



State of Vermont
Department of Health

VERMONT PRESCRIPTION MONITORING SYSTEM RULE

Table of Contents

- I. General Provisions**
 - 1.1 Purpose**
 - 1.2 Authority**
 - 1.3 Effective Date**
 - 1.4 Definitions**
 - 1.5 Distribution of Advisory Notices**
 - 1.6 Confidentiality**
 - 1.7 Correction of Information in the VPMS Database**

- II. Prescription Monitoring Reporting Requirements**
 - 2.1 Report of Controlled Substances Dispensed**
 - 2.2 Form and Filing of Report of Controlled Substances Dispensed**
 - 2.3 Waiver of Electronic Filing Requirement**

- III. Access to VPMS Data**
 - 3.1 Patient**
 - 3.2 Health Care Provider or Dispenser Registration**
 - 3.3 Professional Licensure Boards**
 - 3.4 Disclosures from the VPMS Database**
 - 3.5 Department of Health Use of VPMS Data**

- IV. Training**
 - 4.1 Designation of Training Programs**

- V. Enforcement**
 - 5.1 Administrative Discipline**
 - 5.2 Civil and Criminal Enforcement**

I. General Provisions

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.

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

This rule shall be effective on June 1, 2008.

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.

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.

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.

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.

II. Prescription Monitoring Reporting Requirements

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
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.

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.

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 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.

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.

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.

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.

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.

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

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).

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).

The Department 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.