Vermont Prescription Monitoring System Rule

1.0 Authority

This rule is adopted pursuant to 18 V.S.A. § 4287 and §4289(e).

2.0 Purpose

This rule implements the Vermont Prescription Monitoring System (VPMS) created by 18 V.S.A. chapter 84A, that requires the Department of Health to establish an electronic database and reporting system for monitoring dispensed prescriptions of controlled substances. The intent is to promote public health through enhanced opportunities to prevent, detect and treat misuse of controlled substances, without interfering with the legitimate medical use of those substances. The use of VPMS in treating chronic pain due to cancer, hospice care, and other end-of-life care is not required.

3.0 Definitions

3.1 "Administered" means direct application of a drug to the body of a patient by means of injection, inhalation, ingestion or any other means.

3.2 "Chronic Pain" means pain that continues longer than 90 days, is caused by disease or abnormal conditions, but is not caused by cancer or end-stage terminal disease.

3.3 "Commissioner" means the Commissioner of Health.

3.4 "Controlled substance" means a substance listed on the Federal Drug Enforcement Administration's Schedules II, III or IV as defined in 21 C.F.R. Part 1308.

3.5 "Delegates" are individuals employed by prescribers, pharmacists, or the Vermont Chief Medical Examiner who are authorized by these entities to access the VPMS database related to bona fide current patients of the authorizing health care prescriber or dispenser or related to a bona fide investigation or inquiry into an individual's death by Chief Medical Examiner.

3.6 "Department" means the Vermont Department of Health.

3.7 "Dispensed" means a Schedule II, III, or IV controlled substance given to a patient by a pharmacy or prescriber pursuant to an order by a prescriber.

3.8 "Drug Diversion Investigator" means an employee of the Department of Public Safety whose primary duties include investigations involving violations of laws regarding prescription drugs or the diversion of prescribed controlled substances, and who has completed a training program offered or designated by the Department of Health designed to ensure that officers have the training necessary to use responsibly and properly any information that he or she receives from the VPMS.

3.9 "Pharmacist" means a health care professional licensed to dispense Schedule II, III or IV controlled substances under 26 V.S.A. § 2022(5).

3.10 "Pharmacy" means a licensed retail outlet as defined in 26 V.S.A. § 2016.

3.11 "Prescriber" means a health care professional licensed to prescribe Schedule II, III or IV controlled substances.

3.12 "Query" means the action of accessing VPMS and retrieving information from it regarding controlled substance(s) prescribed or dispensed to a patient in Vermont and other states with whom Vermont has a Reciprocal Agreement.

3.13 "Reciprocal Agreements" means a written agreement that provides for the exchange of information requests and responses of Prescription Drug Monitoring Program data between state data-sharing partners if access under such agreement is consistent with the privacy, security, and disclosure protections under the statute and these regulations.

3.14 "Replacement prescription" means an unscheduled prescription request in the event that the document on which a patient's prescription was written has been lost or stolen, or the patient's prescribed medication is reported to the prescriber as having been lost or stolen.

3.15 "Report of Controlled Substances Dispensed" means the report format used by pharmacies for submitting required data to the VPMS pursuant to this rule.

3.16 "Reportable prescription" means each controlled substance dispensed from any location to a patient within Vermont by a health care provider or dispenser during the reporting period.

3.17 "Threshold Report" is a notification sent to a patient's provider when, according to the VPMS, the patient has frequented a predetermined number of prescribers

and or pharmacies and may be receiving more than a therapeutic amount of one or more controlled substances.

3.18 "Vermont Prescription Monitoring System" (VPMS) means the statewide electronic database that collects data on Schedule II, III, or IV controlled substances dispensed in Vermont.

4.0 Required Reporting for Pharmacies and Prescribers who Dispense Controlled Substances

4.1 Filing of Report of Controlled Substances Dispensed

4.1.1 No less frequently than every calendar week, every pharmacy licensed by the Vermont Board of Pharmacy shall submit to VPMS a Report of Controlled Substances Dispensed for all reportable prescriptions dispensed from the pharmacy during the preceding seven (7) days. This applies to all licensees, irrespective of location or number of prescriptions of controlled substances dispensed.

4.1.2 Pharmacies must submit a "zero controlled substances report" during any week that no controlled substances are dispensed.

4.2 Required Information from Reporting Pharmacy

4.2.1 The reporting pharmacy shall provide the following information for each reportable prescription:

- The patient's full name;
- The patient's date of birth;
- The patient's complete address;
- The name of the drug dispensed;
- The National Drug Code Number for the drug and dosage dispensed;
- The date dispensed;
- The quantity and dosage dispensed;
- The number of days' supply dispensed;
- The number of refills prescribed;
- The prescriber's name;
- The prescriber's DEA number, including suffix if applicable; and
- The dispensing pharmacy DEA number.

4.2.2 Pharmacies with more than one pharmacy location may submit a single report for all of its pharmacies. The report shall identify the specific location from which each reportable prescription was dispensed.

4.3 Distribution of Advisory Notices

4.3.1 Each pharmacy shall provide to every customer to whom a controlled substance is dispensed an advisory notice informing the customer that all prescriptions for controlled substances are entered into a statewide VPMS database in order to protect patients and the public. The advisory notices will be developed and available on the Department's website.

4.3.2 The pharmacy shall provide these notices by:

- Prominently displaying the advisory notice in a manner readily accessible to its customers, or
- Duplicating the complete text of the advisory notice in another format, such as by printing it on customer receipts, patient instructions or on a written insert for delivery to the patient.
- Posting brief advisories in at least six (6) languages offering a referral telephone number for people with limited English proficiency

4.4 Required Data Submission for Prescribers that Dispense

Prescribers who dispense controlled substances to their patients must also submit a Report of Controlled Substances Dispensed to the VPMS following the same frequency and format as described in Sections 4.1 and 4.2 of this rule**.** Directions for doing so are available through the VPMS program technical support.

4.5 Exemptions from Reporting to VPMS

4.5.1 Reporting to VPMS is not required for:

- A drug administered directly to a patient
- 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.

4.5.2 A pharmacy that does not stock or dispense controlled substances may request an exemption from reporting from the VPMS program office. The exemption shall terminate when the pharmacy dispenses any controlled substance.

5.0 Requirements for Pharmacists to Register with VPMS

5.1 All pharmacists who dispense controlled substances shall register with the Department to enable access to query the VPMS system for information relating to a bona fide current patient.

5.2 Pharmacists may designate a delegate or delegates to access and query the VPMS system subject to Section 7.2 of this rule.

5.3 In order to access the VPMS system, pharmacist delegates must register with VPMS.

6.0 Requirements for Prescribers

6.1 Registering with the VPMS

The following professionals and entities must register with the Department to enable their access to the VPMS system:

6.1.1 All Vermont prescribers of controlled substances and their delegates
6.1.2 The Medical Director of the Department of Vermont Health Access
6.1.3 Health care providers licensed to practice in a state with an active reciprocal agreement for Prescription Monitoring Program data-sharing
6.1.4 Health care providers licensed to practice in another state who treat Vermont patients
6.1.5 Vermont's Chief Medical Examiner, and delegate, and medical examiners licensed to practice in another state investigating the death of a Vermont resident

6.2 Required Querying of VPMS

Prior to prescribing a controlled substance for a patient, Vermont licensed prescribers and/or their delegates must query the VPMS system in the following circumstances:

6.2.1 "The first time the provider prescribes an opioid Schedule II, III, or IV controlled substance written to treat chronic pain;" 18 V.S.A. § 4289 (d)(3).

6.2.2 "When starting a patient on a Schedule II, III, or IV controlled substance for nonpalliative long-term pain therapy of 90 days or more;" 18 V.S.A. § 4289 (d)(2)

6.2.3 Prior to writing a replacement prescription for a Schedule II, III, or IV controlled substance." 18 V.S.A. § 4289 (d)(4).

6.2.4 "At least annually for patients who are receiving ongoing treatment with an opioid Schedule II, III, or IV controlled substance;" 18 V.S.A. § 4289 (d)(1).

6.2.5 When prescribing Schedule II, III or IV controlled substances to treat acute pain for a duration longer than 21 days.

6.2.6 In addition, in an Emergency Department or Urgent Care setting:

6.2.6.1 When a patient requests an opioid prescription for chronic pain from an Emergency Department or Urgent Care prescriber if the prescriber intends to write a prescription for an opioid.

6.2.6.2 When a patient requests an extension of a current opioid prescription for acute pain from an Emergency Department or Urgent Care prescriber if the prescriber intends to write a prescription for an opioid.

6.2.6.3 Before prescribing an opioid for longer than 10 days.

6.2.7 Prior to prescribing buprenorphine or a drug containing buprenorphine to a Vermont patient for the first time and at regular intervals thereafter, and:

6.2.7.1 No fewer than two times annually thereafter.

6.2.7.2 Prior to writing a replacement prescription.

6.2.8 Prior to prescribing buprenorphine or a drug containing buprenorphine that exceeds the dosage threshold approved by the Vermont Medicaid

Drug Utilization Review Board and published in its Preferred Drug List[1], prescribers must receive prior approval from the Chief Medical Officer or Medical Director of the Department of Vermont Health Access or designee.

6.3 Delegates

Prescribers may designate a delegate or delegates to access and query the VPMS system subject to Section 7.2 of this rule.

7.0 Access to VPMS Information

7.1 Authority to Query VPMS Directly [18 V.S.A. § 4284 (b)(1)]

Once registered, the following persons and entities may query VPMS directly for the following information:

7.1.1 Pharmacists who dispense controlled substances and their authorized delegates for the purpose of monitoring the prescription and dispensing history of a bona fide current patient.

7.1.2 Prescribers of controlled substances and their authorized delegates for the purpose of monitoring the prescription and dispensing history of a bona fide current patient.

7.1.3 The Vermont Chief Medical Examiner or delegate as required for the purpose of conducting an investigation or inquiry into the cause, manner and circumstances of an individual's death.

7.1.4 The Medical Director of the Department of Vermont Health Access relating to a Medicaid recipient for whom a claim for a Schedule II, III, or IV was submitted. This access is for Medicaid quality assurance, utilization, and federal monitoring purposes.

7.1.5 A prescriber, or medical examiner licensed to practice in another state, may register with the Department to access VPMS information in order to provide medical care to a Vermont resident who is a bona fide current patient or to investigate the death of a Vermont resident.

[1] http://dvha.vermont.gov/for-providers/2013-01-vt-clinical-criteria-january-15-2013-final.pdf

7.1.6 The VPMS program manager, designated program staff, or any contractors acting at the direction of, or as authorized by, the program manager for purposes of management of the VPMS database.

7.2 VPMS Querying by Delegates

7.2.1 Delegates must register with the VPMS under a registered pharmacist, prescriber, or the Vermont Chief Medical Examiner in order to access and query the VPMS system,

7.2.2. The authorizing registrant must approve the delegate before the delegate is issued access, and is responsible for the delegate's appropriate use of the VPMS.

7.2.3. Any and all information requested by the delegate is for the purpose of providing treatment to a bona fide current patient of the authorizing pharmacist or prescriber, or in the case of the Office of the Chief Medical Examiner for the purpose of conducting an inquiry or investigation into an individual's death.

7.2.4 The delegate shall notify the prescriber of findings of the delegate's query, prior to the prescriber writing a new prescription for controlled substances, if the query indicates that the patient has received a controlled substance prescription from another prescriber, is visiting multiple pharmacies or when there is other activity indicating that the patient may be receiving controlled substances unrelated to the prescriber's treatment plan.

7.3 Alternative Access Arrangements

Individuals authorized to access information directly from VPMS but not able to access the system electronically may submit a written request to the Department for an alternative access method such as a written report.

7.4 Requests for VPMS Information by Those Without Direct Access for Querying the System

The following persons and entities may request from the VPMS program manager information for the following purposes: [18 V.S.A. § 4284 (b)(2)]

7.4.1 Patient

7.4.1.1 A patient for whom a prescription for a controlled substance has been written or dispensed may request information from VPMS relating to himself or herself.

7.4.1.2 The request shall be submitted to the Department in writing, shall be signed by the patient and shall include:

- The patient's name;
- The patient's date of birth;
- The time period for which the information is requested;
- The patient's telephone number, mail and address; and
- The patient's original signature.

7.4.1.3 When delivering the requested information, the patient shall show a valid government-issued photographic proof of identity to the Department representative accepting the written request.

7.4.2 Professional Boards

7.4.2.1 A designated representative of a professional board that is responsible for the licensure, regulation or discipline of health care prescribers or dispensers may request information from the VPMS related to a licensee pursuant to a bona fide specific investigation. The request shall be submitted on a form provided by the Department on the VPMS website and shall include:

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

7.4.2.2 The request shall be delivered by secure fax, password-protected e-mail, or in person, to the Division of Alcohol and Drug Abuse Program's office.

8.0 Protections, Disclosure and Use of VPMS Information

Pursuant to 18 V.S.A. § 4284, all data submitted to, or accessed from, the VPMS in conformity with this rule are confidential, exempt from disclosure pursuant to the Public Records Act, and shall only be disclosed as provided in this rule.

8.1 Disclosing Information from the VPMS

8.1.1 When the Department finds that a threshold number of prescribers and pharmacies have been reached or exceeded by a patient during a given quarter, or that a patient may be receiving more than a therapeutic amount of one or more regulated substances, the Department sends a report to those who have prescribed to that patient.

8.1.2 When the Commissioner of Health has credible information that suggests that there may be fraudulent or illegal activity by a health care prescriber or dispenser, the Commissioner may provide relevant data to the appropriate licensing or certification authority.

8.1.2.1 That authority may report the data that are evidence of suspected fraudulent or illegal activity to a drug diversion investigator.

8.1.2.2 The drug diversion investigator shall not have direct access to the VPMS data except for information provided to the officer by the licensing or certification authority.

8.1.2.3 Any disclosure of VPMS information shall document a bona fide specific investigation and shall specify the case number of the investigation.

8.2 Correction of Information in the VPMS Database

A patient, prescriber, pharmacist, professional licensure board or other individual having knowledge of an error in the VPMS database, may submit a request to correct the erroneous information by submitting the request in writing to the VPMS program manager that shall include:

- A statement explaining in detail the basis for the requested correction;
- The precise change requested;
- Documentation of the error and of the correct information;
- The requester's name, address, telephone number and original signature.

8.2.1 The Department shall review all requests to correct information in the VPMS database and contact the reporting pharmacy that provided the data.

8.2.2 If the reporting pharmacy concurs that the data should be corrected as requested, the reporting pharmacy shall correct the data.

8.2.3 If the reporting pharmacy does not concur, the Department will contact the requester and refer the requester to the reporting pharmacy.

8.2.4 Upon a request by a prescriber, pharmacist, professional licensure board or other individual, and as permitted by 18 V.S.A. § 4284 and Section 8.2 of this rule, the Department will notify the requester if the correction has been made.

8.2.5 Any patient who has requested a correction will be notified of whether the requested correction has been made.

9.0 Enforcement

9.1 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).

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

9.3 If the VPMS shows that a patient has filled a prescription for a controlled substance written by a prescriber who is not a registered user of VPMS, the Commissioner of Health will notify the professional by mail and will notify the applicable licensing authority.

9.4 Prescribers are subject to sanctions by their licensing authority.

10.0 Training

10.1 Pharmacist and Prescriber Training

10.1.1 Training will be offered to registered prescribers, dispensers and delegates of prescribers and dispensers, the Vermont Chief Medical Examiner or delegate and the Medical Director of the Department of Vermont Health Access on how to use the VPMS and how to correctly use the information they receive from the VPMS.

10.1.2 Trainings may be done through professional associations representing health care providers or provided by the Department in a web-based format.

10.2 Drug Diversion Investigators must complete a training program offered or approved by the Department.