

**REPORT OF THE
VIRGINIA BOARD OF PHARMACY
DEPARTMENT OF HEALTH PROFESSIONS**

**Report on Development of an Unused
Pharmaceuticals Disposal Program**

**TO THE GOVERNOR AND
THE HOUSE APPROPRIATIONS COMMITTEE AND
THE SENATE FINANCE COMMITTEE
GENERAL ASSEMBLY OF VIRGINIA**



**COMMONWEALTH OF VIRGINIA
RICHMOND
2009**

Legislative Mandate

In the 2009 Session of the General Assembly, language was included in Appropriations Act requiring the Board of Pharmacy to work with the Secretary of Health and Human Resources and the Department of State Police to continue planning for the development of an unused pharmaceuticals disposal program to ensure the safe, effective, and proper disposal of unused pharmaceuticals. The Board was to work to identify any sources of state, federal, local or private funding which can be used to implement the program and to report to the House Appropriations and Senate Finance Committees by November 15, 2009.

Background

In response to House Bill 86 of the 2008 Session of the General Assembly and at the request of Delegate Steve Landes, representatives of the Virginia Department of Health Professions, Board of Pharmacy, State Police, and the Department of Environmental Quality formed a work group and met to discuss options for implementing a system for collection and disposal of unwanted pharmaceuticals. The ad hoc committee reviewed a comprehensive report produced following a study by a large stakeholder group in Oregon. The full report includes a listing of all the different types of current pilots and programs in the United States and one in British Columbia, issues and barriers to such programs, and cost estimates of the different types of programs.

The Oregon group put together four cost proposals based on available data for different types of programs. In the options the term "controlled drugs" is defined as DEA controlled substances (Schedule II-V). The term "non-controlled drugs" is defined as other non-DEA controlled substances (Schedule VI in Virginia). The United States Drug Enforcement Administration (DEA) does not allow consumers to further distribute controlled drugs that have been dispensed to them, to include return to a pharmacy or distribution to a disposal company. This federal prohibition on returns by consumers is a barrier to a lower cost, more consumer-friendly disposal program in which consumers could return unwanted drugs to participating pharmacies. The bolded costs are the anticipated costs of implementing the program in Oregon, which has only about 900 pharmacies compared to 1650 in Virginia, and about 5 million in population compared to approximately 7.6 million (2006).

Of the four options considered for take-back programs described below, the ad hoc workgroup found option #4 the preferable model because of the following reasons:

- 1) There would be less consumer confusion and inconvenience; and
- 2) There would be less opportunity for diversion as everything is mailed to the state police.

The four options for take-back programs were:

1. Drop boxes in participating pharmacies for non-controlled drugs and controlled drugs taken to local law enforcement.

Problems: pharmacy personnel having to take time to sort out the controlled drugs that cannot be accepted, consumers unwilling to take to two separate places, pharmacies would not want to participate.

Cost: \$803,403 Year 1, and \$658,403 annually thereafter

2. Secured drop boxes in participating pharmacies for non-controlled drugs, and controlled drugs mailed to law enforcement by the consumer in a pre-paid mailer provided by the pharmacist.

Problems: the pharmacist would have to take time to assist persons in determining if a drug was controlled and provide the mailer if there were controlled drugs; potential for diversion from the mailbox.

Benefit: less burden on the consumer.

Cost: \$1,150,806 Year 1, and \$825,806 annually thereafter

3. Secured drop boxes, similar to a mailbox, located outside of local law enforcement agencies. In this option, the local police are tasked with separating the controlled from non-controlled drugs, destroying the controlled as they would evidence, and sending the non-controlled to a private hazardous waste disposal company for destruction.

Problems: additional workload on local law enforcement too much to absorb, ability of law enforcement personnel to properly separate, possible diversion from the drop off boxes, discomfort of consumers in bringing medications to local law enforcement office.

Cost: \$1,467,565 Year 1, and \$1,322,566 annually thereafter

4. Mailers provided for consumers to mail all unwanted drugs to the state police. Pharmacies to stock pre-paid mailers. State police would separate the controlled drugs and destroy them as evidence and ship the non-controlled to a private hazardous waste vendor.

Problems: additional workload on state police too much to absorb, ability of state police personnel to properly separate.

Benefits: minimal pharmacy personnel time involved.

Costs: \$875,195 Year 1, and \$835,195 annually thereafter

For Option 3, drop boxes could be placed at area offices, but these offices are not always easily accessible to consumers, as some area offices serve multiple counties and could mean a significant drive. Additionally, the area offices are not manned at all times, are sometimes in remote locations, and VSP has experienced some problems with break-ins at these locations. There were significant concerns about theft of the drop boxes from these locations. The workgroup recommended Option 4 because the state police would not waste resources in trying to sort out controlled from non-controlled drugs, but would take everything to a solid waste incinerator for destruction.

Funding Recommendations

In the Oregon study, options for funding a take-back/drug disposal program were researched and outlined as follows:

- 1) Additional permit fees charged to disposal facilities and disposal fees charged on each ton of waste disposed of in municipal landfills, incinerators, energy recovery facilities and industrial landfills.
- 2) Pharmaceutical fees levied on retail drug outlets, manufacturers, and wholesalers licensed in the state.
- 3) State general fund, requiring an appropriation from the state legislature.
- 4) Surcharge on wastewater or drinking water utilities bills.
- 5) Per prescription fee on each prescription dispensed in the state, requiring a system to track all prescriptions sold and to collect the fees.
- 6) Product stewardship program with industry financing directly related to the manufacturers.

In British Columbia, unwanted and unused drugs are returned to participating pharmacies under a program funded by the Post Consumer Pharmaceutical Stewardship Association, an industry association; and the drugs are incinerated. However, in Canada there is no prohibition against consumers returning controlled drugs as there is in the United States. A product stewardship program for Oregon was recommended but opposed by the Pharmaceutical Research and Manufacturers of America (PhRMA). In PhRMA's response to the Oregon workgroup, it was noted that drug take-back programs are not cost-effective, are potential targets for drug diversion, and have a high potential for becoming costly programs for state and local communities.

S.B.598 was introduced in the 75th Oregon Legislative Assembly in February 2009; it would require a manufacturer of any drug sold in the state to operate a pharmaceutical take-back program approved by the state. The program would have to be operated at no cost to users and would have to accept all prescription and non-prescription drugs from consumers, residents of long-term care facilities and persons enrolled in hospice and home health programs. It would have to be convenient to rural and urban consumers and must dispose of drugs by incineration or hazardous waste disposal. The bill creates an advisory committee and specifies monetary penalties for non-compliance. The legislation currently remains in committee.

In Virginia, the options for funding a drug take-back and disposal program would be similar to those in Oregon: state or local taxes, surcharges on disposal facilities and services, surcharges on pharmaceutical outlets, fees on each prescription, an industry-funded program or a combination of any of the above.

National Activities and Legislation

In December, 2008, the Product Stewardship Institute convened a national workgroup in Washington, D.C. to focus on waste pharmaceuticals from households, long-term care facilities and other similar sources. Among the goals for the Institute's project were to develop and

implement a nationally coordinated system for the safe, practical, legal and environmentally protective management, collection, and disposal of waste pharmaceuticals. Any such system would have to be financially sustainable and not rely on the resources of state and local governments for on-going implementation. Among the participants in the workgroup, there was no agreement on the environmental and safety costs and benefits of in-home trash disposal vs. take-backs. There was also a lack of agreement on a recommended disposal method for unused pharmaceuticals. The pharmaceutical industry noted that the risks associated with trace amounts of pharmaceuticals measured in water are over-stated, estimating that 88% of pharmaceuticals reaching waterways have been excreted and only 12% come from drug disposal. The industry's position is that in-home garbage disposal (with ultimate disposal in incinerators or landfills) is a safe alternative to flushing and an equal choice to take-back programs. Industry-sponsored research found that, if all unused medicines were disposed of in landfills, less than 0.1% of the pharmaceutical compounds detected in the environment would be from landfill leachate – the other 99.9% would be attributable to human excretion.

To address this national issue, four bills have been introduced in the 111th Congress relating to the disposal of controlled substances. H.R. 1191 and S. 1336 are identical and cited as the "Safe Drug Disposal Act of 2009." H.R. 1359 and S. 1292 are identical and cited as the "Secure and Responsible Drug Disposal Act of 2009." The bills address barriers to safe disposal of controlled substances by ultimate users and care takers through state take-back disposal programs. All four bills have been referred to the respective Judiciary Committee of the House or the Senate.