

To: Representative Trevor Squirrel, Chair, Legislative Committee on Administrative Rules
From: Brendan Atwood, Public Health Policy Director, Vermont Department of Health
Re: Rules Governing Medication for Opioid Use Disorder
Date: March 6, 2024

In accordance with the recommendations from Legislative Counsel, the Department of Health (Department) had made the following amendments to the rule:

- Section 3.12: Revised to include “federal and State law, federal regulations, and State rules.”
- Section 3.16: Removed the text of the definition since the statute is cross- referenced.
- Sections 5.1.2 and 5.1.3: Added “An” at the beginning of the sentences.
- Section 5.1.5: Updated to remove “and/or.”
- Section 5.2.2.1.5: Revised to include “federal and State law, federal regulations, and State rules.”
- Section 5.2.2.1.6: Updated to remove “and/or.”
- Section 6.3.2: Made “The” lowercase.
- Section 6.6.1: Revised into two sentences for clarity.
- Section 6.6.1.1.1: Capitalized “state.”
- Sections 6.6.2.1.2: revised to include “laws.”
- 6.6.2.1.4: Revised to include “federal and State law, federal regulations, and State rules.”
- Section 6.6.2.1.3: Updated “ID” to “identification,” added in semi-colons and removed “observation of” for clarity.
- Section 6.2.2.2: Clarified that a provider must be licensed “in Vermont.”
- Section 7.3: Revised the language for clarity.

Chapter 8 – Alcohol and Drug Abuse
Subchapter 6

Rules Governing Medications – ~~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 2014~~3~~.

2.0 Purpose

This rule establishes minimum requirements for ~~authorized~~ Office Based Opioid Treatment (OBOT) providers to prescribe, and in ~~limited~~ defined circumstances, dispense ~~buprenorphine medication to individuals~~ 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 ~~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 (i.e., from MAT by gradually tapering medication for ultimate cessation).

~~3.53.3~~ “DEA” means the Drug Enforcement Administration in the U.S. Department of Justice.

~~3.63.4~~ “DEA Number” means the Drug Enforcement Administration number assigned to each provider granting the provider ~~them~~ authority to prescribe controlled substances.

~~3.73.5~~ “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 that for which the substance was prescribed.

~~3.8~~

~~3.103.7~~ _____ “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. “Eligible MOUD Provider” means a Vermont-licensed healthcare provider with a valid DEA number.

~~3.113.8~~ _____ “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.

~~3.123.9~~ _____ “Maintenance Treatment” means long-term MAT MOUD for an opioid use disorder 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.

~~3.133.11~~ _____ “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 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.

~~3.14~~ “MAT” means medication assisted treatment to treat opioid use disorder. Methadone, buprenorphine and injectable naltrexone are examples of medications used in “MOUD” means medications used to treat opioid use disorder. M such as methadone, buprenorphine, and injectable naltrexone are examples of medications used to treat OUD

~~3.153.12~~ _____ “Office Based Opioid Treatment provider” and “OBOT” provider” means a Office Based Opioid Treatment provider that prescribes MOUD pursuant to federal and State law, federal regulations, and State rules, federal and state regulations and that is not an OTP, 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.

~~3.163.13~~ “OTP” “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. ~~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.

~~3.173.14~~ “Physician” means a licensed medical doctor or a licensed doctor of osteopathy as defined in 26 V.S.A. Ch. 23, Subchapter 3.

~~3.183.15~~ “Preferred providers” means ~~an entity 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.

~~3.193.16~~ “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.

~~3.203.17~~ “Psychosocial Assessment” means an evaluation of the psychological and social factors that are experienced by an individual or family as the result of addiction. The factors may complicate an individual’s recovery or act as assets to recovery.

~~3.21~~ “SAMHSA” means the Substance Abuse and Mental Health Services Administration, an agency within in the U.S. Department of Health and Human Services.

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

~~3.233.19~~ “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 Testsspecimens” means any laboratory analysis of urine, oral mucosa, or serum blood that will be tested for the purpose of detecting the presence of alcohol and/or various scheduled drugs.

~~3.24~~

~~3.26~~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 Prior to treating a patient opioid use disorder with MOUDbuprenorphine, a providers shall hold a valid health care provider license under Title 26 of the Vermont Statutes Annotated Vermont and a valid DEA number.

~~4.1~~ PMOUD providers must shall provide MOUDMAT in accordance with the current version of 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 Pproviders 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.

~~4.2~~

~~4.3~~ For providers treating more than 30 patients for opioid use disorder, they shall receive a DATA 2000 waiver from the Substance Abuse and Mental Health Services Administration (SAMHSA) prior to treating any patient.

~~4.4~~ For providers treating 30 patients or fewer for opioid use disorder, they shall either hold a DATA 2000 waiver from SAMHSA or have received an exemption by submitting an application designated as a “Notice of Intent” to SAMHSA per the Practice Guidelines issued in 86 FR 22439 prior to treating any patient.