

Vermont Prescription Monitoring System Rule

1.0 Authority

This rule is adopted pursuant to 18 V.S.A. §§ 4287 and 289 and Section 2a of Act 173 (2016).

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 patients in hospice care, and other end-of-life care is not required. In the event of electronic or technological failure, the requirements for registering with, uploading to and querying the VPMS are waived.

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 caused by various diseases or abnormal conditions and that continues longer than 90 days.
- 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 “DEA” means the Federal Drug Enforcement Administration.
- 3.6 “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 the clinical care of 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 the Chief Medical Examiner.
- 3.7 “Department” means the Vermont Department of Health.
- 3.8 “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.

- 3.9 “Dispenser” means a pharmacy or prescriber that prepares and delivers a Schedule II, III, or IV controlled substance for a patient pursuant to an order by a prescriber.
- 3.10 “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.
- 3.11 “OBOT” means Office Based Opioid Treatment physician practice for prescribing buprenorphine as established by the Drug Abuse and Treatment Act of 2000. In Vermont, OBOTs are often referred to as “Spokes”. An OBOT may be a preferred provider, an individual physician practice or several physicians practicing as a group.
- 3.12 “OTP” means an Opioid Treatment Program as defined and regulated by federal regulation 42 CFR, Part 8 and DEA regulations related to safe storage and dispensing at OTPs (§1301.72). OTPs are specialty addiction treatment programs for dispensing opioid-replacement medication including methadone and buprenorphine under carefully controlled and observed conditions. OTPs offer onsite ancillary services. In Vermont, OTPs are sometimes referred to as “Hubs”.
- 3.13 "Palliative care" as defined in 18 V.S.A. section 2(6) means interdisciplinary care given to improve the quality of life of patients and their families facing the problems associated with a serious medical condition.
- 3.14 “Pharmacist” means a health care professional licensed to dispense Schedule II, III or IV controlled substances as defined by the Vermont Administrative Rules of the Board of Pharmacy.3.15
- 3.15 “Pharmacy” means an entity that dispenses Controlled Substances, or provides pharmaceutical care, as defined by the Vermont Administrative Rules of the Board of Pharmacy.
- 3.16 “Prescriber” means a health care professional licensed to prescribe Schedule II, III or IV controlled substances.
- 3.17 “Query” means the action of accessing a Prescription Drug Monitoring Program and retrieving information from it regarding controlled substance(s) prescribed or dispensed to a patient.
- 3.18 “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.

- 3.19 “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.
- 3.20 “Report of Controlled Substances Dispensed” means the report format used by pharmacies for submitting required data to the VPMS pursuant to this rule.
- 3.21 “Reportable prescription” means each controlled substance dispensed from any Vermont-licensed pharmacy.
- 3.22 “Unsolicited Report” is a notification sent to a patient’s provider when clinical thresholds established by the Department have been met or exceeded.
- 3.23 “Vermont Prescription Monitoring System” (VPMS) means the statewide database that collects data on Schedule II, III, or IV controlled substances dispensed by a Vermont-licensed pharmacy.

4.0 Required Reporting for Pharmacies and Prescribers who Dispense Controlled Substances

4.1 Filing of Report of Controlled Substances Dispensed

- 4.1.1 Pharmacies and other dispensers shall report each dispensed prescription for a Schedule II, III, or IV controlled substance to the VPMS within either 24 hours or one business day of dispensing the prescription. This applies to all licensees, irrespective of location or number of prescriptions of controlled substances dispensed.
- 4.1.2 Pharmacies and other dispensers must submit a “zero controlled substances report” on any day that no controlled substances are dispensed.

4.2 Required Information from Reporting Pharmacy

- 4.2.1 The Report of Controlled Substances Dispensed from each pharmacy shall include the data elements detailed in the VPMS Data Collection Manual. These data elements include information related to the patient, prescription, dispenser, and prescriber.
- 4.2.2 Those who are responsible for submitting data for multiple pharmacies or locations may submit a single report for all of its their pharmacies. The report shall identify the specific pharmacy or 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 are available on the Department's website.

4.3.1.1 Pharmacies 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.

4.3.2 The pharmacy shall post 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 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.

4.5 Exemptions from Reporting to VPMS

4.5.1 Reporting to VPMS is not required for:

- Pharmacies that do not sell or dispense any Schedule II-IV controlled substances;
- Out-of-State pharmacies that do not sell or dispense any Schedule II-IV controlled substances to any resident in Vermont;
- 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;
- Veterinary Offices; or
- Opioid Treatment Programs that dispense only methadone and buprenorphine.

4.5.2 A pharmacy that meets at least one of the above criteria may request an exemption from reporting from the VPMS program. The exemption shall terminate when the pharmacy dispenses any controlled substance or no longer meets the criteria for exemption.

4.5.3 The pharmacy shall renew the exemption form on an annual basis.

5.0 Requirements for Pharmacists

5.1 Pharmacist Registration with the VPMS

5.1.1 All Vermont-licensed pharmacists shall register to query the VPMS.

5.2 Pharmacist Required Querying of the VPMS

All dispensers, with the exception of hospital-based dispensers dispensing a quantity of a Schedule II, III, or IV opioid controlled substance that is sufficient to treat a patient for fewer than 48 hours shall query the Vermont Prescription Monitoring System in the following circumstances:

- 5.2.1 Prior to dispensing a prescription for a Schedule II, III, or IV opioid controlled substance to a patient who is new to the pharmacy;
- 5.2.2 When an individual pays cash for a prescription for a Schedule II, III, or IV opioid controlled substance and the individual has prescription drug coverage on file;
- 5.2.3 When a patient requests a refill of a prescription for a Schedule II, III, or IV opioid controlled substance substantially in advance of when a refill would ordinarily be due; and
- 5.2.4 When the dispenser is aware that the patient is being prescribed Schedule II, III, or IV opioid controlled substances by more than one prescriber.

5.3 Pharmacist Delegates

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

6.0 Requirements for Prescribers

6.1 Prescriber Registration 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-licensed prescribers of controlled substances and their delegates;
- 6.1.2 The Medical Director of the Department of Vermont Health Access; and
- 6.1.3 Vermont's Medical Examiners, and delegates from the Chief Medical Examiner's Office investigating deaths in Vermont.

6.2 Prescriber-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 pain when such a prescription exceeds 10 pills or the equivalent;
- 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;
- 6.2.3 Prior to writing a replacement prescription for a Schedule II, III, or IV controlled substance;
- 6.2.4 At least annually for patients who are receiving ongoing treatment (treatment without meaningful interruption) with an opioid Schedule II, III, or IV controlled substance;
- 6.2.5 The first time a provider prescribes a benzodiazepine;
- 6.2.6 When a patient requests an opioid prescription or a renewal of an existing prescription for pain from an Emergency Department or Urgent Care prescriber if the prescriber intends to write a prescription for an opioid;
- 6.2.7 With the exception of prescriptions written from an OTP, 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 At regular intervals thereafter, but no less than twice annually; and
 - 6.2.7.2 No fewer than two times annually thereafter; and
 - 6.2.7.3 Prior to writing a replacement prescription.
- 6.2.8 In the case of an OTP, prior to prescribing buprenorphine, methadone, or a drug containing buprenorphine to a Vermont patient for the first time, and:
 - 6.2.8.1 Annually thereafter; and
 - 6.2.8.2 Any other time that is clinically warranted.
- 6.2.9 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 Prescriber Delegates

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

6.4 Exemptions

Patients experiencing chronic pain in the following categories are exempt from the requirements found in this section:

- Chronic pain associated with cancer or cancer treatment;
- Palliative care;
- End-of-life and hospice care; and
- Patients in skilled and intermediate care nursing facilities.

7.0 Access to VPMS Information

7.1 Authority to Query VPMS Directly

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; and
- 7.1.5 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.
- 7.2.1.1 Delegates may register as a delegate under multiple prescribers.
- 7.2.1.2 Delegates must accurately assign each query to the appropriate prescriber.
- 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.

7.3 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:

- 7.3.1 Individual Records
- 7.3.1.1 A patient may request information from VPMS relating to themselves.
- 7.3.1.2 The request shall be submitted to the Department in writing using the Patient Prescription History Request Form, and 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, mailing address;
 - The patient's original signature; and

- A copy of a federally recognized form of photo identification (such as a driver's license or passport) or a Vermont Driver's Privilege Card.

A copy of the Patient Prescription History Request Form can be found on the Health Department's website.

7.3.1.3 In order to submit the Patient Prescription History Request Form, the individual may:

- Mail a notarized original to the Health Department.
- Present the form to the Health Department in-person.

7.3.2 Professional Boards

7.3.2.1 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 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, if applicable;
- 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.

7.3.2.2 The request shall be delivered by secure fax, password-protected e-mail, or in person to VPMS staff.

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 patient meets or exceeds clinical thresholds established by the Department, an Unsolicited Report shall be sent to all providers who have prescribed or dispensed a Controlled Substance 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.

9.0 Enforcement

- 9.1 Prescribers are bound by the requirements of this rule and are subject to sanctions by their licensing authority for failure to comply with it.
- 9.2 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).
- 9.3 The Department may refer to the appropriate licensing authority any pharmacy that fails to submit a timely or complete Report of Controlled Substances Dispensed.
- 9.4 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 email or United States Postal Service and will notify the applicable licensing authority.

10.0 Training

10.1 Pharmacist and Prescriber Training

- 10.1.1 Training on how to access the VPMS and how to correctly use the information from the VPMS will be offered to all registrants.

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

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