ADOPTED RULE # _____

Adopted Filing – Coversheet

Instructions:

In accordance with Title 3 Chapter 25 of the Vermont Statutes Annotated and the "Rule on Rulemaking" adopted by the Office of the Secretary of State, this filing will be considered complete upon filing and acceptance of these forms with the Office of the Secretary of State, and the Legislative Committee on Administrative Rules.

All forms shall be submitted at the Office of the Secretary of State, no later than 3:30 pm on the last scheduled day of the work week.

The data provided in text areas of these forms will be used to generate a notice of rulemaking in the portal of "Proposed Rule Postings" online, and the newspapers of record if the rule is marked for publication. Publication of notices will be charged back to the promulgating agency.

PLEASE REMOVE ANY COVERSHEET OR FORM NOT REQUIRED WITH THE CURRENT FILING BEFORE DELIVERY!

Certification Statement: As the adopting Authority of this rule (see 3 V.S.A. § 801 (b) (11) for a definition), I approve the contents of this filing entitled:

Unused Drug Repository Rule

/s/ Todd W. Daloz _____ , on 7/10/24

(signature) (date)

Printed Name and Title:

Todd W. Daloz
Deputy Secretary
Agency of Human Services

RECEIVED BY: _____

- ☐ Coversheet
- ☐ Adopting Page
- ☐ Clean text of the rule (Amended text without annotation)
- ☐ Letter regarding changes to the final proposed

1. TITLE OF RULE FILING:
   Unused Drug Repository Rule
2. PROPOSED NUMBER ASSIGNED BY THE SECRETARY OF STATE
   24P013
3. ADOPTING AGENCY:
   AHS - Department of Health
4. RECORDS EXEMPTION INCLUDED WITHIN RULE:
   (DOES THE RULE CONTAIN ANY PROVISION DESIGNATING INFORMATION AS CONFIDENTIAL; LIMITING ITS PUBLIC RELEASE; OR OTHERWISE, EXEMPTING IT FROM INSPECTION AND COPYING?) No

   IF YES, CITE THE STATUTORY AUTHORITY FOR THE EXEMPTION:

   PLEASE SUMMARIZE THE REASON FOR THE EXEMPTION:

5. LEGAL AUTHORITY / ENABLING LEGISLATION:
   (THE SPECIFIC STATUTORY OR LEGAL CITATION FROM SESSION LAW INDICATING WHO THE ADOPTING ENTITY IS AND THUS WHO THE SIGNATORY SHOULD BE. THIS SHOULD BE A SPECIFIC CITATION NOT A CHAPTER CITATION).
   18 V.S.A. § 4672.
6. THE FILING HAS CHANGED SINCE THE FILING OF THE FINAL PROPOSED RULE.
7. THE AGENCY HAS INCLUDED WITH THIS FILING A LETTER EXPLAINING IN DETAIL WHAT CHANGES WERE MADE, CITING CHAPTER AND SECTION WHERE APPLICABLE, INCLUDING CHANGES IN ECONOMIC IMPACT.
8. THE LEGISLATIVE COMMITTEE ON ADMINISTRATIVE RULES DID NOT OBJECT TO THE FINAL PROPOSAL.
9. PROCEDURAL HISTORY OF ADOPTION:

   ICAR Filing: 1/8/2024

   Proposal Filed with Office of the Secretary of State: 3/20/2024

   Notices Posted Online: 3/27/2024

   Notices Published in the Newspapers of Record: 4/4/2024

   A Hearing WAS Held.

Hearings Held *(PLEASE USE ADDITIONAL SHEETS TO PROVIDE THE DATE, TIME, AND LOCATION OF ALL HEARINGS, IF THIS FORM IS INSUFFICIENT TO LIST ALL HEARINGS HELD)*:

Date: 4/29/2024
Time: 03:00 PM
Street Address: NOB 2 North, 280 State Dr, Waterbury, VT
Zip Code: 05671, Rm WSOC Beech 20
URL for Virtual: Call in (audio only)

+1 802-828-7667,,967810609# United States, Montpelier

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Time: AM
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Zip Code:
URL for Virtual:

Deadline for Public Comment: 5/6/2024

Final Proposal —

Filed with Secretary of State: 05/16/2024

Filed with LCAR: 05/16/2024

Dates of LCAR Review: 06/27/2024, , , ,

Adopted Rule —

Filed with Secretary of State: 07/23/2024

Filed with LCAR: 07/23/2024

10. EFFECTIVE DATE: 09/01/2024
(A RULE MAY TAKE EFFECT 15 DAYS AFTER ADOPTION IS COMPLETE OR AT A LATER TIME PROVIDED IN THE TEXT OF THE RULE SEE 3 V.S.A. §845(d) FOR DETAILS).

Adopting Page

Instructions:

This form must accompany each filing made during the rulemaking process:

Note: To satisfy the requirement for an annotated text, an agency must submit the entire rule in annotated form with proposed and final proposed filings. Filing an annotated paragraph or page of a larger rule is not sufficient. Annotation must clearly show the changes to the rule.

When possible, the agency shall file the annotated text, using the appropriate page or pages from the Code of Vermont Rules as a basis for the annotated version. New rules need not be accompanied by an annotated text.

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1. TITLE OF RULE FILING:
   Unused Drug Repository Rule
2. ADOPTING AGENCY:
   AHS - Department of Health
3. TYPE OF FILING (*PLEASE CHOOSE THE TYPE OF FILING FROM THE DROPDOWN MENU BASED ON THE DEFINITIONS PROVIDED BELOW*):

   - **AMENDMENT -** Any change to an already existing rule, even if it is a complete rewrite of the rule, it is considered an amendment if the rule is replaced with other text.
   - **NEW RULE -** A rule that did not previously exist even under a different name.
   - **REPEAL** - The removal of a rule in its entirety, without replacing it with other text.

   This filing is **A NEW RULE** .

4. LAST ADOPTED (*PLEASE PROVIDE THE SOS LOG#, TITLE AND EFFECTIVE DATE OF THE LAST ADOPTION FOR THE EXISTING RULE*):

VERMONT
DEPARTMENT OF HEALTH

To: Representative Trevor Squirrell, Chair, Legislative Committee on Administrative Rules
From: Brendan Atwood, Policy Director, Vermont Department of Health
Re: Unused Drug Repository Program Rule
Date: June 19, 2024

Following the filing of the Final Proposed Rule, the Department of Health made the following changes based on the recommendations received from the Legislative Counsel for the Legislative Committee on Administrative Rules:

1. Sec. 3.1 and Sec. 3.7 were updated to reference "long-term care facilities licensed under 33 V.S.A. chapter 71."
2. Sec. 3.8 was updated for clarity:
   "Drug" means both prescription and non-prescription (over-the-counter) drugs as defined in 26 V.S.A. § 2022(6), however, the term excludes compounded drugs in the context of Unused Drug Repositories.
3. Sec. 3.11 was updated to reference 18 V.S.A. § 4631a(15).
4. Sec. 4.10 was removed.
5. Sec. 8.3.2 was updated for clarity:
   "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 or blister packaging, as applicable, remains intact;"
6. Sec. 8.3.5 was update to include reference to the FDA.
7. Sec. 8.3.8 was modified for clarity:
   "~~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.~~ Is not subject to an FDA-managed risk evaluation and mitigation strategy (REMS) pursuant to 21 U.S.C. § 355-1 that includes an element to assure safe use and/or an implementation system.
8. Sec. 9.1 was updated to include reference to the appropriate subchapter.
9. Sec. 9.1.1 was updated to include "or."
10. Sec. 9.1.1 and 9.1.3 were updated to reference Title 18.

280 State Drive
Waterbury, VT 05671
Telephone: 802.863.7280

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 long-term care facilities, including nursing homes, residential care homes, and assisted living residences 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, a long-term care facility, including nursing homes, residential care homes, and assisted living residences, 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, the term 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 the same as defined in 18 V.S.A. § 4631a (15).

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. 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 or blister packaging, as applicable, 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 by the Food and Drug Administration (FDA);

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) pursuant to 21 U.S.C. § 355-1 that includes an element to assure safe use and/or an implementation system

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, subchapter 5, or this Rule:

9.1.1. A person or entity who donates or gives drugs or 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 18 V.S.A. § 9432; 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 18 V.S.A. § 9402, 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.

280 State Drive – Center Building
Waterbury, VT 05671-1000

OFFICE OF THE SECRETARY
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JENNEY SAMUELSON
SECRETARY

TODD W. DALOZ
DEPUTY SECRETARY

STATE OF VERMONT
AGENCY OF HUMAN SERVICES

MEMORANDUM

TO: Sarah Copeland Hanzas, Secretary of State

FROM: Jenney Samuelson, Secretary, Agency of Human Services

DATE: March 7, 2024

SUBJECT: Signatory Authority for Purposes of Authorizing Administrative Rules

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I hereby designate Todd Daloz, Deputy Secretary, Agency of Human Services as signatory to fulfill the duties of the Secretary of the Agency of Human Services as the adopting authority for administrative rules as required by Vermont's Administrative Procedures Act, 3. V.S.A § 801 et seq.

CC: Todd W. Daloz via Todd.Daloz@vermont.gov