

Chapter 8 – Alcohol and Drug Abuse
Subchapter 6

Rules Governing Medication-Assisted ~~Therapy Treatment~~ for Opioid ~~Dependence Use~~
Disorder for:

1. Office-Based Opioid Treatment (OBOT) Providers ~~Prescribing Buprenorphine~~
2. Opioid Treatment ~~Providers Programs~~ (OTP) – State Regulations

1.0 Authority

~~These rules are~~ This rule is established pursuant to 18 V.S.A. § 4752 and Act 195 § 14 of 2013.

2.0 Purpose

This rule establishes minimum requirements for authorized Office Based Opioid Treatment ~~Providers~~ (OBOT) providers to prescribe, and in limited circumstances, dispense buprenorphine to individuals ~~requiring and seeking~~ accessing treatment for opioid ~~addiction use disorder~~. The rule also establishes Vermont-specific requirements for Opioid Treatment Programs (OTPs) that are in addition to the regulatory requirements of 42 CFR, Part 8.

3.0 Definitions

3.1 ~~“ADAP” means the Division of Alcohol and Drug Abuse Programs in the Vermont Department of Health.~~

~~3.2 “ADAP Preferred Providers” means specialty substance abuse treatment services certified, approved and audited by ADAP who may work with OBOT providers known as Spokes or who may work with OTPs known as Hubs.~~

~~3.3 “Administrative Discharge” means the involuntary process of medically supervised withdrawal from MAT a patient separating from an OBOT provider for non-compliance/cause.~~

3.2 “Continuity of Care Plan Checklist” means the Department-published Continuity of Care Plan checklist.

3.3 ~~“3.4~~ “Clinical Discharge” means the ~~voluntary~~ process, agreed upon by both the patient and provider, of medically-supervised withdrawal from MAT by gradually tapering medication for ultimate cessation ~~of opioid replacement therapy~~.

3.54 “DATA 2000” means the federal Drug Addiction Treatment Act of 2000, which permits providers who meet certain qualifications to treat individuals with opioid ~~addiction~~ use disorder by prescribing Food and Drug Administration-approved medications such as buprenorphine.

3.65 “DATA 2000 Waiver” means an authorization from SAMHSA for a ~~licensed~~ provider who has met the training and credentialing registration requirements of DATA 2000 to prescribe specified medications to treat opioid ~~addiction drugs to patients~~ use disorder in settings other than Opioid Treatment Programs (~~OTP’s~~ OTP).

3.76 “DEA” means the Drug Enforcement Administration in the U.S. Department of Justice.

3.87 “DEA Number” means the Drug Enforcement Administration number assigned to each provider granting them authority to prescribe controlled substances.

3.8 “Department” means the Vermont Department of Health.

3.9 “Diversion” means the illegal use of a prescribed controlled substance for a use other than that for which the substance was prescribed.

~~3.10~~ ~~“DVHA” means the Department of Vermont Health Access in the Agency of Human Services.~~

~~3.11~~ 3.10 “Eligible provider” means a Vermont-licensed physician, physician assistant or advanced practice registered nurse, or other provider allowed to prescribe MAT under federal law and regulation.

- 3.1211 “Informed consent” means agreement by a patient to a medical procedure, or for participation in a medical intervention program, after achieving an understanding of the relevant medical facts, benefits, and the risks involved. ~~This includes an understanding of medication risks and benefits.~~
- 3.1312 “Maintenance Treatment” means long-term MAT ~~typically provided by an OBOT~~ for an addiction opioid use disorder lasting longer than one year.
- 3.1413 “MAT” means medication-assisted ~~therapy treatment~~ to treat opioid ~~dependence. Both methadone and~~ use disorder. Methadone, buprenorphine and injectable naltrexone are examples of medications used in MAT ~~drugs. MAT may also be referred to as Opioid Replacement Therapy.~~
- 3.1514 “OBOT” means Office Based Opioid Treatment provider ~~practice for prescribing authorized to prescribe~~ buprenorphine ~~as established by pursuant to~~ the Drug Abuse and Treatment Act of 2000. ~~In Vermont, OBOTs are often referred to as “Spokes”.~~ An OBOT may be a preferred Preferred provider, a specialty addiction practice, an individual provider practice or several ~~-providers practicing~~ as a group.
- 3.1615 “OTP” means an Opioid Treatment Program as defined and regulated by ~~federal regulation~~ 42 CFR, Part 8 and DEA regulations related to safe storage and dispensing of ~~OTP’s~~ medications (§ 1301.72). ~~OTP’s~~ OTPs are specialty ~~addiction~~ treatment programs for dispensing ~~opioid replacement~~ medication, including methadone and buprenorphine to treat opioid use disorder, under ~~carefully~~ controlled and observed conditions. OTPs offer onsite ancillary services. ~~In Vermont, OTPs are sometimes referred to as “Hubs”.~~
- 3.1716 “Physician” means a licensed medical doctor or a licensed doctor of osteopathy as ~~described~~ defined in 26 V.S.A. Ch. 23 ~~subchapter~~, Subchapter 3.
- 3.1.83.17 “Preferred providers” means a program that has attained a certificate from the Department and has an existing contract or grant from the Department to provide treatment for substance use disorder.

3.18 “Provider” means a health care provider as defined by 18 V.S.A. 9402. A person, partnership, or corporation, other than a facility or institution, licensed or certified or authorized by law to provide professional health care service in this State to an individual during that individual's medical care, treatment, or confinement.

3.19 “Psychosocial Assessment” means an evaluation of the psychological and social factors that are experienced by an individual or family as the result of addiction. The factors may complicate an individual’s recovery or act as assets to recovery.

3.20 “SAMHSA” means the Substance Abuse and Mental Health Services Administration, an agency ~~under~~within the U.S. Department of Health and Human Services.

~~3.21~~

3.21 “Treatment Agreement” means a document outlining the responsibilities and expectations of the OBOT provider and the patient that is signed and dated by the patient.

3.22 “Toxicology Tests” means any laboratory analysis of urine, oral mucosa, or serum blood for the purpose of detecting the presence of alcohol and/or various scheduled drugs.

~~3.223~~ “VPMS” means the Vermont Prescription Monitoring System, the ~~statewide~~ electronic database that collects data on Schedule II, III, or IV controlled substances dispensed in Vermont.

4.0 Requirements for ~~eligible providers to Prescribe Buprenorphine as Treatment for Opioid Dependence~~Providers

~~4.1~~

4.1 Prior to ~~prescribing~~treating opioid use disorder with buprenorphine, all ~~eligible~~ providers shall:

~~4.1.2~~

4.1.1 Hold a health care provider license under Title 26 of the Vermont license Statutes Annotated Vermont and a DEA number.

~~4.1.2~~ ~~4.1.3~~ Receive a DATA 2000 waiver from the Substance Abuse and Mental Health Services Administration (SAMHSA).[‡]

~~4.2 Patient Load Limitations for Eligible Providers~~

~~4.2.1 30 or Fewer Patients~~

~~During the first year prescribing buprenorphine, an eligible provider may maintain a patient load of up to 30 or fewer individuals receiving MAT at any point in time.~~

~~4.2.2 100 or Fewer Patients~~

~~After one year of prescribing to 30 or fewer patients, an eligible provider may apply for a waiver from SAMHSA to treat a maximum of 100 patients.~~

~~4.2.3 275 or Fewer 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 a 275 patient waiver every three years.~~

~~5.0~~

5.0 OBOT Program Administration and ~~Operations~~Operation Requirements

~~5.1 All Vermont OBOTs~~

5.1 Each OBOT provider shall ~~have and~~ maintain all of the following ~~in order to initiate and continue prescribing buprenorphine:~~

5.1.1 ~~5.1.1~~ Office or facility with ~~sufficient~~adequate space and ~~adequate~~ equipment to provide quality patient care and monitoring.;

[‡] ~~http://buprenorphine.samhsa.gov/waiver_qualifications.html~~

5.1.2 Office space that is clean, well-maintained and has appropriate climate controls for patient comfort and safety~~;~~

5.1.3 Adequate space for private conversations if psychosocial assessment and counseling services are provided on-site~~;~~

5.1.4 Office space adequate for the protection of ~~all~~ confidential medical information and records in hard-copy or electronic formats~~;~~ and

5.1.5 ~~Adequate referral arrangements~~ Arrangements with other providers and practitioners to evaluate and treat all medical and psychological issues that ~~any~~ a patient may experience. This ensures that MAT is provided in the context of any other health issues the patient may have.

5.2 Emergency and Closure Preparedness

~~5.2.1~~ 5.2.1—Continuity of Services for Unexpected Temporary Closure

5.2.1.1 Each OBOT provider shall develop and maintain a written plan for the administration of medications in the event of a temporary closure due to ~~inclement weather~~, provider illness or ~~similar~~ unanticipated service interruptions. The plan shall include:

5.2.1.1.1 ~~5.2.1.1~~—~~A plan for a~~ A reliable mechanism to inform patients of these emergency arrangements~~;~~ and

5.2.1.1.2 ~~5.2.1.2~~—The identification of emergency procedures for obtaining prescriptions/access to medications in case of temporary program/office closure. This may include an agreement with another OBOT provider ~~authorized to prescribe buprenorphine~~ or with an OTP. It may also include the ability to transfer patient records.

~~5.2.2 Permanent Program Closure~~

5.2.2 Continuity of Care Plan

5.2.2.1 Each OBOT provider shall have a written plan for continuity of care in the event ~~that of a future~~ voluntary or involuntary ~~program closure occurs. Programs shall have an operational plan for managing a program closure.~~ The plan shall ~~include~~ account for:

5.2.2.1.1 ~~A plan for the orderly~~ Orderly and timely transfer of patients to another OBOT provider or an OTP.

~~—A plan~~

~~5.2.2.2~~ 5.2.2.1.2 Notification to ~~notify~~ patients of any upcoming closure and to reassure ~~—~~ them of transition plans for continuity of care.

~~5.2.2.3 A plan to notify ADAP and DVHA~~

5.2.2.1.3 Notification to the Department no fewer than 60 days prior to closure to discuss the rationale for closure, and plans for continuity of care.

~~—A plan for the transfer~~

~~5.2.2.4~~ 5.2.2.1.4 Transfer of patient records to another OBOT ~~—~~ provider or an OTP.

5.2.2.1.5 ~~5.2.2.5~~ ~~A plan to ensure~~ Ensuring that patient records are secured and maintained in accordance with State and Federal regulations. ~~—~~

5.2.2.1.6 ~~6.0~~ At a minimum, the OBOT provider shall review their Continuity of Care Plan annually and update it if needed, and shall have documentation that the review and/or updating has occurred.

5.2.2.1.7 The Department may request to review an OBOT provider's Continuity of Care Plan at any time. The OBOT shall respond to all verbal and written requests on the timeline(s) provided by the Department.

5.2.3 Continuity of Care Plan Checklist

5.2.3.1 Within 30 days of the enrollment of the OBOT provider's 100th patient, the OBOT provider shall complete and submit for approval the Continuity of Care Checklist published by the Department.

5.2.3.2 The OBOT provider shall submit a current and accurate Continuity of Care Plan Checklist [insert link] to the Department upon request.

5.3 OBOT providers shall register with VPMS and comply with the Vermont Prescription Monitoring Rule.

6.0 Clinical Care and Management Requirements

~~6.1 Acceptance for Buprenorphine Treatment (MAT)~~

~~6.1 Prior to commencing MAT, and in addition to ensuring that any patient has a comprehensive medical evaluation as described in Section 6.2.1 Assessment and Diagnosis~~

6.1.1 Prior to initiating MAT, the OBOT provider shall assess the patient and diagnose and document an opioid use disorder as defined by either the current edition of the Diagnostic and Statistical Manual of Mental Disorders, or the current edition of the International Classification of Diseases.

6.2 Evaluation of the Patient's Health Status

~~6.2.1~~ ~~6.2.1~~—Medical Evaluation

Prior ~~to commencing~~initiating MAT, the OBOT provider shall either conduct an intake examination that includes ~~any relevant~~all appropriate physical and laboratory tests,

~~6.2.1.1~~ or refer the patient to a medical professional who can perform such an examination.

~~6.2.2~~ ~~6.2.2~~—Psychosocial Assessment and Referral to Services

~~6.2.2.1~~ ~~6.2.2.1~~The OBOT provider shall complete the psychosocial assessment of a patient inducted on MAT by the end of the third patient visit.

~~6.2.2.2~~ The psychosocial assessment shall be completed ~~before the fourth patient visit to the provider prescribing or dispensing MAT. The psychosocial assessment must be completed by~~ by a provider ~~who is a licensed in one of the following disciplines:~~

~~6.2.2.2.1~~ Psychiatrist, ~~a physician;~~

~~6.2.2.2.2~~ Physician certified by the American Board of Addiction Medicine, ~~a;~~

~~6.2.2.2.3~~ Psychiatric Nurse Practitioner, ~~a;~~

~~6.2.2.2.4~~ Psychiatric Physician Assistant, ~~a licensed mental;~~

~~6.2.2.2.5~~ Mental health/addictions clinician (such as a Licensed or Certified Social Worker, ~~a);~~

~~6.2.2.2.6~~ Psychologist, ~~a;~~

~~6.2.2.2.7~~ Psychologist – Master;

~~6.2.2.2.8~~ Licensed Mental Health Counselor, ~~a;~~

~~6.2.2.2.9~~ Licensed Marriage and Family Therapist; or ~~a~~

~~6.2.2.2.10~~ Licensed Alcohol and Drug ~~Abuse~~ Counselor.

If the ~~prescribing~~OBOT provider ~~is not certified in one of these disciplines then the patient shall be referred for the psychosocial assessment.~~

~~6.2.3 6.2.2.2~~ If the provider prescribing or dispensing buprenorphine does not meet ~~any of~~ the specifications in Section 6.2.2.12, a referral to a provider who does meet those specifications ~~must~~ shall be made for a psychosocial assessment. The referral ~~must~~ shall be made ~~before~~ by the end of the ~~fourth~~ third patient visit ~~to the provider prescribing or dispensing MAT~~ and shall be documented in the patient's record.

~~6.2.4 6.2.2.3~~ Based on the outcomes of the psychosocial assessment, the OBOT provider may recommend to the patient that ~~he or she should~~ the patient participate in ongoing counseling or other behavioral interventions such as recovery support programs.

~~6.2.4.1 6.2.2.4A~~ An OBOT provider may not deny or discontinue MAT based solely on a patient's decision not to follow a referral or recommendation to seek counseling or other behavioral interventions unless the patient is otherwise non-compliant with ~~program expectations~~ the treatment agreement.

6.3 Developing a ~~MAT~~ Treatment Plan

6.3.1 Individuals who are clinically indicated for methadone ~~therapy~~ treatment, or who need more clinical oversight or structure than available through an OBOT provider, shall be ~~referred~~ transferred to an appropriate OTP.

~~6.3.2~~ Providers dispensing buprenorphine from an OBOT setting shall register with VPMS and comply with Vermont's VPMS rule regarding reporting on dispensed controlled substances.

~~6.3.3~~ The OBOT provider prescribing buprenorphine shall adhere to all applicable standards of medical practice for providing treatment.

6.4 Informed Consent and Patient Treatment Agreement²

~~Templates for documents or references in Sections~~

~~6.4.1 through 6.4.3 are available on the Physician Clinical Support System website. A link to the website shall be maintained on the Department's web page.~~

_____ Prior to treating a patient with buprenorphine, ~~an~~ OBOT provider shall:

6.4.1.1 Obtain voluntary, written, informed consent ~~to treatment~~ from each patient~~—~~;

6.4.1.2 Obtain a signed treatment agreement ~~outlining the responsibilities and expectations of the prescribing provider and the patient;~~ and

6.4.1.3 Make reasonable efforts to obtain releases of information for any health care providers or others important for the coordination of care to the extent allowed by ~~Health Insurance Portability and Accountability Act (HIPAA) and 42 CFR, Part 2~~ applicable law.

6.5 Ongoing Patient Treatment and Monitoring

~~Beyond~~ In addition to adhering to standard clinical ~~practices~~ practice, the OBOT providers shall adhere to the following provisions ~~must be followed by OBOT providers~~:

6.5.1 Referral and Consultation Provider Network Requirements

6.5.1.1 Each OBOT provider shall maintain a referral and consultative ~~relationship~~ network with a range of providers capable of providing primary and specialty medical services and consultation for patients ~~receiving MAT~~.

² Templates for documents referenced in Section 6.4 are available on the Physician Clinical Support System website. A link to the website is available on the Department's web page.

6.5.1.21.1 Exchanges of information ~~acrossthrough~~ this provider network shall facilitate patient treatment and conform to the protection of patient privacy consistent with ~~HPAA and for covered programs 42 CFR, Part 2~~applicable federal and state privacy law.

6.5.2 Monitoring for Diversion

6.5.2.1 To ensure patient and public safety, each MATOBOT provider shall develop clinical ~~practices~~practice to minimize risk of diversion. These clinical practices shall include ~~the following:~~
:

6.5.32.1—1 Querying VPMS as required by ~~Vermont's VPMS rule regarding system queries~~the Vermont Prescription Monitoring PMS Rule.

6.5.32.1.2 Informing patients ~~on~~being treated with buprenorphine that diversion is a criminal offense.

6.5.2.1.3.3—3 Using the following clinical tools, as appropriate, to monitor a patient's conformity with his or her treatment agreement and for monitoring diversion:

- Routine toxicological screens;
- Random requests for medication counts;
- Bubble-packaging of prescriptions, if in tablet form;
- Recording the ID numbers listed on the medication "strip" packaging for matching with observation of ID numbers during random call-backs; or
- 6.5.3.4 Observed dosing.

6.5.2.1.4 Determining the frequency of monitoring procedures described in Section 6.5.3.1.3 based on the unique clinical treatment plan for each patient and his or her level of stability. For patients receiving services from multiple providers, the coordination and sharing of toxicology results is ~~expected~~required, pursuant to applicable law.

6.5.2.1.5 ~~6.5.3.5~~ Collecting all urine and toxicological specimens in a therapeutic context.

~~6.5.3.6~~ Addressing Promptly reviewing the ~~results of~~ toxicological ~~tests promptly~~ test results with 6.5.2.1.6 ~~_____~~ patients.

6.6 Administrative Discharge from ~~MAT~~an OBOT Provider

6.6.1 The following situations may result in a patient being ~~involuntarily~~administratively discharged from ~~MAT through medically supervised withdrawal~~an OBOT provider:

6.6.1.1 Disruptive behavior that has an adverse ~~effect~~impact on the OBOT ~~practice~~provider, staff or other patients. ~~These include~~This includes, but ~~are~~is not limited, to:

- violence
- aggression
- threats of violence
- drug diversion
- trafficking of illicit drugs
- continued use of substances
- repeated loitering
- noncompliance with the treatment plan resulting in an observable, negative impact on the program, staff and other patients.

6.6.1.2 Incarceration or other relevant change of circumstance.

6.6.1.3 Violation of the treatment agreement.

6.6.1.4 Nonpayment of fees for medical services rendered by the OBOT provider.

6.6.2 When an OBOT provider ~~or practice~~ decides to administratively discharge a patient ~~from MAT~~, the OBOT provider will offer shall:

6.6.2.1 Offer a clinically appropriate withdrawal schedule ~~as long as it that~~ does not compromise the safety of ~~providers~~ the patient, provider or ~~program staff;~~

~~6.6.1.2.1~~ A2 Refer the patient who is involuntarily discharged from MAT should be referred to another program a level of care that is more clinically appropriate or affordable for the patient, and/or behavioral health services; and

~~6.6.1.2.2~~ AH3 Document all factors contributing to the involuntary administrative discharge ~~from the program shall be documented~~ in the patient's record.

~~6.6.1.2.3~~ All efforts to refer the patient to a suitable alternative treatment program or to behavioral health services shall be documented in the patient's record.

6.7 Additional Requirements for Persons who are Pregnant Women

6.7.1 Due to the risks of opioid ~~addiction to use disorder to persons who are pregnant women and their fetuses~~, a person who is pregnant woman and seeking buprenorphine from an OBOT provider shall either be admitted to the OBOT provider or referred to an OTP within 48 hours of initial contact.

6.7.2 OBOT providers unable to admit a person who is pregnant women, or unable to otherwise arrange for MAT ~~care~~ within 48 hours of initial

contact, shall notify ~~ADAP~~the Department within that same ~~48-hour~~ hour period to ensure continuity of care.

~~6.7.3~~ 6.7.3—In the event that a person who is pregnant ~~woman~~ is involuntarily withdrawn ~~administratively discharged~~ from ~~MAT~~ an OBOT provider, for reasons specified in Section 6.6.1 of this rule, the OBOT provider shall refer the ~~woman~~ person to the most appropriate obstetrical care available.

~~7.0~~

7.0 Requirements for OTPs

~~In addition to the OTP regulatory requirements of 42 CFR, Part 8, Vermont OTP's shall:~~

- 7.1 Query VPMS as required by the statute and the Vermont Prescription Monitoring System Rule. ~~Because federal law prohibits the reporting of MAT dispensed from an OTP to a prescription monitoring system, other providers may be unaware of a patient's enrollment in an OTP for MAT.~~
- 7.2 In an emergency, ~~a non-physician~~ as determined by an eligible provider, an eligible provider in an OTP may admit a patient for MAT ~~treatment to avoid delays in treatment.~~ In these situations, a MAT physician shall review the medical evaluation and substance ~~opioid~~ use disorder diagnosis to certify the diagnosis within 72 hours of the patient being admitted to the ~~program~~ OTP. The MAT physician shall certify the diagnosis in the patient's record and have either ~~a face-to-face~~ an in-person meeting or visual contact through ~~an~~ a federally approved form of communication technology to review the assessment and discuss medical services.
- 7.3 Review, update and document the patient's treatment plan ~~quarterly~~ every three months during a patient's first year of continuous treatment. In subsequent years of treatment, a treatment plan shall be reviewed no less frequently than every 180 days.

~~Advanced practice registered nurses and physician assistants who are granted a SAMHSA waiver to order and dispense methadone and buprenorphine from an OTP shall comply with the requirements of Section 7 of this rule.~~

7.4 To the extent allowed by a signed release of information, notify each patient's primary care provider about ~~plans for prescribing methadone~~their treatment ~~to the patient plan.~~

8.0 Inspection

The Department may, without notice, perform an inspection and survey OBOT providers and OTPs for compliance with this rule at any time.