PROPOSED RULE # _____.

Proposed Filing - Coversheet

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 and enclosures with the Office of the Secretary of State, and the Legislative Committee on Administrative Rules.

All forms shall be submitted to 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 Proposed Filing Coversheet will be used to generate a notice of rulemaking in the portal of "Proposed Rule Postings" online, and the newspapers of record. 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 Medications for Opioid Use Disorder

/s/ Todd W. Daloz , on 10/2/23

(signature) (date)

Printed Name and Title:

Todd W. Daloz
Deputy 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 Medications for Opioid Use Disorder

2. ADOPTING AGENCY:
Vermont AHS/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: AHS/Department of Health

Mailing Address: 108 Cherry Street, Burlington, VT 05401

Telephone: 802-863-728 Fax: 802-951-127

E-Mail: ahs.vdhrules@vermont.gov

Web URL *(WHERE THE RULE WILL BE POSTED)*:
http://www.healthvermont.gov/about-us/laws-regulations/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: Natalie Weill

Agency: AHS/Department of Health

Mailing Address: 108 Cherry Street, Burlington, VT 05401

Telephone: 802-863-728 Fax: 802-951-127

E-Mail: ahs.vdhrules@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); 18 V.S.A. § 4752.

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

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 rule establishes the requirements for providers treating patients with opioid use dispoeder (OUD). On December 29, 2022, Congress eliminated the federal requirement for healthcare providers who dispense medication for opioid use disorder to obtain an "X Waiver" prior to dispensing buprenorphine and ended the program that issued those waivers. However, the legislation does not impact current state regulations; the current (non-emergency) Vermont MOUD regulations still require providers to obtain this X Waiver (which is no longer obtainable) in order to dispense buprenorphine to treat substance use disorder. This rule eliminates the X Waiver requirements. Doing so will ensure Vermont's MOUD regulations do not inhibit access to MOUD providers by those in need.

The rule also aligns telehealth requirements with federal law.

Finally, a number of clarifications, terminology updates, and formatting changes were made.

9. EXPLANATION OF WHY THE RULE IS NECESSARY:

Without this rule, some health care providers may be restricted from providing MOUD to patients due to the X Waiver requirements in the Vermont MOUD Rule. This rule will eliminate that potentiality and bring the rule into alignment with federal requirements.

10. EXPLANATION OF HOW THE RULE IS NOT ARBITRARY AS DEFINED IN 3 V.S.A. § 801(b)(13)(A):

This rule aligns Vermont requirements with federal requirements. The decisions made by the Department regarding these regulations are factually based,

rationally connected to those factual bases, and would make sense to a reasonable person.

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

Individuals with opioid use disorder, Office Based Opioid Treatment Providers, and Opioid Treatment Programs.

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

This rulemaking is not expected to have any economic impact.

13. A HEARING WILL BE SCHEDULED.

IF A HEARING WILL NOT BE SCHEDULED, PLEASE EXPLAIN WHY.

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:

Time: AM

Street Address:

Zip Code:

URL for Virtual:

Date:

Time: AM

Street Address:

Zip Code:

URL for Virtual:

Date:

Time: AM

Street Address:

Zip Code:

URL for Virtual:

Date:
Time: AM
Street Address:
Zip Code:
URL for Virtual:

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15. DEADLINE FOR COMMENT (NO EARLIER THAN 7 DAYS FOLLOWING LAST HEARING):
16. KEYWORDS (PLEASE PROVIDE AT LEAST 3 KEYWORDS OR PHRASES TO AID IN THE SEARCHABILITY OF THE RULE NOTICE ONLINE).

Opioid use disorder

Medication for Opioid Use disorder

MOUD

OBOT

OTP

Opioid treatment

Buprenorphine

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.

1. TITLE OF RULE FILING:
   Rules Governing Medications for Opioid Use Disorder
2. ADOPTING AGENCY:
   Vermont AHS/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 if 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 Treatment for Opioid Use Disorder for:

   1. Office-Based Opioid Treatment (OBOT) Providers

   2. Opioid Treatment Programs (OTP)

   October 15, 2021 Secretary of State Rule Log #21-024

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. If no impacts are anticipated, please specify "No impact anticipated" in the field.

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 Medications for Opioid Use Disorder

2. ADOPTING AGENCY:

   Vermont AHS/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 use disorder: No impact is anticipated.

   Office Based Opioid Treatment Providers, and Opioid Treatment Programs: No economic impact is anticipated.

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 is anticipated.

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.*

   Given there will be no impacts to school districts, those alternatives have not been considered.

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):

   No impact is anticipated.

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.*

   Given there will be no impacts to small businesses, those alternatives have not been considered.

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:
   Without this rulemaking, some providers may not be able to comply with the regulations.

9. SUFFICIENCY: *DESCRIBE HOW THE ANALYSIS WAS CONDUCTED, IDENTIFYING RELEVANT INTERNAL AND/OR EXTERNAL SOURCES OF INFORMATION USED.*
   The Department has provided the relevant information that is available.

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. If no impacts are anticipated, please specify "No impact anticipated" in the field.

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 Medications for Opioid Use Disorder

2. ADOPTING AGENCY:

   Vermont AHS/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 is anticipated.

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 is anticipated.

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

6. RECREATION: *EXPLAIN HOW THE RULE IMPACTS RECREATION IN THE STATE:*
   No impact is anticipated.

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

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

9. SUFFICIENCY: *DESCRIBE HOW THE ANALYSIS WAS CONDUCTED, IDENTIFYING RELEVANT INTERNAL AND/OR EXTERNAL SOURCES OF INFORMATION USED.*
   This analysis considered the potential impacts of these amendments to the areas listed above, and there will be none.

Public Input Maximization Plan

Instructions:

Agencies are encouraged to hold hearings as part of their strategy to maximize the involvement of the public in the development of rules. Please complete the form below by describing the agency's strategy for maximizing public input (what it did do, or will do to maximize the involvement of the public).

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

1. TITLE OF RULE FILING:

   Rules Governing Medications for Opioid Use Disorder

2. ADOPTING AGENCY:

   Vermont AHS/Department of Health

3. PLEASE DESCRIBE THE AGENCY'S STRATEGY TO MAXIMIZE PUBLIC INVOLVEMENT IN THE DEVELOPMENT OF THE PROPOSED RULE, LISTING THE STEPS THAT HAVE BEEN OR WILL BE TAKEN TO COMPLY WITH THAT STRATEGY:

   A public hearing will be held.

   The rule will be posted on the Department of Health website: https://www.healthvermont.gov/laws-regulations/laws/public-comment

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

   Vermont Medical Society (VMS)

   Vermont Association of Hospitals and Health Systems (VAHHS)

   Vermont Department of Vermont Health Access

   Vermont Office of Professional Regulation

   Vermont Board of Nursing

   Vermont Board of Medical Practice

   Dr. Fred Lord, MOUD provider

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).~~

~~3.5~~3.3 "DEA" means the Drug Enforcement Administration in the U.S. Department of Justice.

~~3.6~~3.4 "DEA Number" means the Drug Enforcement Administration number assigned to each provider granting the provider~~them~~ authority to prescribe controlled substances.

~~3.7~~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 usethat for which the substance was prescribed.

~~3.8~~

~~3.10~~3.7 ~~"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 regulati~~"Eligible MOUD Provider" means a Vermont-licensed ~~healthcare~~ provider with a valid DEA number.

~~3.11~~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.

~~3.12~~3.9 "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.

~~3.13~~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 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~~

~~3.15~~3.12 "Office Based Opioid Treatment provider" and "OBOT~~"~~ provider" means a ~~Office Based Opioid Treatment~~ provider that prescribes MOUD pursuant to 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.

DRAFT

3.20 "Toxicology ~~Tests~~specimens" 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 Prior to treating a patient with 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 ~~P~~MOUD providers ~~must~~ shall provide MOUD~~MAT~~ in accordance with ~~the current version of~~ the American Society of Addiction Medicine (ASAM) National Practice Guideline for the Treatment of Opioid Use Disorder 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 ~~P~~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 regulations 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.~~

DRAFT

5.0 OBOT Administration and Operation Requirements

5.1 Each OBOT provider shall maintain ~~all of~~ the following:

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

~~5.1.1~~5.1.2 Office or facility with adequate space and equipment to provide quality patient care and monitoring;

~~5.1.2~~5.1.3 Office or facility ~~space~~ that is clean, well-maintained and has appropriate climate controls for patient comfort and safety;

~~5.1.3~~5.1.4 Adequate space for private conversations if psychosocial assessment and counseling services are provided on-site;

~~5.1.4~~5.1.5 ~~Office space~~ A~~a~~dequate space for the protection of confidential medical information and records in hard-copy and/or electronic formats; and

~~5.1.5 Arrangements~~Agreements ~~with other providers and practitioners to evaluate and treat all medical and psychological issues that a patient may experience. This ensures that~~ MOUD~~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 interruption~~s~~. 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~~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 provider shall respond to ~~all~~ verbal and written requests on the timeline(s) provided by the Department.

5.2.3 Continuity of Care Plan Checklist

5.2.3.1 Within 30 days of the enrollment of the OBOT provider's 100th patient, the OBOT provider shall complete and submit for approval the Continuity of Care Checklist, as provided by the Department.

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

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

6.0 Clinical Care and Management Requirements for OBOTs

6.1 Assessment and Diagnosis

6.1.1 Prior to ~~initiating~~ prescribing MOUD~~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.

~~6.1.0~~

~~6.3~~6.2 Evaluation of the Patient's Health Status

~~6.3.1~~6.2.1 Medical Evaluation

~~6.3.1.1~~6.2.1.1 ~~Prior~~ Upon~~to~~ ~~initiating~~ prescribing MOUD~~MAT~~, and as early as is practical, the OBOT provider shall either conduct an intake examination that includes ~~all~~ appropriate physical and laboratory tests, including by telehealth when consistent with federal guidelines, or refer the patient to a ~~medical professional~~provider who can perform such an examination.

~~6.3.2~~6.2.2 Psychosocial Assessment and Referral to Services

~~6.3.2.1~~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 document that referral in the patient's record.~~The OBOT provider shall complete the psychosocial assessment of a patient inducted on MOUDMAT by the end of the third patient visit.~~

~~6.3.2.2~~6.2.2.2 The psychosocial assessment shall be completed by a provider who is ~~in one of the following disciplines~~licensed as a:

~~6.3.2.2.1~~6.2.2.2.1 Psychiatrist;
~~6.3.2.2.2~~6.2.2.2.2 Physician;
~~6.3.2.2.3~~6.2.2.2.3 Advanced Practice Registered Nurse;
~~6.3.2.2.4~~6.2.2.2.4 Physician Assistant;
~~6.3.2.2.5~~6.2.2.2.5 Psychiatric Nurse Practitioner;
~~6.3.2.2.6~~6.2.2.2.6 Psychiatric Physician Assistant;
~~6.3.2.2.7~~6.2.2.2.7 Mental health/addictions clinician (such as a Licensed or Certified Social Worker);
~~6.3.2.2.8~~6.2.2.2.8 Psychologist;
~~6.3.2.2.9~~6.2.2.2.9 Psychologist – Master;
~~6.3.2.2.10~~6.2.2.2.10 Licensed Mental Health Counselor;
~~6.3.2.2.11~~6.2.2.2.11 Licensed Marriage and Family Therapist; or
~~6.3.2.2.12~~6.2.2.2.12 Licensed Alcohol and Drug Counselor.

~~If the OBOT provider does not meet the specifications~~one of the criteria of ~~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~~prior to the conclusion ~~of the third patient visit and shall be documented in the patient's record.~~

~~6.3.4~~6.3 Treatment Plan

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

~~6.3.5~~6.3.2 As part of the treatment plan, ~~Based on the outcomes of the psychosocial assessment, t~~The OBOT provider may recommend to the patient that the patient participate in ongoing counseling or other ~~behavioral~~ interventions, such as recovery support programs.

6.3.2.1 An OBOT provider may not deny or discontinue MOUD~~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.

~~6.3.5.1~~6.4 Individuals who are clinically indicated for methadone treatment, or who ~~need~~require more clinical oversight or structure than available through an OBOT provider, as determined by the provider, shall be referred to an OTP.

~~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.~~

6.5 ~~6.4~~ 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

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

[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.

and specialty medical services and consultation for patients, and 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 healthcare confidentiality regulations and policies.

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 ID numbers listed on the medication "strip" packaging for matching with observation of ID numbers during random call-backs.
- Observed dosing.

6.6.2.1.4 Determining the frequency of monitoring procedures described in Section 6.5.2.1.3 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 regulation and law.

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

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

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

~~6.4.1.2 Obtain a signed treatment agreement; and~~

~~6.4.1.3 Make reasonable efforts to obtain releases of information for any health care providers or others important for the coordination of care to the extent allowed by applicable law.~~

~~6.5 Ongoing Patient Treatment and Monitoring~~

~~In addition to adhering to standard clinical practice, t~~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 practices and operational procedures to minimize risk of diversion. These clinical practices and operational procedures shall include:~~

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

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

~~6.5.2.1.3 Using the following clinical tools, as appropriate, to monitor a patient's conformity with a patient's treatment agreement and for monitoring diversion:~~

- ~~Routine toxicological screens~~
- ~~Random requests for medication counts~~
- ~~Bubble-packaging of prescriptions, if in tablet form~~
- ~~Recording the ID numbers listed on the medication "strip" packaging for matching with observation of ID numbers during random call-backs~~
- ~~Observed dosing~~

~~6.3.5.1.1 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 eachhis or her patient's level of stability. For patients receiving services from multiple providers, the coordination and sharing of toxicology results is required, pursuant to applicable regulation and law.~~

~~6.3.5.1.2 Collecting all urine and toxicological specimens in a therapeutic context.~~

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, and other patients.

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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, 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 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.

~~6.3.6~~ 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

7.1.2 .

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 that in the patient's record. The OTP physician shall have either an in-person meeting or visual contact within 14 days through a federally approved form of communication technology to review the assessment and discuss medical services.

~~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.~~

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~~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~~ or type ~~of~~ clinical ~~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~~ MOUDMAT ~~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~~If a person who is pregnant is administratively ~~discharged from an OBOT provider, for reasons specified in Section 6.6.1 of this rule, the OBOT provider shall refer the person to the most appropriate obstetrical care available.~~

~~7.0 Requirements for OTPs~~

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

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~~7.2 In an emergency, as determined by an eligible provider, an eligible provider in an OTP may admit a patient for~~ MOUD~~MAT. In these situations, a~~ MOUD~~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~~ and record in the patient's record. The~~ MOUD~~MAT physician shall certify the diagnosis in the patient's record and have either an in-person meeting or visual contact~~ within 14 days ~~through a federally approved form of communication technology to review the assessment and discuss medical services.~~

~~7.3 Review, update, and document a~~the patient's treatment plan ~~every~~ 90 days~~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 At a minimum, t~~To the extent allowed by a signed release of ~~information, notify a~~each patient's ~~primary care provider about their~~ treatment plan.

~~7.5 Establishment of a Medication Unit must be approved by the~~ Department.~~

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.

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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.

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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 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 regulations 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. 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.

3.17 "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.

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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 regulations 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.

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

5.1.3 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;

5.1.5 Adequate space for the protection of confidential medical information and records in hard-copy and/or electronic formats; and

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.

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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 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 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 100th patient, the OBOT provider shall complete and submit for approval the Continuity of Care Checklist, as provided by the Department.

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

6.0 Clinical Care and Management Requirements for OBOTs

6.1 Assessment and Diagnosis

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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 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 document that referral in the patient's record.

6.2.2.2 The psychosocial assessment shall be completed by a provider who is licensed 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

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6.2.2.2.12 Licensed Alcohol and Drug Counselor.

6.3 Treatment Plan

6.3.1 The OBOT provider will 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.

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[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.

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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.

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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:

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6.6.2.1.2 Informing patients that instances of medication diversion may not be covered by healthcare confidentiality regulations and policies.

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:

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- Observed dosing.

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6.6.2.1.4 Determining the frequency of monitoring procedures described in Section 6.5.2.1.3 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 regulation and law.

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

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- aggression
- threats of violence
- drug diversion
- trafficking of illicit drugs
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- noncompliance with the treatment plan resulting in an observable, negative impact on the program, staff, patient, and other patients.

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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.

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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, 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 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.

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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 that in the patient's record. The OTP physician shall have either an in-person meeting or visual contact 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.

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JENNEY SAMUELSON
SECRETARY

TODD W. DALOZ
DEPUTY SECRETARY

STATE OF VERMONT
AGENCY OF HUMAN SERVICES

MEMORANDUM

TO: Sarah Copeland Hanzas, Secretary of State

FROM: Jenney Samuelson, Secretary, Agency of Human Services

DATE: January 31, 2023

SUBJECT: Signatory Authority for Purposes of Authorizing Administrative Rules

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I hereby designate Deputy Secretary of Human Services Todd W. Daloz as signatory to fulfill the duties of the Secretary of the Agency of Human Services as the adopting authority for administrative rules as required by Vermont's Administrative Procedure Act, 3. V.S.A § 801 et seq.

Cc: Todd W. Daloz