Chapter 8 –Division of Substance Use Programs
Subchapter 10

Unused Drug Repository Program Rule

1.0 Authority

This Rule is adopted pursuant to 18 V.S.A. § 4672.

2.0 Purpose

The purpose of this Rule is to establish the requirements for the operation of an Unused Drug Repository Program.

3.0 Definitions

3.1. "Collection Site" means a pharmacy, hospital, cancer center, or residential treatment care facility that has been approved by the Program Administrator to accept drugs from individual donors for transfer to the Program Administrator.

3.2. "Controlled Substance" means a drug, substance, or immediate precursor in schedules I-V of 21 CFR Part 1308.

3.3. "Department" means the Vermont Department of Health.

3.4. "Dispense" means to prepare and deliver a prescription drug pursuant to a lawful order of a practitioner in a suitable container appropriately labeled for subsequent administration to or use by a patient or other individual entitled to receive the prescription drug.

3.5. "Dispenser" means an individual who is authorized to dispense drugs in Vermont under 26 V.S.A. § 2041 and applicable licensing statutes and regulations.

3.6. "Dispensing Site" means a facility with a dispenser who owns or is employed by or under contract with the facility. A Dispensing Site's participation in the Program shall be subject to the Program Administrator's approval.

3.7. "Donor" means an individual or entity that donates unused drugs to a Collection Site or to the Program Administrator. A donor may include but is not limited to an individual, a health care facility, an assisted living facility, a residential care home, a pharmacy, a drug wholesaler, or a drug manufacturer.

3.8. "Drug" means both prescription and non-prescription (over-the-counter) drugs as defined in 26 V.S.A. § 2022(6), however, excludes compounded drugs in the context of Unused Drug Repositories.

3.9. "Eligible recipient" means a patient, Collection Site, Dispensing Site, or Program Administrator, as defined in this Rule.

3.10. "General supervision" means that the supervisor is readily available for consultation or intervention on the premises where the inspection of drugs occurs.

3.11. "Medical device" means articles used to cure, mitigate, treat, prevent, or diagnose illness or injury. Medical devices do not include surgical devices or medical or surgical equipment.

3.12. "Program Administrator" means the entity authorized by the Department to manage and operate the Unused Drug Repository Program.

3.13. "Tamper-evident packaging" means a packaging system that may not be accessed without obvious destruction of the seal or some portion of the packaging system.

3.14. "Transfer" means shipping drugs or medical devices from a Collection Site and/or a Dispensing site to the Program Administrator, or from the Program Administrator to a Dispensing Site.

3.15. "Underinsured" means a person who lacks adequate prescription-related insurance coverage such that purchasing prescription drugs and/or medical devices creates a financial hardship.

3.16. "US Pharmacopeia (USP)" means the independent, scientific nonprofit organization that establishes standards for the supply of safe, quality drugs.

3.17. "Unused Drug Repository Program" and "Program" means the Program under these Rules that collects and inspects unused drugs and medical devices for transfer to participating facilities serving patients in need.

4.0 General Program Requirements

4.1. Participation in the Program by any individual or entity is voluntary.

4.2. An entity that meets the requirements of this Rule may apply to participate in the Program as a Collection Site and/or Dispensing Site by providing written notice to the Program Administrator. The notice shall include:

4.2.1. The name, street address, and telephone number of the entity.

4.2.2. Any state-issued medical and/or pharmacy license or registration number issued

to the entity, including the name of the issuing agency.

4.2.3. A statement, signed and dated by the responsible health care provider, indicating that the entity meets the eligibility requirements under this Rule and will comply with the requirements of this Rule.

4.2.4. For participation as a Dispensing Site, the name, license number, and telephone number of the dispenser who owns or is employed by or under contract with the entity.

4.3. An entity may withdraw from participation in the Program at any time by providing written notice to the Program Administrator.

4.4. The Program Administrator may remove Collection Site and/or Dispensing Site from participation in the Program at any time by providing written notification to the entity.

4.5. Any entity, or any individual 18 years of age or older, may donate legally obtained drugs or medical devices to a Collection Site.

4.6. Medical devices and drugs that have been approved for medical use in the United States, that are listed in the USP or National Formulary (USP/NF), and that meet the criteria for donation in sections 8.3.1-8.3.8 may be dispensed under the Program.

4.7. A Collection Site and/or Dispensing Site may receive, transfer to the Program Administrator, dispose of, and store drugs that were donated, in accordance with this Rule, the Vermont Board of Pharmacy Administrative Rules, and all other applicable regulations.

4.8. A donor, Collection Site, Dispensing Site, or patient shall not be required to pay to participate in the Program.

4.9. Donated drugs and medical devices shall not be resold and shall be considered nonsaleable.

4.10. A drug dispensed through the Program shall not be eligible for reimbursement under the medical assistance Program.

4.11. The donation, transfer, receipt, or facilitation of donations, transfers, and receipt of drugs pursuant to this program shall not be considered wholesale distribution and shall not require licensing as a wholesale distributor. Wholesale distribution outside of the Program, even if conducted by a Program participant, shall remain subject to wholesale distribution licensure requirements.

5.0 Collection Site Requirements

5.1. A Collection Site may participate in this Program upon approval by the Program Administrator by submitting a completed enrollment application, found on the Department's website, to the Program Administrator.

5.2. To be eligible for participation in the Program, a Collection Site shall be in compliance with all applicable federal and state laws, including laws applicable to the storage and transfer of drugs, and shall maintain donated drugs physically and/or electronically separate from other inventory and in a secure environment that meets the drug manufacturer's recommendations and the USP standards.

5.3. Upon accepting a donated drug, a Collection Site shall maintain an electronic record of individual donations, which shall include the name, strength, and quantity of each accepted drug, but not identifying information of any individual donor or patient to whom the drug was originally dispensed. This record shall be provided to the Program Administrator when the drug is transferred to the Program Administrator.

5.4. A Collection Site shall transfer drugs to the Program Administrator in accordance with the logistics system established by the Program Administrator.

5.5. A collection site shall dispose of any donated drugs that do not meet the requirements of this Rule by returning it to the donor, or through another lawful method such as destroying it by incineration or through a medical waste hauler.

6.0 Dispensing Site Requirements

6.1. A Dispensing Site may participate in this Program upon approval by the Program Administrator by submitting a completed enrollment application, found on the Department's website, to the Program Administrator.

6.2. Entities that do not meet Dispensing Site requirements may participate in the Program as a Dispensing Site for the purposes of dispensing non-prescription drugs and/or medical devices, at the discretion of the Program Administrator.

6.3. A Dispensing Site shall only dispense drugs through this Program that have been provided by the Program Administrator and meet the requirements of sections 8.3.1-8.3.8.

6.4. Drugs shall be properly labeled and dispensed in accordance with state and federal regulations. This includes but is not limited to the inclusion of the Dispensing Site's name and contact information, and current patient information.

6.5. A Dispensing Site shall provide the Program Administrator with access to Program records upon request for the purpose of reporting and ensuring compliance with Program requirements.

7.0 Patient Participation

7.1. Any individual may receive drugs through the Program through a participating Dispensing Site. However, the Dispensing Site shall prioritize patients who meet one or more of the following criteria:

7.1.1. Patients whose household income is below 400% of the Federal Poverty Level;

7.1.2. Patients who are uninsured;

7.1.3. Patients who are underinsured;

7.1.4. Patients who are Medicare beneficiaries and are experiencing a coverage gap in their Medicare prescription drug coverage; or

7.1.5. Patients who are on a high-deductible health plan or on a plan with high co-payment requirements for prescription drugs, or both.

8.0 Program Administrator Requirements

8.1. The Program Administrator shall be authorized to operate in Vermont by the Department and shall have a valid license to operate from the Vermont Board of Pharmacy.

8.2. All donated drugs shall be inspected by a licensed pharmacist employed by the Program Administrator before being transferred to a participating Dispensing Site.

8.3. The Program Administrator shall ensure that any drug made available for dispensing through the Program has been inspected by a pharmacist licensed within a U.S. State. The pharmacist shall be responsible for ensuring that the drug:

8.3.1. Is not a controlled substance;

8.3.2. Is in unopened, tamper-evident packaging. A drug in a single-unit dose or blister pack with the outside packaging opened may be accepted if the single-unit dose packaging remains intact;

8.3.3. Is not adulterated or misbranded;

8.3.4. Includes an expiration date on the packaging and has not expired;

8.3.5. Has been approved for medical use in the United States;

8.3.6. Is not a compounded drug;

8.3.7. Has a USP-recognized method to detect improper temperature variation if the drug requires temperature control other than "room temperature storage" as defined by the manufacturer, unless the drug is donated directly by the manufacturer; and

8.3.8. Is not subject to an FDA managed risk evaluation and mitigation strategy (REMS) with an element to assure safe use, and/or an implementation system pursuant to 21 U.S.C. Section 355-1.

8.4. The Program Administrator may repackage drugs as necessary for storage, replenishment, dispensing, administration, or transfers, and drugs must be labeled in compliance with FDA and Vermont Board of Pharmacy Rules.

8.4.1. If multiple packaged donated drugs with varied expiration dates are repackaged together, the shortest expiration date shall be adhered to.

8.4.2. All repackaging must be performed by, or under the general supervision of, a pharmacist licensed within a U.S. State.

8.5. The Program Administrator shall ensure all potentially identifiable information from the donated drugs has been removed, including patient name and prescription number.

8.6. The Program Administrator shall complete a drug transfer form containing the inventory information on file for each drug transferred to a Dispensing Site.

8.7. The Program Administrator shall assist Collection and Dispensing Sites with logistics and compliance with this Rule.

8.8. The Program Administrator shall maintain records including but not limited to:

8.8.1. Current and former participating Collection Sites and participating Dispensing Sites;

8.8.2. Records of all donations accepted, transferred, and destroyed; and

8.8.3. Current inventory of all available drugs and medical devices.

8.9. These records shall be maintained for a period of five years and provided to the Department upon request.

8.10. At least annually, the Program Administrator shall provide to the Department a report that includes, at a minimum, the following data from the previous year of operation:

8.10.1. Aggregate Program participation levels from all entities and individuals;

8.10.2. The total quantity and type of drugs accepted or inventoried and transferred by the Program Administrator;

8.10.3. An estimate on the dollar value of the drugs donated and transferred.

9.0 Limitations on Liability

9.1. Pursuant to 18 V.S.A. § 4673, except in cases of bad faith, gross negligence, intentional misconduct, or noncompliance with applicable law or this Rule, the following persons shall not be subject to civil or criminal liability or professional disciplinary action for participating in or otherwise complying with the Program established by 18 V.S.A. Chapter 91 or this Rule:

9.1.1. A person or entity who donates or gives drugs, medical devices to an eligible recipient, including a drug manufacturer; wholesaler; reverse distributor pharmacy; third-party logistics provider; governmental entity; hospital or other health care facility, as defined in section 9432 of this title; or long-term care facility licensed under 33 V.S.A. chapter 71;

9.1.2. An eligible recipient, as defined by this Rule.

9.1.3. A health care provider, as defined in section 9402 of this title, who prescribes or dispenses a donated drug;

9.1.4. An intermediary that helps administer the Program by facilitating the donation or transfer of drugs to eligible recipients;

9.1.5. A manufacturer or repackager of a donated drug; and

9.1.6. Any employee, volunteer, trainee, or other staff of any person listed in this section.