

**DEPARTMENT OF VERMONT HEALTH ACCESS  
MANAGED CARE ENTITY  
VERMONT SUBSTANCE USE DISORDER  
MEDICATION ASSISTED TREATMENT GUIDELINES**

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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.

## **OVERVIEW**

### **Opioid Use Disorder and Medication Assisted Treatment**

Substance use disorder (SUD) 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 substance use disorder also exhibit compulsive drug taking due to intense feelings of “craving” for the substance. Opioid use disorder (OUD) may include the use of illicit opioids in addition to compulsive, prolonged self-administration of opioid substances that are not clinically indicated and are used in doses that exceed the prescribed amount for pain management.

Opioid use disorder is a chronic, relapsing illness diagnosed on the presence of at least two of eleven criteria over a 12-month period (Appendix A). 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 opioids, 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 receiving treatment for addiction to other opiates have 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

To address the growing opioid use disorder issue and need for increased treatment capacity in Vermont, the DVHA and The Vermont Department of Health (VDH) worked together to launch the “Hub and Spoke” which includes:

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 use disorder 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, [www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title42/42cfr8\\_main\\_02.tpl](http://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title42/42cfr8_main_02.tpl))

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 (Appendix C) for Vermonters with opioid use disorder.

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 medication assisted treatment for clinically complex patients, and provide consultation support to primary care and specialists prescribing MAT.
- *Embeds clinical staff (a registered nurse and a licensed, master’s prepared mental health clinician) in medical practices that prescribe buprenorphine (Spokes)* to provide Health Home services, including clinical and social supports to individuals receiving medication assisted treatment.

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;
- Individual and Family Support;
- Referral to Community and Social Support Services;
- Health Promotion;
- Comprehensive Transitional Care.

## 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

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III–V controlled substances specifically approved by the FDA for addiction treatment in physician offices, primarily buprenorphine-containing products, instead of referring patients to specialized opioid treatment programs (OTPs), as previously required under federal law.

Providers who consider providing office-based treatment of opioid use disorder must be able to recognize the condition of substance use disorder or opioid use disorder and be knowledgeable about the appropriate use of opioid agonist, antagonist, and partial agonist medications. Providers 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 provider a special identification number. DEA regulations require this ID number to be included on all buprenorphine prescriptions for opioid addiction therapy, along with the provider'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](http://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.

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- Additional qualification criteria may be added through legislative enactment.

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

*DATA 2000*, as amended in 2006, places limits on the number of patients a physician may treat with buprenorphine. During a waived physician's first year, a maximum of 30 patients may be treated at any one time. One year from the date on which the physician submitted the 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. After one year of prescribing under a waiver to treat a maximum of 100 patients, an eligible physician may apply to SAMHSA for a waiver to treat up to 275 patients. Eligible physicians must reapply for 275-patient waiver every three years.

In July 2016, federal law was amended to allow physician assistants and nurse practitioners to qualify to pre-scribe buprenorphine for medication-assisted treatment (MAT). In order to prescribe for MAT, a clinician must obtain what is frequently referred to as *X-license* or a *DATA waiver*. DATA stands for *Drug Abuse Treatment Act (of 2000)*, the law that legalized the prescribing of buprenorphine by physicians outside of an Opioid Treatment Program. The waiver program is administered by the U.S. Substance Abuse and Mental Health Services Administration (SAMHSA), an agency within the U.S. Department of Health and Human Services.

**IMPORTANT:**

- A PA or NP must complete 24 hours of specialized training to qualify for a DATA waiver.
- The 24 hours include the same 8-hour course that physicians are required to complete.
- PAs and NPs must complete an additional 16 hours of training.
- There are two critical things to remember about the 16-hours of additional training:

(1) The training must be by an organization that is approved for this specific purpose by SAMHSA.

(2) All 16 hours must be completed with the same approved organization.

Vermont physician assistants who are considering offering MAT services need to be aware of one additional requirement: **Physician assistants are authorized to perform only those medical services that are within the scope of practice of their primary supervising physician and delegated by the primary supervising physician.**

Two websites offer everything a PA needs to learn about qualifying for and applying for a DATA waiver.

1) **PCSS-MAT:** an organization funded by SAMHSA grants that provides training, information, and other resources for MAT clinicians. There you can find information about accessing the PCSS-MAT training – which is all **free** to participants.

2) **SAMHSA:** There you can access the forms to apply, as well as a link to sign up for notices about training events.

Rules were amended by Vermont statute in 2016 and apply to all prescribers who treat thirty (30) or

more patients with buprenorphine and to all the Opioid Treatment Programs (OTPs). Please refer to the current *Vermont Department of Health Medication Assisted Treatment for Opioid Dependence Rules* at: ([http://www.healthvermont.gov/sites/default/files/documents/pdf/REG\\_opioids-medication-assisted-therapy-for-dependence.pdf](http://www.healthvermont.gov/sites/default/files/documents/pdf/REG_opioids-medication-assisted-therapy-for-dependence.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 indicated for OUD are available in several dosage forms including sublingual tablet, sublingual film, buccal film, implant, and depot injections.

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 can 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. (<https://www.samhsa.gov/medication-assisted-treatment/treatment/naloxone>)

Suboxone® sublingual film, buprenorphine/naloxone (formerly Suboxone®) sublingual tablets, generic buprenorphine (formerly Subutex®) sublingual tablets, Bunavail® buccal film, and Zubsolv® (sublingual) tablets are the only approved oral options for use in an office-based setting. In addition, there is a subdermal implant called ProBuphine® that can be surgically implanted under the skin for six month’s duration by properly certified practitioners. Recently, a new monthly depot injection called Sublocade® was approved and is available in 100mg and 300mg injections. It is indicated in moderate to severe OUD in patients who have initiated treatment with oral buprenorphine-containing products followed by dose titration for a minimum of 7 days. Two additional depot injections are expected to reach the market in mid-2018, one of which will be a weekly depot injection. Please see the section below entitled “**Vermont Medicaid – Available Buprenorphine Preparations**” for a summary of available products and Medicaid coverage limitations.

### **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.

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Naloxone, marketed as Narcan® Nasal Spray and other formulations, is an opioid antagonist indicated for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression. Naloxone is widely available at any pharmacy, emergency medical teams (EMT), and other sites around the state. A complete list of these sites can be found via this link: <http://www.healthvermont.gov/response/alcohol-drugs/narcan-naloxone-overdose-rescue> . While it can be made available to individuals taking buprenorphine, there is a risk of limited efficacy with partial agonists or mixed agonists/antagonists. Reversal of respiratory depression caused by buprenorphine may be incomplete and larger or repeat doses may be required.

## 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. Concomitant use of serotonergic drugs may result in an increased risk of serotonin syndrome.

Also, some patients may attempt to potentiate the effects of buprenorphine/naloxone by abusing drugs such as gabapentin or quetiapine (Ref: Reeves RR, Ladner ME. Potentiation of the effect of buprenorphine/naloxone with gabapentin or quetiapine. *Am J Psychiatry*. 2014 Jun;171(6):691.). (<http://www.suboxone.com/content/pdfs/prescribing-information.pdf>)

## Treatment of Opioid Use Disorder with Buprenorphine

A waived buprenorphine prescriber, (see requirements in Appendix) must follow referral requirements per the MAT rules These services include but are not limited to the following:

- Different levels of substance use disorder treatment services.
- Family Planning services
- Psychiatric consultation
- Recovery support services
- Consultation for medical co-morbidities

Waivered prescribers 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

- o Treating patients with substance use disorders
- o Role and importance of medication in treatment of opioid dependence
- o Maintenance of confidentiality
- o Treatment philosophy
- o Providing medication
- o Role of non-pharmacological treatments

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- o Universal precautions
  - o Recognition of patient behaviors indicating misuse or diversion of medication
2. Patient Information
- o Informed consent (**Appendix G-III**)
  - o Treatment agreement (**Appendix G-IV**)

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

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

### **Diversion and Abuse of Buprenorphine**

Buprenorphine may 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). Diversion can also occur for financial gain or to help pay for treatment such as an individual selling half of a prescribed dose. 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.

Prescribers 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 System (VPMS) to monitor for opioid prescriptions or other medication that may be abused.
- Random toxicology screens with minimal 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 nor buprenorphine, which is a metabolite of buprenorphine.
- Film/tablet call backs (for counting), also ideally administered randomly with minimal prior notice.
  - o Film packets are designed with serialized identification numbers

### **Vermont Prescription Monitoring System**

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

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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. VPMS is located at the following:

<http://www.healthvermont.gov/health-statistics-vital-records/registries/vpms>

Prescribers must query VPMS in the following circumstances:

- The first time the provider prescribes an opioid Schedule II, III, or IV controlled substance written to treat pain when such a prescription exceeds 10 pills or the equivalent;
- When starting a patient on a Schedule II, III, or IV controlled substance for nonpalliative long-term pain therapy of 90 days or more;
- Prior to writing a replacement prescription for a Schedule II, III, or IV controlled substance;
- At least annually for patients who are receiving ongoing treatment (treatment without meaningful interruption) with an opioid Schedule II, III, or IV controlled substance;
- The first time a provider prescribes a benzodiazepine;
- When a patient requests an opioid prescription or a renewal of an existing prescription for pain from an Emergency Department or Urgent Care prescriber if the prescriber intends to write a prescription for an opioid;
- Apart from prescriptions written from an OTP, prior to prescribing buprenorphine or a drug containing buprenorphine to a Vermont patient for the first time and at regular intervals thereafter, and:
  - At regular intervals thereafter, but no less than twice annually; and
  - No fewer than two times annually thereafter; and
  - Prior to writing a replacement prescription.
- In the case of an OTP, prior to prescribing buprenorphine, methadone, or a drug containing buprenorphine to a Vermont patient for the first time, and:
  - Annually thereafter; and
  - Any other time that is clinically warranted.
- Prior to prescribing buprenorphine or a drug containing buprenorphine that exceeds the dosage threshold approved by the Vermont Medicaid Drug Utilization Review Board and published in its Preferred Drug List [1], prescribers must receive prior approval from the Chief Medical Officer or Medical Director of the Department of Vermont Health Access or designee.

The Vermont Prescription Monitoring System Rules created by 18 V.S.A. chapter 84A and further guidance can be reviewed at ([http://www.healthvermont.gov/sites/default/files/documents/pdf/REG\\_vpms-20170701.pdf](http://www.healthvermont.gov/sites/default/files/documents/pdf/REG_vpms-20170701.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.

<https://www.gpo.gov/fdsys/granule/CFR-2002-title42-vol1/CFR-2002-title42-vol1-sec8-12>

### **Pregnant Women**

Pregnant women who are actively using opioids or experiencing withdrawal symptoms should be treated with methadone or buprenorphine in preference to withdrawal management or abstinence. During the initiation of methadone or buprenorphine treatment, hospitalization of a pregnant women maybe preferred because of the potential for adverse events. However, the use of Naloxone to combat opioids dependence in pregnant women is not recommended aside from events of life-threatening overdose.

<https://www.asam.org/docs/default-source/practice-support/guidelines-and-consensus-docs/asam-national-practice-guideline-supplement.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 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,*

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*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, 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 the patients requiring 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 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).

#### **Prior Authorization for SUD Medications-Vermont Medicaid**

Vermont Medicaid insurance requires medication precertification prior to starting a patient on all buprenorphine formulations Suboxone Film® is the preferred formulation and is limited to a 14 days' supply per prescription. Buprenorphine (mono) tablets can be approved for pregnant women or women breast-feeding an opiate dependent baby.

(see **Appendix D-I** for the *DVHA Clinical Criteria for Suboxone®/Buprenorphine Prior Approval*, **Appendix D-II** for the *DVHA Buprenorphine Spoke (OBOT) Prior Authorization Request Form*, and **Appendix D-III** for the *DVHA Hub (OTP) Buprenorphine Prior Authorization Request Form*).

#### **Vermont Medicaid – Available Buprenorphine Preparations**

Buprenorphine for treatment of opioid use disorder is currently available in several formulations. Sublingual tablet or film administration involves placing a drug under the tongue, while buccal administration involves placing a drug between the gums and cheek. The following lists DVHA's preferred and non-preferred formulations on the Preferred Drug List (PDL).

##### Preferred:

*Suboxone® Film* is a sublingually-administered combination therapy, containing both buprenorphine and naloxone. Naloxone has been added to help minimize diversion and intravenous abuse. *Suboxone® Film* is the recommended preparation for induction, maintenance, and, if necessary, supervised withdrawal (detoxification). **This is DVHA's only preferred dosage form.**

##### Non-Preferred:

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- *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.
- 
- *Zubsolv* sublingual tablet contains buprenorphine and naloxone and is also indicated for the treatment of opioid use disorders.
- 
- *Bunavail* buccal tablets contain buprenorphine and naloxone and are indicated for the maintenance treatment of opioid dependence.
- 
- *ProBuphine*® is a set of four sub-dermal implants that can be surgically implanted under the skin for six months duration by properly certified practitioners.
- 
- *Sublocade*® is a 100mg and 300mg monthly depot injection indicated for patients that have been on oral buprenorphine for at least seven days and have been titrated to a stable dose.

## **Naltrexone**

### **What Is Naltrexone?**

Naltrexone is a medication approved by the Food and Drug Administration (FDA) to treat opioid use disorder and alcohol use disorder. It comes as an oral tablet or as a monthly depot injection. The oral form of naltrexone (ReVia, Depade) can be taken at 50 mg once per day. The injectable extended-release form of the drug (Vivitrol) is administered at 380 mg intramuscular once a month. Naltrexone can be prescribed by any health care provider who is licensed to prescribe medications. To reduce the risk of precipitated withdrawal, patients are warned to abstain from illegal opioids and opioid medication for a minimum of 7-10 days before starting naltrexone. If switching from methadone to naltrexone, the patient must be completely withdrawn from opiates. A naloxone challenge test is recommended prior to beginning Vivitrol therapy to assure patients are opioid free. A trial of oral naltrexone is recommended to determine tolerance.

### **How Naltrexone Works**

Naltrexone blocks the euphoric and sedative effects of drugs such as heroin, morphine, and codeine. It works differently in the body than buprenorphine and methadone, which activate opioid receptors in the body that suppress cravings. Naltrexone binds and blocks opioid receptors and is reported to reduce opioid cravings. There is no abuse and diversion potential with naltrexone.

If a person relapses and uses the problem drug, naltrexone prevents the feeling of getting high. People using naltrexone should not use any other opioids or illicit drugs; drink alcohol; or take sedatives, tranquilizers, or other drugs.

Patients on naltrexone may have reduced tolerance to opioids and may be unaware of their potential sensitivity to the same, or lower, doses of opioids that they used to take. If patients who are treated with

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naltrexone relapse after a period of abstinence, it is possible that the dosage of opioid that was previously used may have life-threatening consequences, including respiratory arrest and circulatory collapse.

As with all medications used in medication-assisted treatment (MAT), naltrexone is to be prescribed as part of a comprehensive treatment plan that includes counseling and participation in social support programs. Further guidance on Naltrexone products can be found at (<https://www.samhsa.gov/medication-assisted-treatment/treatment/naltrexone>).

Vivitrol requires a prior authorization from Vermont Medicaid and a PA form can be found via this link: <http://dvha.vermont.gov/for-providers/vivitrol-2017-11.pdf>.

### **Drug Testing in Clinical Addiction Treatment**

Drug testing uses a biological sample to detect the presence or absence of a specific drug (or drugs) as well as drug metabolites within a specific window of time. The Department of Vermont Health Access (DVHA) fully endorses the *American Society of Addiction Medicine (ASAM) Consensus document “Appropriate Use of Drug Testing in Clinical Addiction Medicine”*, for continued guidance. ([https://www.asam.org/docs/default-source/quality-science/appropriate\\_use\\_of\\_drug\\_testing\\_in\\_clinical-1-\(7\).pdf?sfvrsn=2](https://www.asam.org/docs/default-source/quality-science/appropriate_use_of_drug_testing_in_clinical-1-(7).pdf?sfvrsn=2))

### **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**

Prescribers 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.

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- Individuals need to be engaged in treatment for an adequate period.
- 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:

- 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.
- Psychiatric history with attention to treatment adherence, including medications and counseling.
- 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,

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*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

- known previous prescription pattern (through VPMS) or if the initial projected daily dose is to be
- 8 mg or less then, then a waived prescriber may begin home based induction.
- Social, work, and family circumstances history.
- Complete physical exam including a mental status exam.
- Due to these patients having a higher risk of blood-borne pathogens such as hepatitis and sexually-transmitted diseases, it is recommended to do lab screening for ALT, AST, creatinine, Hepatitis B and C, HIV, syphilis, TB and others as clinically indicated.
- Urine screen (collected under observation) with attention to opioids and other illicit drugs, including methadone, buprenorphine, and benzodiazepines.
- 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 (Appendix E). The urine specimen can also be sent to an outside laboratory for more sensitive measures for detecting commonly-abused synthetic opioids.
- 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. Prescribers are encouraged to consult with a substance abuse counselor or addiction specialist in these cases.
- 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 prescriber and patient review and sign a *Consent for Treatment* form and a *Treatment Agreement/Contract* (**Appendices G-I, G-II, G-III and G-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 (Appendix G-I for sample *Release of Information* forms). All the listed partners (and others not mentioned) have the potential to create team-based care through coordination if the patient chooses to have information shared.

### **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 (**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;
- 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 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:**

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- Begin induction early in the week.
- Plan on 3-5 days for stable dosing.
- Patient's last reported use should have been at least 6 hours prior to induction.
- 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.)
- Begin with a prescription for #2 2 mg Suboxone® film/tablets.
- Patient takes the prescription to the pharmacy and returns to the office with the medication.
- Patient lets the film dissolve under the tongue for 5 minutes (or 10 minutes if using the tablet) with no talking, drinking, or swallowing.
- Target buprenorphine dose range is 6 mg to 12 mg per day, with a recommended maximum of 16mg daily.
- If targeted dose is greater than 8-mg,, gradually increase the dose in 2mg increments over the next several days.
- The patient's condition just prior to the scheduled dosing time is one of the best ways to assess adequacy of the dose. (Refer to **Appendix F, Clinical Opiate Withdrawal Scale (COWS)**, for assessing withdrawal symptoms. Assessment should occur prior to the first dose 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 patient's dependent on opioids:**

- 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.
- 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.
- Monitor the patient in the office for up to 2 hours to ensure no vomiting and/or intolerance of the dose.
- Send patient home with the additional 2 mg dose and instructions to re-dose in 2-4 hours if withdrawal subsides, then reappears. Maximum dose for first day: 4 mg.
- Day 2: Patient returns to office. If there are no visible signs of withdrawal, 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

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home and re-dose later in the day if needed. Maximum dose for second day: 8 mg.

- Day 3: If patient needed the dose adjustment on Day 2, have the patient return for direct observation pre-dose and if there are no visible signs of withdrawal, give prescription for 8 mg film per day 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 film per day for the next 3 days.
- 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.
- 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 per day.
- 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 per day. Maximum recommended dose: 16 mg per day.

*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.**

**Specific recommendations for patients dependent on LONG ACTING opioids:**

- Doses of methadone should be decreased to a stable state of 30 mg of methadone or equivalent
- 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
- Begin induction consistent with observed withdrawal (at least 24 hours after last methadone dose ) No additional methadone given after induction begins.
- 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 an Opioid Treatment Program, "Hub," or some other higher level of care where daily dosing and directly observed therapy can be done is highly recommended. The patient should receive daily dosing 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.

- Urine screens should be done as clinically indicated but no less than monthly, optimally screens should be done randomly.
- Non-attendance for counseling for more than two consecutive sessions should trigger an automatic call from the counselor. The provider 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.

- Write 7 days' worth of medication prescriptions at a time for 2-month stabilization period.

### Maintenance and Follow Up

- Once the patient has demonstrated an active recovery process with counseling and prescriber visits, has demonstrated adherence with the Suboxone®, and indicates readiness to do so, the prescriber can extend the prescriptions to 14 days for the next 2 months. Film or pill counts may be a useful monitoring tool at this point. 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.
- After a period that varies with each patient but should reflect compliance with treatment, a prescription for 14 days may be written.
- 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, it is worth noting 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).

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(\*dose noted is the dose of buprenorphine)

		28-DAY Taper period	
*Stabilization Dose	8 mg	16mg	24 mg
Study Day			
1	8	16	24
2	8	16	24
3	6	12	20
4	6	12	20
5	6	12	20
6	6	10	16
7	6	10	16
8	6	10	16
9-11	6	8	12
12-14	6	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 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).

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**GUIDE FOR DOSE TARGETS (oral administration)**

<b><u>Buprenorphine</u></b> <b><u>Doses</u></b>	<b><u>Oxycodone</u></b>	<b><u>Morphine</u></b>	<b><u>Heroin</u></b>	<b><u>Methadone</u></b>
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

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## **PROVIDER INFORMATION AND SUPPORTS**

### **Prescriber Clinical Support System (PCSS-B)**

The SAMHSA-funded *PCSS-B* is designed to assist practicing prescribers 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)*. Prescribers 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 prescribers and staff. <http://pcssmat.org>.

### **SAMHSA Websites**

Substance Abuse and Mental Health Services Administration (SAMHSA)— [www.samhsa.gov](http://www.samhsa.gov) and <http://buprenorphine.samhsa.gov/> . Provides information on the DATA 2000, prescriber waiver qualifications, how to request a waiver form, buprenorphine trainings, and other information.

Center for Substance Abuse Treatment (CSAT) — <https://www.samhsa.gov/about-us/who-we-are/offices-centers/csat>

National Clearinghouse for Alcohol and Drug Information (NCADI)—a Department of Health and Human Services and SAMHSA website — [www.health.org](http://www.health.org).

### **Staff and Patient Education Resources**

*Medication-Assisted Treatment For Opioid Addiction in Opioid Treatment Programs In-service Training*, based on *Treatment Improvement Protocol 43*:

[https://www.ncbi.nlm.nih.gov/books/NBK64164/pdf/Bookshelf\\_NBK64164.pdf](https://www.ncbi.nlm.nih.gov/books/NBK64164/pdf/Bookshelf_NBK64164.pdf)

*Buprenorphine: A Guide for Nurses*: [https://www.integration.samhsa.gov/workforce/team-members/SAMHSA%e2%80%99s\\_Buprenorphine\\_\\_A\\_Guide\\_for\\_Nurses.pdf](https://www.integration.samhsa.gov/workforce/team-members/SAMHSA%e2%80%99s_Buprenorphine__A_Guide_for_Nurses.pdf)

*Note*: Guides for counselors and pharmacists will be made available soon through SAMHSA. For questions: [info@buprenorphine.samhsa.gov](mailto: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:

<https://www.aaap.org/education-training/buprenorphine/>

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AL-ANON and ALATEEN: [www.al-anon.alateen.org](http://www.al-anon.alateen.org)

American Association for the Treatment of Opioid Dependence (AATOD)—formerly the American Methadone Treatment Association, Inc.: [www.aatod.org](http://www.aatod.org)

Narcotics Anonymous: [www.na.org](http://www.na.org)

National Alliance of Methadone Advocates (NAMA): [www.methadone.org](http://www.methadone.org)

*Project Cork, Authoritative Information on Substance Abuse, Dartmouth Medical School:*  
<https://www.centerforebp.case.edu/resources/tools/project-cork-clinical-screening-tools>

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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>

<b>Diagnostic Criteria</b>	<b>Meets criteria?</b>	<b>Notes/Supporting information</b>
(Opioid Use Disorder requires at least 2 criteria be met within a 12-month period)	Yes OR 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		

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<p>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.</p>		
<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.

**Severity:** Mild: 2-3 symptoms, Moderate: 4-5 symptoms. Severe: 6 or more symptoms.

Signed \_\_\_\_\_ Date \_\_\_\_\_

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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 prescribers 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, D, 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: \_\_\_\_\_

<b>Ask patient each question, circle answer for each:</b>		
<b>Questions</b>	<b>Yes</b>	<b>No</b>
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
<b>Calculate total points.</b>		

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.

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- Design and implement quality improvement activities to improve the provision of care (learning collaborative, PDSA cycles).

**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 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.

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- Supports for smoking cessation and reduction of use of alcohol and other drugs.
- 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 Care are the** 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 are** 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.

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- Providing information about services and formal and informal resources, and education about health conditions and recommended treatments.
- Helping with navigating the health and human services systems.
- Aiding 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** are 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:
  - o 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
  - o Patient is breastfeeding a methadone or morphine dependent baby and history from the neonatologist or pediatrician has been submitted.

**APPENDIX D-II: BUPRENORPHINE Prior Authorization Request Form (Spokes/OBOTS)**

All formulations of buprenorphine require Prior Authorization. The forms can be found via this link for Spokes (Office-Based Opioid Treatment):

<http://dvha.vermont.gov/for-providers/buprenorphine-spokes.pdf>

A sample copy of the form appears below; however, it is recommended that you use the link above to access the most current version of this form.

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Department of Vermont Health Access  
NOB 1 South, 280 State Drive  
Waterbury, Vermont 05671-1010

**~BUPRENORPHINE~**

**Prior Authorization Request Form (Spokes/OBOTS)**

In order for beneficiaries to receive Medicaid coverage for medications that require prior authorization, the prescriber must complete and fax this form to Change Healthcare. Please complete this form in its entirety, sign and date below. Incomplete requests will be returned for additional information. For questions, please contact the Change Healthcare help desk at 1-844-679-5363.

**Submit request via Fax: 1-844-679-5366**

Prescribing physician: Name: _____ Physician NPI: _____ Specialty: _____ Phone#: _____ Fax#: _____ Address: _____ Contact Person at Office: _____	Beneficiary: Name: _____ Medicaid ID#: _____ Date of Birth: _____ Sex: _____ Pharmacy Name: _____ Pharmacy NPI: _____ Pharmacy Phone: _____ Pharmacy Fax: _____
--	---

Anticipated maintenance dose/ frequency (target dose  $\leq$  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: _____	<input type="checkbox"/> Yes <input type="checkbox"/> No
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
*Additional clinical information to support PA request: Please attach if necessary *Requests for non-preferred formulation(s) <u>must</u> include a completed MedWatch form	

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: \_\_\_\_\_

Last Updated: 11/2016



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

All formulations of buprenorphine require Prior Authorization except Suboxone Film in doses  $\leq 16$ mg. The forms can be found via this link for Hubs (Opiate Treatment Programs): <http://dvha.vermont.gov/for-providers/hub-buprenorphine-2016.11.pdf>

A sample copy of the form appears below; however, it is recommended that you use the link above to access the most current version of this form.

	
Department of Vermont Health Access NOB 1 South, 280 State Drive Waterbury, Vermont 05671-1010	
<b>~ HUB (OTP) BUPRENORPHINE Prior Authorization Form ~</b>	
All requests for Suboxone® Film > 16mg and Buprenorphine monotherapy in women who are pregnant or who are breastfeeding a morphine or methadone-dependent baby must be reviewed by the Change Healthcare Clinical Call Center. Documentation must accompany this form. For questions, please contact the Change Healthcare help desk at 1-844-679-5363.	
<b>Submit request via Fax: 844-679-5366</b>	
Prescribing physician: Name: _____ NPI: _____ Specialty: _____ Phone#: _____ Fax#: _____ Address: _____ Contact Person at HUB (OTP): _____	Beneficiary: Name: _____ Medicaid ID#: _____ Date of Birth: _____ Sex: _____ Diagnosis: _____ Date of Admission to HUB: _____
CHECK HERE IF PATIENT IS ADAP UNINSURED <input type="checkbox"/>	
Request is from the following HUB location: _____ / _____	
Name	NPI
<input type="checkbox"/> Suboxone® Film > 16 mg    Dose per day requested: _____ mg	
* Clinical note/letter from prescriber that documents the prescriber's clinical rationale for requesting Suboxone® Film >16mg must be attached (REQUIRED)	
<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)	
*Clinical note/letter from a pediatrician/neonatologist that documents that the member is breastfeeding a morphine or methadone dependent baby must be attached (REQUIRED)	
<input type="checkbox"/> Using buprenorphine mono to switch from methadone to Suboxone® Dates buprenorphine mono will be administered: _____	
<b>Please Note: All requests other than for Suboxone Film <math>\leq 16</math>mg must be directed to Change Healthcare by Fax: 844-679-5366</b>	
Prescriber Signature: _____ (stamps not acceptable) Date of request: _____	
	
Last Updated: 11/2016	

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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.

<b><u>PARAMETERS</u></b>	<b><u>FINDINGS</u></b>	<b><u>POINTS</u></b>
<b><i>Parameters based on Questions and Observation:</i></b>		
(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
<b><i>Parameters based on Observation Alone:</i></b>		
(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
<b>TOTAL SCORE</b>	[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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<b>Total Score</b>			
<b>Observer's Initials</b>			
<b>Blood Pressure/Pulse</b>			
<b>Dose of Suboxone<sup>®</sup> Given</b>			

**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.

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**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)
- (6) How much and what kind of information is to be disclosed.
- (7) 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.
- (8) The date on which the consent is signed.
- (9) 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.
- (10) 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 0930–099)

**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?**

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 should 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 if 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 prescriber 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<sup>®</sup> from methadone maintenance, your methadone dose should 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 understand that I have a substance use disorder. Medication alone is cannot treat my disease. I agree to participate in the recommended patient education and relapse prevention program, to help me in my treatment. I agree to have my doctor give me buprenorphine/naloxone treatment for opioid use disorder. I agree to this treatment:

1. I agree to keep, all my appointments with the doctor and his/her assistant. I agree to be on time.
2. I agree to be courteous in the prescriber's or clinic's office.
3. I agree to pay all office fees for this treatment at the time of my visits. I understand that this medication will cost between \$5 to \$10 a day just for medication and that the office visits are separate charges. I will be given a receipt that I can use to get reimbursement from my insurance company if this treatment is a covered service.
4. I agree to arrive at the office sober. If I am not sober, 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 know that this is a serious violation of this agreement that would result in my treatment being terminated with no chance for appeal.
6. I understand that the use of buprenorphine/naloxone (Suboxone®) by someone who is actively using 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 near the doctor's office.
8. I agree that my medication can only be given to me at my regular office visits. If I miss my appointment I will not get my medication until my 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.
10. I agree to tell my treating provider about any medications I take or get from another doctor or

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person. I know that mixing buprenorphine/naloxone (Suboxone®) with other medications, especially benzodiazepines, such as Valium® (diazepam), Xanax® (alprazolam), Librium® (chlordiazepoxide), Ativan® (lorazepam), and/or other drugs, is dangerous. I know that many deaths have been reported in persons mixing buprenorphine with benzodiazepines. I also know that drinking alcohol while taking this medication is dangerous. I know that drinking alcohol can cause excessive sedation or impaired thinking or other medically dangerous events.

11. I will take my medication as prescribed. I will ask the doctor if I would like to change the way I take my medication.

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

12. I understand that there are alternatives to buprenorphine/naloxone (Suboxone®) treatment for opioid use disorder including:

- o medical withdrawal and drug-free treatment
- o naltrexone treatment
- o methadone treatment

I understand that 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	<p><b>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.</b></p>
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<p><b>1. I agree to keep appointments and let appropriate staff know if I will be unable to show up as scheduled.</b></p>
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<p><b>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.</b></p>
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<p><b>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.</b></p>
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<p><b>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®.</b></p>

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<input type="checkbox"/> Yes	<input type="checkbox"/> No	<b>5.</b> 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	<b>6.</b> 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	<b>7.</b> 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	<b>8.</b> 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	<b>9.</b> 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	<b>10.</b> 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	<b>11.</b> 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	<b>12.</b> 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	<b>13.</b> I agree that I will arrange transportation to and from the treatment facility during my first days of taking Suboxone® so that I do not have to drive myself to and from the clinic or hospital.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<b>14.</b> 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 <b>accidental overdose, over-sedation, coma, or death.</b> I agree to use <b>no alcoholic beverages</b> and to take <b>no sedative drugs</b> 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.

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<input type="checkbox"/> Yes	<input type="checkbox"/> No	<b>15.</b> If a female, I am not pregnant, and will not attempt to become pregnant. I will not have unprotected sex while I am taking Suboxone®, because of the unknown safety of buprenorphine during pregnancy. I will tell my doctor if I become pregnant so that other treatment options can be discussed with me.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<b>16.</b> I want to be in recovery from addiction to all drugs, and I have been informed that any active addiction to other drugs besides heroin and other opiates must be treated by counseling and other methods. I have been informed that buprenorphine, as found in Suboxone®, is a treatment designed to treat opioid dependence, not addiction to other classes of drugs.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<b>17.</b> I agree that medication management of addiction with buprenorphine, as found in Suboxone®, is only one part of the treatment of my addiction, and I agree to participate in a regular program of professional counseling while being treated with Suboxone®.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<b>18.</b> 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.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<b>19.</b> I agree to participate in a regular program of peer/self-help while being treated with Suboxone®.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<b>20.</b> I agree that the support of loved ones is an important part of recovery, and I agree to invite significant persons in my life to participate in my treatment.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<b>21.</b> I agree that a network of support, and communication among persons in that network, is an important part of my recovery. I will be asked for my authorization, if required (which it almost always is) to allow telephone, email, or face-to-face contact, as appropriate, between my treatment team and outside parties, including physicians, therapists, probation and parole officers, and other parties, when the staff has decided that open communication about my case, on my behalf, is necessary.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<b>22.</b> I agree that I will be open and honest with my counselors and inform staff about cravings, potential for relapse to the extent that I am aware of such, and specifically about any relapse which <i>has</i> occurred -- <i>before</i> a drug test result shows it.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<b>23.</b> I have been given a copy of clinic procedures, including hours of operation, the clinic phone number, and responsibilities to me as a recipient of addiction treatment services, including buprenorphine treatment with Suboxone®.

Patient Signature: \_\_\_\_\_

Date: \_\_\_\_\_

Staff Signature/Title: \_\_\_\_\_

Date: \_\_\_\_\_

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**APPENDIX H: ASAM ADULT ADMISSION CROSSWALK**

<b>Criteria Dimensions</b>	<b>Level 0.5 Early Intervention</b>	<b>OMT Opioid Maintenance Therapy</b>	<b>Level 1 Outpatient Services</b>	<b>Level II.1 Intensive Outpatient</b>	<b>Level II.5 Partial Hospitalization</b>
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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Dimension 5: Relapse, Continued use or Continued potential problem	Needs an understanding of, or skills to change current alcohol and drug use patterns	At high risk of relapse or continued use without OMT and structured therapy to promoted treatment progress	Able to maintain abstinence or control use and pursue recovery or motivational goals with minimal support	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	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
Dimension 6: Recovery Environment	Social support system or significant others increase the risk of personal conflict about alcohol or drug use	Recovery environment is supportive and/or the client has skills to cope	Recovery environment is supportive and /or the client has skills to cope	Recovery environment is not supportive but, with structure & support, the client can cope	Recovery environment is not supportive but, w/ structure & support & relief from the home environment, the client can cope

<b>Criteria dimensions</b>	<b>Level III.1 Clinically Managed Low Intensity Residential Services</b>	<b>Level III.3 Clinically- managed Medium Intensity Residential Services</b>	<b>Level III.5 Clinically- managed Medium / High Intensity Residential Services</b>
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	None or stable, or receiving concurrent	None or stable, or receiving concurrent medical monitoring	None or stable, or receiving concurrent medical

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Conditions & Complications	medical monitoring		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 III
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 support environment	Environment is dangerous but recovery is achievable if Level III.1 24-hour structure is available	Environment is dangerous and client needs 24-hour structure to learn to cope	Environment is dangerous, and the client lacks the skills to cope outside a highly structured 24-hour setting

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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 require 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>