EMERGENCY RULE # 23-E01

Emergency 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 emergency filing will be considered complete upon filing and acceptance of these forms with the Office of the Secretary of State, the Legislative Committee on Administrative Rules and a copy with the Chair of the Interagency 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 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.

This emergency rule may remain in effect for a total of 180 days from the date it first takes effect.

Certification Statement: As the adopting Authority of this rule (see 3 V.S.A. § 801(b)(11) for a definition), I believe there exists an imminent peril to public health, safety or welfare, requiring the adoption of this emergency rule.

The nature of the peril is as follows (*PLEASE USE ADDITIONAL SHEETS IF SPACE IS INSUFFICIENT*). In December 2022, Congress removed the federal requirement for medical practitioners to receive a waiver in order to prescribe medications, like buprenorphine, for the treatment of opioid use disorder (OUD). This rulemaking similarly removes those provisions from state law, allowing practitioners who have a current DEA registration that includes Schedule III authority to prescribe buprenorphine for OUD with immediate effect.

I approve the contents of this filing entitled:

Rules Governing Medication-Assisted Treatment for Opioid Use Disorder.

/s/ Todd W. Daloz , on 1/30/23

(signature) (date)

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)

Printed Name and Title:
Todd W. Daloz
Deputy Secretary
Agency of Human Services

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 05401

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

   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: David Englander

   Agency: Vermont Department of Health

   Mailing Address: 108 Cherry Street, Burlington, VT 05401

   Telephone: 802-863-7280 Fax: 8029511275

   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**):

On December 29, 2022, Congress eliminated the federal requirement for healthcare providers who dispense medication for substance 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 Vermont MAT 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 emergency rule eliminates the X Waiver requirements. Doing so will ensure Vermont's MAT regulations do not inhibit access to MAT providers by those in need.

9. EXPLANATION OF WHY THE RULE IS NECESSARY:

Currently, some healthcare providers may be restricted from providing MAT to patients due to the X Waiver requirements in the Vermont MAT Rule. This rule will eliminate that potentiality and bring the MAT rule into alignment with newly promulgated 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):

Practitioners will no longer have to go through the waiver application process before prescribing MAT. Persons wishing to be treated for OUD may more easily and quickly find a local provider. This may reduce travel/off-work time and speed their recovery with all the attendant benefits.

13. A HEARING IS NOT 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:

Time: AM

Street Address: AM

Zip Code:

URL for Virtual:

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

16. EMERGENCY RULE EFFECTIVE: 02/01/2023

17. EMERGENCY RULE WILL REMAIN IN EFFECT UNTIL
(A DATE NO LATER THAN 180 DAYS FOLLOWING ADOPTION OF THIS EMERGENCY RULE):

07/31/2023

18. NOTICE OF THIS EMERGENCY RULE SHOULD BE PUBLISHED IN THE WEEKLY NOTICES OF RULEMAKING IN THE NEWSPAPERS OF RECORD.

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

Medication-Assisted Treatment

OTP

OBOT

MAT

Buprenorphine

280 State Drive - Center Building
Waterbury, VT 05671-1000

OFFICE OF THE SECRETARY
TEL: (802) 241-0440
FAX: (802) 241-0450

JENNEY SAMUELSON
SECRETARY

TODD W. DALOZ
DEPUTY SECRETARY

STATE OF VERMONT
AGENCY OF HUMAN SERVICES

MEMORANDUM

TO: Jim Condos, Secretary of State

FROM: Jenney Samuelson, Secretary, Agency of Human Services

DATE: April 1, 2022

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

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 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 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

VERMONT

State of Vermont
Agency of Administration
Office of the Secretary
Pavilion Office Building
109 State Street, 5th Floor
Montpelier, VT 05609-0201
www.aoa.vermont.gov

[phone] 802-828-3322
[fax] 802-828-2428

Kristin L. Clouser, Secretary

MEMORANDUM

TO: **Copeland Hanzas, Secretary of State**
FROM: **Sean Brown, ICAR Chair**
DATE: **January 31, 2023**
RE: **Emergency Rule Titled 'Rules Governing Medication-Assisted Treatment for Opioid Use Disorder' by the Agency of Human Services, Department of Health**

Sean Brown Digitally signed by Sean Brown Date: 2023.01.31 15:59:19 -05'00'

The use of rulemaking procedures under the provisions of 3 V.S.A. §844 is appropriate for this rule. I have reviewed the proposed rule titled 'Rules Governing Medication-Assisted Treatment for Opioid Use Disorder', provided by the Agency of Human Services, Department of Health, and agree that emergency rulemaking is necessary.

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VERMONT

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 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:

   Practitioners will no longer have to go through the waiver application process before prescribing MAT. Persons wishing to be treated for OUD may more easily and quickly find a local provider. This may reduce travel/off-work time and speed their recovery with all the attendant benefits.

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:

None.

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):

   None.

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:
   The only alternative is to not update the rule, in which case providers would 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 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 IMPACTS 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: *DESCRIBE HOW THE ANALYSIS WAS CONDUCTED, IDENTIFYING RELEVANT INTERNAL AND/OR EXTERNAL SOURCES OF INFORMATION USED.*
   The rule does not impact any of the areas listed above, and therefore, this analysis sufficiently captures that there will be no environmental impact.

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:

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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 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:

   Following the adoption of this emergency rule, the Department will work with stakeholders to update the non-emergency MAT rule.

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)

Annotated Text

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

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, a providers shall hold a valid health care provider license under Title 26 of the Vermont Statutes Annotated Vermont and a valid DEA number.

4.2 Providers must provide 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.

~~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.~~

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 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

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 to 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;
6.2.2.2.3 Advanced Practice Registered Nurse;
6.2.2.2.4 Physician Assistant;
6.2.2.2.5 Psychiatric Nurse Practitioner;
6.2.2.2.6 Psychiatric Physician Assistant;
6.2.2.2.7 Mental health/addictions clinician (such as a Licensed or Certified Social Worker);
6.2.2.2.8 Psychologist;
6.2.2.2.9 Psychologist – Master;
6.2.2.2.10 Licensed Mental Health Counselor;
6.2.2.2.11 Licensed Marriage and Family Therapist; or
6.2.2.2.12 Licensed Alcohol and Drug Counselor.

6.2.3 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:

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

[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.

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

6.5.2.1.2 Informing patients being treated with 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 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

6.5.2.1.4 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 System 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.

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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.

3.6 "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 healthcare provider with a valid DEA number.

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, a provider shall hold a valid health care provider license under Title 26 of the Vermont Statutes Annotated Vermont and a valid DEA number.

4.2 Providers must provide 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.

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 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

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 to 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;
6.2.2.2.3 Advanced Practice Registered Nurse;
6.2.2.2.4 Physician Assistant;
6.2.2.2.5 Psychiatric Nurse Practitioner;
6.2.2.2.6 Psychiatric Physician Assistant;
6.2.2.2.7 Mental health/addictions clinician (such as a Licensed or Certified Social Worker);
6.2.2.2.8 Psychologist;
6.2.2.2.9 Psychologist – Master;
6.2.2.2.10 Licensed Mental Health Counselor;
6.2.2.2.11 Licensed Marriage and Family Therapist; or
6.2.2.2.12 Licensed Alcohol and Drug Counselor.

6.2.3 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:

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

[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.

6.5.1.1 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 to minimize risk of diversion. These clinical practices 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 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 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

6.5.2.1.4 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 System 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.

VERMONT **GENERAL ASSEMBLY**

The Vermont Statutes Online

Title 3 : Executive

Chapter 025 : Administrative Procedure

Subchapter 001 : General Provisions

(Cite as: 3 V.S.A. § 801)

§ 801. Short title and definitions

(a) This chapter may be cited as the "Vermont Administrative Procedure Act."

(b) As used in this chapter:

(1) "Agency" means a State board, commission, department, agency, or other entity or officer of State government, other than the Legislature, the courts, the Commander in Chief, and the Military Department, authorized by law to make rules or to determine contested cases.

(2) "Contested case" means a proceeding, including but not restricted to rate-making and licensing, in which the legal rights, duties, or privileges of a party are required by law to be determined by an agency after an opportunity for hearing.

(3) "License" includes the whole or part of any agency permit, certificate, approval, registration, charter, or similar form of permission required by law.

(4) "Licensing" includes the agency process respecting the grant, denial, renewal, revocation, suspension, annulment, withdrawal, or amendment of a license.

(5) "Party" means each person or agency named or admitted as a party, or properly seeking and entitled as of right to be admitted as a party.

(6) "Person" means any individual, partnership, corporation, association, governmental subdivision, or public or private organization of any character other than an agency.

(7) "Practice" means a substantive or procedural requirement of an agency, affecting one or more persons who are not employees of the agency, that is used by the agency in the discharge of its powers and duties. The term includes all such requirements, regardless of whether they are stated in writing.

(8) "Procedure" means a practice that has been adopted in writing, either at the election of the agency or as the result of a request under subsection 831(b) of this title. The term includes any practice of any agency that has been adopted in writing, whether or not labeled as a procedure, except for each of the following:

(A) a rule adopted under sections 836-844 of this title;

(B) a written document issued in a contested case that imposes substantive or procedural requirements on the parties to the case;

(C) a statement that concerns only:

(i) the internal management of an agency and does not affect private rights or procedures available to the public;

(ii) the internal management of facilities that are secured for the safety of the public and the individuals residing within them; or

(iii) guidance regarding the safety or security of the staff of an agency or its designated service providers or of individuals being provided services by the agency or such a provider;

(D) an intergovernmental or interagency memorandum, directive, or communication that does not affect private rights or procedures available to the public;

(E) an opinion of the Attorney General; or

(F) a statement that establishes criteria or guidelines to be used by the staff of an agency in performing audits, investigations, or inspections, in settling commercial disputes or negotiating commercial arrangements, or in the defense, prosecution, or settlement of cases, if disclosure of the criteria or guidelines would compromise an investigation or the health and safety of an employee or member of the public, enable law violators to avoid detection, facilitate disregard of requirements imposed by law, or give a clearly improper advantage to persons that are in an adverse position to the State.

(9) "Rule" means each agency statement of general applicability that implements, interprets, or prescribes law or policy and that has been adopted in the manner provided by sections 836-844 of this title.

(10) "Incorporation by reference" means the use of language in the text of a regulation that expressly refers to a document other than the regulation itself.

(11) "Adopting authority" means, for agencies that are attached to the Agencies of Administration, of Commerce and Community Development, of Natural Resources, of Human Services, and of Transportation, or any of their components, the secretaries of those agencies; for agencies attached to other departments or any of their components, the commissioners of those departments; and for other agencies, the chief officer of the agency. However, for the procedural rules of boards with quasi-judicial powers, for the Transportation Board, for the Vermont Veterans' Memorial Cemetery Advisory Board, and for the Fish and Wildlife Board, the chair or executive secretary of the board shall be the adopting authority. The Secretary of State shall be the adopting authority for the Office of Professional Regulation.

(12) "Small business" means a business employing no more than 20 full-time

employees.

(13)(A) "Arbitrary," when applied to an agency rule or action, means that one or more of the following apply:

(i) There is no factual basis for the decision made by the agency.

(ii) The decision made by the agency is not rationally connected to the factual basis asserted for the decision.

(iii) The decision made by the agency would not make sense to a reasonable person.

(B) The General Assembly intends that this definition be applied in accordance with the Vermont Supreme Court's application of "arbitrary" in , 2006 VT 65, and , 154 Vt. 596 (1990).

(14) "Guidance document" means a written record that has not been adopted in accordance with sections 836-844 of this title and that is issued by an agency to assist the public by providing an agency's current approach to or interpretation of law or describing how and when an agency will exercise discretionary functions. The term does not include the documents described in subdivisions (8)(A) through (F) of this section.

(15) "Index" means a searchable list of entries that contains subjects and titles with page numbers, hyperlinks, or other connections that link each entry to the text or document to which it refers. (Added 1967, No. 360 (Adj. Sess.), § 1, eff. July 1, 1969; amended 1981, No. 82, § 1; 1983, No. 158 (Adj. Sess.), eff. April 13, 1984; 1985, No. 56, § 1; 1985, No. 269 (Adj. Sess.), § 4; 1987, No. 76, § 18; 1989, No. 69, § 2, eff. May 27, 1989; 1989, No. 250 (Adj. Sess.), § 88; 2001, No. 149 (Adj. Sess.), § 46, eff. June 27, 2002; 2017, No. 113 (Adj. Sess.), § 3; 2017, No. 156 (Adj. Sess.), § 2.)

VERMONT **GENERAL ASSEMBLY**

The Vermont Statutes Online

Title 18 : Health

Chapter 093 : Opioid Use Disorder

Subchapter 001 : Treatment Of Opioid Use Disorder

(Cite as: 18 V.S.A. § 4752)

§ 4752. Opioid addiction treatment system

(a) The Departments of Health and of Vermont Health Access shall establish by rule a regional system of opioid addiction treatment.

(b) The rules shall include the following requirements:

(1) Patients shall receive appropriate, comprehensive assessment and therapy from a physician or advanced practice registered nurse and from a licensed clinical professional with clinical experience in addiction treatment, including a psychiatrist, master's- or doctorate-level psychologist, mental health counselor, clinical social worker, or drug and alcohol abuse counselor.

(2) A medical assessment shall be conducted to determine whether pharmacological treatment, which may include methadone, buprenorphine, and other federally approved medications to treat opioid addiction, is medically appropriate.

(3) A routine medical assessment of the appropriateness for the patient of continued pharmacological treatment based on protocols designed to encourage cessation of pharmacological treatment as medically appropriate for the individual treatment needs of the patient.

(4) Controlled substances for use in federally approved pharmacological treatments for opioid addiction shall be dispensed only by:

(A) a treatment program authorized by the Department of Health; or

(B) a physician or advanced practice registered nurse who is not affiliated with an authorized treatment program but who meets federal requirements for use of controlled substances in the pharmacological treatment of opioid addiction.

(5) Comprehensive education and training requirements shall apply for health care providers, pharmacists, and the licensed clinical professionals listed in subdivision (1) of this subsection, including relevant aspects of therapy and pharmacological treatment.

(6) Patients shall abide by rules of conduct, violation of which may result in discharge from the treatment program, including:

(A) provisions requiring urinalysis at such times as the program may direct;

(B) restrictions on medication dispensing designed to prevent diversion of medications and to diminish the potential for patient relapse; and

(C) such other rules of conduct as a provider authorized to provide treatment under subdivision (4) of this subsection (b) may require.

(c) [Repealed.] (Added 2011, No. 135 (Adj. Sess.), § 1, eff. May 14, 2012; amended 2015, No. 173 (Adj. Sess.), § 3.)