PROPOSED RULE # _____.

Proposed Filing - Coversheet

Instructions:

In accordance with Title 3 Chapter 25 of the Vermont Statutes Annotated and the "Rule on Rulemaking" (CVR 04-000-001) adopted by the Office of the Secretary of State, this filing will be considered complete upon filing and acceptance of these forms and enclosures with the Office of the Secretary of State, and the Legislative Committee on Administrative Rules.

All forms shall be submitted to 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 Proposed Filing Coversheet will be used to generate a notice of rulemaking in the portal of "Proposed Rule Postings" online, and the newspapers of record. 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 3/15/2024

(signature) (date)

Printed Name and Title:

Todd W. Daloz
Deputy Secretary
Agency of Human Services

RECEIVED BY: _____

- ☐ Coversheet
- ☐ Adopting Page
- ☐ Economic Impact Analysis
- ☐ Environmental Impact Analysis
- ☐ Strategy for Maximizing Public Input
- ☐ Scientific Information Statement (if applicable)
- ☐ Incorporated by Reference Statement (if applicable)
- ☐ Clean text of the rule (Amended text without annotation)
- ☐ Annotated text (Clearly marking changes from previous rule)
- ☐ ICAR Filing Confirmed

1. TITLE OF RULE FILING:
Unused Drug Repository Rule

2. ADOPTING AGENCY:
AHS - Department of Health

3. PRIMARY CONTACT PERSON:
(A PERSON WHO IS ABLE TO ANSWER QUESTIONS ABOUT THE CONTENT OF THE RULE).

Name: Brendan Atwood

Agency: Department of Health

Mailing Address: 280 State Street, Waterbury, VT 05671-8300

Telephone: 802-863-7280 Fax: 802-951-1275

E-Mail: ahs.vdhrules@vermont.gov

Web URL *(WHERE THE RULE WILL BE POSTED)*:
http://www.healthvermont.gov/about-us/laws-regulations/public-comment

4. SECONDARY CONTACT PERSON:
(A SPECIFIC PERSON FROM WHOM COPIES OF FILINGS MAY BE REQUESTED OR WHO MAY ANSWER QUESTIONS ABOUT FORMS SUBMITTED FOR FILING IF DIFFERENT FROM THE PRIMARY CONTACT PERSON).

Name: Natalie Weill

Agency: Department of Health

Mailing Address: 280 State Street, Waterbury, VT 05671-8300

Telephone: 802-863-7280 Fax: 802-9511275

E-Mail: ahs.vdhrules@vermont.gov

5. 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:

6. 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.

7. EXPLANATION OF HOW THE RULE IS WITHIN THE AUTHORITY OF THE AGENCY:

18 V.S.A. § 4672 states, "The Agency of Human Services shall adopt rules for the administration of the program…"

8. CONCISE SUMMARY **(150 WORDS OR LESS)**:

This rulemaking establishes the requirements for the administration of, and participation in, the Unused Drug Repository program. The purpose of this program is to get medicine to those who need it and who may have difficulty affording it. This Program will collect, inspect, and dispense medicine to patients, with priority given to those who meet the statutory criteria. This rulemaking outlines the program requirements for the Program Administrator, Collection Sites, Dispensing Sites, donors, and recipients.

9. EXPLANATION OF WHY THE RULE IS NECESSARY:

18 V.S.A. § 4672 states, "The Agency of Human Services shall adopt rules for the administration of the program…"

10. EXPLANATION OF HOW THE RULE IS NOT ARBITRARY AS DEFINED IN 3 V.S.A. § 801(b)(13)(A):

This rule establishes the requirements outlined in 18 V.S.A. § 4672. The decisions made by the Department regarding these regulations were made in consultation with stakeholders and are factually based, rationally connected to those factual bases, and would make sense to a reasonable person.

11. LIST OF PEOPLE, ENTERPRISES AND GOVERNMENT ENTITIES AFFECTED BY THIS RULE:

Drug recipients

Drug Collection Sites

Drug Dispensing Sites

Health care Providers

12. BRIEF SUMMARY OF ECONOMIC IMPACT **(150 WORDS OR LESS)**:

This program is anticipated to save millions of dollars in medicine from being discarded and instead donated to those in need, providing a direct economic benefit to recipients. Annual estimates for the value of this medicine is > $3.5 Million. Additionally, participating facilities that

currently pay to discard unused drugs (e.g. hospitals, long-term care facilities) will see cost savings associated with no longer needing to pay to dispose of these drugs. Finally, improved health outcomes associated with increased access to medicine is likely to yield long-term healthcare cost savings.

13. A HEARING WILL BE SCHEDULED.

IF A HEARING WILL NOT BE SCHEDULED, PLEASE EXPLAIN WHY.

14. HEARING INFORMATION

(THE FIRST HEARING SHALL BE NO SOONER THAN 30 DAYS FOLLOWING THE POSTING OF NOTICES ONLINE).

IF THIS FORM IS INSUFFICIENT TO LIST THE INFORMATION FOR EACH HEARING, PLEASE ATTACH A SEPARATE SHEET TO COMPLETE THE HEARING INFORMATION NEEDED FOR THE NOTICE OF RULEMAKING.

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

Phone Conference ID: 967 810 609#

Find a local number | Reset PIN

Date:
Time: AM
Street Address:
Zip Code:
URL for Virtual:

Date:
Time: AM
Street Address:
Zip Code:

URL for Virtual:

Date:
Time: AM
Street Address:
Zip Code:
URL for Virtual:

---

15. DEADLINE FOR COMMENT (NO EARLIER THAN 7 DAYS FOLLOWING LAST HEARING): 5/6/2024
16. KEYWORDS (PLEASE PROVIDE AT LEAST 3 KEYWORDS OR PHRASES TO AID IN THE SEARCHABILITY OF THE RULE NOTICE ONLINE).

Unused Drug

Medication

Drug Repository

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.

---

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*):

Economic Impact Analysis

Instructions:

In completing the economic impact analysis, an agency analyzes and evaluates the anticipated costs and benefits to be expected from adoption of the rule; estimates the costs and benefits for each category of people enterprises and government entities affected by the rule; compares alternatives to adopting the rule; and explains their analysis concluding that rulemaking is the most appropriate method of achieving the regulatory purpose. If no impacts are anticipated, please specify "No impact anticipated" in the field.

Rules affecting or regulating schools or school districts must include cost implications to local school districts and taxpayers in the impact statement, a clear statement of associated costs, and consideration of alternatives to the rule to reduce or ameliorate costs to local school districts while still achieving the objectives of the rule (see 3 V.S.A. § 832b for details).

Rules affecting small businesses (excluding impacts incidental to the purchase and payment of goods and services by the State or an agency thereof), must include ways that a business can reduce the cost or burden of compliance or an explanation of why the agency determines that such evaluation isn't appropriate, and an evaluation of creative, innovative or flexible methods of compliance that would not significantly impair the effectiveness of the rule or increase the risk to the health, safety, or welfare of the public or those affected by the rule.

---

1. TITLE OF RULE FILING:

   Unused Drug Repository Rule

2. ADOPTING AGENCY:

   AHS - Department of Health

3. CATEGORY OF AFFECTED PARTIES:

   LIST CATEGORIES OF PEOPLE, ENTERPRISES, AND GOVERNMENTAL ENTITIES POTENTIALLY AFFECTED BY THE ADOPTION OF THIS RULE AND THE ESTIMATED COSTS AND BENEFITS ANTICIPATED:

   Drug recipients: will likely receive millions of dollars (collectively) worth of medication.

   Drug Collection Sites: May see de minimus administrative costs associated with participation. Participation is voluntary. To the extent a collection site currently pays to discard medicine, there will be

a cost-saving associated with donating the medicine instead.

Drug Dispensing Sites: De minimus administrative costs associated with participation, which is voluntary.

Health care providers: no economic impact is anticipated.

Program administrator: the annual cost to operate this program is estimated to be about $350,000.

4. IMPACT ON SCHOOLS:
INDICATE ANY IMPACT THAT THE RULE WILL HAVE ON PUBLIC EDUCATION, PUBLIC SCHOOLS, LOCAL SCHOOL DISTRICTS AND/OR TAXPAYERS CLEARLY STATING ANY ASSOCIATED COSTS:

No impact is anticipated.

5. ALTERNATIVES: *CONSIDERATION OF ALTERNATIVES TO THE RULE TO REDUCE OR AMELIORATE COSTS TO LOCAL SCHOOL DISTRICTS WHILE STILL ACHIEVING THE OBJECTIVE OF THE RULE.*

Because there are no impacts, alternatives have not been considered.

6. IMPACT ON SMALL BUSINESSES:
INDICATE ANY IMPACT THAT THE RULE WILL HAVE ON SMALL BUSINESSES (EXCLUDING IMPACTS INCIDENTAL TO THE PURCHASE AND PAYMENT OF GOODS AND SERVICES BY THE STATE OR AN AGENCY THEREOF):

No impact is anticipated.

7. SMALL BUSINESS COMPLIANCE: *EXPLAIN WAYS A BUSINESS CAN REDUCE THE COST/BURDEN OF COMPLIANCE OR AN EXPLANATION OF WHY THE AGENCY DETERMINES THAT SUCH EVALUATION ISN'T APPROPRIATE.*

Because no impacts are anticipated, this evaluation was not conducted.

8. COMPARISON:
COMPARE THE IMPACT OF THE RULE WITH THE ECONOMIC IMPACT OF OTHER ALTERNATIVES TO THE RULE, INCLUDING NO RULE ON THE SUBJECT OR A RULE HAVING SEPARATE REQUIREMENTS FOR SMALL BUSINESS:
A rule is required by statute. The program is voluntary for all participants, allowing each entity to decide whether to take on any potential ecopnomic impacts.

9. SUFFICIENCY: *DESCRIBE HOW THE ANALYSIS WAS CONDUCTED, IDENTIFYING RELEVANT INTERNAL AND/OR EXTERNAL SOURCES OF INFORMATION USED.*

The Department has provided the information that is available, including information provided by unused drug repositories in other states.

Environmental Impact Analysis

Instructions:

In completing the environmental impact analysis, an agency analyzes and evaluates the anticipated environmental impacts (positive or negative) to be expected from adoption of the rule; compares alternatives to adopting the rule; explains the sufficiency of the environmental impact analysis. If no impacts are anticipated, please specify "No impact anticipated" in the field.

Examples of Environmental Impacts include but are not limited to:

- Impacts on the emission of greenhouse gases
- Impacts on the discharge of pollutants to water
- Impacts on the arability of land
- Impacts on the climate
- Impacts on the flow of water
- Impacts on recreation
- Or other environmental impacts

---

1. TITLE OF RULE FILING:

   Unused Drug Repository Rule

2. ADOPTING AGENCY:

   AHS - Department of Health

3. GREENHOUSE GAS: *EXPLAIN HOW THE RULE IMPACTS THE EMISSION OF GREENHOUSE GASES (E.G. TRANSPORTATION OF PEOPLE OR GOODS; BUILDING INFRASTRUCTURE; LAND USE AND DEVELOPMENT, WASTE GENERATION, ETC.):*
   No impact is anticipated.

4. WATER: *EXPLAIN HOW THE RULE IMPACTS WATER (E.G. DISCHARGE / ELIMINATION OF POLLUTION INTO VERMONT WATERS, THE FLOW OF WATER IN THE STATE, WATER QUALITY ETC.):*
   This program is anticipated to divert tons of medications from the waste stream, which could reduce sources of water, including groundwater, pollution.

5. LAND: *EXPLAIN HOW THE RULE IMPACTS LAND (E.G. IMPACTS ON FORESTRY, AGRICULTURE ETC.):*
   This program is anticipated to divert tons of

medications from the waste stream, which could reduce sources of land pollution.

6. RECREATION: *EXPLAIN HOW THE RULE IMPACTS RECREATION IN THE STATE:*
   No impact is anticipated.
7. CLIMATE: *EXPLAIN HOW THE RULE IMPACTS THE CLIMATE IN THE STATE:*
   No impact is anticipated.
8. OTHER: *EXPLAIN HOW THE RULE IMPACT OTHER ASPECTS OF VERMONT'S ENVIRONMENT:*
   No impact is anticipated.
9. SUFFICIENCY: *DESCRIBE HOW THE ANALYSIS WAS CONDUCTED, IDENTIFYING RELEVANT INTERNAL AND/OR EXTERNAL SOURCES OF INFORMATION USED.*
   The Department has provided the information that is available, including information provided by operators of unused drug repositories in other states.

Public Input Maximization Plan

Instructions:

Agencies are encouraged to hold hearings as part of their strategy to maximize the involvement of the public in the development of rules. Please complete the form below by describing the agency's strategy for maximizing public input (what it did do, or will do to maximize the involvement of the public).

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

---

1. TITLE OF RULE FILING:

   Unused Drug Repository Rule

2. ADOPTING AGENCY:

   AHS - Department of Health

3. PLEASE DESCRIBE THE AGENCY'S STRATEGY TO MAXIMIZE PUBLIC INVOLVEMENT IN THE DEVELOPMENT OF THE PROPOSED RULE, LISTING THE STEPS THAT HAVE BEEN OR WILL BE TAKEN TO COMPLY WITH THAT STRATEGY:

   The rule is posted on the Department of Health's website:

   https://www.healthvermont.gov/about-us/laws-regulations/public-comment

   The Department will hold a public hearing.

4. BEYOND GENERAL ADVERTISEMENTS, PLEASE LIST THE PEOPLE AND ORGANIZATIONS THAT HAVE BEEN OR WILL BE INVOLVED IN THE DEVELOPMENT OF THE PROPOSED RULE:

   The Vermont Office of Professional Regulation

   The Department of Vermont Health Access

   The Vermont Board of Medical Practice

   The Vermont Board of Pharmacy

   Vermont Legal Aid

   Vermont Medical Society

   Vermont Association for Hospitals and Health Systems

- Vermont Health Care Association
- Pharmaceutical manufacturers (represented by MMR and Morris Government Affairs)
- SafeNet RX (drug repository program administrator)
- Sirum (drug repository program administrator)

State of Vermont
Agency of Administration
109 State Street
Montpelier, VT 05609-0201
www.aoa.vermont.gov

[phone] 802-828-3322

Kristin L. Clouser, Secretary

INTERAGENCY COMMITTEE ON ADMINISTRATIVE RULES (ICAR) MINUTES

Meeting Date/Location: February 23, 2024, virtually via Microsoft Teams
Members Present: Chair Sean Brown, Jennifer Mojo, John Kessler, Diane Sherman, Michael Obuchowski, Nicole Dubuque, Jared Adler (voted on the 1st two rules only then exited meeting at 1:55 PM), Natalie Weill (did not vote)
Minutes By: Melissa Mazza-Paquette

- 1:01 p.m. meeting called to order, welcome and introduction of newest Committee member Natalie Weill who will begin voting at the next ICAR meeting.
- Review and approval of minutes from the January 8, 2024 meeting.
- No additions/deletions to agenda.
- No public comments made.
- Presentation of Proposed Rules on pages 2-7 to follow.
  1) Aboveground Storage Tank Rules, Agency of Natural Resources, Department of Environmental Conservation, page 2
  2) Unused Drug Repository Rule, Agency of Human Services, Department of Health, page 3
  3) Improved Tracking of Workplace Injuries and Illnesses, Vermont Department of Labor, page 4
  4) Reportable and Communicable Diseases Rule, Agency of Human Services, Department of Health, page 5
  5) Rule 3.300 Disconnection of Residential Gas, Electric and Water Service, Vermont Public Utility Commission, page 6
  6) Rule 3.400 Disconnection of Cable Television Service and Non-Residential Electric, Gas and Water Service, Vermont Public Utility Commission, page 7
- Other business:
  - Diane will create draft public guidance for the Committee's review at a future meeting to aid those filing proposed rules.
- Next scheduled meeting is Monday, March 11, 2024 at 2:00 p.m.
- 3:02 p.m. meeting adjourned.

Proposed Rule: Unused Drug Repository Rule, Agency of Human Services, Department of Health

Presented By: Brendan Atwood

Motion made to accept the rule by John Kessler, seconded by Nicole Dubuque, and passed unanimously with the following recommendations:

1. Proposed Filing – Coversheet, #10: Include the "how" as required.
2. Economic Impact Analysis:
    a. Include any relevant data, costs and/or information pertaining to new hires to administer the program.
    b. #3: Correct spelling "emdicine".
    c. #9: Describe how the analysis was conducted and identifying the source of information.
3. Environmental Impact Analysis, #9: Include more detail.
4. Public Input Maximization Plan:
    a. #3: Include positive impacts, such as those to health, economic and environmental.
    b. #4: Change "Aide" to "Aid".
    c. Consider reaching out to others who might be interested in this proposed rule, such as community members and those involved in solid waste.

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, 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.

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, 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.

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

OFFICE OF THE SECRETARY
TEL: (802) 241-0440
FAX: (802) 241-0450

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

---

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