VERMONT2007

Drugs and Medical Supply Repository Study

Report to the Legislature on **Act 139**
Sec. 6 – Report Relating to 8 V.S.A. § 107
January 15, 2007

DEPARTMENT OF HEALTH
Agency of Human Services

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Table of Contents

Executive Summary 3

Introduction 4

Study Methodology 5

Overview 6

Details of New England States Programs 8

Consultation with Other Agencies 9

Barriers to Implementation 10

Financial Feasibility 12

Findings & Recommendations 14

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Executive Summary

In accordance with ***Act 139, Section 6,*** the Legislature asked the Department of Health to study the feasibility of developing a repository in Vermont that would coordinate the collection of excess drugs and medical supplies that cannot be used by health care facilities, and drug wholesalers and manufacturers, and redistribute them for use by patients who are uninsured or underinsured. A number of states have studied this concept over the past few years, and a few states appear to have programs in place. The Legislature asked the Department to consult with five other agencies of State government (Board of Pharmacy, the Board of Medical Practice, the Department of Aging and Independent Living, the Department of Public Safety, and the Office of Vermont Health Access) to determine if such a program was feasible in Vermont. Over the last several months, the Department has talked with staff at the other State agencies, and at several other key non-profit health associations in Vermont. These agencies and organizations have been given the opportunity to provide input into the study, including a draft of the final report. The Department has also studied national reports of the repository program concept, and examined a number of individual state programs, including those of the five other New England states.

Overall, it appears that states are moving very slowly in their efforts to adopt and implement repository programs. Of those states with programs, they are often being done on a "pilot" or totally volunteer basis. Many of the other programs are tied up in rulemaking, or, while passed by the legislature, are not being implemented due to the lack of funding.

There are two major hurdles that are preventing such repository programs from moving ahead. First, there is legitimate concern that contaminated or counterfeit drugs could undermine the operation of the program, as well as harm the current programs of drug requisition, purchase, and distribution. A related factor is that all the programs, in one form or another, rely on local retail and health facility pharmacies to serve as the physical repositories for the program. No state has developed a program that operates a centralized facility for the receipt and distribution of the drugs and supplies. Yet the incentives for pharmacies to participate in the program are quite limited, while the costs of the program could be substantial.

Given the information uncovered by this study, the Department of Health urges the Legislature to proceed with caution in its further consideration of a drug and medical supply repository program. Should the Legislature choose to pursue this matter further, the goals and objectives of such a program need to be clearly articulated at the outset. In addition, a mechanism should be in place from the start to monitor the program and evaluate its economic and clinical benefits. Finally, the lesson learned from other fledgling programs across the country is that the program needs to be adequately funded.

Introduction

In 2006, the General Assembly passed Act 139, and the Governor signed, "Sec.6 Drugs and Medical Supply Repository Study." It requires the Department of Health to study the feasibility of creating a repository program through which licensed health care facilities, wholesale drug distributors, and drug manufacturers can donate drugs. This study was to be done in consultation with five other state agencies, including the Board of Pharmacy, the Board of Medical Practice, the Department of Ageing and Independent Living, the Department of Public Safety, and the Office of Vermont Health Access. The drugs could go to persons needing these medicines who are income-eligible or uninsured. The donated drugs would need to be unused, unopened or surplus prescription drugs. In addition, the program would also accept donated medical supplies. There would be no charge to the patient for the drugs or supplies dispensed through the repository, although a "handling fee" could be applied.

The legislation asked that the study include findings and recommendations reflecting the cost of creating and overseeing such a program. The Department was also asked to identify the benefits of a repository program, and to identify the standards and procedures necessary for the development and implementation of such a program. The study is due by January 15, 2007.

A related bill, H.71, was introduced in the House during the last Biennium, but did not move beyond the Committee level during the Session. The bill was co-introduced by 35 House members, reflecting wide interest in this topic. The bill proposed to create a drug repository program through which licensed facilities, wholesale drug distributors, and drug manufacturers could donate unused, unopened prescription drugs and medical supplies to pharmacies, hospitals and clinics. These entities would then dispense the donated items to low income people. The bill specifies that the repository would be established by the Board of Pharmacy. Although the program is voluntary, the entities which are the source of the drugs and supplies must either give "any unsold or unused prescription drugs and medical supplies that the facility or distributor cannot sell or other wise use," or submit a statement to the Board as to why the drugs or supplies will not be given. The bill would also extend liability protection to all organizations involved in the repository program for any tort or other civil action for injury, death, or loss to person or property. This model is also examined as part of this study.

Study Methodology

In conducting this study, five Vermont state agencies noted previously were contacted to determine whether they had done any work in the past that examined a drug repository or recycling program, and whether the agencies had a specific position on the topic. In addition, several other health care organizations in Vermont were contacted for input to this study. These included: The American Cancer Society; the Vermont Medical Society; the Vermont Association of Hospitals and Health Systems; the Vermont Home Health Assembly; the Vermont Health Care Association; and the Retail Pharmacists Association. All of these state agencies and organizations were also asked to review and comment on a draft of this report to insure that it appropriately reflected their thinking on the topic.

A review of existing state repository programs both regionally and nationally was also conducted, and the results of that inquiry are contained in this report. A key reference for this work was a summary of prescription drug reuse and recycling laws prepared by the National Conference of State Legislatures and dated June 27, 2006. Also, the results of a survey by the Association of State Boards of Pharmacy were used in this work.

To learn more about the specific repository program experience regionally, agencies in the five other New England states were contacted, and the results of those inquiries are reported here as well. Finally, this report examines the feasibility and cost components of three basic repository models. With this information in hand, the Department has framed recommendations for the Legislature's consideration.

Overview

Over the past few years, there appears to have been considerable interest nationally in establishing drug and medical supply repositories. A summary of Drug Reuse and Recycling laws published by the National Conference of State Legislatures in June 2006, notes that 33 states have enacted laws or rules for programs in this area. However, not all these programs are currently operational. A recent study of the issue by the Association of State Boards of Pharmacy yielded some further information on the status of programs. Of the 31 states that responded to a survey in February 2006, 11 indicated that their states "allow for drug repositories to exist or operate." Four states noted some program activity, although it was often quite limited. The remaining seven states are in various stages of program development, often awaiting rule making by the responsible state agency.

The public policy of these state laws varies significantly, with the laws focusing on a number of different goals, including:

Avoid drug diversion and misuse by collecting unused medications at the time of a patient's death.

- Reducing the amount of drugs being introduced directly into waste treatment systems.
- Relieving the cost of medications for the uninsured and underinsured.
- Reducing drug expenses for the state Medicaid programs by requiring pharmacies to accept returned drugs, and providing a credit to the purchaser or insurer.
- Offering some relief from the high cost of long-term drug regimes by providing recycled drugs to patients with chronic illnesses.

The state programs are usually voluntary in nature for all parties involved. Generally, the patient or family member, or the health care facility, may return the drugs to a pharmacy. In some states, drug manufacturers or wholesalers are also allowed to donate drugs. The pharmacies, for their part, may elect whether or not to participate. In virtually all cases, the success of the program, however, appears to hinge on the willingness of pharmacies to abide by the rules laid out for the return, storage, identification, and reuse of the donated medications.

In virtually every state, the standards for a drug to be accepted into the repository and reused are the same. The drugs must be:

- In sealed packages in original container, or individually wrapped in tamper-proof packaging.
- Clearly labeled with specifics about the medication, dose, and expiration date.
- Unexpired – with three to six months remaining before the manufacturer's expiration date.

In all states, pharmacists must identify that the donated drugs are appropriate for the repository, and dispense the drugs to eligible patients upon receipt of a written prescription by a medical practitioner. A nominal handling fee may be charged by the pharmacy, but the drugs themselves are free of charge. In some states, when a drug is returned a refund must be issued by the pharmacy to the patient or the insurance carrier. This requires the pharmacist to inventory returned medications, identify the original payment source, and refund the payer.

Generally, persons eligible for drugs from the repository are individuals without insurance for medications or those with high co-pays and other limited insurance coverage.

Responsibility for administration of the programs has been given to a range of state and regional agencies, including:

- Department of Health
- Department of Social Welfare
- State Board of Pharmacy
- County government
- Cabinet of Health and Family Services
- Department of Corrections
- Joint program of the Health Department and the Board of Pharmacy.

Details of New England States Programs

1. Connecticut. Since January 2001, skilled nursing facilities must return certain unused drugs to the vendor pharmacies for a credit to the CT Medical Assistance Program operated by the Department of Social Services. Fifty specific drugs are included in a list of items that must be returned for credit. Controlled substances are excluded from the program. The vendor pharmacy received a $5.00 fee for each drug returned, and may resell the drugs. No one was able to estimate the savings that the state receives from the program.

2. Maine. Maine has initiated a "first in the Country" program to encourage citizens to safely dispose of drugs at collection points around the state. The program is operated by the Department of Natural Resources, and is focused on removing harmful chemicals from the waste system. Only one collection has been held to date with very limited results. More collection events are planned for the coming year.

3. Massachusetts. In 2002, Massachusetts began work with a Task Force to Reduce Medication Waste. No final report is available on this work.

4. New Hampshire. This year, state law established an Unused Prescription Drug Program to be administered by the NH Board of Pharmacy. Under the program a patient, or authorized representative, may donate unused prescription drugs and medical devices to the program. Any person licensed to dispense drugs or medical devices may re-dispense these. Donations may be accepted by:

- A pharmacy
- A hospital, hospice, nursing home, outpatient centers
- State health care facilities or a prescriber of drugs.

The law establishes an allowable handling fee of $15.00. The drugs may be re-dispensed to uninsured or under-insured individuals as defined by the Board of Pharmacy or to other patients if no such person is available.

The law offers limited immunity to drug manufacturers for drugs that are returned and redistributed.

The legislature gave the Board of Pharmacy no additional funds to operate this program. At this point, therefore, the Board has not moved ahead with implementation. One hearing has been held regarding the rules for this program, and the Board will probably hold additional hearings next year.

5. Rhode Island. In July 2005, the "Utilization of Unused Pharmaceutical Medications Act" was enacted that allows nursing homes, assisted living centers and drug manufacturers to donate unused drugs to authorized participating pharmacies for redistribution to medically indigent state residents. The program is totally voluntary, and is currently operating as a statewide pilot program. No one was available at the Department of Health to provide details on the results of the program so far.

Consultation with Other Agencies

The Study directs the Department of Health to consult with five other agencies of State Government in preparing this report. The five agencies are: the Department of Public Safety; the Department of Aging and Independent Living; the Board of Pharmacy; the Board of Medical Practice; and, the Office of Vermont Health Access. Each of these agencies was queried regarding past efforts in their organizations that addressed the repository or drug recycling concepts. Generally speaking, little has been done by state agencies in Vermont. The Board of Pharmacy has had some discussion of the idea of maintaining a Repository, and concluded that it would not be a good idea. In particular, the Board was concerned about the safety of drugs that would be dispensed through such a program. If these drugs come from individuals and have been outside the control of the medical system, there is no way to insure that the drugs have been properly handled while in private hands. None of the other state agencies had done past work related to this topic.

A number of health care organizations were also contacted to determine if they had examined this topic, or had information that might be of help in this Study. The agencies contacted included: The Cancer Society; the Vermont Medical Society; the Vermont Health Care Association; the Vermont Association of Hospitals and Health Systems; and, the retail pharmacists association. None of these organizations had done specific work in this area, or had a specific position on the idea of developing a repository. All of these state agencies and organizations were also provided with a draft of this Study to review and comment on it.

It should be noted that the Board of Pharmacy did register concerns about its ability to manage any type of repository program, given its limited resources. It also noted that it is studying ways to insure that drugs received by pharmacies and hospitals through the drug distribution systems are what they purport to be. Apparently counterfeit and fraudulent drugs getting into the distribution system is a major problem nationally.

Barriers to Implementation

A number of barriers make the development and implementation of a repository program very challenging. First, pharmacies, whether retail operations or health care facility in-house operations, must be convinced that there are foolproof ways to determine if the returned drugs are safe. The pharmacies will also need to be convinced that participating in the program is a worthwhile effort on their parts, even though the program appears to offers them no benefits, and, in fact implementation is likely to increase their costs. Finally, pharmacists and pharmacies will be very concerned about any additional liability they might incur through participating in a recycling program.

While no specific Vermont law or rule was noted as a problem, laws and regulations regarding the dispensing of medications would need to be examined in detail to insure that they present no barriers to a repository program. However, while the flow of drugs from manufacturer to the patient may seem well controlled, there is growing concern in the US that the system of manufacturing and distributing drugs is quite vulnerable to the introduction of counterfeit drugs into the system. The Vermont Board of Pharmacy was asked by the Legislature in S.22 to examine the feasibility of having a drug pedigree system to track the distribution of all prescription drugs. The full report from the Board will be delivered to the Legislature shortly. It seems clear, however, that a drug pedigree system cannot be successfully initiated by any one state, and will require a national initiative

The concept of reintroducing drugs into a supply chain from private hands raises a number of public policy concerns that will need to be addressed. Safety and efficacy issues are numerous. For any returned drug, a pharmacist will need to verify the source of the drug, identify exactly what each pill is, determine whether it has expired, and whether it has been altered or tampered with. Ideally, the examination of each drug would also include an evaluation of how the medication was stored, and whether the drug has been compromised by such storage. The current single-dose, tamper-proof packaging may still be inadequate to satisfy the concerns of both the health professional and the public.

For health care facilities, recycling drugs could mean significant additional work. While facilities do work to control their costs of health care with the interest of the patient in mind, they will not be enthusiastic about participating in this program which will not directly impact their patients – or their costs – and may add additional costs to their operations. Finally, distributors, and drug manufacturers will have to be convinced to participate in the program. Most drug companies already have some type of drug donation program in place to supply free or reduced priced medications to patients for certain conditions. It must be assumed that they offer these programs, in part, because they see some economic benefit in doing so. Asking the manufacturers to shift their contributions to a state repository may alter the economic equation, making such donations less desirable.

In the same way, health care facilities, clinics, and pharmacies may be reluctant to reuse medication for patient safety reasons.

Perhaps the most significant barrier to the repository is the need to convince the public that "used" drugs are safe and efficacious. One of the major points raised during recent national debates about using drugs obtained from Canada or other foreign countries was that there is no FDA control over the quality of those drugs. The American public has been sensitized to the issue of drug quality, and a recycling program may be met with some public resistance. When it comes to American's personal health care, we want only the best. Does a patient with cancer or HIV really want to "take a chance" by using a recycled drug?

In the survey done by the Association of Boards of Pharmacy, several of these problems were highlighted in the states with active repositories. In Hawaii, there have been problems with storage, expirations dates, and integrity of donated drugs. Recordkeeping, legal liability, and the fee to be charged are also problematic.

In Ohio, there have been problems with establishing dispensing points as pharmacies are reluctant to participate. This is particularly true of long-term care facility pharmacies that have the potential of producing the majority of eligible drugs. In particular, although the law offers liability protection, the pharmacies are reluctant to participate because of the unknown liability of participating in the program.

Finally, in Wisconsin, there have been problems with the integrity of donated drugs. Tampering has been evident, and the questions around the storage of items needing refrigeration present a concern.

Financial Feasibility

The cost of a state-operated drug repository program will vary greatly depending on the policy decisions made by the legislature. The title language in S.22 identifies "Cancer Drugs", and the Study language lays out a set of program specifications that includes:

- Licensed health care facilities, wholesale drug distributors, and drug manufacturers would donate unused, unopened prescription drugs and medical supplies.
- Donations would go to pharmacies, hospitals and clinics to that would dispense the items.
- Donated drugs would be dispensed to persons who are income-eligible or uninsured.

Even in such a well-defined program, the costs could vary greatly. In one model, the program would be voluntary for all concerned. The responsible state agency might publicize the program and encouraging donations, but do very little by way of program operation and evaluation. Such an approach would have a negligible impact on the State budget.

By contrast, a fully developed program based on these program specifics could require substantial state resources. In such a program, the responsible agency would need to employ staff to actively pursue drug and supply donations, and enroll pharmacies, hospitals, and clinics in the program. Such an aggressive program would also include a Public Information campaign to increase the public's awareness of, and comfort in, the Repository program. The program staff would need to develop systems to receive and equitably distribute donations throughout the state. If the program maintained a central facility to receive, process, and redistribute donated items, significant additional expenses would be incurred. Finally, evaluation of the program would be critically important, including an analysis of both its clinical and its financial benefits.

A third program model is contained in H.711 that was introduced in the last session of the General Assembly. This bill would establish a Repository program operated by the Board of Pharmacy. As envisioned in the bill, each health care facility and wholesale drug distributor would give a participating pharmacy, hospital, or nonprofit clinic "any unsold or unused prescription drugs or medical supplies that the facility or distributor cannot sell or otherwise use." If such drugs or supplies are not donated, the facility or distributor would be required to submit to the Board "a statement as to why the distributor will not give the drug to the program." Participating in the program, however, is voluntary on the part of recipients.

Three forms would need to be completed as part of the dispensing process:

1. Each donor must sign a form acknowledging ownership of the drug or supply, and affirming it is a voluntary donation.

2. The individual receiving drugs or supplies from the repository must sign a form acknowledging that he/she understands the immunity provisions of the program.
3. An identification card system would need to be developed for persons eligible for participation in the program.

It does not appear that third model specifically envisions a central repository facility to receive and redistribute the drugs and supplies. However, there are additional costs associated with this model, especially in the administration of the paperwork necessary for the program noted in 1 through 3 above.

In addition to these direct costs, it must be recognized that donors, pharmacies, and recipients would incur some additional costs for such items as administration of the repository, maintenance of records, and filing reports necessary to evaluate the program. These costs might become substantial, particularly if the program operates with a "virtual repository", using pharmacies as the recipient and storage point for drugs and supplies. In this model, the receiving pharmacy would have to receive and verify that the donated drugs are correctly labeled, are unexpired, and are eligible for reuse. The pharmacy would most likely have to separately store the donated items, maintaining an inventory of how the drugs were received and dispensed.

While it may be possible to obtain some grant funds to develop the repository program, direct operating expenses for any of the options above would most likely need to come from state appropriations.

Findings and Recommendations

The Legislative Study language asked the Department to make findings and recommendations on the cost, benefits, and standards and procedures necessary to develop and implement a Repository program. As noted above, these findings are likely to vary greatly based on the type of program adopted. However, some overall findings in these categories are contained in the discussion below.

COST

Research on the operation of repository programs in other states found that the cost to the states ranged from zero to $400,000 in Ohio. In many states, the programs are voluntary in nature, with the state having minimal oversight of the program. None of the programs appear to directly produce revenue that might offset expenses of operating the program. In theory, a program that required the pharmacies to rebate the price of returned drugs to the insurer could produce some revenue. To the extent that such rebates accrue to the state's Medicaid program, there would be an indirect benefit to the state. In Vermont, the state supports about 60% of the Medicaid benefits paid. More likely, the cost savings of the repository would accrue to patients and/or the insurance company that initially paid for the pharmaceuticals.

BENEFITS

Background research for this Study was not able to identify any rigorous evaluation of the benefits of a Repository program since even those that are operational are fairly new. In general terms, a repository program has the potential to:

- Reduce the medication costs of patients with a serious illness.
- Reduce the medication costs of individuals who are uninsured or under-insured.
- Reduce drug expenditures for the Medicaid program.
- Reduce the diversion or misuse of unused pharmaceuticals.

Specific benefits flow from and will vary with the goals and objectives of the program adopted eventually adopted by the Legislature.

STANDARDS AND PROCEDURES NECESSARY TO DEVELOP AND IMPLEMENT A REPOSITORY PROGRAM.

In framing legislation in this area, a number of policy decisions must be made by the legislature before the full operational and financial results of a program can be assessed. These policy considerations include:

- Who may donate drugs - Health care facilities, drug manufacturers, wholesalers, individual patients or family members?
- Which types of drugs and supplies may be donated to the pharmacy?
- Will scheduled drugs be accepted?
- What condition must the donations be in to be accepted?
- If the donation comes from an individual, is it tax deductible?
- Does the insurer who paid for the drugs or supplies receive a rebate?

- Is the donation voluntary, or are certain "donors" required to participate?
- Will the state operate the Repository and accept and redistribute the donated drugs and supplies in a central location?
- If health facilities or pharmacies can accept donated items, is this done on a voluntary basis, or are they required to accept the items?
- Can the repository charge for the items. If a pharmacy reuses the items, can it charge a dispensing fee?
- Who is eligible to receive items from the Repository?
- Will drug manufacturers, health care providers and pharmacies that reuse drugs be provided with any immunity protection for an untoward event that occurs as the result of using the reused item?

RECOMMENDATIONS

Given the complexity of operating a program to receive, screen, distribute, and re-dispense drugs and medical supplies, the Department would urge the Legislature to proceed with extreme caution in the adoption of such a program. Of particular concern to the Department is the lack of any concrete information on the availability of drugs and medical supplies that would be available for distribution by a repository program. It was outside the scope of this study to examine this issue. However, developing a repository program assumes that drugs and supplies are available in sufficient quantities to make such a program worthwhile in Vermont. This assumption needs to be supported by solid estimates or specific numbers before any program proceeds.

There is virtually no experience from Repository Programs in other states on which the Department can draw solid conclusions. Generally speaking, states that have adopted such programs are proceeding cautiously with implementation. The Department believes that if the Legislature is interested in establishing a program at this time, it should be done in a quite limited and controlled manner. Ideally, the initial program would focus on a single class of drugs, perhaps related to a limited number of medical conditions. The initial program should also be voluntary for all parties involved. Finally, the Legislature must appropriate sufficient funds to allow the responsible agency of state government to do a complete job of implementing and evaluating the program as state government can no longer absorb state or federal unfunded mandates. Only after some experience has been gained in this new approach should the Legislature consider expansion of the program. Such an approach would produce a solid foundation for any expansion of the program, and would offer realistic expectations of program results for all concerned.

While not a specific part of this Study, the Department would note that there is increasing concern nationally about the disposal of unused drugs, particularly by individuals. In most cases, quantities of unused drugs are around for long periods, eventually being disposed of in the trash, or flushed into the sewer system. This uncontrolled disposal of drugs creates two problems. First, the unused drugs present an opportunity for diversion and misuse. Second, when disposed of, the drugs are polluting our water systems, mingling in our solid waste systems, and creating public health problems. A structured

drug disposal program such as the one recently established in Maine, may be worth considering for Vermont.