**Chapter 8 – Alcohol and Drug Abuse**
**Subchapter 6**

# Rules Governing Medications 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.

## 2.0 Purpose

This rule establishes minimum requirements for Office Based Opioid Treatment (OBOT) providers to prescribe, and in defined circumstances, dispense medication to patients accessing treatment for opioid use disorder. The rule also establishes Vermont-specific requirements for Opioid Treatment Programs (OTPs) that are in addition to the 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 "DEA" means the Drug Enforcement Administration in the U.S. Department of Justice.

3.4 "DEA Number" means the Drug Enforcement Administration number assigned to each provider granting the provider authority to prescribe controlled substances.

3.5 "Department" means the Vermont Department of Health.

3.6 "Diversion" means the illegal use of a prescribed controlled substance for a use other than the use for which the substance was prescribed.

3.7 "Eligible MOUD Provider" means a Vermont-licensed provider with a valid DEA number.

3.8 “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.

3.9 “Maintenance Treatment” means MOUD lasting longer than one year.

3.10 “Medication for Opioid Use Disorder,” or “MOUD” means medications used to treat opioid use disorder such as methadone, buprenorphine, and naltrexone.

3.11 “Medication Unit” means a facility that has been established as part of, but is geographically separate from, an opioid treatment program (OTP) from which eligible MOUD providers dispense or administer medications used to treat opioid use disorder and/or collect samples for drug testing or analysis. A Medication Unit is regulated pursuant to 42 CFR Part 8.

3.12 “Office Based Opioid Treatment provider” and “OBOT provider” means a provider that prescribes MOUD pursuant to federal and State law, federal regulations, and State rules, and that is not an OTP. An OBOT may be a preferred provider, a specialty addiction practice, an individual provider practice or several providers practicing as a group.

3.13 “Opioid Treatment Program” and “OTP” means a program or practitioner registered under 21 U.S.C. 823(g)(1) engaged in treatment of individuals with OUD. 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.

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

3.15 “Preferred provider” means an entity 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.

3.16 “Provider” means a health care provider as defined by 18 V.S.A. § 9402.

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

3.18 “Telehealth” means methods for healthcare service delivery using telecommunications technologies. Telehealth includes telemedicine, store and forward, and telemonitoring.

3.19 “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.

3.20 “Toxicology specimens” means urine, oral mucosa, or serum blood that will be tested for the purpose of detecting the presence of alcohol and/or various scheduled drugs.

3.21 “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 General Requirements for OBOT and OTP Providers

4.1 Eligible MOUD providers shall provide MOUD in accordance with the American Society of Addiction Medicine (ASAM) National Practice Guideline for the Treatment of Opioid Use Disorder, current at the time of treatment.

4.1.1 The eligible MOUD provider shall document in the patient’s records the clinical basis for any deviation from the ASAM guidelines.

4.2 Eligible MOUD providers shall register with VPMS and query VPMS pursuant to the Vermont Prescription Monitoring System rule.

4.3 Eligible MOUD providers may prescribe MOUD and conduct the evaluation requirements included in this rule via telehealth in accordance with federal law and clinical need.

## 5.0 OBOT Administration and Operation Requirements

5.1 Each OBOT provider shall maintain the following:

5.1.1 Medication storage and security policies in accordance with 21 CFR §1301.74-1301.76.

5.1.2 An office or facility with adequate space and equipment to provide quality patient care and monitoring;

5.1.3 An office or facility that is clean, well-maintained, and has appropriate climate controls for patient comfort and safety;

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

5.1.5 Adequate space for the protection of confidential medical information and records in hard-copy, electronic formats, or both.

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 interruption. 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 plans to close the practice 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 federal and State law, federal regulations, and State rules.

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, the updating, or both, 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 provider shall respond to 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 100$^{th}$ 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.

## 6.0 Clinical Care and Management Requirements for OBOTs

6.1 Assessment and Diagnosis

6.1.1 Prior to prescribing MOUD, 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 Upon prescribing MOUD, and as early as is practical, the OBOT provider shall either conduct an intake examination that includes appropriate physical and laboratory tests, including by telehealth when consistent with federal guidelines, or shall refer the patient to a provider who can perform such an examination.

6.2.2 Psychosocial Assessment and Referral to Services

6.2.2.1 A psychosocial assessment of a patient inducted on MOUD shall be completed by the end of the third patient visit. If this assessment is not conducted by the OBOT Provider, the OBOT Provider shall refer the patient to a provider licensed in accordance with section 6.2.2.2 who is able to complete the assessment and shall document that referral in the patient’s record.

6.2.2.2 The psychosocial assessment shall be completed by a provider who is licensed in Vermont as a:

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.

6.3 Treatment Plan

6.3.1 The OBOT provider shall develop an appropriate treatment plan, consistent with ASAM guidelines, based on the outcomes of the medical evaluation and the psychosocial assessment.

6.3.2 As part of the treatment plan, the OBOT provider may recommend to the patient that the patient participate in ongoing counseling or other interventions, such as recovery support programs.

6.3.2.1 An OBOT provider may not deny or discontinue MOUD 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.

6.4 Individuals who are clinically indicated for methadone treatment, or who require more clinical oversight or structure than available through an OBOT provider, as determined by the provider, shall be referred to an OTP.

6.5 Informed Consent and Patient Treatment Agreement[1]

6.5.1 Prior to treating a patient with MOUD, an OBOT provider shall:

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

6.5.1.2 Obtain a signed treatment agreement; and

6.5.1.3 Make reasonable efforts to obtain the patient's written consent for the disclosure of OUD information to any health care providers or others who are important for the coordination of care to the extent allowed by applicable law.

6.6 Ongoing Patient Treatment and Monitoring

[1] Templates for documents are available on the Physician Clinical Support System website. A link to the website is available on the Department's web page.

6.6.1 Referral and Consultation Provider Network Requirements

6.6.1.1 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. Providers shall access this network as clinically indicated.

6.6.1.1.1 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.

6.6.2 Monitoring for Diversion

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

6.6.2.1.1 Informing patients that ingestion of MOUD by small children and infants can be lethal.

6.6.2.1.2 Informing patients that instances of medication diversion may not be covered by federal or State healthcare confidentiality laws.

6.6.2.1.3 Guidance on use of the following clinical tools when 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 identification numbers listed on the medication "strip" packaging for matching with the identification numbers during random call-backs; and
- Observed dosing;

6.6.2.1.4 Determining the frequency of monitoring procedures described in Section 6.6.2.1.3 based on the clinical treatment plan for each patient and each patient's level of stability. For patients receiving services from multiple providers, the coordination and sharing of toxicology results is required, pursuant to applicable federal and State law, federal regulations, and State rules.

6.6.2.1.5 That toxicology specimens are used to monitor and adjust treatment plans, as appropriate.

6.6.2.1.6 Promptly reviewing the toxicological test results with patients.

6.7 Administrative Discharge from an OBOT Provider

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

6.7.1.1 Behavior that has an adverse impact on the OBOT provider, staff, the patient, 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, patient, or other patients.

6.7.1.2 Incarceration or other relevant change of circumstance (e.g. moving to a different geographic location, a significant change in health status, or entering a full-time residential treatment program).

6.7.1.3 Violation of the treatment agreement or program policies.

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

6.7.2 When an OBOT provider decides to administratively discharge a patient, the OBOT provider shall:

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

6.7.2.2 Refer the patient to a level or type of clinical care that is more appropriate or affordable for the patient; and

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

6.8 Requirements for Persons who are Pregnant

6.8.1 Due to the risks of opioid use disorder to persons who are pregnant, a person who is pregnant and seeking MOUD from an OBOT provider shall either be admitted to the OBOT provider or referred to an OTP within 48 hours of initial contact.

6.8.2 OBOT providers unable to admit a person who is pregnant, or unable to otherwise arrange for MOUD within 48 hours of initial contact, shall notify the Department within that same 48-hour period to ensure continuity of care.

6.8.3 If a person who is pregnant is administratively discharged from an OBOT provider the OBOT provider shall refer the person to the most appropriate obstetrical care available.

## 7.0 Requirements for OTPs

7.1 Opioid Treatment Programs shall:

7.1.1 Review, update, and document a patient's treatment plan every 90 days 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.

7.1.2 At a minimum, to the extent authorized by the patient's signed consent, provide the patient's treatment plan to the patient's primary care provider, and other relevant providers involved in the patient's care.

7.2 Establishment of a Medication Unit must be approved by the Department.

7.3 In an emergency, as determined by an eligible provider, an eligible MOUD provider in an OTP may admit a patient for MOUD. In these situations, the OTP 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 and record the review in the patient's record. The OTP physician shall have either an in-person meeting or visual contact with the patient within 14 days through a federally approved form of communication technology to review the assessment and discuss medical services.

## 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.