="checkbox"/> No | 5. I have been informed that Suboxone® is to be placed under the tongue for it to dissolve and be absorbed, and that it should never be injected. I have been informed that injecting Suboxone® after taking Suboxone® or any other opiate regularly could lead to sudden and severe opioid withdrawal. |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | 6. I have been informed that Suboxone® is a powerful drug and that supplies of it must be protected from theft or unauthorized use, since persons who want to get high by using it or who want to sell it for profit may be motivated to steal my take-home prescription supplies of Suboxone®. |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | 7. I have a means to store take-home prescription supplies of Suboxone® safely, where it cannot be taken accidentally by children or pets, or stolen by unauthorized users. I agree that if my Suboxone® pills are swallowed by anyone besides me, I will call 911 or Poison Control at 1-800-222-1222 immediately. |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | 8. I agree that if my doctor recommends that my home supplies of Suboxone® should be kept in the care of a responsible member of my family or another third party, I will abide by such recommendations. |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | 9. I will be careful with my take-home prescription supplies of Suboxone®, and agree that I have been informed that if I report that my supplies have been lost or stolen, my doctors will not be requested or expected to provide me with make-up supplies. This means that if I run out of my medication supplies it could result in my experiencing symptoms of opiate withdrawal. Also, I agree that if there has been a theft of my medications, I will report this to the police and will bring a copy of the police report to my next visit. |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | 10. I agree to bring my 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. |

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| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <p>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.</p> |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <p>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.</p> |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <p>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.</p> |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <p>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®.</p> |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <p>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.</p> |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <p>19. I agree to participate in a regular program of peer/self-help while being treated with Suboxone®.</p> |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <p>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.</p> |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <p>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.</p> |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <p>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.</p> |

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| <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: _____

APPENDIX H: ASAM ADULT ADMISSION CROSSWALK

| Criteria Dimensions | Level 0.5 Early Intervention | OMT Opioid Maintenance Therapy | Level 1 Outpatient Services | Level II.1 Intensive Outpatient | Level II.5 Partial Hospitalization |
|----------------------------------------------------------------------------|------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Dimension 1: Acute Intoxication and/or Withdrawal Potential | No withdrawal risk | Patient is physiologically dependent on opiates and requires OMT to prevent withdrawal | Not experiencing significant withdrawal, or at minimal risk of severe withdrawal | Minimal risk of severe withdrawal | Moderate risk of severe withdrawal |
| Dimension 2: Biomedical Conditions and Complications | None or very stable | None or manageable with outpatient medical monitoring | None or very stable, or is receiving concurrent medical monitoring | None or not a distraction from treatment. Such problems are manageable at Level II.1. | None or not sufficient to distract from treatment. Such problems are manageable at Level II.5. |
| Dimension 3: Emotional, Behavioral or Cognitive Conditions & Complications | None or very stable | None or manageable in an outpatient structured environment | None or very stable, or is receiving concurrent mental health monitoring | Mild severity with potential to distract from recovery; needs monitoring | Mild to moderate severity w/ potential to distract from recovery; needs stabilization |
| Dimension 4: Readiness to Change | Willing to explore how current alcohol or drug use may affect personal goals | Ready to change the negative effects of opiate use, but is not ready for total abstinence | Ready for recovery but needs motivating and monitoring strategies to strengthen readiness. Or high severity in this dimension but not in other dimensions. Needs a Level I motivational enhancement program | Has variable odd engagement in treatment, ambivalence, or lack of awareness of the substance use or mental health problem, and requires a structured program several times a week to promote progress through the stages of change | Has poor engagement in treatment, significant ambivalence, or lack of awareness of the substance use or mental health problem, requiring a near-daily structured program or intensive engagement services to promote progress through stages of change |

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|-----------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>Dimension 5: Relapse, Continued use or Continued potential problem</p> | <p>Needs an understanding of, or skills to change current alcohol and drug use patterns</p> | <p>At high risk of relapse or continued use without OMT and structured therapy to promoted treatment progress</p> | <p>Able to maintain abstinence or control use and pursue recovery or motivational goals with minimal support</p> | <p>Intensification of addiction or mental health symptoms indicate a high likelihood of relapse or continued use or continued problems w/o close monitoring & support several times a week</p> | <p>Intensification of addiction or mental health symptoms, despite active participation in a Level I or II.1 program, indicates a high likelihood of relapse or continued use or continued problems w/o near daily monitoring and support</p> |
| <p>Dimension 6: Recovery Environment</p> | <p>Social support system or significant others increase the risk of personal conflict about alcohol or drug use</p> | <p>Recovery environment is supportive and/or the client has skills to cope</p> | <p>Recovery environment is supportive and /or the client has skills to cope</p> | <p>Recovery environment is not supportive but, with structure & support, the client can cope</p> | <p>Recovery environment is not supportive but, w/ structure & support & relief from the home environment, the client can cope</p> |

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| Criteria dimensions | Level III.1 Clinically Managed Low Intensity Residential Services | Level III.3 Clinically-managed Medium Intensity Residential Services | Level III.5 Clinically-managed Medium / High Intensity Residential Services |
|---------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Dimension 1: Acute Intoxication &/or Withdrawal Potential | No withdrawal risk or minimal or stable withdrawal. Concurrently receiving Level I-D (minimal) or Level II-D (moderate services) | Not at risk of severe withdrawal, or moderate withdrawal is manageable at Level III.2-D | At minimal risk of severe withdrawal at Levels III.3 or III.5. If withdrawal is present, it meets Level III.2-D criteria |
| Dimension 2: Biomedical Conditions & Complications | None or stable, or receiving concurrent medical monitoring | None or stable, or receiving concurrent medical monitoring | None or stable, or receiving concurrent medical monitoring |
| Dimension 3: Emotional Behavioral or Cognitive Conditions & Complications | None or minimal; not distracting to recovery. If stable, a Dual Diagnosis Capable program is appropriate. If not, a Dual diagnosis Enhanced program is required. | Mild to moderate severity; needs structure to focus on recovery. If stable, a Dual Diagnosis Capable program is appropriate. If not, a Dual Diagnosis Enhanced program is required. Treatment should be designed to respond to the client's cognitive deficits | Demonstrates repeated inability to control impulses, or a personality disorder requires structure to shape behavior. Other functional deficits require a 24-hour setting to teach coping skills. A Dual Diagnosis Enhanced setting is required for SPMI – Severely and Persistently Mentally Ill |
| Dimension 4: Readiness to Change | Open to recovery, but needs a structured environment to maintain therapeutic gains | Has little awareness & needs interventions available only at Level III.3 to engage and stay in treatment; or there is high severity in this dimension but not in others. The client therefore needs a Level I motivational enhancement program | Has marked difficulty with, or opposition to treatment, with dangerous consequences; or there is high severity in this dimension but not in others. The client therefore needs a Level I motivational enhancement program. |
| Dimension 5: Relapse, Continued Use Or Continued Problem Potential | Understands relapse but needs structure to maintain therapeutic gains | Has little awareness and needs intervention available only at Level III.3 to prevent continued use, with imminent dangerous consequences, because of cognitive deficits or comparable dysfunction | Has no recognitions of the skills needed to prevent continued use, with imminently dangerous consequences |
| Dimension 6: Recovery Environment | Environment is dangerous but recovery is achievable if Level III.1 24-hour | Environment is dangerous and client needs 24-hour structure to learn to cope | Environment is dangerous and the client lacks skills to cope outside of a highly structured |

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| | structure is available | 24-hour setting |
|--|------------------------|-----------------|

| Criteria dimensions | Level III.7 Medically-monitored Intensive Inpatient Services | Level IV Medically-Managed Intensive Inpatient Services |
|---------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------|
| Dimension 1: Acute Intoxication &/or Withdrawal Potential | At high risk of withdrawal, but manageable at Level III.7-D and does not require the full resources of a licensed hospital | At high risk of withdrawal and requires the full resources of a licensed hospital |
| Dimension 2: Biomedical Conditions & Complications | Requires 24-hour medical monitoring but not intensive treatment | Requires 24-hour medical and nursing care and the full resources of a licensed hospital |
| Dimension 3: Emotional Behavioral or Cognitive Conditions & Complications | Moderate severity; needs a 24-hour structured setting. If the client has a co-occurring mental disorder, requires concurrent mental health services in a medically monitored setting. | Because of severe and unstable problems requires 24-hour psychiatric care with concomitant addiction treatment (Dual Diagnosis Enhanced) |
| Dimension 4: Readiness to Change | Resistance is high and impulse control poor, despite negative consequences; needs motivating strategies available only in a 24-hour structured setting. Or, if 24-hr setting is not required, the client needs a Level I motivational enhancement program. | Problems in this dimension do not qualify the client for Level IV services |
| Dimension 5: Relapse, Continued Use Or Continued Problem Potential | Unable to control use, with imminently dangerous consequences, despite active participation at less intensive levels of care | Problems in this dimension do not qualify the client for Level IV services |
| Dimension 6: Recovery Environment | Environment is dangerous and the client lacks skills to cope outside of a highly structured 24-hour setting | Problems in this dimension do not qualify the client for Level IV services |

Understanding and Using ASAM PPC-2R, The Change Companies
<http://www.gilariverrbha.org/Forms/Understanding%20and%20Using%20ASAM%206.2010.pdf>