
**Report to
The Vermont Legislature**

**Unused Drug Repository Report
2023 Report to the Legislature**

**Submitted to: House Committees on Human Services and Health Care
Senate Committee on Health and Welfare**

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Contents

Introduction.....	3
Program Overview.....	3
Benefits	3
Administration and Cost.....	4
Program Administration.....	4
Program Costs.....	4
Department of Health Personnel.....	4
Funding Source.....	4
Program Rules	4
Donors	5
Drugs Accepted.....	5
Drug Inspection	5
Patient Eligibility.....	5
Liability Protections	6
Conclusion	6

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Introduction

In 2022, the Senate Committee on Health and Welfare requested that the Department of Health (Department) provide this update to the 2018 Unused Drug Repository Report. As directed by the Legislature in Act 114 (2018), this report provides “an analysis and recommendations regarding the implementation of an unused prescription drug repository program in Vermont.”

The Department’s analysis is informed by research and consultations with stakeholders, including the Vermont Office of Professional Regulation, the Vermont Board of Pharmacy, the Vermont Department of Health Access, several charitable pharmacies that operate unused drug repository programs, and representatives of pharmaceutical manufacturers. Additional stakeholders reviewed and commented on this report prior to submission.

As in 2018, there remains a clear consensus that Vermont should participate in an unused drug repository program (UDRP) because of the significant health, economic, and environmental benefits anticipated from such a program. Additional recommendations, regarding the implementation and operation of a UDRP, are discussed below.

Program Overview

Benefits

Unused Drug Repository Programs improve access to critical medications for those experiencing economic hardship, reduce healthcare system costs, and reduce drug waste. SafeNet Rx, a nonprofit charitable pharmacy that has administered the UDRP in Iowa since 2007, estimates that for every \$1 invested, \$8 of medication has been donated.¹ SafeNet Rx and SIRUM, a nonprofit organization that helps operate a UDRP in Georgia, project an annual value of medicine distributed to Vermonters of approximately \$3.5 - \$7 million (based on the distribution of up to 35,000 thirty-day prescriptions to Vermonters). Critically, these figures reflect only the dollar value of medications received by Vermonters and do not account for presumptive cost savings associated with improved health outcomes derived from patient access to needed medications, decreased drug disposal costs by institutions, nor the environmental benefits associated with fewer drugs being discarded and entered into the waste stream.² Notably, many of the unused medications that would be distributed to Vermonters in need include those paid for with taxpayer dollars (e.g. Medicare, the Veteran’s Administration or the Department of Corrections).

¹ <https://legislature.vermont.gov/assets/Documents/2018/WorkGroups/Senate%20Health%20and%20Welfare/Bills/S.164/S.164~Jon-Michael%20Rosmann~Testimony~1-25-2018.pdf>

² There is no way to specifically track medical waste in the U.S., but in 2015 the Environmental Protection Agency (EPA) estimated that approximately 740 tons of drugs are disposed of by nursing homes each year. Allen, M. (2017, April 27). America’s Other Drug Problem. Pro Publica. Retrieved October 6, 2022, from: <https://www.propublica.org/article/americas-other-drug-problem>

Administration and Cost

Program Administration

While over 40 states have passed laws allowing for unused drug repository programs, only about half of them have successfully implemented a UDRP. Of those states, most currently restrict participation to in-state residents, meaning that Vermonters cannot currently be served by those programs. The Department is aware of two organizations that are able to serve Vermonters through contracted service to operate a UDRP: SafeNet Rx and SIRUM. There may also be other entities that could offer to implement and manage a UDRP. Any charitable pharmacy that operates in Vermont would need to be appropriately licensed (e.g. wholesale pharmacy license).

While Vermont could establish its own UDRP, doing so would result in higher costs and less value compared to working with an existing unused drug repository program, and is therefore not recommended by the Department. If Vermont contracts with a third-party to implement and manage a UDRP, Vermonters will benefit from both a greater inventory of drugs than if Vermont is the only donor state, and fewer infrastructure and startup costs associated with:

- Leasing or purchasing warehouse space that could also be used for drug inspection, sorting and shipping;
- Purchasing or creating an inventory software system; and
- Developing a shipping and collection method.

Program Costs

Based on estimates provided by SafeNet Rx and SIRUM, contracting with either entity would cost Vermont approximately \$300,000 - \$400,000 annually. The scope and pace of implementing an unfunded program would be both limited and incremental, as would the associated benefits, compared to a fully funded program in which the start-up costs have been paid for through a state investment.

Department of Health Personnel

If a third-party was contracted to operate a UDRP, the Department would need to manage the contracting process and provide support for an outreach campaign to providers, pharmacists, institutions, and patients to make them aware of the program as well as educate providers on which patients qualify, and how to order medications. The Department estimates this will require 0.25 full-time employee (FTE) position, or ~\$25,000 annually.

Funding Source

In order to increase access to this program, the Department recommends that patients, pharmacies, and clinics who use the program not be required to pay to do so. However, service fees should not be prohibited by statute (though perhaps limited by rulemaking), as there may be a need to implement a fee-for-service model in the event of an absence or decrease in state funding for this program. The Department's analysis concludes that a State investment in this program is likely to yield a substantial return on investment on behalf of Vermonters.

Program Rules

As with other states, program rules about donors, the types of drugs accepted, recipient eligibility

and other program requirements would need to be developed. Rulemaking will ensure broad public participation in developing these regulations, as well as the flexibility to modify them as needed. Regardless of the forum for developing regulations, the recommendations below should be considered as parameters for a Vermont unused drug repository program.

Donors

Drugs should be permitted to be collected from institutional settings (pharmacies, long-term care facilities, Veteran’s Administration facilities, correctional facilities, hospitals, etc.) and individual patients.

Collecting from institutions will limit the number of collection points, ensure greater volume per collection run, and increase the probability that the medication will be usable (e.g. in a sealed blister pack), while individual patients are likely to be a primary source of expensive medication donations, such as those for treatment of cancer.

Drugs Accepted

To ensure that drugs are safe to be redistributed, the program would be required to determine that the drugs:

- Are in sealed or original packaging, or tamper-evident packaging (e.g. blister pack), unless they are opened bulk bottles from a secured pharmacy setting (such as hospitals, or retail pharmacies);
- Are not a controlled substance; and
- Have not expired.

Drug Inspection

Inspection of the drugs must be done by a licensed healthcare provider from the UDRP management entity before being redistributed to ensure that the drugs and packaging have not been damaged or tampered with in any way. The healthcare provider must also check to make sure that the drug label matches the drug. Once inspected, all patient information must be removed; but the drug name, strength, National Drug Code (NDC), and expiration date must be included on the packaging.

In the event of a drug recall, since lot numbers will not always be available, all drugs of the name and dose being recalled will be disposed of unless the drug has an affixed lot number to exclude it from the recall. The participating pharmacies and clinics would then be responsible for notifying patients.

Patient Eligibility

Patients would be screened for eligibility and/or prioritization by the dispensing pharmacy that is participating in the UDRP or by the prescribing provider. It is recommended priority be given to patients who meet at least one the following eligibility criteria:

- Be under 400% of the federal poverty level;
- Be uninsured;
- Be underinsured;
- Be in the Medicare ‘donut hole’; and/or
- Have high deductible coverage, or high copays.

Liability Protections

In order to ensure participation in the program by institutions, the Department recommends that any participant in an unused drug repository program (including pharmacies, healthcare institutions, pharmacists, healthcare workers, manufacturers, distributors, participating entities, and governmental entities) shall not be subject to criminal or civil liability for injury caused when any entity or person donates, accepts, or dispenses prescription drugs in compliance with statute and program rules. These immunities should not apply in cases of noncompliance with regulations, bad faith, gross negligence, or the like.

Conclusion

In recognition of the substantial financial, health, and environmental benefits to Vermonters, and the significant return on investment that is anticipated, the Department of Health recommends that the Vermont Legislature provide the statutory authority for the Department to contract with a third-party entity to implement and manage an unused drug repository program in Vermont, as well as the authority to draft rules for the program. If the legislature chooses to proceed with implementing an unused drug repository program, the estimated annual cost would be approximately \$300,000-\$400,000.