

**VIRGINIA BOARD OF PHARMACY**

**MINUTES OF AD HOC COMMITTEE FOR DRUG DONATION PROGRAM AND DRUG DISPOSAL**

July 23, 2008  
Second Floor  
Board Room 1

Perimeter Center  
9960 Mayland Drive, Suite 300  
Richmond, Virginia 23233

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**CALL TO ORDER:** A working meeting of an ad hoc committee of the Board of Pharmacy for the purpose of drafting emergency regulations to establish a prescription drug donation program as required by 2008 House Bill 85 was called to order at 10am.

**PRESIDING:** David C. Kozera, Committee Chair

**MEMBERS PRESENT:** John Beckner  
Jennifer H. Edwards  
Timothy S. Musselman  
Keith Kittinger  
Rachel Cain  
Major Robert Tavenner, Virginia State Police joined the meeting at approximately 1PM for the discussion of a drug disposal program.

**MEMBERS ABSENT:** Brandon K. Yi

**STAFF PRESENT:** Elizabeth Scott Russell, Executive Director  
Caroline D. Juran, Deputy Executive Director  
Howard M. Casway, Senior Assistant Attorney General  
Elaine J. Yeatts, Senior Regulatory Analyst  
Sammy Johnson, Deputy Director of Enforcement

**REVIEW OF DRAFT REGULATIONS:** The ad hoc committee of the Board of Pharmacy for drafting regulations to establish the drug donation program met Wednesday, July 23 and completed work on draft regulations which will go to the Board on September 3 for adoption as emergency regulations. In summary the regulations allow any pharmacy to register as a drug donation site. Such sites will be able to collect donated drugs; re-dispense donated drugs to free-clinic patients themselves; or transfer the drugs to another site, such as a free clinic pharmacy, for re-dispensing.

**DISCUSSION OF POSSIBLE LEGISLATION NEEDED:** There were a couple of issues identified that may need to be corrected in statute. First, the Virginia Trial Lawyers Association feels that the provision in subsection D of §54.1-3411.1 giving immunity to pharmaceutical manufacturers is too broad. The organization is concerned that the immunity could extend beyond problems that occurred within the donation program itself, and does not want to have a law that would give manufacturers an argument against all product liability. The representative, Steve Pearson, requested that the Board include a paragraph in its regulations limiting the immunity. Mr. Casway agreed to further discuss this with Mr. Pearson and provide guidance to the Board in

September, but his initial advice was that the limitation needed to be in statute, not regulation. In either case, it is anticipated that the Virginia Trial Lawyers Association will be seeking a change in the statute next session.

The second issue is that the language in subsection C, which is not new language, expressly prohibits the donation of any drugs paid for by Medicare Part D or Medicaid. The primary source for donated drugs in any drug donation program will be from long term care facilities, and if the majority of these patients are Medicaid or Medicare Part D patients, then the donation program will not really get off the ground. CMS does not want drugs donated if the drugs can be returned to the pharmacy for re-sale, and a credit given. However, according to the two long term care pharmacists on the committee, there are many instances where drugs cannot be credited, and these are the drugs that they would like to be able to donate. Rachel Cain, DMAS representative to the committee had a directive from CMS related to drugs at "nursing facilities" not being able to be donated, and DMAS is suggesting that the phrase "in nursing facilities" be added to subsection C. However, this may not resolve the problem of an express prohibition in statute. Board counsel suggested that the wording in that paragraph could be re-written in the positive to say something to the effect that "Unused prescription drugs dispensed for use by persons eligible for coverage under Title XIX or Title XXI of the Social Security Act, as amended, may be donated unless such donation is prohibited." Ms. Cain was not able to advise at this time if this language would satisfy her department or CMS.

**DISCUSSION OF 2008  
HB86 AND  
ESTABLISHMENT OF A  
PROGRAM TO COLLECT  
AND DISPOSE OF  
UNWANTED DRUGS**

The ad hoc committee with representation of the state police began discussion of the issue of a drug disposal program. Delegate Landes, the patron of HB86 had asked that this bill be carried over until 2009 to provide the Virginia State Police and the Board of Pharmacy an opportunity to explore the different methods being used throughout the country and make a recommendation for Virginia. The ad hoc committee reviewed a comprehensive report put together following a study by a large stakeholder group in Oregon. The report includes a listing of 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 proposals based on available data for five different types of programs as follows. In the options, "controlled drugs" is defined as DEA controlled substances (Schedule II-V). "Non-controlled drugs" is defined as other non-DEA controlled substances (Schedule VI in Virginia). The fifth option which involves direct return to a reverse distributor is not currently available in the U.S., because of the prohibition of consumer return of controlled drugs.

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.

**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**

Of the four options, the ad hoc committee felt that there was less opportunity for consumer confusion and for diversion with Option 4 where everything is mailed to the state police. Major Tavenner stated that in Virginia, for Option 3, drop boxes could be placed at area offices, but that these offices were not always easily accessible to consumers. Some area offices serve multiple counties and could mean a significant drive for some people. 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. He had concerns about theft of the drop boxes from these locations.

It was decided that over the next couple of weeks, staff of the Department of Health Professions and the State Police will meet and put together a summary for Delegate Landes with recommendations for a program in Virginia and a cost estimate, based on the Oregon research, extrapolated as best possible to the population in Virginia. The Department of Environmental Quality (DEQ) will also be consulted as there are EPA and DEQ laws that such programs must take into account as well as federal DEA regulations that prohibit the return of Schedule II-V controlled substances to entities other than law enforcement personnel.

**ADJOURN:**

The meeting was adjourned at approximately 2:30PM.

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Elizabeth Scott Russell  
Executive Director

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David C. Kozera, Chairman

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Date