PROPOSED RULE # _____

Administrative Procedures – Proposed Rule Filing

Instructions:

In accordance with Title 3 Chapter 25 of the Vermont Statutes Annotated and the "Rule on Rulemaking" (CVR 04-000-001) adopted by the Office of the Secretary of State, this filing will be considered complete upon filing and acceptance of these forms with the Office of the Secretary of State, and the Legislative Committee on Administrative Rules.

All forms requiring a signature shall be original signatures of the appropriate adopting authority or authorized person, and all filings are to be submitted at the Office of the Secretary of State, no later than 3:30 pm on the last scheduled day of the work week.

The data provided in text areas of these forms will be used to generate a notice of rulemaking in the portal of "Proposed Rule Postings" online, and the newspapers of record if the rule is marked for publication. Publication of notices will be charged back to the promulgating agency.

PLEASE REMOVE ANY COVERSHEET OR FORM NOT REQUIRED WITH THE CURRENT FILING BEFORE DELIVERY!

Certification Statement: As the adopting Authority of this rule (see 3 V.S.A. § 801 (b) (11) for a definition), I approve the contents of this filing entitled:

Rules Governing Medication-Assisted Treatment for Opioid Use Disorder.

/s/ Michael K. Smith , on 1/21/2021

(signature) (date)

Printed Name and Title:
Michael K. Smith
Secretary
Agency of Human Services

RECEIVED BY: _____

- ☐ Coversheet
- ☐ Adopting Page
- ☐ Economic Impact Analysis
- ☐ Environmental Impact Analysis
- ☐ Strategy for Maximizing Public Input
- ☐ Scientific Information Statement (if applicable)
- ☐ Incorporated by Reference Statement (if applicable)
- ☐ Clean text of the rule (Amended text without annotation)
- ☐ Annotated text (Clearly marking changes from previous rule)
- ☐ ICAR Filing Confirmed

1. TITLE OF RULE FILING:
   Rules Governing Medication-Assisted Treatment for Opioid Use Disorder.
2. ADOPTING AGENCY:
   Vermont Department of Health
3. PRIMARY CONTACT PERSON:
   (A PERSON WHO IS ABLE TO ANSWER QUESTIONS ABOUT THE CONTENT OF THE RULE).

   Name: Brendan Atwood

   Agency: Vermont Department of Health

   Mailing Address: 108 Cherry Street, Burlington, VT 05402

   Telephone: 802 863 - 7280 Fax: 802 951 - 1275

   E-Mail: brendan.atwood@vermont.gov

   Web URL*(WHERE THE RULE WILL BE POSTED)*:
   https://www.healthvermont.gov/about-us/laws-reglations/public-comment
4. SECONDARY CONTACT PERSON:
   (A SPECIFIC PERSON FROM WHOM COPIES OF FILINGS MAY BE REQUESTED OR WHO MAY ANSWER QUESTIONS ABOUT FORMS SUBMITTED FOR FILING IF DIFFERENT FROM THE PRIMARY CONTACT PERSON).

   Name: Shayla Livingston

   Agency: Department of Health

   Mailing Address: 108 Cherry Street, Burlington, VT 05401

   Telephone: 802 863 - 7280 Fax: 802 951 - 1275

   E-Mail: shayla.livingston@vermont.gov
5. RECORDS EXEMPTION INCLUDED WITHIN RULE:
   (DOES THE RULE CONTAIN ANY PROVISION DESIGNATING INFORMATION AS CONFIDENTIAL; LIMITING ITS PUBLIC RELEASE; OR OTHERWISE EXEMPTING IT FROM INSPECTION AND COPYING?) No

   IF YES, CITE THE STATUTORY AUTHORITY FOR THE EXEMPTION:

   PLEASE SUMMARIZE THE REASON FOR THE EXEMPTION:
6. LEGAL AUTHORITY / ENABLING LEGISLATION:
   (THE SPECIFIC STATUTORY OR LEGAL CITATION FROM SESSION LAW INDICATING WHO THE ADOPTING ENTITY IS AND THUS WHO THE SIGNATORY SHOULD BE. THIS SHOULD BE A SPECIFIC CITATION NOT A CHAPTER CITATION).
   3 V.S.A. § 801(b)(11); Section 14; 18 V.S.A. § 4752.

7. EXPLANATION OF HOW THE RULE IS WITHIN THE AUTHORITY OF THE AGENCY:

   The statutes state the following:

   3 V.S.A. § 801(b)(11) states, "'Adopting authority' means, for agencies that are attached to the Agenc[y] of...Human Services...the commissioner of [that] department."

   18 V.S.A. § 4752 states, "[t]he Departments of Health and of Vermont Health Access shall establish by rule a system of opioid addiction treatment."

8. CONCISE SUMMARY **(150 WORDS OR LESS)**:

   This rulemaking amends the MAT Rule to (1) remove patient load limits that are determined at the federal level and change periodically; (2) Require providers with >100 clients to submit to the Department for review a continuity of care checklist to ensure they have an adequate plan for the continued care of their patients should there be an issue with a practitioner's ability to provide services; and (3) update terms, references, and formatting.

9. EXPLANATION OF WHY THE RULE IS NECESSARY:

   This rulemaking coordinates the state rule with federal regulations in regards to client limits. The rulemaking will also help ensure that practitioners have an adequate plan in place for the continued care of their patients should there be an issue with the practitioner’s ability to provide services.

10. EXPLANATION OF HOW THE RULE IS NOT ARBITRARY:

    18 V.S.A. § 4752 requires that the Department establish by rule "a system of opioid addiction treatment." This rule specifically achieves this by operation requirements for medication-assisted treatment by authorized providers, specific requirements for treatment programs, and continuity of care plans to provide a more structured system for individuals with opioid dependence.

11. LIST OF PEOPLE, ENTERPRISES AND GOVERNMENT ENTITIES AFFECTED BY THIS RULE:

Individuals with opioid dependence and their families, Office Based Opioid Treatment Providers, and Opioid Treatment Programs.

12. BRIEF SUMMARY OF ECONOMIC IMPACT **(150 WORDS OR LESS)**:

With expanded treatment capacity for individuals dependent upon opioids, Vermont is expected to see a decrease in emergency care, criminal justice, and social costs associated with untreated individuals dependent on opioids.

13. A HEARING IS SCHEDULED .

14. HEARING INFORMATION

(THE FIRST HEARING SHALL BE NO SOONER THAN 30 DAYS FOLLOWING THE POSTING OF NOTICES ONLINE).

IF THIS FORM IS INSUFFICIENT TO LIST THE INFORMATION FOR EACH HEARING PLEASE ATTACH A SEPARATE SHEET TO COMPLETE THE HEARING INFORMATION NEEDED FOR THE NOTICE OF RULEMAKING.

Date: 3/26/2021

Time: 10:00 AM

Street Address: Virtual Hearing

Zip Code:

Date:

Time: AM

Street Address:

Zip Code:

Date:

Time: AM

Street Address:

Zip Code:

Date:

Time: AM

Street Address:

Zip Code:

15. DEADLINE FOR COMMENT (NO EARLIER THAN 7 DAYS FOLLOWING LAST HEARING): 4/2/2021

16. KEYWORDS (PLEASE PROVIDE AT LEAST 3 KEYWORDS OR PHRASES TO AID IN THE SEARCHABILITY OF THE RULE NOTICE ONLINE).

Medication-Assisted Treatment

OTP

Buprenorphine

Opioid Treatment Program

Treatment of Opioid Dependence

Prescribing Rights

Administrative Procedures – Adopting Page

Instructions:

This form must accompany each filing made during the rulemaking process:

Note: To satisfy the requirement for an annotated text, an agency must submit the entire rule in annotated form with proposed and final proposed filings. Filing an annotated paragraph or page of a larger rule is not sufficient. Annotation must clearly show the changes to the rule.

When possible, the agency shall file the annotated text, using the appropriate page or pages from the Code of Vermont Rules as a basis for the annotated version. New rules need not be accompanied by an annotated text.

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1. TITLE OF RULE FILING:
   Rules Governing Medication-Assisted Treatment for Opioid Use Disorder.
2. ADOPTING AGENCY:
   Vermont Department of Health
3. TYPE OF FILING (*PLEASE CHOOSE THE TYPE OF FILING FROM THE DROPDOWN MENU BASED ON THE DEFINITIONS PROVIDED BELOW*):

   - **AMENDMENT -** Any change to an already existing rule, even if it is a complete rewrite of the rule, it is considered an amendment as long as the rule is replaced with other text.
   - **NEW RULE -** A rule that did not previously exist even under a different name.
   - **REPEAL** - The removal of a rule in its entirety, without replacing it with other text.

   This filing is **AN AMENDMENT OF AN EXISTING RULE .**

4. LAST ADOPTED (*PLEASE PROVIDE THE SOS LOG#, TITLE AND EFFECTIVE DATE OF THE LAST ADOPTION FOR THE EXISTING RULE*):

   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; July 15, 2017 Secretary of State Rule Log #17-039.

Administrative Procedures – Economic Impact Analysis

Instructions:

In completing the economic impact analysis, an agency analyzes and evaluates the anticipated costs and benefits to be expected from adoption of the rule; estimates the costs and benefits for each category of people enterprises and government entities affected by the rule; compares alternatives to adopting the rule; and explains their analysis concluding that rulemaking is the most appropriate method of achieving the regulatory purpose.

Rules affecting or regulating schools or school districts must include cost implications to local school districts and taxpayers in the impact statement, a clear statement of associated costs, and consideration of alternatives to the rule to reduce or ameliorate costs to local school districts while still achieving the objectives of the rule (see 3 V.S.A. § 832b for details).

Rules affecting small businesses (excluding impacts incidental to the purchase and payment of goods and services by the State or an agency thereof), must include ways that a business can reduce the cost or burden of compliance or an explanation of why the agency determines that such evaluation isn't appropriate, and an evaluation of creative, innovative or flexible methods of compliance that would not significantly impair the effectiveness of the rule or increase the risk to the health, safety, or welfare of the public or those affected by the rule.

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1. TITLE OF RULE FILING:

   Rules Governing Medication-Assisted Treatment for Opioid Use Disorder.

2. ADOPTING AGENCY:

   Vermont Department of Health

3. CATEGORY OF AFFECTED PARTIES:

   LIST CATEGORIES OF PEOPLE, ENTERPRISES, AND GOVERNMENTAL ENTITIES POTENTIALLY AFFECTED BY THE ADOPTION OF THIS RULE AND THE ESTIMATED COSTS AND BENEFITS ANTICIPATED:

   Individuals with opioid dependence: may have fewer contiuity of care issues that interfere with treatment, which can mitigate risks to the economic prospects for these individuals.

Office Based Opioid Treatment Providers and Opioid Treatment Programs: may see increased revenue due to an expanded number of clients.

4. IMPACT ON SCHOOLS:
INDICATE ANY IMPACT THAT THE RULE WILL HAVE ON PUBLIC EDUCATION, PUBLIC SCHOOLS, LOCAL SCHOOL DISTRICTS AND/OR TAXPAYERS CLEARLY STATING ANY ASSOCIATED COSTS:

No impact.

5. ALTERNATIVES: *CONSIDERATION OF ALTERNATIVES TO THE RULE TO REDUCE OR AMELIORATE COSTS TO LOCAL SCHOOL DISTRICTS WHILE STILL ACHIEVING THE OBJECTIVE OF THE RULE.*

Not applicable.

6. IMPACT ON SMALL BUSINESSES:
INDICATE ANY IMPACT THAT THE RULE WILL HAVE ON SMALL BUSINESSES (EXCLUDING IMPACTS INCIDENTAL TO THE PURCHASE AND PAYMENT OF GOODS AND SERVICES BY THE STATE OR AN AGENCY THEREOF):

To the extent OBOT providers can increase their client capacity, they may see an increase in revenue.

7. SMALL BUSINESS COMPLIANCE: *EXPLAIN WAYS A BUSINESS CAN REDUCE THE COST/BURDEN OF COMPLIANCE OR AN EXPLANATION OF WHY THE AGENCY DETERMINES THAT SUCH EVALUATION ISN'T APPROPRIATE.*

Not applicable.

8. COMPARISON:
COMPARE THE IMPACT OF THE RULE WITH THE ECONOMIC IMPACT OF OTHER ALTERNATIVES TO THE RULE, INCLUDING NO RULE ON THE SUBJECT OR A RULE HAVING SEPARATE REQUIREMENTS FOR SMALL BUSINESS:
Not applicable.

9. SUFFICIENCY: *EXPLAIN THE SUFFICIENCY OF THIS ECONOMIC IMPACT ANALYSIS.*
The cost savings cannot be estimated. Given this rule is consistent with federal law, and most of these requirements exist in the current rule, the Department of Health believes this analysis is sufficient.

Administrative Procedures – Environmental Impact Analysis

Instructions:

In completing the environmental impact analysis, an agency analyzes and evaluates the anticipated environmental impacts (positive or negative) to be expected from adoption of the rule; compares alternatives to adopting the rule; explains the sufficiency of the environmental impact analysis.

Examples of Environmental Impacts include but are not limited to:

- Impacts on the emission of greenhouse gases
- Impacts on the discharge of pollutants to water
- Impacts on the arability of land
- Impacts on the climate
- Impacts on the flow of water
- Impacts on recreation
- Or other environmental impacts

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1. TITLE OF RULE FILING:

   Rules Governing Medication-Assisted Treatment for Opioid Use Disorder.

2. ADOPTING AGENCY:

   Vermont Department of Health

3. GREENHOUSE GAS: *EXPLAIN HOW THE RULE IMPACTS THE EMISSION OF GREENHOUSE GASES (E.G. TRANSPORTATION OF PEOPLE OR GOODS; BUILDING INFRASTRUCTURE; LAND USE AND DEVELOPMENT, WASTE GENERATION, ETC.):*
   No impact.

4. WATER: *EXPLAIN HOW THE RULE IMPACTS WATER (E.G. DISCHARGE / ELIMINATION OF POLLUTION INTO VERMONT WATERS, THE FLOW OF WATER IN THE STATE, WATER QUALITY ETC.):*
   No impact.

5. LAND: *EXPLAIN HOW THE RULE IMPACTS LAND (E.G. IMPACTS ON FORESTRY, AGRICULTURE ETC.):*
   No impact.

6. RECREATION: *EXPLAIN HOW THE RULE IMPACT RECREATION IN THE STATE:*
   No impact.

7. CLIMATE: *EXPLAIN HOW THE RULE IMPACTS THE CLIMATE IN THE STATE:*
   No impact.

8. OTHER: *EXPLAIN HOW THE RULE IMPACT OTHER ASPECTS OF VERMONT'S ENVIRONMENT:*
   No impact.

9. SUFFICIENCY: *EXPLAIN THE SUFFICIENCY OF THIS ENVIRONMENTAL IMPACT ANALYSIS.*
   As this rule will have no environmental impact, the Department believes this environmental impact analysis to be sufficient.

Administrative Procedures – Public Input

Instructions:

In completing the public input statement, an agency describes the strategy prescribed by ICAR to maximize public input, what it did do, or will do to comply with that plan to maximize the involvement of the public in the development of the rule.

This form must accompany each filing made during the rulemaking process:

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1. TITLE OF RULE FILING:

   Rules Governing Medication-Assisted Treatment for Opioid Use Disorder.

2. ADOPTING AGENCY:

   Vermont Department of Health

3. PLEASE DESCRIBE THE STRATEGY PRESCRIBED BY ICAR TO MAXIMIZE PUBLIC INVOLVEMENT IN THE DEVELOPMENT OF THE PROPOSED RULE:

   A public hearing will be held.

   The rule will be posted on the Department of Health website:
   http://healthvermont.gov/admin/public_comment.aspx.

4. PLEASE LIST THE STEPS THAT HAVE BEEN OR WILL BE TAKEN TO COMPLY WITH THAT STRATEGY:

   Preliminary conversations with stakeholders have occurred to get initial feedback on the rule changes.

5. BEYOND GENERAL ADVERTISEMENTS, PLEASE LIST THE PEOPLE AND ORGANIZATIONS THAT HAVE BEEN OR WILL BE INVOLVED IN THE DEVELOPMENT OF THE PROPOSED RULE:

   The Department of Vermont Health Access

   MAT Providers

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.~~5~~4 "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.~~6~~5 "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.~~7~~6 "DEA" means the Drug Enforcement Administration in the U.S. Department of Justice.

3.~~8~~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 "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.~~12~~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. ~~This includes an understanding of medication risks and benefits.~~

3.~~13~~12 "Maintenance Treatment" means long-term MAT ~~typically provided by an OBOT~~ for an ~~addiction~~opioid use disorder lasting longer than one year.

3.~~14~~13 "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.~~15~~14 "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.~~16~~15 "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.~~17~~16 "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.

~~3.1.8~~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 ~~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.~~22~~23 "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).~~[1]~~

~~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~~.~~:

~~[1] 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~~ 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~~ 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 with all verbal and written requests on the timeline(s) provided to 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.~~1~~2, 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 ~~6.2.2.4 A~~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 Agreement[2]

~~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, ~~a~~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.~~2~~1.1 Exchanges of information ~~across~~through this provider network shall facilitate patient treatment and conform to the protection of patient privacy consistent with ~~HIPAA 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 ~~MAT~~OBOT provider shall develop clinical ~~practices~~practice to minimize risk of diversion. These clinical practices shall include ~~the following:~~ :

6.5.~~3~~2.1~~.~~.1 Querying VPMS as required by ~~Vermont's VPMS rule regarding system queries~~the Vermont Prescription Monitoring PMS Rule.

6.5.~~3~~2.1.2 Informing patients ~~on~~ being treated with buprenorphine that diversion is a criminal offense.

6.5.2.1.3.~~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~~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 ~~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 A~~2 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 All~~3 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~~ hours~~ 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.

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.

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

3.5 "DATA 2000 Waiver" means an authorization from SAMHSA for a provider who has met the training and credentialing registration requirements of DATA 2000 to

prescribe specified medications to treat opioid use disorder in settings other than Opioid Treatment Programs (OTP).

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 physician, physician assistant or advanced practice registered nurse, or other provider allowed to prescribe MAT under federal law and regulation.

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, all providers shall:

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

4.1.2 Receive a DATA 2000 waiver from the Substance Abuse and Mental Health Services Administration (SAMHSA).

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 with all verbal and written requests on the timeline(s) provided to 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 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 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 certified by the American Board of Addiction Medicine;

6.2.2.2.3 Psychiatric Nurse Practitioner;
6.2.2.2.4 Psychiatric Physician Assistant;
6.2.2.2.5 Mental health/addictions clinician (such as a Licensed or Certified Social Worker);
6.2.2.2.6 Psychologist;
6.2.2.2.7 Psychologist – Master;
6.2.2.2.8 Licensed Mental Health Counselor;
6.2.2.2.9 Licensed Marriage and Family Therapist; or
6.2.2.2.10 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:

[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.

6.4.1.1 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

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 practice to minimize risk of diversion. These clinical practices shall include:

6.5.2.1.1 Querying VPMS as required by the Vermont Prescription Monitoring PMS 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 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
- 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 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.