Chapter 8 – Alcohol and Drug Abuse
Subchapter 6

Rules Governing Medication-Assisted Treatment for Opioid Use Disorder for: 1. Office-Based Opioid Treatment (OBOT) Providers 2. Opioid Treatment Programs (OTP) – State Regulations

1.0 Authority

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 (OBOT) providers to prescribe, and in limited circumstances, dispense buprenorphine to individuals accessing treatment for opioid 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 "Administrative Discharge" means the process of 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 "Clinical Discharge" means the process, agreed upon by both the patient and provider, of medically supervised withdrawal from MAT by gradually tapering medication for ultimate cessation.

3.6 "DEA" means the Drug Enforcement Administration in the U.S. Department of Justice.

3.7 "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 “Eligible Provider” means a Vermont-licensed healthcare provider with a valid DEA number.

3.11 “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.

3.12 “Maintenance Treatment” means long-term MAT for an opioid use disorder lasting longer than one year.

3.13 “MAT” means medication-assisted treatment to treat opioid use disorder. Methadone, buprenorphine and injectable naltrexone are examples of medications used in MAT.

3.14 “OBOT” means Office Based Opioid Treatment provider authorized to prescribe buprenorphine pursuant to the Drug Abuse and Treatment Act of 2000. An OBOT may be a preferred provider, a specialty addiction practice, an individual provider practice or several providers practicing as a group.

3.15 “OTP” means an Opioid Treatment Program as defined and regulated by 42 CFR, Part 8 and DEA regulations related to safe storage and dispensing of medications (§1301.72). OTPs are specialty treatment programs for dispensing medication, including methadone and buprenorphine to treat opioid use disorder, under controlled and observed conditions. OTPs offer onsite ancillary services.

3.16 “Physician” means a licensed medical doctor or a licensed doctor of osteopathy as defined in 26 V.S.A. Ch. 23, Subchapter 3.

3.17 “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 within the U.S. Department of Health and Human Services.

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.

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

4.0 Requirements for Providers

4.1 Prior to treating opioid use disorder with buprenorphine, a provider shall hold a valid health care provider license under Title 26 of the Vermont Statutes Annotated Vermont and a valid DEA number.

4.2 Providers must provide MAT in accordance with the current version of the American Society of Addiction Medicine (ASAM) National Practice Guideline for the Treatment of Opioid Use Disorder.

5.0 OBOT Administration and Operation Requirements

5.1 Each OBOT provider shall maintain all of the following:

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

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 confidential medical information and records in hard-copy or electronic formats; and

5.1.5 Arrangements with other providers and practitioners to evaluate and treat all medical and psychological issues that 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 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 provider illness or unanticipated service interruptions. The plan shall include:

5.2.1.1.1 A reliable mechanism to inform patients of these emergency arrangements; and

5.2.1.1.2 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 or with an OTP. It may also include the ability to transfer patient records.

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 of a voluntary or involuntary closure. The plan shall account for:

5.2.2.1.1 Orderly and timely transfer of patients to another OBOT provider or an OTP.

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

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.

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

5.2.2.1.5 Ensuring that patient records are secured and maintained in accordance with State and Federal regulations.

5.2.2.1.6 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, as provided by the Department.

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

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

6.0 Clinical Care and Management Requirements

6.1 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 Medical Evaluation

6.2.1.1 Prior to initiating MAT, the OBOT provider shall either conduct an intake examination that includes all appropriate physical and laboratory tests, or refer the patient to a medical professional who can perform such an examination.

6.2.2 Psychosocial Assessment and Referral to Services

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 by a provider in one of the following disciplines:

6.2.2.2.1 Psychiatrist;
6.2.2.2.2 Physician;
6.2.2.2.3 Advanced Practice Registered Nurse;
6.2.2.2.4 Physician Assistant;
6.2.2.2.5 Psychiatric Nurse Practitioner;
6.2.2.2.6 Psychiatric Physician Assistant;
6.2.2.2.7 Mental health/addictions clinician (such as a Licensed or Certified Social Worker);
6.2.2.2.8 Psychologist;
6.2.2.2.9 Psychologist – Master;
6.2.2.2.10 Licensed Mental Health Counselor;
6.2.2.2.11 Licensed Marriage and Family Therapist; or
6.2.2.2.12 Licensed Alcohol and Drug Counselor.

6.2.3 If the OBOT provider does not meet the specifications in Section 6.2.2.2, a referral to a provider who does meet those specifications shall be made for

a psychosocial assessment. The referral shall be made by the end of the third patient visit and shall be documented in the patient's record.

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

6.2.4.1 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 the treatment agreement.

6.3 Developing a Treatment Plan

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

6.4 Informed Consent and Patient Treatment Agreement[1]

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

6.4.1.1 Obtain voluntary, written, informed consent from each patient;

6.4.1.2 Obtain a signed treatment agreement; 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 applicable law.

6.5 Ongoing Patient Treatment and Monitoring

In addition to adhering to standard clinical practice, the OBOT providers shall adhere to the following provisions:

6.5.1 Referral and Consultation Provider Network Requirements

[1] 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.

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

6.5.1.1.1 Exchanges of information through this provider network shall facilitate patient treatment and conform to the protection of patient privacy consistent with applicable federal and state privacy law.

6.5.2 Monitoring for Diversion

6.5.2.1 To ensure patient and public safety, each OBOT provider shall develop clinical practices to minimize risk of diversion. These clinical practices shall include:

6.5.2.1.1 Querying VPMS as required by the Vermont Prescription Monitoring System Rule.

6.5.2.1.2 Informing patients being treated with buprenorphine that diversion is a criminal offense.

6.5.2.1.3 Using the following clinical tools, as appropriate, to monitor a patient's conformity with a patient's 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
- Observed dosing

6.5.2.1.4 Determining the frequency of monitoring procedures described in Section 6.5.2.1.3 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 required, pursuant to applicable law.

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

6.5.2.1.6 Promptly reviewing the toxicological test results with patients.

6.6 Administrative Discharge from an OBOT Provider

6.6.1 The following situations may result in a patient being administratively discharged from an OBOT provider:

6.6.1.1 Disruptive behavior that has an adverse impact on the OBOT provider, staff or other patients. This includes, but 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 decides to administratively discharge a patient, the OBOT provider shall:

6.6.2.1 Offer a clinically appropriate withdrawal schedule that does not compromise the safety of the patient, provider or staff;

6.6.2.2 Refer the patient to a level of care that is more clinically appropriate or affordable for the patient and/or behavioral health services; and

6.6.2.3 Document all factors contributing to the administrative discharge in the patient's record.

6.7 Additional Requirements for Persons who are Pregnant

6.7.1 Due to the risks of opioid use disorder to persons who are pregnant, a person who is pregnant 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, or unable to otherwise arrange for MAT within 48 hours of initial contact, shall notify the Department within that same 48-hour period to ensure continuity of care.

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

7.0 Requirements for OTPs

7.1 Query VPMS as required by the statute and the Vermont Prescription Monitoring System Rule.

7.2 In an emergency, as determined by an eligible provider, an eligible provider in an OTP may admit a patient for MAT. In these situations, a MAT physician shall review the medical evaluation and opioid use disorder diagnosis to certify the diagnosis within 72 hours of the patient being admitted to the OTP. The MAT physician shall certify the diagnosis in the patient's record and have either an in-person meeting or visual contact through 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 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.

7.4 To the extent allowed by a signed release of information, notify each patient's primary care provider about their treatment 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.