



# Prescription Monitoring Program State Profiles - Vermont

**Research current through December 2014.**

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# VERMONT

<http://healthvermont.gov/adap/VPMS.aspx#about>

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- Status of Program – operational
- Housing Entity – Department of Health
- Advisory Commission – no
- Funding – grants; drug manufacturer fees
- Drugs Monitored – Schedules II – IV
- Who’s Required to Report Dispensing Information – all dispensers licensed by the Board of Pharmacy; dispenser means any person who dispenses or engages in dispensing a controlled substance
- Exemptions from Reporting – drugs administered directly to a patient; drugs dispensed by a health care provider at a facility licensed by the department provided that the quantity dispensed is limited to an amount adequate to treat the patient for a maximum of 48 hours
- Nonresident Pharmacies Required to Report – yes
- Veterinarians Required to Report – no
- Data Collection Interval – weekly/7 days
- Notice to Consumers – yes
- Interstate Sharing – with other PMPs and authorized users in other states
- Persons Authorized to Receive Information – medical examiner; Commissioner of Public Safety; licensing/regulatory boards; Medical Director of the Department of Vermont Health Access for Medicaid purposes; patient; prescribers; dispensers
- Delegates Allowed – yes
- De-identified Data Provided – yes
- Unsolicited Reports – to prescribers, pharmacists, and licensing boards
- Training Required – yes; law enforcement only
- Mandatory Enrollment – yes; all prescribers and dispensers
- Mandatory Access – yes; multiple circumstances; see States that Require Prescribers and/or Dispensers to Access PMP in Certain Circumstances, compilation of statutes, on NAMSDDL’s website for further information

West's Vermont Statutes Annotated (2014)  
Title Eighteen. Health  
Part 5. Foods and Drugs  
Chapter 84A. Vermont Prescription Monitoring System

§ 4283. Creation; implementation

(a) The Department shall maintain an electronic database and reporting system for monitoring Schedules II, III, and IV controlled substances, as defined in 21 C.F.R. Part 1308, as amended and as may be amended, that are dispensed within the State of Vermont by a health care provider or dispenser or dispensed to an address within the State by a pharmacy licensed by the Vermont Board of Pharmacy.

(b) As required by the department, every dispenser who is licensed by the Vermont board of pharmacy shall report to the department in a timely manner data for each controlled substance in Schedules II, III, and IV, as amended and as may be amended, dispensed to a patient within Vermont. Reporting shall not be required for:

(1) a drug administered directly to a patient; or

(2) a drug dispensed by a health care provider at a facility licensed by the department, provided that the quantity dispensed is limited to an amount adequate to treat the patient for a maximum of 48 hours.

(c) Data for each controlled substance that is dispensed shall include the following:

(1) patient identifier, which may include the patient's name and date of birth;

(2) drug dispensed;

(3) date of dispensing;

(4) quantity and dosage dispensed;

(5) the number of days' supply;

(6) health care provider; and

(7) dispenser.

(d) The data shall be provided in the electronic format defined by the department. To the extent possible, the format shall not require data entry in excess of that required in the regular course of business. Electronic transmission is not required if a waiver has been granted by the department to an individual dispenser. The department shall strive to create VPMS in a manner that will enable real-time transmittal to VPMS and real-time retrieval of information stored in VPMS.

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(e) It is not the intention of the Department that a health care provider or a dispenser shall have to pay a fee or tax or purchase hardware or proprietary software required by the Department specifically for the use, establishment, maintenance, or transmission of the data. The Department shall seek grant funds and take any other action within its financial capability to minimize any cost impact to health care providers and dispensers.

(f) The department shall purge from VPMS all data that is more than six years old.

(g) The commissioner shall develop and provide advisory notices, which shall make clear that all prescriptions for controlled drugs in Schedules II, III, and IV are entered into a statewide database in order to protect the public. The notices shall be distributed at no cost to dispensers and health care providers who are subject to this chapter.

(h) A dispenser shall be subject to discipline by the board of pharmacy or by the applicable licensing entity if the dispenser intentionally fails to comply with the requirements of subsection (b), (c), or (d) of this section.

West's Vermont Statutes Annotated (2014)  
Title Eighteen. Health  
Part 5. Foods and Drugs  
Chapter 84A. Vermont Prescription Monitoring System

§ 4284. Protection and disclosure of information

(a) The data collected pursuant to this chapter and all related information and records shall be confidential, except as provided in this chapter, and shall not be subject to the Public Records Act. The Department shall maintain procedures to protect patient privacy, ensure the confidentiality of patient information collected, recorded, transmitted, and maintained, and ensure that information is not disclosed to any person except as provided in this section.

(b)(1) The Department shall provide only the following persons with access to query the VPMS:

(A) A health care provider, dispenser, or delegate who is registered with the VPMS and certifies that the requested information is for the purpose of providing medical or pharmaceutical treatment to a bona fide current patient.

(B) Personnel or contractors, as necessary for establishing and maintaining the VPMS.

(C) The Medical Director of the Department of Vermont Health Access, for the purposes of Medicaid quality assurance, utilization, and federal monitoring requirements with respect to Medicaid recipients for whom a Medicaid claim for a Schedule II, III, or IV controlled substance has been submitted.

(D) A medical examiner or delegate from the Office of the Chief Medical Examiner, for the purpose of conducting an investigation or inquiry into the cause, manner, and circumstances of an individual's death.

(E) A health care provider or medical examiner licensed to practice in another state, to the extent necessary to provide appropriate medical care to a Vermont resident or to investigate the death of a Vermont resident.

(2) The Department shall provide reports of data available to the Department through the VPMS only to the following persons:

(A) A patient or that person's health care provider, or both, when VPMS reveals that a patient may be receiving more than a therapeutic amount of one or more regulated substances.

(B) A designated representative of a board responsible for the licensure, regulation, or discipline of health care providers or dispensers pursuant to a bona fide specific investigation.

(C) A patient for whom a prescription is written, insofar as the information relates to that patient.

(D) The relevant occupational licensing or certification authority if the Commissioner reasonably suspects fraudulent or illegal activity by a health care provider. The licensing or certification authority may report the data that are the evidence for the suspected fraudulent or illegal activity to a drug diversion investigator.

(E)(i) The Commissioner of Public Safety, personally, or the Deputy Commissioner of Public Safety, personally, if the Commissioner of Health, personally, or a Deputy Commissioner of Health, personally, makes the disclosure and has consulted with at least one of the patient's health care providers, when the disclosure is necessary to avert a serious and imminent threat to a person or the public.

(ii) The Commissioner of Public Safety, personally, or the Deputy Commissioner of Public Safety, personally, when he or she requests data from the Commissioner of Health, and the Commissioner of Health believes, after consultation with at least one of the patient's health care providers, that disclosure is necessary to avert a serious and imminent threat to a person or the public.

(iii) The Commissioner or Deputy Commissioner of Public Safety may disclose such data received pursuant to this subdivision (E) as is necessary, in his or her discretion, to avert the serious and imminent threat.

(F) A prescription monitoring system or similar entity in another state pursuant to a reciprocal agreement to share prescription monitoring information with the Vermont Department of Health as described in section 4288 of this title.

(c) A person who receives data or a report from VPMS or from the Department shall not share that data or report with any other person or entity not eligible to receive that data pursuant to subsection (b) of this section, except as necessary and consistent with the purpose of the disclosure and in the normal course of business. Nothing shall restrict the right of a patient to share his or her own data.

(d) The Commissioner shall offer health care providers and dispensers training in the proper use of information they may receive from VPMS. Training may be provided in collaboration with professional associations representing health care providers and dispensers.

(e) A drug diversion investigator who may receive information pursuant to this section shall not have access to VPMS except for information provided to the officer by the licensing or certification authority.

(f) The Department is authorized to use information from VPMS for research, trend analysis, and other public health promotion purposes provided that data are aggregated or otherwise de-identified. The Department shall post the results of trend analyses on its website for use by health care providers, dispensers, and the general public. When appropriate, the Department shall send alerts relating to identified trends to health care providers and dispensers by electronic mail.

(g) Following consultation with the Unified Pain Management System Advisory Council and an opportunity for input from stakeholders, the Department shall develop a policy that will enable it to use information from VPMS to determine if individual prescribers and dispensers are using VPMS appropriately.

(h) Following consultation with the Unified Pain Management System Advisory Council and an opportunity for input from stakeholders, the Department shall develop a policy that will enable it to evaluate the prescription of regulated drugs by prescribers.

(i) Knowing disclosure of transmitted data to a person not authorized by subsection (b) of this section, or obtaining information under this section not relating to a bona fide specific investigation, shall be punishable by imprisonment for not more than one year or a fine of not more than \$1,000.00, or both, in addition to any penalties under federal law.

(j) All information and correspondence relating to the disclosure of information by the Commissioner to a patient's health care provider pursuant to subdivision (b)(2)(A) of this section shall be confidential and privileged, exempt from public inspection and copying under the Public Records Act, immune from subpoena or other disclosure, and not subject to discovery or introduction into evidence.

(k) Each request for disclosure of data pursuant to subdivision (b)(2)(B) of this section shall document a bona fide specific investigation and shall specify the case number of the investigation.

West's Vermont Statutes Annotated (2014)  
Title Eighteen. Health  
Part 5. Foods and Drugs  
Chapter 84A. Vermont Prescription Monitoring System

§ 4288. Reciprocal agreements

The Department of Health may enter into reciprocal agreements with other states that have prescription monitoring programs so long as access under such agreement is consistent with the privacy, security, and disclosure protections in this chapter.



West's Vermont Statutes Annotated (2014)  
Title Eighteen. Health  
Part 5. Foods and Drugs  
Chapter 84A. Vermont Prescription Monitoring System

§ 4289. Standards and guidelines for health care providers and dispensers

(a) Each professional licensing authority for health care providers shall develop evidence-based standards to guide health care providers in the appropriate prescription of Schedules II, III, and IV controlled substances for treatment of chronic pain and for other medical conditions to be determined by the licensing authority. The standards developed by the licensing authorities shall be consistent with rules adopted by the Department of Health.

(b)(1) Each health care provider who prescribes any Schedule II, III, or IV controlled substances shall register with the VPMS by November 15, 2013.

(2) If the VPMS shows that a patient has filled a prescription for a controlled substance written by a health care provider who is not a registered user of VPMS, the Commissioner of Health shall notify the applicable licensing authority and the provider by mail of the provider's registration requirement pursuant to subdivision (1) of this subsection.

(3) The Commissioner of Health shall develop additional procedures to ensure that all health care providers who prescribe controlled substances are registered in compliance with subdivision (1) of this subsection.

(c) Each dispenser who dispenses any Schedule II, III, or IV controlled substances shall register with the VPMS.

(d) Health care providers shall query the VPMS with respect to an individual patient in the following circumstances:

(1) at least annually for patients who are receiving ongoing treatment with an opioid Schedule II, III, or IV controlled substance;

(2) when starting a patient on a Schedule II, III, or IV controlled substance for nonpalliative long-term pain therapy of 90 days or more;

(3) the first time the provider prescribes an opioid Schedule II, III, or IV controlled substance written to treat chronic pain; and

(4) prior to writing a replacement prescription for a Schedule II, III, or IV controlled substance pursuant to section 4290 of this title.

(e) The Commissioner of Health shall, after consultation with the Unified Pain Management System Advisory Council, adopt rules necessary to effect the purposes of this section. The

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Commissioner and the Council shall consider additional circumstances under which health care providers should be required to query the VPMS, including whether health care providers should be required to query the VPMS when a patient requests renewal of a prescription for an opioid Schedule II, III, or IV controlled substance written to treat acute pain.

(f) Each professional licensing authority for dispensers shall adopt standards, consistent with rules adopted by the Department of Health under this section, regarding the frequency and circumstances under which its respective licensees shall:

(1) query the VPMS; and

(2) report to the VPMS, which shall be no less than once every seven days.

(g) Each professional licensing authority for health care providers and dispensers shall consider the statutory requirements, rules, and standards adopted pursuant to this section in disciplinary proceedings when determining whether a licensee has complied with the applicable standard of care.

West's Vermont Statutes Annotated (2014)  
Title Eighteen. Health  
Part 5. Foods and Drugs  
Chapter 84A. Vermont Prescription Monitoring System

§ 4290. Replacement prescriptions and medications

- (a) As used in this section, “replacement prescription” means an unscheduled prescription request in the event that the document on which a patient's prescription was written or the patient's prescribed medication is reported to the prescriber as having been lost or stolen.
- (b) When a patient or a patient's parent or guardian requests a replacement prescription for a Schedule II, III, or IV controlled substance, the patient's health care provider shall query the VPMS prior to writing the replacement prescription to determine whether the patient may be receiving more than a therapeutic dosage of the controlled substance.
- (c) When a health care provider writes a replacement prescription pursuant to this section, the provider shall clearly indicate as much by writing the word “REPLACEMENT” on the face of the prescription. The health care provider shall document the writing of the replacement prescription in the patient's medical record.

West's Vermont Statutes Annotated (2014)  
Title Thirty-Three. Human Services  
Part 2. Economic Assistance  
Chapter 19. Medical Assistance  
Subchapter 5. Prescription Drug Cost Containment

§ 2004. Manufacturer fee

(a) Annually, each pharmaceutical manufacturer or labeler of prescription drugs that are paid for by the Department of Vermont Health Access for individuals participating in Medicaid, Dr. Dynasaur, or VPharm shall pay a fee to the Agency of Human Services. The fee shall be 0.5 percent of the previous calendar year's prescription drug spending by the Department and shall be assessed based on manufacturer labeler codes as used in the Medicaid rebate program.

(b) Fees collected under this section shall fund collection and analysis of information on pharmaceutical marketing activities under 18 V.S.A. §§ 4632 and 4633, analysis of prescription drug data needed by the Office of the Attorney General for enforcement activities, the Vermont prescription monitoring system established in 18 V.S.A. chapter 84A, the Evidence-Based Education Program established in 18 V.S.A. chapter 91, subchapter 2, and any opioid-antagonist education, training, and distribution program operated by the Department of Health or its agents. The fees shall be collected in the evidence-based education and advertising fund established in section 2004a of this title.

(c) The secretary of human services or designee shall make rules for the implementation of this section.

West's Vermont Statutes Annotated (2014)  
Title Thirty-Three. Human Services  
Part 2. Economic Assistance  
Chapter 19. Medical Assistance  
Subchapter 5. Prescription Drug Cost Containment

§ 2004a. Evidence-Based Education and Advertising Fund

(a) The Evidence-Based Education and Advertising Fund is established in the State Treasury as a special fund to be a source of financing for activities relating to fund collection and analysis of information on pharmaceutical marketing activities under 18 V.S.A. §§ 4632 and 4633, for analysis of prescription drug data needed by the Office of the Attorney General for enforcement activities, for the Vermont Prescription Monitoring System established in 18 V.S.A. chapter 84A, for the Evidence-Based Education Program established in 18 V.S.A. chapter 91, subchapter 2, and for the support of any opioid-antagonist education, training, and distribution program operated by the Department of Health or its agents. Monies deposited into the Fund shall be used for the purposes described in this section.

(b) Into the Fund shall be deposited:

(1) revenue from the manufacturer fee established under section 2004 of this title; and

(2) the proceeds from grants, donations, contributions, taxes, and any other sources of revenue as may be provided by statute, rule, or act of the General Assembly.

(c) The Fund shall be administered pursuant to 32 V.S.A. chapter 7, subchapter 5, except that interest earned on the fund and any remaining balance shall be retained in the Fund.

West's Vermont Administrative Code (2014)  
Title 12. Agency of Human Services  
Subtitle 5. Department of Health  
General  
Rule 21. Prescription Monitoring System

## 12-5-21:1. GENERAL PROVISIONS

### Section 1.1 Purpose.

This rule implements the Vermont Prescription Monitoring System (“VPMS”) created by 18 V.S.A. Chapter 84A, which authorizes the Department to establish an electronic database and reporting system for electronic monitoring of prescriptions of certain controlled substances to promote the public health through enhanced opportunities for treatment for and prevention of abuse of controlled substances, without interfering with the legal medical use of those substances.

### Section 1.2 Authority.

This rule is adopted under the authority of 3 V.S.A. §§ 801(b)(11) and 3003(a) and 18 V.S.A. §§ 102 and 4287.

### Section 1.3 Effective Date.

This rule shall be effective on June 1, 2008.

### Section 1.4 Definitions.

The definitions of terms contained in these rules are the same as those contained in 18 V.S.A. § 4282. If any of such legislative definitions are amended, the amended definitions shall be the definitions of the terms contained in these rules.

Additional definitions for purposes of these rules:

1. “Commissioner” means the Commissioner of the Vermont Department of Health.
2. “Controlled substance” means a substance listed on Schedules II, III or IV as defined in 21 C.F.R. Part 1308, as amended and as may be amended.
3. “Report of Controlled Substances Dispensed” means the report generated by dispensers of required data on each reportable prescription dispensed pursuant to this rule.
4. “Department” means the Vermont Department of Health.

5. “Dispense” or “dispensing” shall have the same meaning as those terms are defined in 26 V.S.A. § 2022(5).

6. “Pharmacist-manager” shall have the same meaning as defined in the Vermont Board of Pharmacy Administrative Rules.

7. “Reportable prescription” means each controlled substance dispensed from any pharmacy to a patient within Vermont during the reporting period, except (1) a controlled substance administered directly to a patient; or (2) a controlled substance dispensed by a health care provider at a facility licensed by the Department of Health, provided that the quantity dispensed is limited to an amount adequate to treat the patient for a maximum of 48 hours.

8. “VPMS report” means a report released by the Department of information from the VPMS database to an individual or entity eligible to receive the information pursuant to a specific provision of law.

#### Section 1.5 Distribution of Advisory Notices.

Each dispenser shall provide to customers to whom a reportable prescription is dispensed the advisory notice developed and distributed by the Department by: 1) prominently displaying the advisory notice in a manner readily accessible to its customers, or 2) duplicating the complete text of the advisory notice in another format, such as by printing on customer receipts or on patient instructions or providing a written insert for delivery to the patient, or 3) both.

#### Section 1.6 Confidentiality.

All data submitted to the VPMS database pursuant to this rule are confidential, not subject to disclosure pursuant to public records law, and shall only be disclosed as provided in 18 V.S.A. § 4284 or this rule.

A person who receives information from the VPMS database shall only use that information as permitted by law and shall share that information only with other persons eligible by law to receive it. There is no restriction on the right of a patient to share his or her own data received from the VPMS database.

#### Section 1.7 Correction of Information in the VPMS Database.

A patient, health care provider, dispenser, or professional licensure board, or other individual having knowledge of what they believe to be an error in the VPMS database, may submit a request to correct information in writing to the Department that shall include:

1. A statement explaining in detail the basis for the requested correction;
2. The precise change requested;

3. Documentation of the error and of the correct information;
4. The requester's name, address, telephone number and original signature.

The Department will review all requests to correct information in the VPMS database and contact the reporting pharmacy that provided the data. If the reporting pharmacy concurs that the data should be corrected as requested, the Department will correct the data. If the reporting pharmacy does not concur, the Department will decline to make the change and refer the requester to the reporting pharmacy. Upon request by a health care provider, dispenser or professional licensure board or other individual, and as permitted by 18 V.S.A. § 4284 and Part III of this rule, the Department will notify the requester whether the requested correction has been made. Any patient who has requested a correction will be notified of whether the requested correction has been made.



West's Vermont Administrative Code (2014)  
Title 12. Agency of Human Services  
Subtitle 5. Department of Health  
General  
Rule 21. Prescription Monitoring System

## 12-5-21:2. PRESCRIPTION MONITORING REPORTING REQUIREMENTS

### Section 2.1 Report of Controlled Substances Dispensed.

Commencing within 60 days of notice from the Commissioner to each pharmacy licensed by the Vermont Board of Pharmacy, including those located outside of Vermont, that the VPMS database is operational, each pharmacy shall submit a Report of Controlled Substances Dispensed for each reportable prescription dispensed beginning with data as of July 1, 2008 as provided in this rule.

At least once each week, every pharmacist-manager of a pharmacy licensed by the Vermont Board of Pharmacy, including those located outside of Vermont, shall submit a Report of Controlled Substances Dispensed to the VMPS database of all reportable prescriptions dispensed from the pharmacy to a patient in Vermont in the immediately preceding seven (7) days.

Each pharmacist-manager shall provide the following information on each reportable prescription:

1. The patient's full name;
2. The patient's date of birth;
3. The patient's complete address;
4. The name of the drug dispensed;
5. The National Drug Code Number for the drug and dosage dispensed;
6. The date dispensed;
7. The quantity and dosage dispensed;
8. The number of days' supply dispensed;
9. The number of refills prescribed;
10. The prescriber's name;
11. The prescriber's DEA number, including suffix if applicable; and

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## 12. The dispensing pharmacy DEA number.

Any entity with more than one pharmacy licensed by the Vermont Board of Pharmacy, including those located outside of Vermont, may submit a single report for all of its pharmacies and shall identify in the report the specific location from which each reportable prescription was dispensed.

### Section 2.2 Form and Filing of Report of Controlled Substances Dispensed.

Each pharmacist-manager shall submit the Report of Controlled Substances Dispensed directly to the VPMS database, or the Department's designated agent, through the secure electronic filing system and in an electronic format as established by the Department, unless a waiver of the electronic filing requirement is granted by the Commissioner.

### Section 2.3 Waiver of Electronic Filing Requirement.

A dispenser may file a request in writing with the Commissioner for a waiver of the electronic filing requirement. The request for waiver must demonstrate good cause for the request and propose an alternate method of secure submission of the required reports. In his or her discretion, the Commissioner may grant or deny the request for waiver and alternate submission method. If the Commissioner grants a request for waiver, the dispenser shall submit its Report of Controlled Substances Dispensed in a format as determined by the Department.

West's Vermont Administrative Code (2014)  
Title 12. Agency of Human Services  
Subtitle 5. Department of Health  
General  
Rule 21. Prescription Monitoring System

#### 12-5-21:3. ACCESS TO VPMS DATA

Information from the VPMS database may be disclosed only as provided in this section. Disclosures authorized by this rule shall be limited to the minimum information necessary for the purposes of 18 V.S.A. Chapter 84A.

The prescriber's DEA number shall not be disclosed to a patient or to another prescriber and shall be disclosed only to the prescriber him or herself or the prescriber's professional licensure board or the Commissioner of Public Safety consistent with the requirement that disclosures shall be limited to the minimum information necessary for the purposes of 18 V.S.A. Chapter 84A.

#### Section 3.1 Patient.

A patient for whom a prescription for a controlled substance is written may request information from the VPMS database relating to himself or herself. The request shall be submitted to the Department in writing on a form approved by the Department and shall include:

1. The patient's name;
2. The patient's date of birth;
3. The time period for which the information is requested;
4. The patient's telephone number, mail and street address; and
5. The patient's original signature.

The original signed form shall be delivered by mail or in person to the Department, Division of Alcohol and Drug Abuse Programs office. To receive the requested information, the patient shall appear personally and produce a valid government issued photographic proof of identity at the Department, Division of Alcohol and Drug Abuse Programs office, or at one of the Department's District Offices.

The patient may choose to share, or choose not to share, the information received from the VPMS database pursuant to this section without restriction.

#### Section 3.2 Health Care Provider or Dispenser Registration.

1. A health care provider or dispenser shall register with the Department to be eligible to request information relating to a bona fide current patient from the VPMS database. The registration application shall be in a format approved by the Department. The Department will issue a VPMS registration number to an eligible applicant who demonstrates he or she holds a current Vermont license issued by the applicable board of licensure.

2. A health care provider or dispenser with a current Vermont license registered with the Department may request information from the VPMS database relating to a bona fide current patient. The request shall be submitted in a format approved by the Department and shall include:

1. The patient's full name;
2. The patient's date of birth;
3. The patient's complete address;
4. Time period for which information is requested;
5. The requester's name;
6. The requester's VPMS registration number;
7. A statement certifying that the request is for the purpose of providing medical or pharmaceutical treatment to a bona fide current patient;
8. A statement certifying that the requester currently holds a Vermont license issued by the applicable board of licensure; and
9. The requester's telephone number, mail and street address.

A registered health care provider or dispenser may access the VPMS database through the secure web portal to request and receive the information electronically, or may submit a written request to the Department and receive the information by secure mail or fax.

### Section 3.3 Professional Licensure Boards.

A representative of a professional board that is responsible for the licensure, regulation or discipline of health care providers or dispensers, may request information from the VPMS database relating to a licensee pursuant to a bona fide specific investigation of that licensee. The request shall be submitted in writing and in a format approved by the Department, and shall include:

1. The name of the licensee;

2. The licensee's DEA number, if applicable;
3. The timeframe under investigation;
4. The requester's name;
5. The requester's telephone number, mail and street address;
6. A statement certifying that the request is pursuant to a bona fide specific investigation of the licensee; and
7. A statement certifying that the requester is duly designated by the board of licensure to make the request.

The original, signed form shall be delivered by secure mail, fax, or in person to the Department, Division of Alcohol and Drug Abuse Programs office. The Department will transmit the information by secure mail or fax.

#### Section 3.4 Disclosures from the VPMS Database.

Disclosures from the VPMS database pursuant to the provisions in this rule 3.4 will be in accordance with a protocol approved by the Commissioner to identify when disclosures should be made pursuant to this subsection. The protocol will be developed, and periodically reviewed and updated, in consultation with the Advisory Committee and with health care providers designated by the Commissioner with particular expertise in relevant clinical specialties including the use of controlled substances for the treatment of acute and chronic pain, palliative care, end-of-life care and the treatment for and prevention of abuse of controlled substances and will be consistent with current standards of care and practice in those clinical specialties. Disclosures from the VPMS database pursuant to subsections 1, 2 or 3 below shall occur only in accordance with the protocol and as otherwise permitted by this rule.

1. The Department may provide data to a patient and/or that person's health care provider when the VPMS database reveals that a patient may be receiving more than a therapeutic amount of one or more regulated substances.
2. When the Commissioner of Health reasonably suspects that there is fraudulent or illegal activity by a health care provider or dispenser, the Department may provide data on such an instance to the appropriate licensing or certification authority. That authority may report the data that are evidence of suspected fraudulent or illegal activity to a trained law enforcement officer. The trained law enforcement officer shall not have access to the VPMS data except for information provided to the officer by the licensing or certification authority.
3. The Commissioner of Health may personally disclose data from the VPMS database to the Commissioner of Public Safety personally when the Commissioner of Health has consulted with

at least one of the patient's health care providers and believes such disclosure is necessary to avert a serious and imminent threat to a person or the public.

### Section 3.5 Department of Health Use of Data.

1. The Department may use the data contained in the VPMS database for health promotion purposes including the publication of aggregate, de-identified data about the extent of reportable prescription drug use in Vermont or the change in the consumption of certain controlled substances.
2. The Department may use aggregated, de-identified data in the VPMS database to evaluate the effectiveness of its drug prevention and treatment programs, and the benefits received from educational programs directed at providers and pharmacists on the use and abuse of controlled substances.

West's Vermont Administrative Code (2014)  
Title 12. Agency of Human Services  
Subtitle 5. Department of Health  
General  
Rule 21. Prescription Monitoring System

#### 12-5-21:4. TRAINING

##### Section 4.1 Designation of Training Programs.

The Department, in consultation with the Advisory Committee and one or more individuals with medical expertise relating to prescribing controlled substances and treatment of drug addiction and dependence, will periodically designate one or more training programs for law enforcement officers relating to responsible and proper use of VPMS data. The Department will maintain a list of current trained law enforcement officers qualified to receive a report from a professional licensure board as authorized by 18 V.S.A. § 4284(b)(5).

West's Vermont Administrative Code (2014)  
Title 12. Agency of Human Services  
Subtitle 5. Department of Health  
General  
Rule 21. Prescription Monitoring System

#### 12-5-21:5. ENFORCEMENT

##### Section 5.1 Administrative Discipline.

A dispenser who intentionally fails to comply with the reporting requirements specified in this rule shall be subject to discipline by the board of pharmacy, or other appropriate licensing authority, as provided in 18 V.S.A. § 4283(h).

The Department may refer to the appropriate licensing authority any dispenser who fails to submit a timely or complete Report of Controlled Substances Dispensed.

##### Section 5.2 Civil and Criminal Enforcement.

Any person who knowingly discloses confidential information not authorized by 18 V.S.A. § 4284(b), or obtains information under that section not relating to a bona fide specific investigation, shall be subject to imprisonment for not more than one year or a fine of not more than \$1,000, or both, in addition to any penalties under state or federal law, as provided in 18 V.S.A. § 4284.



West's Vermont Administrative Code (2014)

Title 12. Agency of Human Services

Subtitle 5. Department of Health

General

Rule 50. Rules Governing the Prescription of Extended Release Hydrocodone Manufactured Without Abuse-Deterrent Formulations.

#### 12-5-50:4.0. Prescription of Extended Release Hydrocodones without ADFs

Prior to prescribing an extended release hydrocodone that is manufactured without an ADF, the prescriber shall:

4.1 Conduct and document a thorough medical evaluation and physical examination as part of the patient's medical record;

4.2 Evaluate and document relative risks and benefits for the individual patient of the use of hydrocodones that are manufactured without an ADF prior to writing a prescription for such a hydrocodone. The evaluation shall include but not be limited to a Risk Assessment as defined in Section 3.3;

4.3 Document in the medical record that the prescription of a hydrocodone without an ADF is required for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment for which alternative treatment options, including non-pharmacological treatments, are ineffective, not tolerated, or would otherwise be inadequate to provide sufficient management of pain;

4.4 Receive a signed Informed Consent form from the patient, or if the patient is not competent to provide informed consent, from the patient's legal representative, that shall include information regarding the drug's potential for addiction, abuse, and misuse; and the risks associated with the drug of life-threatening respiratory depression; overdose as a result of accidental exposure potentially fatal especially in children; neonatal opioid withdrawal symptoms; and potentially fatal overdose when interacting with alcohol;

4.5 Receive a signed Controlled Substance Treatment Agreement from the patient that shall include requirements such as urine screening (no less frequent than every 120 days), pill counts, safe storage and disposal, and other appropriate conditions as determined by the prescriber to reasonably and timely inform the prescriber if the patient is misusing the prescribed substance;

4.6 Query the Vermont Prescription Monitoring System (VMPS) and review other controlled substances prescribed to the patient prior to the first prescription. For any patient prescribed 40 mg or greater per day, the prescriber shall query the VPMS no less frequently than once every 120 days for as long as the patient possesses a valid prescription for that amount;

4.7 Determine a maximum daily dose, or a "not to exceed value" for the prescription to be transmitted to the pharmacy;

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4.8 Write a prescription that must be filled within seven (7) days and that does not exceed 30 days in duration;

4.8 Schedule and undertake periodic follow-up visits and evaluations.

West's Vermont Administrative Code (2014)  
Title 12. Agency of Human Services  
Subtitle 5. Department of Health  
Division of Alcohol and Drug Abuse Programs  
Rule 102. Medication Assisted Therapy for Opioid Dependence Rules

## 12-5-102:2. OPIOID TREATMENT APPROVAL RULES

These rules are based on the Center for Substance Abuse Treatment (CSAT) Guidelines for the Accreditation of Opioid Treatment Programs, revised 2007 and The Vermont Buprenorphine Treatment Guidelines, revised 2010, and have been written to comply with Vermont statute. These rules will also apply to office based programs or pre-scribers who have 30 or more patients on narcotic replacement treatment.

### Section I. Introduction.

Treatment Considerations Related to the Natural History of the Disease:

1. The clinical assessment of all patients should take into account the patient's history of opioid addiction as altered by time and treatment. Patients normally proceed from one stage of treatment to the next, or move back and forth among the naturally occurring stages.
2. The stages of pharmacological treatment are listed below. It is important at all stages that psychosocial, as well as medical treatment, be of sufficient intensity and duration to be effective.
  - a. Initial treatment/Induction
  - b. Stabilization
  - c. Long-term treatment/maintenance
  - d. Medically supervised withdrawal with continuing care, if and when appropriate
3. The patient's response to treatment determines her/ his progression through the stages of treatment.

### Section II. Administrative Organization and Responsibilities.

1. Administrative responsibilities, both for organizations and individual practitioners, must be adequate to en-sure quality patient care and to meet the requirements of the laws and regulations of the U.S. Department of Health and Human Services, Drug Enforcement Administration, and the State of Vermont.

2. Physician authority over the medical aspects of treatment is essential. Physicians retain the autonomy to make continuing treatment decisions in accord with clinical course and emergent research findings.

3. Each provider will develop a referral and consultative relationship with a network of agencies and providers capable of providing primary and specialty services for the range of behavioral difficulties, psychiatric co-morbid conditions, medical complications, and communicable diseases that may be part of a patient's problem list. Information exchange across this network must both facilitate treatment and protect patient pri-vacy, consistent with HIPAA and 42 CFR part 2.

#### 4. Mission Statement and Goals

a. Each treatment program shall have a written statement of its mission and/or goals for patient care.

#### 5. Human Resources Management

a. Programs/providers will maintain individualized personnel files as a record of employment. These files contain employment and credentialing data deemed appropriate by the employer. The files will also retain employment application data, date of employment, updated licensing and credentialing data, detailed job descriptions, performance evaluations, and appropriate intramural and extramural training records.

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### Section IV. Quality Improvement.

#### 1. Risk Management and Continuous Quality Improvement

a. Life Safety Issues: each treatment program/provider will:

i. Establish procedures to guard against critical incidents, which are defined as any events that could have a negative impact on patients and their family members and the program or staff. This includes events that involve the loss of life or function, any serious physical or psychological injury, and significant medication errors.

ii. Provide a mechanism to address patient emergencies by establishing an emergency contact system, as appropriate under confidentiality regulations. Treatment offices and waiting areas should display the names and telephone number of individuals (e.g., physicians, hospitals, emergency medical technicians) who should be contacted in case of emergency, or utilize 9-1-1 or similar local emergency resources.

iii. Ensure that there are appropriately trained staff members on duty who are trained and proficient in cardiopulmonary resuscitation (CPR), management of opioid overdose, medical emergencies, and other techniques as appropriate.

iv. Establish regularly updated policies and/or procedures that address safety and security issues for patients and staff, including training for staff to handle physical or verbal threats, acts of violence, inappropriate behavior, or other escalating and potentially dangerous situations, with emphasis on situations in which security guards or police need to be summoned.

## b. Program Emergencies

i. Each treatment program/provider will maintain a plan for emergency administration of medications in case the program must be closed temporarily. The plan should include a mechanism for informing patients of these emergency arrangements. For all MAT programs the plan should identify emergency procedures for obtaining prescriptions/access to medications in case of temporary program/office closure. OTP programs should develop a cooperative agreement with their local emergency room to utilize the “72 Hour Rule” in case of inclement weather, emergency shut down, etc.

## 2. Events That Require Immediate Response and Investigation

Each treatment program/provider will:

a. Develop procedures for reporting critical incidents to appropriate program staff and the Vermont Department of Health, State Opioid Treatment Authority (SOTA).

b. Establish procedures, in case a critical incident occurs, to ensure:

i. Full documentation of the incident

ii. Prompt investigation and review of the situation surrounding the incident

iii. Implementation of timely and appropriate corrective action(s)

iv. Monitor corrective actions until their effectiveness is established

c. Report each critical incident to the appropriate accrediting organization, and the Vermont Department of Health, State Opioid Treatment Authority (SOTA), within 24 business hours of the incident. Some examples of reportable critical incidents involving patient deaths include:

i. Drug-related deaths

ii. Methadone or buprenorphine deaths

iii. Suspicious deaths

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iv. Treatment-context deaths that raise individual, family, community, or public concern

d. As appropriate, report critical incidents to the Food and Drug Administration (FDA) Adverse Event Reporting Program regarding (MedWatch, <http://www.fda.gov/medwatch/>; at 1-800-332-1088). Examples of reportable critical incidents include:

i. Serious adverse events and medications errors

ii. All types of deaths related to any drug

### 3. Voluntary and Involuntary Program Closure

In the event of involuntary or voluntary program closure, each program/provider will:

a. Develop a plan, through State authority, detailing procedures to ensure continuity of care for patients in the event of voluntary or involuntary closure of programs or individual medical practices. The plan includes steps for the orderly transfer of patients, records, and assets to other programs or practitioners.

b. No less than 30 days prior, the program/provider will notify the Vermont Department of Health; SOTA of the anticipated closure, discuss the rationale for closure and efforts to establish continuity of care for the patients. It is expected that providers/programs experiencing difficulties will demonstrate all due diligence to ensure patients have access to reasonable care, dependent upon state and local resources.

c. Develop a plan to ensure that patient records are secured and maintained for a specified period of time in accordance with State and Federal regulations.

### 4. Diversion Control Program

Each treatment provider must develop:

a. A diversion control plan (DCP) that demonstrates accountability to its patients and to the community. The DCP should reflect the efficient use of personnel and other resources to achieve the highest quality of patient care, while reducing possibilities for diversion of controlled substances from legitimate treatment to illicit use.

b. Diversion of both the mono and combination buprenorphine preparations present additional challenges, due to the office based nature of OBOT. While not a mandatory reportable offense, programs/providers must inform patients that diversion is a reportable criminal offense, and indicate how suspicions or evidence of diversion will be clinically handled. Physicians/programs should have clinical procedures in place for minimizing diversion risk to ensure appropriate addiction treatment, such as the following:

- Routine toxicology screens

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- Pill call backs (for counting)
- Bubble packing of prescriptions
- Making copies of the ID numbers listed on the “strip” packaging to be available for call backs

c. MAT prescribers/programs shall register with the Vermont Prescription Drug Monitoring System (VPMS), established by the Vermont Department of Health to provide health care professionals an electronic database and reporting system for electronic monitoring of prescriptions for controlled substances. The VPMS may be accessed online by registered prescribers and pharmacists at <http://healthvermont.gov/adap/VPMS.aspx>. Additional information is available through the Alcohol and Drug Abuse Programs (ADAP) office at 802-652-4147.

## 5. Continuous Quality Improvement Policies

a. Each treatment program/provider:

- i. Provides regular and continuous staff education.
- ii. Reviews program policies and procedures at least annually.
- iii. Adheres to universal or standard infection control precautions promulgated by the Centers for Disease Control and Prevention (CDC) and the Vermont Occupational Safety and Health Administration (VOSHA) requirements.

## Section V. General Program Medical and Behavioral Health Standards.

### 1. Medical Standards/Patient Admission Criteria

a. Evidence of Current Physiological Dependence and Opioid Addiction

i. The program physician must either diagnose or certify opioid addiction or dependence, as defined in either the current edition of the Diagnostic and Statistical Manual of Mental Disorders, or the current edition of the International Classification of Diseases. In either situation, the physician will document or co-sign that diagnosis, and admit each patient to maintenance or detoxification treatment as medically necessary. If pharmacological treatment is medically appropriate, there is an assessment conducted to determine the appropriateness of treatment with buprenorphine, prior to prescribing Methadone.

ii. A 1-year history of addiction is necessary for admission to a MAT maintenance treatment program. Individuals with less than a 1 year history of dependence may require pharmacological intervention, however medically supervised withdrawal would be the rationale for admission rather than the expectation of long-term maintenance. The absence of current physiological dependence should not be an exclusion criterion, and admission is acceptable when clinically

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justified. MAT providers can accept arrest and medical records, information from significant others and relatives, and other information to document the 1-year history of addiction.

iii. For populations of individuals who have a prior history of narcotic dependence however who may not have any current or active use, such as those being released from penal institutions or previously treated patients, Federal OTP regulations waive the 1-year history of active addiction for these special populations. However in OBOT situations it is strongly recommended that programs/providers seek consultation with an addiction specialist.

iv. A physician assesses/reviews assessment results with each patient before admission to medication-assisted treatment. The exceptional circumstance is that the physician may review the medical examination performed by another qualified health professional and make/certify the required diagnosis, and admit the patient in an emergent situation. The physician would then review and countersign the patient record within 72 hours. The patient/physician would then have either a face-to-face meeting or contact through an approved form of communicative technology to review the assessment and discuss the medical services.

v. Consistent with Federal regulations, OTP's must consider drug injecting patients (IV drug users) as a priority population and prioritize those patients for admission.

vi. OBOT programs that are ADAP Preferred Providers must prioritize drug injecting patients for admission, provided the patient is determined clinically appropriate for an OBOT level of care. Otherwise OBOT providers will refer patients to an appropriate treatment program.

## 2. Medical Evaluation

At a minimum it is expected that patients receive:

a. Comprehensive physical examination inclusive of the patient, reviewing: health history, identification of other chronic or acute health conditions, current objective measures of health, pregnancy status of female patients, and selected lab work as deemed medically appropriate by the physician and as available given the existing community resources.

b. Based on an individual's history and physical examination, programs/providers will evaluate the possibility of infectious disease, liver or pulmonary conditions, cardiac abnormalities, psychiatric problems, dermatologic sequelae of addiction, and/or possible concurrent surgical and other problems by conducting testing or referring patients for consultation and testing, as deemed appropriate by the physician.

## 3. Informed Consent

Each treatment program will:



- a. Obtain voluntary, written, program-specific informed consent to treatment from each patient at admission. Releases of information for all ancillary individuals/providers should also be obtained from each patient receiving a copy and 1 copy of each form for the record.
- b. Inform each patient about all relevant treatment procedures, services, and other policies and regulations throughout the course of treatment.
- c. Before medicating the patient, each program/provider obtains voluntary, written, informed consent from each patient to the specific pharmacotherapy ordered by the physician. In cases of OBOT a copy of the Buprenorphine Treatment Agreement should also be forwarded to the identified pharmacy.
- d. Informs each patient of the following:
  - i. That the goal of medication-assisted treatment is stabilization of functioning.
  - ii. That, at periodic intervals, in full consultation with the patient, the provider discusses present level of functioning, course of treatment, and future goals. These discussions should not place an unfair burden or pressure on the patient to withdraw from medication or to remain on medication maintenance unless medically indicated.
- e. As a mandated reporter, informs each patient, at admission, about State-specific requirements and program policies regarding the report of suspected child abuse and neglect, danger of harm to self and/or others, abuse or neglect of a disabled individual, and other behaviors having negative impact on the client or others.
- f. Adheres to all requirements of the Federal confidentiality regulations (42 CFR Part 2) and HIPAA (45 CFR Part 160 and Subparts A and E of Part 164).

#### 4. Treatment Considerations

##### a. Medical Services:

Providing basic primary care or integrated psychiatric care onsite is highly recommended but not required. Programs make referrals for medical and/or psychiatric treatment when indicated.

##### b. Retention in Treatment

- i. Programs/providers will make every effort to retain patients in treatment as long as clinically appropriate, medically necessary, and acceptable to the patient.
- ii. The treatment program/provider takes appropriate therapeutic measures to address the other problems identified in the treatment plan, either directly or through referral.

iii. All MAT programs informed consent should consist of discussion of treatment expectations, “clinical appropriateness”, anticipated responses to use of licit/illicit substance, physician tolerance for behavior, and potential MAT alternatives, or non-MAT alternatives.

c. Voluntary Patient Relocations, Program Transfers, and “Guest Dosing”

i. When a patient relocates, transfers to another treatment program, or needs temporary care at another program (“guest dosing”), the original MAT program ensures that the patient makes as smooth a transition as is feasible, and the program attempts to avoid interruptions in treatment that could lead to relapse.

ii. The original treatment program should forward relevant medical records to the receiving treatment program, with patient consent in accordance with the privacy standards of 42 CFR 2.

d. Relapse Prevention:

Psychosocial treatment continues for patients electing to discontinue pharmacotherapy in OTP programs while either continued treatment, or referrals for continued psychosocial supports, should be offered to OBOT patients as needed

5. Record Keeping and Documentation

All records required by 42 CFR § 8.12 (g) should be retained for a minimum of 3 years.

a. Patient Records:

MAT programs/providers are required under 42 CFR § 8.11(f) (3) to comply with the Federal confidentiality regulations set forth under 42 CFR Part 2. As such, records of the identity, diagnosis, prognosis, or treatment of any patient that are maintained in connection with the performance of any program or activity relating to substance abuse education, prevention, training, treatment, or research, which is conducted, regulated, or directly or indirectly assisted by any department or agency of the program shall, except as provided in subsection (e) of 42 CFR Part 2, be confidential and be disclosed only for the purposes or circumstances expressly authorized under subsection 42 CFR section 2(b).

b. Records of Storage (Only for Programs that Dispense and Administer Opioid Medication):

Each program/provider must maintain policies and procedures consistent with Drug Enforcement Administration (DEA) statutes and regulations.

c. Each medication order and/or dosage change must be written on an acceptable order sheet signed by the physician (Note: only for programs that dispense and administer opioid medication).

- i. Each dosage dispensed, prepared, or received will be recorded and accounted for by signed notation, in a manner that creates a perpetual and accurate inventory of all medications and/or prescriptions, including controlled substances in stock at all times.
  - ii. Every dose is recorded on an administration sheet, at the time that the dose is administered or dispensed, and recorded on the patient's individual medication dose history.
  - iii. The qualified person administering or dispensing medications signs his or her name or initials at each notation.
  - iv. If initials are used, the full signature of the qualified person administering or dispensing will be placed at the end of each page of the medication sheet.
- d. Programs/providers will have a procedure for calibrating medication-dispensing instruments, consistent with manufacturers' recommendations, to ensure accurate patient dosing and substance tracking (Note: only for programs that dispense and administer opioid medication).

## 6. Guidelines for Therapeutic Dosage

### a. General Dosage Principles:

The physician will employ clinical judgment to determine the individual dose of opioid medication and should have training in medication assisted treatment.

### b. Effective therapy involving medication-assisted treatment has the following desired outcomes:

- i. Preventing the onset of opioid abstinence syndrome for at least 24 hours:
- ii. Reducing or eliminating the drug craving routinely experienced by the patient:
- iii. Blocking the euphoric effects of opioids, without inducing undesirable effects experienced by the patient.

## 7. Maintenance Therapy

- a. The total dose of medication and the interval between doses may require adjustments for the patient who has concurrent health conditions or atypical metabolic patterns, or if the patient takes other prescribed medications that alter the rates of opioid medication metabolism
- b. Programs/providers utilize available evaluations, including documented history, physical and/or psychiatric examinations, to support the judgment by the physician that the patient is a suitable candidate for opioid therapy.
- c. Medication induction should be guided by clinical presentation, patient ability to tolerate the medication and avoidance of negative effects.

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d. Federal regulations stipulate that the initial dose of Methadone, within the OTP, should not exceed 30 mg. with medical discretion to consider a Maximum 40 mg total first day administration.

e. Buprenorphine induction guidelines are also designed with flexibility to adjust based upon clinical presentation, presenting illness, and physician discretion.

f. Programs/providers do not adjust medication doses to reinforce positive behavior or to punish negative behavior, unless the patient is non-compliant with programmatic expectations and the taper constitutes the start of medically supervised withdrawal or the dosage increase is to address patient symptomology.

g. Programs/providers continue medication-assisted treatment as long as the patient derives benefit from treatment, desires treatment, that the treatment is medically necessary and that the patient is considered to be adherent with the established rules of the program.

h. The program/providers should have the capability to obtain serum methadone levels when clinically indicated and/or urine based buprenorphine/norbuprenorphine levels.

## 8. Avoiding Multiple Program Enrollments

Reasonable measures will be taken to prevent patients from enrolling in treatment provided by more than one clinic or individual practitioner. Use of the Vermont Prescription Monitoring System (VPMS) is required.

## 9. Detoxification, Tapering, or Medically Supervised Withdrawal

a. As clinically appropriate, a physician may admit a patient to MAT for “detoxification” treatment, hereinafter referred to as “medically supervised withdrawal.”

b. Medically supervised withdrawal is conducted under the following conditions:

i. As a voluntary and therapeutic process, agreed on by physician and patient, or;

ii. In response to the request of the patient--against the advice of the physician, counselor, and other staff, or in other words, against medical advice (AMA).

c. The physician will initiate voluntary supervised withdrawal from medication-assisted treatment in collaboration with and at the request of the patient. NOTE: Voluntary supervised withdrawal is completely different and distinct from involuntary tapering or administrative withdrawal or other types of medically supervised withdrawal.

i. In initiating medically supervised withdrawal, the physician reduces dosages of medication at a rate well tolerated by the patient and in accordance with sound clinical judgment.

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ii. For women of childbearing potential, the program/provider will conduct, or refer for, an assessment for pregnancy and review the results of a pregnancy test before initiating medically supervised withdrawal (See 2. I. (5) (d)--The physician should not initiate withdrawal before 14 weeks' or after 32 weeks' gestation, per OTP guidelines for Methadone).

d. The program/provider resumes medication-assisted treatment if the patient experiences impending or actual relapse, as applicable and based upon the availability of resources

## 10. Support of Medically Supervised Withdrawal

a. The following program policies and procedures promote successful medically supervised withdrawal, whether conducted with or against medical advice:

i. Increased counseling will be made available prior to discharge

ii. Patients are encouraged to attend a 12-step or other mutual-help program that is sensitive to the needs of patients receiving medication-assisted treatment.

b. Consideration/discussion with patients of utilizing alternative pharmacology following medically supervised withdrawal. Potential examples of medications to support on-going recovery might include opioid antagonists (eg. Naltrexone and/or Vivitrol).

c. Additional Considerations for Medically Supervised Withdrawal Against Medical Advice.

i. The patient has the right to leave treatment when he or she chooses to do so. The program/provider will explain the risks of leaving treatment and offer information about, or referral to, alternative treatment options.

ii. In the case of a patient who leaves an OTP program abruptly, the program may readmit the patient within 30 days without repeating the initial assessment procedure required by regulation 42 CFR § 8. OBOT providers/programs utilize their discretion to re-admit without repeating an assessment although consideration for pregnancy testing for women of child bearing age should be considered.

iii. If medically supervised withdrawal fails, the program/provider will consider initiating maintenance treatment in conjunction with the patient and ancillary treatment providers.

iv. In the case of a pregnant patient, the program/provider keeps the OBGYN informed. consistent with privacy standards of 42 CFR 2.

## 11. Administrative Withdrawal and Discharge

a. A major goal for programs/providers is to retain patients for as long as they can benefit from treatment, express a desire to continue and are clinically appropriate. However it is not always possible to retain the patient due to various circumstances. When a program makes the decision

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to administratively discharge a patient from pharmacotherapy, the program/provider will offer a humane schedule of medically supervised withdrawal, when clinically appropriate and as long as it does not compromise the safety of providers or program staff.

b. Administrative withdrawal may result from:

i. Nonpayment of fees. Remedies may include referral to a more affordable treatment program.

ii. Disruptive conduct or behavior. Such behaviors may have an adverse effect on the program, staff, or patient population of such gravity as to justify the involuntary medically supervised withdrawal and discharge of a patient, despite an extremely poor prognosis. Disruptive behaviors include but are not limited to: violence/aggression, direct threat of violence, dealing drugs, repeated loitering, and flagrant noncompliance, resulting in an observable, negative impact on the program, staff, and other patients. Per OTP guidelines, patients who exhibit disruptive behaviors should receive a mental health evaluation and referral, as appropriate, prior to administrative withdrawal while OBOT providers should clinically monitor patients for potential mental health symptoms.

c. Incarceration or other confinement

d. Providers determine during the process of on-going assessment that the patient is not appropriate for OBOT treatment and may be better served by other treatment modalities. Indicators of this may include: continued use of substances, medication diversion, and/or lack of response to the treatment plan.

e. Clinical Determination of the provider/program

f. Violation of contract with the provider/program:

i. The provider/program will take into consideration all factors affecting the patient on a case-by-case basis, and document procedures for any involuntary terminations of patients.

ii. Efforts made regarding referral or transfer of the patient to a suitable alternative treatment program should be documented. inclusive of psycho-social support referrals.

iii. The program/provider makes specific efforts to ensure referrals are followed through to completion for the pregnant patient, in the event the patient is administratively withdrawn and discharged. Provider/program(s) should carefully follow up with both patient's pregnancy and opioid dependency. It may be helpful for the program to establish prearranged agreements for treatment for this very purpose.

g. Continuing Care:

i. An essential part of treatment is continuing care that includes discharge planning and relapse prevention.

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ii. Each program/provider will ensure the discharge planning process includes procedures that address patients' physical and mental health problems following medically supervised withdrawal, as clinically appropriate.

iii. The treatment program/provider will provide for continuing care following the last dose of medication, including making a referral for continuing outpatient care, as needed, and planning for reentry to maintenance treatment if relapse occurs and resumption of care continues to be appropriate and as resources are available.

## 12. Psychosocial Assessment/Behavioral Health Services:

Each program/provider will ensure that for each patient receives:

### a. Comprehensive Psychosocial Assessment:

A comprehensive psychosocial evaluation will be completed on all patients receiving medication assisted treatment. In MAT programs with on-site licensed, Behavioral Health clinicians, it is expected that this assessment be completed by the 3rd visit. For those OBOT providers without co-located Behavioral Health Clinicians, it is anticipated that these individuals are referred for an evaluation of behavioral therapy supports and that releases are signed such that the prescriber obtains a copy of this assessment from the referred clinician.

b. The assessment must include an evidenced based tool and should, minimally, include the following domains: Mental Health history and mental status examination with current DSM categorization, interpretive summary, diagnosis, and ASAM patient placement criteria.

c. Refers patients who have the need for services not provided by the program/provider to other care providers, as appropriate.

d. For patients referred elsewhere, ensures that the exchange of information conforms to confidentiality regulations for patients in drug or alcohol treatment (42 CFR Part 2) and HIPAA regulations (45 CFR Part 160 and Subparts A and E of Part 164).

e. Clinicians must possess a substance abuse apprentice certification, certification and/or licensure in addiction treatment. Clinicians with other behavioral health licensures with sufficient experience in addictions would also be considered qualified.

f. For patients determined by assessment to benefit from behavioral interventions, services provided are of the intensity and duration to meet the needs of the individual patient. Cessation of behavioral treatment should be done in consultation with the patient, clinician and physician.

## 13. Treatment Planning, Evaluation of Patient Progress in Treatment, and Continuous Clinical Assessment

a. The behavioral health clinician/treatment team will complete assessment reviews and treatment plan updates quarterly for the first year of continuous treatment. In subsequent years, the program/provider updates assessments and treatment plans semiannually.

#### 14. Concurrent Services

a. Orientation to Treatment and ongoing education on:

i. Signs and symptoms of overdose and when to seek emergency assistance

ii. The medication they are taking, including side effects and common myths about the medication or modality of treatment

iii. The nature of addictive disorders

iv. The benefits of treatment and nature of the recovery process, including phases of treatment

v. Clinic guidelines, rules, and regulations, including the requirement to sign a formal agreement of informed consent, and fees and billing procedures

vi. Noncompliance and discharge procedures, including administrative withdrawal from medication

vii. Patient's rights

viii. Confidentiality and how release of information is permitted in accordance with 42 CFR Part 2

ix. Toxicology testing procedures

x. Dispensing medication or prescriptions

xi. HIV-spectrum and other infectious diseases

xii. Potential drug interactions

b. Counseling on HIV Infection and Other Conditions or Diseases of Public Health Importance

i. Programs/providers will provide basic counseling/information on HIV infection and other prevalent infectious diseases, such as hepatitis, sexually transmitted infections, and TB. Counseling also includes infectious disease prevention for at-risk patients, and the need for patients to adhere to treatment and to communicate honestly with the provider when treatment has begun.

ii. Programs will provide risk reduction education to patients, as appropriate.

© 2015 Research is current as of December 2014. In order to ensure that the information contained herein is as current as possible, research is conducted using nationwide legal database software, individual state legislative websites and direct communications with state PDMP representatives. Please contact Heather Gray at (703) 836-6100, ext. 114 or hgray@namsdl.org with any additional updates or information that may be relevant to this document. This document is intended for educational purposes only and does not constitute legal advice or opinion. Headquarters Office: THE NATIONAL ALLIANCE FOR MODEL STATE DRUG LAWS, 420 Park Street, Charlottesville, VA 22902.



## 15. Drug Testing

### a. Each program/provider will:

- i. Use drug and alcohol screening and testing as aids in monitoring and evaluating a patient's progress in treatment.
- ii. Ensure that treatment personnel in a medication-assisted treatment program understand the benefits and the limitations of toxicological testing procedures.
- iii. Collect all urine or other toxicological specimens in a therapeutic context
- iv. Determine the drug-testing regime by analyzing community drug-use patterns and individual medical indications.
- v. Address results of toxicology testing with patients promptly. Programs document in the patient record both the results of toxicology tests and follow-up therapeutic interventions.
- vi. Ensure that following the patient's admission toxicology screening, clinicians determine the frequency of toxicological testing by evaluating the clinical appropriateness for each patient in relation to the patient's stage in treatment. For patients receiving services from multiple providers, attention to coordinating/sharing toxicology results is expected.
- vii. Ensure that clinicians consider confirming the results of drug screening tests with additional testing. Treatment programs will establish procedures for addressing potentially false positive and false negative urine or other toxicology test results following principles outlined in TIP 43, "Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs" (CSAT 2005, chapter 9).
- viii. Ensure compliance with all federal regulations related to urine toxicology results, 42 CFR § 8.12(f) Drug abuse testing services. OTPs must provide adequate testing or analysis for drugs of abuse, including at least eight random drug abuse tests per year, per patient, in maintenance treatment (defined as on a stable dosage for a period in excess of 21 days per 42 CFR 8.2), in accordance with generally accepted clinical practice. For patients in short-term detoxification treatment (less than 30 days per 42 CFR 8.2), the OTP shall perform at least one initial drug abuse test. For patients receiving long-term detoxification treatment (30-180 day duration per 42 CFR 8.2), the program shall perform initial and monthly random tests on each patient.

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West's Vermont Administrative Code (2014)  
Title 12. Agency of Human Services  
Subtitle 7. Department for Children and Families (Dcf)  
General  
Rule 5. Pharmaceuticals, Medical Supplies and Equipment (7500)

12-7-5:7502. Prescribed Drugs.

...

7502.7 Vermont Prescription Monitoring System (07/01/2014, 14-03E)

All Medicaid participating providers who prescribe buprenorphine or a drug containing buprenorphine to a Vermont Medicaid beneficiary must query the Vermont Prescription Monitoring System the first time they prescribe buprenorphine or a drug containing buprenorphine for the patient and no fewer than two times annually thereafter.

Dosage criteria, as approved by the Drug Utilization Review Board and meeting the requirements described in the Preferred Drug List, may only be exceeded with prior approval from the Chief Medical Officer of the DVHA or designee.

Sec. 13. VPMS Query; Rulemaking

The Secretary of Human Services shall adopt rules requiring:

(1) All Medicaid participating providers, whether licensed in or outside Vermont, who prescribe buprenorphine or a drug containing buprenorphine to a Vermont Medicaid beneficiary to query the Vermont Prescription Monitoring System the first time they prescribe buprenorphine or a drug containing buprenorphine for the patient and at regular intervals thereafter. Regular intervals shall exceed the requirements for other Schedule III pharmaceuticals, and queries shall be done prior to prescribing a replacement prescription. The rules shall also include dosage thresholds, which may be exceeded only with prior approval from the Chief Medical Officer of the Department of Vermont Health Access or designee.

(2) All providers licensed in Vermont who prescribe buprenorphine or a drug containing buprenorphine to a Vermont patient who is not a Medicaid beneficiary to query the Vermont Prescription Monitoring System for the first time they prescribe buprenorphine or a drug containing buprenorphine for the patient and at regular intervals thereafter. Regular intervals shall exceed the requirements for other Schedule III pharmaceuticals, and queries shall be done prior to prescribing a replacement prescription. The rules shall also include dosage thresholds.