



State of Vermont  
Department of Health

**PROPOSED RULE**

**VERMONT PRESCRIPTION MONITORING SYSTEM RULE**

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## **I. General Provisions**

### **1.1 Purpose**

This rule implements the Vermont Prescription Monitoring System (“VPMS”) created by 18 V.S.A. Chapter 84A.

### **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.

### **1.3 Effective Date**

All provisions of this rule shall be effective on \_\_\_\_\_, 2007.

### **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 format used by dispensers for submitting required data to the VPMS 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 location 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 VPMS of information from the VPMS database to an individual or entity eligible to receive the information pursuant to a specific provision of law.

### **1.5 Distribution of Advisory Notices**

Each dispenser shall post, display and generally make available to its customers advisory notices developed and distributed by VMPS.

### **1.6 Confidentiality**

All data submitted to the VPMS 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 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.

### **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 an error in the VPMS database, may submit a request to correct erroneous information by submitting the request in writing to VPMS 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.

VPMS will review all requests to correct information in the VPMS database and, in the sole discretion of the Commissioner, will take such actions as necessary to confirm the accuracy of the subject data and make corrections as appropriate. Upon request, and as permitted by 18 V.S.A. § 4284 and Part III of this rule, VPMS will notify the requester whether the requested correction has been made.

## **II. Prescription Monitoring Reporting Requirements**

### **2.1 Report of Controlled Substances Dispensed**

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 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;
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;
12. The dispensing pharmacist's name or initials;
13. The dispensing pharmacy;
14. The source of payment; and,
15. If the patient is an animal, then the report shall indicate the patient name and species and the owner's full name, date of birth and complete address.

Dispensers with more than one pharmacy location may submit a single report for all of their pharmacies so long as the report identifies the specific location from which each reportable prescription was dispensed.

## **2.2 Form and Filing of Report of Controlled Substances Dispensed**

Each pharmacist-manager shall submit the Report of Controlled Substances Dispensed to VPMS, or its 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.

## **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.

### **III. Access to VPMS Data**

Information from the VPMS database may only be disclosed 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.

#### **3.1 Patient**

A patient for whom a prescription for a controlled substance is written may request information from VPMS relating to himself or herself. The request shall be submitted 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 VPMS office. To receive the requested information, the patient shall appear personally and produce a valid government issued photographic proof of identity at the VPMS 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 VPMS pursuant to this section without restriction.

#### **3.2 Health Care Provider or Dispenser Registration**

1. A health care provider or dispenser shall register with VPMS 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. VPMS will issue a registration number to eligible applicants who demonstrate they hold 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 VPMS may request information from VPMS 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 complete address;
3. The patient's date of birth;

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 VPMS and receive from VPMS the information by secure mail or fax.

### **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 data from VPMS 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 VPMS office. VPMS will transmit the information by secure mail or fax.

### **3.4 VPMS Disclosures**

1. VPMS 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. The Department will establish a protocol, approved by the Commissioner in consultation with the Advisory Committee, and one or more individuals with appropriate medical expertise, to identify when a patient may be receiving more than a therapeutic amount of one or more regulated substances. The protocol will establish thresholds, based on current medical expertise for the treatment for and prevention of abuse of controlled substances, which will provide the basis for determining whether and when to provide data from the VPMS database to a patient or that person's health care provider.

2. When the Commissioner of Health reasonably suspects that there is fraudulent or illegal activity by a health care provider or dispenser, the VPMS 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 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. For purposes of this section, if the Commissioner of Health is unavailable or unable to fulfill this responsibility, then a Department of Health Deputy Commissioner may personally disclose data from the VPMS to the Commissioner of Public Safety personally when the Deputy 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. For purposes of this section, if the Commissioner of Public Safety is unavailable or unable to personally receive the information, then the information may be disclosed personally to the Department of Public Safety Deputy Commissioner, the Director of the Vermont State Police, or other management designated by the Commissioner of Public Safety to receive and act upon the information from the Department of Health under such circumstances. The Commissioner of Public Safety may, in his or her discretion, disclose the information and take such action as he or she believes may be reasonably necessary to avert the serious and imminent threat to a person or the public that he or she believes exists.

### **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.

## **IV. Training**

The Department will periodically designate one or more training programs for law enforcement officers relating to responsible and proper use of VPMS data. VPMS 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).

## **V. Enforcement**

### **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).

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

### **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.