Rules Governing Medication-Assisted Therapy for Opioid Dependence for:
1. Office-Based Opioid Treatment (OBOT) Providers Prescribing Buprenorphine
2. Opioid Treatment Providers (OTP) –State Regulations

1.0 Authority

These rules are 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 to prescribe, and in limited circumstances, dispense buprenorphine to individuals requiring and seeking treatment for opioid addiction. The rule also establishes Vermont-specific requirements for Opioid Treatment Programs 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 physicians 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.

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.

3.5 "DATA 2000" means the federal Drug Addiction Treatment Act of 2000, which permits physicians who meet certain qualifications to treat individuals with opioid addiction by prescribing FDA-approved medications such as buprenorphine.

3.6 "DATA 2000 Waiver" means an authorization for a licensed physician who has met the training and credentialing registration requirements of DATA 2000 to prescribe

specified opioid addiction drugs to patients in settings other than Opioid Treatment Programs (OTP's).

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

3.8 "DVHA" means the Department of Vermont Health Access in the Agency of Human Services.

3.9 "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 and the risks involved. This includes an understanding of medication risks and benefits.

3.10 "Maintenance Treatment" means long-term MAT typically provided by an OBOT for an addiction lasting longer than one year.

3.11 "MAT" means medication-assisted therapy to treat opioid dependence. Both methadone and buprenorphine are examples of MAT drugs. MAT may also be referred to as Opioid Replacement Therapy.

3.12 "OBOT" means Office Based Opioid Treatment physician practice for prescribing buprenorphine as established by the Drug Abuse and Treatment Act of 2000. In Vermont, OBOTs are often referred to as "Spokes". An OBOT may be a preferred provider, an individual physician practice or several physicians practicing as a group.

3.13 "Physician" means a licensed medical doctor or a licensed doctor of osteopathy.

3.14 "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 (§1301.72). OTP's are specialty addiction treatment programs for dispensing opioid-replacement medication including methadone and buprenorphine under carefully controlled and observed conditions. OTPs offer onsite ancillary services. In Vermont, OTPs are sometimes referred to as "Hubs".

3.15 "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.

3.16 "SAMHSA" means the Substance Abuse and Mental Health Services Administration, an agency under the U.S. Department of Health and Human Services.

3.17 "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.

3.18 "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 Physicians to Prescribe Buprenorphine as Treatment for Opioid Dependence

OBOT providers may be a preferred provider, an individual physician practice or several physicians practicing MAT as a group. For the purposes of this rule, they are all treated as a unit for the following program administration and operations requirements:

4.1 Each physician who practices as or in an OBOT shall be a Vermont-licensed physician until such time as the federal law is changed to allow other providers to prescribe MAT.

4.2 Prior to prescribing buprenorphine from an OBOT, and consistent with the provisions of DATA 2000, physicians shall have received a DATA 2000 waiver from the Substance Abuse and Mental Health Services Administration (SAMHSA). [1]

4.2.1 During the first year of prescribing buprenorphine , the waived physician may maintain a patient load of up to 30 individuals receiving MAT at any point in time.

4.2.2 After prescribing buprenorphine for one year, the physician may notify SAMHSA of his or her intent to treat up to 100 patients at any point in time with buprenorphine.

[1] http:/buprenorphine.samhsa.gov/waiver_qualifications.html

5.0 OBOT Program Administration and Operations Requirements

5.1 All Vermont OBOTs shall have the following in place to initiate and continue prescribing buprenorphine:

5.1.1 Office or facility with sufficient space and adequate 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 all confidential medical information and records in hard-copy or electronic formats.

5.1.5 Adequate referral arrangements with other physicians and practitioners to evaluate and treat all medical and psychological issues that any 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

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

5.2.1.1 A plan for a reliable mechanism to inform patients of these emergency arrangements.

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 physician authorized to prescribe buprenorphine or with an OTP (Hub). It may also include the ability to transfer patient records.

5.2.2 **Permanent Program Closure**

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

5.2.2.1 A plan for the orderly and timely transfer of patients to another OBOT provider.

5.2.2.2 A plan to notify patients of any upcoming closure and reassure them of transition plans for continuity of care.

5.2.2.3 A plan to notify ADAP and DVHA no fewer than 60 days prior to closure to discuss the rationale for closure, and plans for continuity of care.

5.2.2.4 A plan for the transfer of patient records to another OBOT provider.

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

6.0 Clinical Care and Management Requirements

6.1 Referral to and Acceptance for Buprenorphine Treatment (MAT)

6.1.1 Patients may self-refer or be referred into MAT treatment from a variety of sources.

6.1.2 Prior to commencing MAT, and in addition to ensuring that any patient has a comprehensive medical evaluation as described in Section 6.2.1, the OBOT physician 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

Prior to commencing MAT, the physician shall either conduct an intake examination that includes any relevant physical and laboratory tests, or refer the patient to a medical professional who can perform the examination.

6.2.2 Psychosocial Assessment and Referral to Services

6.2.2.1 If the physician prescribing or dispensing buprenorphine is a licensed Psychiatrist or a physician certified by the American Board of Addiction Medicine, a psychosocial assessment shall be completed before the fourth patient visit to the physician prescribing or dispensing MAT.

6.2.2.2 If the physician prescribing or dispensing buprenorphine is not a licensed Psychiatrist or a physician certified by the American Board of Addiction Medicine, a referral to a licensed mental health/addictions clinician such as a Licensed or Certified Social Worker, a Psychologist, a Licensed Mental Health Counselor, a Licensed Marriage and Family Therapist or a Licensed Alcohol and Drug Abuse Counselor must be made for a psychosocial assessment. The referral must be made before the fourth patient visit to the physician prescribing or dispensing MAT and shall be documented in the patient's record.

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

6.2.2.4 A physician may not deny or discontinue MAT based solely on a patient's decision not to follow a recommendation to seek counseling or other behavioral interventions unless the patient is otherwise non-compliant with program expectations.

6.3 Developing a MAT Treatment Plan

6.3.1 OBOT physicians who are employed by ADAP Preferred Providers shall prioritize drug-injecting patients and pregnant women for MAT treatment if clinically appropriate.

6.3.2 Individuals who are clinically indicated for Methadone Therapy, or who need more clinical oversight or structure than available through an OBOT, shall be referred for appropriate treatment by an OTP.

6.3.3 Physicians prescribing buprenorphine in an OBOT setting shall register with VPMS and comply with Vermont's VPMS rule regarding system queries.

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

6.3.5 The OBOT physician prescribing buprenorphine shall adhere to all applicable standards of medical practice for providing treatment.

6.4 Informed Consent and Patient Treatment Agreement

Prior to treating a patient with buprenorphine, a physician shall:

6.4.1 Obtain voluntary, written, informed consent to treatment from each patient before admission to MAT treatment.

6.4.2 Obtain a treatment agreement outlining the responsibilities and expectations of the prescribing physician and the patient.

6.4.3 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 HIPPA and 42 CFR, Part 2. .

6.4.4 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.

6.5 Ongoing Patient Treatment and Monitoring

Beyond adhering to standard clinical practices, the following provisions must be followed by OBOT providers:

6.5.1 Referral and Consultation Network Requirements

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

6.5.1.2 Exchanges of information across this network shall facilitate patient treatment and conform to the protection of patient privacy consistent with HIPAA and for covered programs 42 CFR, Part 2.

6.5.2 Monitoring for Diversion

To ensure patient and public safety, each MAT physician shall develop clinical practices to minimize risk of diversion. These practices shall include the following:

6.5.3.1 Querying VPMS as required by Section 6.3.3 of this rule.

6.5.3.2 Informing patients on buprenorphine that diversion is a criminal offense.

6.5.3.3 Using the following clinical tools to monitor a patient's conformity with his or her treatment agreement and for monitoring diversion:

- Routine toxicological screens
- Random requests for pill counts
- Bubble-packaging of prescriptions
- Recording the ID numbers listed on the medication "strip" packaging for matching with observation of ID numbers during random call-backs.

6.5.3.4 Determining the frequency of monitoring procedures in 6.5.3.3 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.

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

6.5.3.6 Addressing the results of toxicological tests promptly with patients

6.5.3.9 If an OBOT dispenses buprenorphine, reporting to VPMS as required by Section 6.3.3 of this rule is required.

6.6 Discharge from MAT Treatment

6.6.1 Administrative Discharge from Treatment

6.6.1.1 The following situations may result in a patient being involuntarily discharged from MAT through medically supervised withdrawal:

6.6.1.1.1 Disruptive behavior that has an adverse effect on the OBOT practice, staff or other patients. These include, but are 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.

6.6.1.1.2 Incarceration or other relevant change of circumstance.

6.6.1.1.3 Violation of the treatment agreement.

6.6.1.1.4 Nonpayment of fees.

6.6.2.2 When an OBOT physician or practice decides to administratively discharge a patient from MAT, the physician will offer a clinically appropriate withdrawal schedule as long as it does not compromise the safety of physicians or program staff.

6.6.2.2.1 A patient who is involuntarily discharged from MAT may be referred to another program that is more clinically appropriate or affordable for the patient.

6.6.2.2.2 All factors contributing to the involuntary discharge from the program shall be documented in the patient's record.

6.6.2.2.3 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 Pregnant Women

6.7.1 Due to the risks of opioid addiction to pregnant women and their fetuses, a pregnant woman seeking buprenorphine from an OBOT shall either be admitted to the OBOT or referred to an OTP within 48 hours of initial contact.

6.7.2 OBOT physicians unable to admit pregnant women, or unable to otherwise arrange for MAT care within 48 hours, shall notify ADAP within 48 hours to ensure continuity of care.

6.7.3 In the event that a pregnant woman is involuntarily withdrawn from MAT, for reasons specified in Section 6.6.2.1 of this rule, the physician shall refer the woman to a high-risk obstetrical (OB) physician for care. If no high-risk OB is available, the woman can see a local obstetrician who prescribes buprenorphine until a high-risk OB is available.

7.0 Requirements for OTP's

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

7.1 Query VPMS as required by the Vermont Prescription Monitoring System Rule. Because federal law prohibits the reporting of MAT dispensed from an OTP, other providers may be unaware of a patient's enrollment in an OTP for MAT.

7.2 In emergencies, particularly those involving intravenous drug use, a non-physician 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 diagnosis to certify the diagnosis within 72 hours of the patient being admitted to the program. The MAT physician shall certify the diagnosis in the patient's record and have either a face-to face meeting or contact through an approved form of communication technology (tele-health) to review the assessment and discuss medical services.

7.3 Review, update and document the patient's treatment plan quarterly 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 If SAMHSA's requirement that only licensed physicians can order and dispense methadone and buprenorphine from an OTP changes, a non-physician, who is granted state approval and a waiver from SAMHSA in the future shall comply with all the requirements of Section 7 of this rule.

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