

DEPARTMENT OF VERMONT HEALTH ACCESS
VERMONT SUBSTANCE USE DISORDER
OFFICE BASED OPIOID TREATMENT GUIDELINES

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Table of Contents

INTRODUCTION	3
Guideline Purpose and Limitations	3
OVERVIEW	3
Regulatory Background	4
Buprenorphine Treatment	5
Buprenorphine & Naloxone	5
Safety Issues with Buprenorphine	6
Treatment of Opioid Use Disorder with Buprenorphine	7
Diversion and Misuse of Buprenorphine	8
Vermont Prescription Monitoring System (VPMS)	8
Special Populations	9
Vermont Medicaid – Available Buprenorphine Preparations	11
Drug Testing in Clinical Addiction Treatment	12
Pharmacy Home	13
Primary Therapy and Continuing Care	13
PHASES OF BUPRENORPHINE TREATMENT	14
Determining a Patient’s Motivation and Readiness (Stages of Change)	14
Screening/Intake	14
Sublingual Administration	16
Induction	16
Stabilization, Maintenance and Follow Up	18
GUIDE FOR DOSE TARGETS (oral administration)	19
Dosing Frequency	19
Patients Who Do Not Stabilize	19
Tapering Patients off a Stable Buprenorphine Dose	19
ACKNOWLEDGEMENTS	21
PROVIDER INFORMATION AND SUPPORTS	22
REFERENCES	24
Appendix A: DSM-V DIAGNOSIS OF OPIOID USE DISORDER	27
APPENDIX B: TREATMENT NEEDS QUESTIONNAIRE	29
APPENDIX C: Office Based Opioid Treatment (OBOT) Stability Index	31
APPENDIX D: Health Home Services Hub & Spoke	32
APPENDIX E-I: DVHA CLINICAL CRITERIA FOR SUBOXONE®/BUPRENORPHINE PRIOR APPROVAL	36
APPENDIX E-II: BUPRENORPHINE Prior Authorization Request Form (Spokes/OBOTS)	37

*DEPARTMENT OF VERMONT HEALTH ACCESS MANAGED CARE ENTITY
VERMONT OFFICE BASED OPIOID TREATMENT PRACTICE GUIDELINES*

APPENDIX E-III: HUB (OTP) BUPRENORPHINE Prior Authorization Form38
APPENDIX F: CLINICAL INSITUTE NARCOTIC ASSESSMENT (CINA) SCALE FOR WITHDRAWAL SYMPTOMS40
APPENDIX G: CLINICAL OPIATE WITHDRAWAL SCALE (COWS)41
APPENDIX H: SAMPLE 28-DAY TAPER43
APPENDIX I: PATIENT CONSENT FOR RELEASE OF INFORMATION44
APPENDIX I-II: BUPRENORPHINE/NALOXONE (SUBOXONE®) TREATMENT INFORMATION TO SHARE WITH PATIENTS
.....46

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 periodically. Guidelines may not apply to every patient or clinical situation; some divergence from guidelines is expected. Guidelines are flexible 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/or 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.”

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 in a general medical setting with the required training and ability to provide clinical evaluation, buprenorphine

DEPARTMENT OF VERMONT HEALTH ACCESS MANAGED CARE ENTITY
VERMONT OFFICE BASED OPIOID TREATMENT PRACTICE GUIDELINES

induction, maintenance prescriptions, and follow up. In addition, OBOT may offer other medications consistent with FDA approval for the management of Opioid Use Disorder.

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)

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 D**) for Vermonters with opioid use disorder.

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

- *Enhances Methadone treatment programs OTPs (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 OBOTs (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 at least one of the following Health Home services monthly:

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

Implementation materials for the Vermont OBOT (Spoke) program can be found here:

<https://blueprintforhealth.vermont.gov/implementation-materials>

Regulatory Background

On October 17, 2000, "The Children's Health Act of 2000" (HR 4365) was signed into federal law. Section 3502 of that act set forth "Drug Addiction Treatment Act of 2000 (DATA)". This legislation provided significant changes in the oversight of the medical treatment of opioid addiction by allowing physicians to provide treatment with opioid medications in office-based settings under certain restrictions. This new treatment modality made it possible for physicians to treat patients for opioid addiction with Schedules III–V controlled substances specifically approved by the FDA for addiction treatment in physician offices,

*DEPARTMENT OF VERMONT HEALTH ACCESS MANAGED CARE ENTITY
VERMONT OFFICE BASED OPIOID TREATMENT PRACTICE GUIDELINES*

primarily buprenorphine-containing products, instead of referring patients to specialized opioid treatment programs (OTPs), as previously required under federal law. Subsequent Federal Legislation allows for Advanced Practice Nurses and Physician’s Assistants to also become waived to prescribe Buprenorphine related products for the management of Opioid Use Disorder.

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.

Rules apply to all prescribers who treat thirty (30) or more patients with buprenorphine and to all the Opioid Treatment Programs (OTPs). For the latest regulations, please refer to the current *Vermont Department of Health Medication Assisted Treatment for Opioid Dependence Rules* at:

https://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 misused due to its opioid agonist effects, naloxone is added to buprenorphine to decrease the likelihood of diversion and misuse of the combination product. <https://www.samhsa.gov/medication-assisted-treatment/treatment/naloxone>

DEPARTMENT OF VERMONT HEALTH ACCESS MANAGED CARE ENTITY
VERMONT OFFICE BASED OPIOID TREATMENT PRACTICE GUIDELINES

There are several different formulations of buprenorphine and buprenorphine/naloxone including oral sublingual, oral buccal, depot injections, and implants. For a current list of available products covered by Vermont Medicaid and coverage criteria, please refer to the Preferred Drug List at <https://dvha.vermont.gov/providers/pharmacy/preferred-drug-list-pdl-clinical-criteria>

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 of buprenorphine exposure in children and opiate naïve individuals and instructed on safe storage, including keeping medications in a secure place such as a lock box or locked cabinet.

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.

The Vermont Department of Health has partnered with a growing number of community-based organizations to distribute overdose rescue kits containing naloxone. Individuals can get naloxone as well as prevention and overdose response training designed and approved by the Health Department at these distribution sites: <https://www.healthvermont.gov/emergency/injury/opioid-overdose-prevention> 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.

VT Helplink is the Vermont Department of Health's statewide resource for finding substance use treatment & recovery services, information, and other resources: <https://vthelplink.org/>

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/overdosing. 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 must follow referral requirements per the MAT rules, which can be found here: https://www.healthvermont.gov/sites/default/files/documents/pdf/REG_opioids-medication-assisted-therapy-for-dependence.pdf

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

Waivered prescribers 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.

Waivered prescribers must also develop succession plans per the MAT rule to assure continuity of care to their patients should they no longer be able to treat them.

Diversion and Misuse of Buprenorphine

Buprenorphine may be diverted for use by individuals who are seeking euphoria who are relatively opioid naïve, by individuals who are not currently accessing treatment 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.

Overly high or low doses of buprenorphine can 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 suspicion 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) per the VPMS Rule to monitor for opioid prescriptions or other medication that may be misused. The VPMS Rule can be found here: https://www.healthvermont.gov/sites/default/files/documents/pdf/REG_vpms-20170701.pdf
- More frequent checks of the VPMS system are recommended for new patients and/or patients experiencing instability or at risk for instability (to be checked at least quarterly).
- 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 norbuprenorphine, which is a metabolite of buprenorphine.
- Observed urine specimen collection when clinically indicated for high-risk individuals such as illicit use of opioids or history of overdosing.
- Film/tablet call-backs (for counting), ideally administered randomly with minimal prior notice.
 - o Film packets are designed with serialized identification numbers

Vermont Prescription Monitoring System (VPMS)

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

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 misuse, 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

*DEPARTMENT OF VERMONT HEALTH ACCESS MANAGED CARE ENTITY
VERMONT OFFICE BASED OPIOID TREATMENT PRACTICE GUIDELINES*

Vermont and so prescription activity in border towns may not be reflected in the VPMS. The VPMS is located here: <https://vermont.pmpaware.net/login>

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;
- Prior to prescribing buprenorphine or a drug containing buprenorphine to a Vermont patient for the first time and at regular intervals thereafter:
 - No less than twice annually. However, this guideline recommends quarterly.
 - Prior to writing a replacement prescription.
- In the case of an OTP, prior to prescribing a drug containing buprenorphine or methadone, to a Vermont patient for the first time, and:
 - Annually thereafter; and
 - Any other time that is clinically warranted.

Prior to prescribing 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 (PDL), prescribers must receive prior approval. Please refer to the PDL for coverage and clinical criteria:

<https://dvha.vermont.gov/providers/pharmacy/preferred-drug-list-pdl-clinical-criteria>

The Vermont Prescription Monitoring System Rules created by 18 V.S.A. chapter 84A and further guidance can be reviewed at:

https://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

DEPARTMENT OF VERMONT HEALTH ACCESS MANAGED CARE ENTITY
VERMONT OFFICE BASED OPIOID TREATMENT PRACTICE GUIDELINES

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.

ASAM Guidance: “Buprenorphine Monoprodut versus Buprenorphine/Naloxone. While the evidence on the safety and efficacy of naloxone in pregnant women remains limited, the combination buprenorphine/naloxone product is frequently used, and the consensus of the guideline committee is that the combination product is safe and effective for this population. Naloxone is minimally absorbed when these medications are taken as prescribed.”

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.

The following list indicates the recommended pain management steps in ascending order:

- 1) NSAIDS are effective and underutilized and are safe to prescribe with buprenorphine. Simple dental extractions are an example.
- 2) Buprenorphine is typically taken as a once-a-day medication for the treatment of opioid use disorder. A patient’s daily dose could be divided and taken three to four times daily to increase analgesic effect. Increasing the dose of buprenorphine may provide additional analgesic relief.
- 3) Recent research is showing full strength agonists (e.g. morphine, hydromorphone) are effective in low doses for pain of limited intensity and limited duration. Some examples are following cesarean section or complicated dental extractions. If this is the preferred treatment, local pharmacies will need to be forewarned and assured that our practice is aware. Otherwise, the patient will not be able to fill your prescription.
- 4) More painful procedures require a more complicated strategy. The buprenorphine dose should be reduced by 50% and this deleted amount should be replaced by an equivalent dose of a full agonist on the day of surgery and through the period of expected post-operative pain. In addition to this, a typical post-operative pain regimen can be prescribed.
- 5) For procedures that will result in significant pain, it may be necessary to cease buprenorphine and convert to full agonist opioids. In such cases, the patient’s post-operative dosage on the full agonist will be a sum of the dosage for pain plus that opioid’s buprenorphine equivalent.

DEPARTMENT OF VERMONT HEALTH ACCESS MANAGED CARE ENTITY
VERMONT OFFICE BASED OPIOID TREATMENT PRACTICE GUIDELINES

- 6) Treat patients receiving Sublocade with a non-opioid analgesic whenever possible. Patients requiring opioid therapy for analgesia may be treated with a high-affinity full opioid analgesic under the supervision of a physician, with particular attention to respiratory function. Surgical removal of the Sublocade depot is possible within the first 14 days following injection, if necessary.
- 7) Dependent on the patient's setting, additional strategies might include: regional anesthesia, IV anesthetics, steroids, or gabapentin. For other non-pharmacologic approaches, additional strategies might include: yoga, acupuncture, or other mindful-based activities.

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).

Vermont Medicaid – Available Buprenorphine Preparations

Vermont Medicaid covers all forms of MAT therapy, including buprenorphine and buprenorphine/naloxone preparations. The Preferred Drug List (PDL) contains a list of all preferred and non-preferred products along with the clinical criteria for use. For our preferred products, no PA is required unless the dose exceeds 16mg per day. The maximum allowed days' supply is 30-days. Please refer to the PDL for the most current information on drugs and coverage criteria:

<https://dvha.vermont.gov/providers/pharmacy/preferred-drug-list-pdl-clinical-criteria>.

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.

DEPARTMENT OF VERMONT HEALTH ACCESS MANAGED CARE ENTITY
VERMONT OFFICE BASED OPIOID TREATMENT PRACTICE GUIDELINES

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 misuse 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 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:

<https://dvha.vermont.gov/providers/pharmacy/preferred-drug-list-pdl-clinical-criteria>

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) recommends urine testing as one component of a plan to monitor treatment response. There is no clinical consensus on the frequency of urine drug testing therefore DVHA recommends providers develop testing protocols based on the following principles:

- (1) Patients receiving MAT should be stratified into groups of predicted risk for relapse.
- (2) The frequency of testing should be determined by the risk stratification grouping.
- (3) Testing at random intervals is the strongest practice.
- (4) Point of care testing is fully acceptable.
- (5) Test results should be used to regularly adjust the patient's treatment plan.
- (6) Treatment plan adjustments based on urine drug screening results should be individualized to each patient and therefore reflect differences in:
 - Frequency of contact;
 - Type of supports and interventions provided, and;
 - Intensity of interventions including referral to higher levels of care.

DEPARTMENT OF VERMONT HEALTH ACCESS MANAGED CARE ENTITY
VERMONT OFFICE BASED OPIOID TREATMENT PRACTICE GUIDELINES

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)

DVHA also fully endorses BlueCross BlueShield of Vermont’s *Substance Use Disorder Treatment and Pain Management: Urine Drug Testing*, for continued guidance.

<https://www.bcbsvt.com/sites/default/files/2020-12/substance-use-disorder-treatment-and-pain-management-urine-drug-testing-20210101.pdf>

Pharmacy Home

The use of a single pharmacy for all prescriptions, called a *Pharmacy Home* or a *Pharmacy Lock-In*, is not required for DVHA buprenorphine patients. However, it is an option that providers may choose via a Prior Authorization request form. A *Pharmacy Home* or *Pharmacy Lock-In* program may be a useful option for members who may need additional support. This requires patients to receive their medication from a single pharmacy to better control medication access and help prevent misuse.

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 use disorders, for example, such as Cognitive Behavioral Therapy, Motivation Enhancement Therapy, and Dialectical Behavioral Therapy. Research has shown comprehensive and sustained substance use 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 use 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
- 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** and **C** 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 use and treatment history to identify whether the patient has ever been on buprenorphine, methadone, or other medications for opioid addiction and to ensure patient meets criteria for moderate or severe opioid use disorder and is not currently on methadone (see page 540, DSM-5, *Diagnosis of Opioid Use Disorder*). If a patient reports they have been using buprenorphine obtained on the street, and even provides the dose they have been taking, they still should go through the induction process to determine the appropriate clinical dose. If there is evidence of a
 - 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. Physical and mental health status exam focused on assuring safety and suitability to receive treatment with buprenorphine such as:
 - 14 | 47
 - objective signs of impairment or withdrawal, sequelae of injection drug use and the like.

DEPARTMENT OF VERMONT HEALTH ACCESS MANAGED CARE ENTITY
VERMONT OFFICE BASED OPIOID TREATMENT PRACTICE GUIDELINES

- 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 or with utilization of validity markers of point of care testing) 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 F**). The urine specimen can also be sent to an outside laboratory for more sensitive measures for detecting commonly used 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 use 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) may be considered.

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 I-I, I-II, I-III and I-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 use 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 or others. Signed releases should be placed in the patient chart (see **Appendix 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 Further Assessment

Certain factors *may* suggest a patient is less likely to be an appropriate candidate for office-based buprenorphine treatment (see **Appendix B** 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;

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VERMONT OFFICE BASED OPIOID TREATMENT PRACTICE GUIDELINES

- Active psychiatric co-morbidity;
- Active or chronic suicidal or homicidal ideation or attempts (current or very recent);
- 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* table in the Stabilization section.)

General Guidelines for patients physically dependent on opioids:

- Plan on 3-5 days for stable dosing.
- 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.)
- Fentanyl and other high potency synthetic opioids will not show up on a standard CLIA-waived urine toxicology screen and should be checked using LCMSMS. Additionally checking for fentanyl is strongly encouraged as even low dose buprenorphine may precipitate severe withdrawal in fentanyl predominant users.

DEPARTMENT OF VERMONT HEALTH ACCESS MANAGED CARE ENTITY
VERMONT OFFICE BASED OPIOID TREATMENT PRACTICE GUIDELINES

- 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 G**, *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).

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 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.

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VERMONT OFFICE BASED OPIOID TREATMENT PRACTICE GUIDELINES*

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.

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.

Stabilization, Maintenance and Follow Up

Many patients become stable with consistent access to buprenorphine. Patients may remain on a stabilizing dose indefinitely.

- Urine screens should be done as clinically indicated but no less than monthly, optimally screens should be done randomly.
- Counseling is an augmentation to treatment but is not required to receive medication. It is strongly recommended that patients who are not stable engage in counseling. Medication only may be recommended for individuals stable in their recovery and meeting all requirements and treatment plan expectations of their medical provider. Please see **Appendix C** for the OBOT Stability Index.
- When providers begin prescribing buprenorphine/naloxone, begin with a 7-day prescription as recommended in the OBOT Stability Index. As patients stabilize, increasing the days' supply of prescriptions may be appropriate. Up to 30 days' buprenorphine is allowed depending on the patient's needs and stability, as determined by the provider. Film or pill counts may be a useful monitoring tool at this point.
- When a patient becomes stable on medication, the focus on treatment shifts to other

DEPARTMENT OF VERMONT HEALTH ACCESS MANAGED CARE ENTITY
VERMONT OFFICE BASED OPIOID TREATMENT PRACTICE GUIDELINES

additional supportive services and/or treatments. This is to help maintain continued engagement and relapse prevention.

GUIDE FOR DOSE TARGETS (oral administration)

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

Dosing Frequency

Buprenorphine is generally recommended to be administered once daily.

Patients Who Do Not Stabilize

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. Alternatively, if the patient cannot be transferred to a Hub, an option is to shift to observed dosing on a less frequent basis (e.g. every other day) by increasing the amount on the dosing day by the amount not received on the intervening days. For individuals who achieve a stable dose but who may not stabilize otherwise (e.g. risk of diversion), a depot formulation may be in consideration.

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 28-day taper is not necessarily the standard of care, this is just one example

*DEPARTMENT OF VERMONT HEALTH ACCESS MANAGED CARE ENTITY
VERMONT OFFICE BASED OPIOID TREATMENT PRACTICE GUIDELINES*

of a taper schedule. Tapering should be tailored to the patient and may be longer or shorter in duration depending on specific patient needs.

A subset of opioid-dependent patients may do well with antagonist therapy. Antagonist therapy, for example sustained-released naltrexone formulations, may provide ongoing pharmacological support in the weeks and months following opioid taper. Other psychosocial services will likely be important for good long-term outcomes (Sigmon et al., 2012).

For an example of a 28-day taper, please refer to **Appendix H**.

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For more information from Vermont-specific resources and clinical supports, please refer to the following websites:

<https://www.healthvermont.gov/alcohol-drugs>

<https://dvha.vermont.gov/providers>

<http://www.med.uvm.edu/vchip/home>

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. <https://pcssnow.org/>

SAMHSA Websites

Substance Abuse and Mental Health Services Administration (SAMHSA)— www.samhsa.gov and <https://www.samhsa.gov/medication-assisted-treatment/become-buprenorphine-waivered-practitioner> 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>

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

Buprenorphine: A Guide for Nurses: <https://www.naabt.org/documents/TAP30.pdf>

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 Use-Related Websites

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

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

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

American Association for the Treatment of Opioid Dependence (AATOD)—formerly the American

*DEPARTMENT OF VERMONT HEALTH ACCESS MANAGED CARE ENTITY
VERMONT OFFICE BASED OPIOID TREATMENT PRACTICE GUIDELINES*

Methadone Treatment Association, Inc.: www.aatod.org

American Society of Addiction Medicine (ASAM): <https://www.asam.org/asam-home-page>

Narcotics Anonymous: www.na.org

National Alliance of Methadone Advocates (NAMA): 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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<https://bup.clinicalencounters.com/provider-materials/>

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DEPARTMENT OF VERMONT HEALTH ACCESS MANAGED CARE ENTITY
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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>

Diagnostic Criteria (Opioid Use Disorder requires at least 2 criteria be met within a 12-month period)	Meets criteria? Yes OR No	Notes/Supporting information
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.		

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VERMONT OFFICE BASED OPIOID TREATMENT PRACTICE GUIDELINES*

8. Recurrent opioid use in situations in which it is physically hazardous		
9. Continued use despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by opioids.		
10. *Tolerance, as defined by either of the following: (a) a need for markedly increased amounts of opioids to achieve intoxication or desired effect (b) markedly diminished effect with continued use of the same amount of an opioid		
11. *Withdrawal, as manifested by either of the following: (a) the characteristic opioid withdrawal syndrome (b) the same (or a closely related) substance are taken to relieve or avoid withdrawal symptoms		

*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 _____

APPENDIX B: 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.

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VERMONT OFFICE BASED OPIOID TREATMENT PRACTICE GUIDELINES

TREATMENT NEEDS QUESTIONNAIRE

Patient Name/ID: _____ Date: _____ Staff Name/ID: _____

Ask patient each question, circle answer for each	Yes	No
Have you ever used a drug intravenously?	2	0
If you have ever been on medication-assisted treatment (e.g. methadone, buprenorphine) before, were you successful? (If never in treatment before, leave answer blank)	0	2
Do you have a chronic pain issue that needs treatment?	2	0
Do you have any significant medical problems (e.g. hepatitis, heart disease, COPD, diabetes)?	1	0
Do you ever use stimulants (cocaine, methamphetamines), even occasionally?	2	0
Do you ever use benzodiazepines, even occasionally?	2	0
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
Do you have any psychiatric problems (e.g. major depression, bipolar, severe anxiety, ADHD, PTSD, schizophrenia, personality subtype of antisocial, borderline, or sociopathy)?	1	0
Are you currently going to any counseling, AA or NA?	0	1
Are you motivated for treatment?	0	1
Do you have a partner that uses drugs or alcohol?	1	0
Do you have 2 or more close friends or family members who do not use alcohol or drugs?	0	1
Is your housing stable?	0	1
Do you have access to reliable transportation?	0	1
Do you have a reliable phone number?	0	1
Did you receive a high school diploma or equivalent (e.g. did you complete 12 years of education)?	0	1
Are you employed?	0	1
Do you have any legal issues (e.g. charges pending, probation/parole, etc)?	1	0
Are you currently on probation or parole?	1	0
Have you ever been charged (not necessarily convicted) with drug dealing or distribution?	1	0

Totals _____ + _____

Total possible points is 26. The following are **recommendations**:
 Scores 0-5 candidate for spoke with minimal additional supports
 Scores 6-10 candidate for spoke with structured on-site behavioral health and/or case management services
 Scores 11-15 candidate for spoke by board certified addiction physician in a tightly structured program or HUB evaluation and induction with follow up by office based provider or continued HUB status
 Scores above 16 recommended HUB (Opioid Treatment Program-OTP) or highly structured spoke program

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APPENDIX C: Office Based Opioid Treatment (OBOT) Stability Index

OBOT Stability Index

1) Was the patient's previous urine drug screen positive for illicit substances? <input type="checkbox"/> Yes <input type="checkbox"/> No
2) If YES to #1 or if the patient was recently started on buprenorphine, does the patient have fewer than four consecutive weekly drug-free urine drug screens? <input type="checkbox"/> Yes <input type="checkbox"/> No
3) Is the patient using sedative-hypnotic drugs (e.g. benzodiazepines) or admitting to alcohol use? <input type="checkbox"/> Yes <input type="checkbox"/> No
4) Does the patient report drug craving that is difficult to control? <input type="checkbox"/> Yes <input type="checkbox"/> No
5) Does the patient endorse having used illicit substances in the past month? <input type="checkbox"/> Yes <input type="checkbox"/> No
6) Does the query of the Vermont Prescription Monitoring System (VPMS) show evidence of the unexplained, unadmitted, or otherwise concerning provision of controlled substances? <input type="checkbox"/> Yes <input type="checkbox"/> No
7) Did the patient report their last prescription as being lost or stolen? <input type="checkbox"/> Yes <input type="checkbox"/> No
8) Did the patient run out of medication early from his/ her last prescription? <input type="checkbox"/> Yes <input type="checkbox"/> No

SCORING:

If **NO** to all, the patient is "stable" can be seen monthly for prescriptions and urine drug screens.

If **YES** to any of the above, the patient is "unstable" and needs to be seen weekly for prescriptions and urine drug screens.

Additionally, if **YES** to 1-6, the patient should be referred for addiction services.

APPENDIX D: 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 use 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,

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VERMONT OFFICE BASED OPIOID TREATMENT PRACTICE GUIDELINES*

and patient experience of care.

- 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 use 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 use 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 use.
- Supports for management of chronic pain and depression.

*DEPARTMENT OF VERMONT HEALTH ACCESS MANAGED CARE ENTITY
VERMONT OFFICE BASED OPIOID TREATMENT PRACTICE GUIDELINES*

- 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.

*DEPARTMENT OF VERMONT HEALTH ACCESS MANAGED CARE ENTITY
VERMONT OFFICE BASED OPIOID TREATMENT PRACTICE GUIDELINES*

- 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 E-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”).

AND

BUPRENORPHINE/NALOXONE (formerly Suboxone®) sublingual TABLET

QTY LIMIT: 8 mg = 2 tablets/day (Maximum Daily Dose = 16 mg/day for Hubs, 24mg/day for Hubs-PA required for doses exceeding the maximum).

SUBOXONE® sublingual FILM(buprenorphine/naloxone)

QTY LIMIT: 8 mg = 2 films per day, 4 and 12 mg = 1 film per day (Maximum daily Dose = 16 mg/day, 24mg/day for Hubs- PA required for doses exceeding the maximum)

Buprenorphine (Mono) Tablets

Patient is either pregnant and copy of positive pregnancy test has been submitted (duration of PA will be one 1 month post anticipated delivery date) OR Patient is breastfeeding an opiate dependent baby and history from the neonatologist or pediatrician has been submitted. Other requests will be considered after a documented trial and failure of all oral buprenorphine/naloxone combination products.

Maximum days’ supply for oral buprenorphine/naloxone films or buprenorphine is 30 days. Requests to exceed quantity limits or maximum daily dose: documentation must be submitted detailing medical necessity for requested dosage regimen.

CLINICAL CONSIDERATIONS: Prescriber must have a DATA 2000waiver ID number (“X DEA License”) to prescribe buprenorphine or buprenorphine/naloxone combination products used for the treatment of opioid dependence. These products are not FDA approved for alleviation of pain. For Buprenorphine products indicated for pain, please refer to the Opioid Analgesics PDL category.

DEPARTMENT OF VERMONT HEALTH ACCESS MANAGED CARE ENTITY
VERMONT OFFICE BASED OPIOID TREATMENT PRACTICE GUIDELINES

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

Some doses and formulations of buprenorphine require Prior Authorization. The forms can be found via this link for Spokes (Office-Based Opioid Treatment):
<https://dvha.vermont.gov/forms-manuals/forms/pharmacy-prior-authorization-request-forms-and-order-forms>

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.

VERMONT
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 members 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 ≤ 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
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 MAY BE selected, but is no longer required. Write the name of the pharmacy if a lock in is being requested.	
If this request is for Buprenorphine (formerly Subutex®), please answer the following questions: Is the member pregnant? (please provide positive pregnancy test copy) If yes, anticipated date of delivery: _____ Duration of approval will be up to 1 month post anticipated due date.	<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
*Other requests will be considered after documented trial and failure of ALL oral Buprenorphine/Naloxone combination products.	
*Requests for non-preferred formulation(s) must include a completed MedWatch form documenting a provider-observed reaction severe enough to require discontinuation. Documentation of measures tried to mitigate/manage symptoms is required. *Requests to exceed quantity limits or max daily dose must include documentation detailing medical necessity for requested dosing regimen. *If multiple doses are being requested to facilitate TITRATION, please indicate below:	

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: _____

CHANGE
HEALTHCARE

Last Updated: 10/2018

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

All formulations of buprenorphine require Prior Authorization except Suboxone Film and Buprenorphine/Naloxone Tablets in doses \leq 16mg. The forms can be found via this link:

<https://dvha.vermont.gov/forms-manuals/forms/pharmacy-prior-authorization-request-forms-and-order-forms>

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 MANAGED CARE ENTITY
VERMONT OFFICE BASED OPIOID TREATMENT PRACTICE GUIDELINES



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

~ HUB (OTP) BUPRENORPHINE Prior Authorization Form ~

All requests for Suboxone® Film > 24mg, Buprenorphine/Naloxone tablets, and Buprenorphine monotherapy 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.

Submit request via Fax: 844-679-5366

Prescribing physician:	Member:
Name: _____	Name: _____
NPI: _____	Medicaid ID#: _____
Specialty: _____	Date of Birth: _____ Sex: _____
Phone#: _____	Diagnosis: _____
Fax#: _____	Date of Admission to HUB: _____
Address: _____	
Contact Person at HUB (OTP): _____	

CHECK HERE IF PATIENT IS ADAP UNINSURED

Request is from the following HUB location: _____ / _____

Name	NPI
<input type="checkbox"/> Suboxone® Film > 24 mg Dose per day requested: _____ mg	
* Clinical note/letter from prescriber that documents the prescriber's clinical rationale for requesting Suboxone® Film >24mg must be attached (REQUIRED). Requests for doses >24mg will require review by DVHA Medical Director.	
<input type="checkbox"/> Buprenorphine/Naloxone tablets Dose per day requested: _____ mg	
* FDA Medwatch form documenting a provider observed reaction to Suboxone® Film severe enough to require discontinuation including measures taken to mitigate/manage symptoms must be attached (REQUIRED)	
<input type="checkbox"/> Buprenorphine (mono formulation) 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 an opiate dependent baby (baby is being administered morphine or methadone for opiate withdrawal symptoms) *Clinical note/letter from a pediatrician/neonatologist must be attached (REQUIRED)	
<input type="checkbox"/> Using buprenorphine mono to switch from methadone to Suboxone® Dates buprenorphine mono will be administered: _____	
<input type="checkbox"/> Using buprenorphine mono due to provider observed reaction to both Suboxone® Film and Buprenorphine/Naloxone tablets severe enough to require discontinuation * FDA Medwatch form documenting reaction and measures taken to mitigate/manage symptoms must be attached (REQUIRED)	

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



Last Updated: 05/2019

**DEPARTMENT OF VERMONT HEALTH ACCESS MANAGED CARE ENTITY
VERMONT OFFICE BASED OPIOID TREATMENT PRACTICE GUIDELINES**

APPENDIX F: CLINICAL INSITUTE NARCOTIC ASSESSMENT (CINA) SCALE FOR WITHDRAWAL SYMPTOMS

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

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

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

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

DEPARTMENT OF VERMONT HEALTH ACCESS MANAGED CARE ENTITY
VERMONT OFFICE BASED OPIOID TREATMENT PRACTICE GUIDELINES

APPENDIX G: CLINICAL OPIATE WITHDRAWAL SCALE (COWS)

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

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

DEPARTMENT OF VERMONT HEALTH ACCESS MANAGED CARE ENTITY
 VERMONT OFFICE BASED OPIOID TREATMENT PRACTICE GUIDELINES

Total Score			
Observer's Initials			
Blood Pressure/Pulse			
Dose of Suboxone® Given			

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

APPENDIX H: SAMPLE 28-DAY TAPER

SUBOXONE® TAPER REGIMEN
 (*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.

APPENDIX I: PATIENT CONSENT FOR RELEASE OF INFORMATION

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

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

DEPARTMENT OF VERMONT HEALTH ACCESS MANAGED CARE ENTITY
VERMONT OFFICE BASED OPIOID TREATMENT PRACTICE GUIDELINES

APPENDIX I: PATIENT CONSENT FOR RELEASE OF INFORMATION

-- Sample--

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 _____

Additional sample consent forms can be found at <https://pcssnow.org/resources/clinical-tools/>.

APPENDIX I-II: BUPRENORPHINE/NALOXONE (SUBOXONE®) TREATMENT INFORMATION TO SHARE WITH PATIENTS

Suboxone Film: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/022410s042lbl.pdf#page=34

Buprenorphine/Naloxone

Tablets: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/020733s028lbl.pdf#page=32

Buprenorphine Mono

Tablets: https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/020732s006s007mg.pdf

Sublocade: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/209819s017s018lbl.pdf#page=43