

**VIRGINIA BOARD OF PHARMACY  
MINUTES OF AD HOC COMMITTEE FOR DRUG DONATION PROGRAM**

June 17, 2008  
Second Floor  
Board Room 3

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  
Bill Hancock  
Keith Kittinger  
Rachel Cain

**MEMBERS ABSENT:** Brandon K. Yi

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

**DISCUSSION:** The committee was comprised of several members of the Board of Pharmacy, a representative of the Department of Medical Assistance Services (DMAS), a representative from the Virginia Pharmacists Association, and two pharmacists who work for pharmacies providing services to long term care facilities. There were also interested parties present representing several groups including associations that represent the different long term care facilities and the Virginia Trial Lawyers Association. Steve Pearson representing the Virginia Trial Lawyers Association spoke about his concerns that the language in the statute providing immunity from liability to pharmaceutical manufacturers was too broad and may encourage manufacturers to try to use it to avoid complete product liability, when he considered that the intention of the language was to prevent any additional liability for manufacturers just by virtue of the fact that someone may receive a drug that had been previously dispensed through such a program. He plans to seek legislative clarification, but wanted the Board to also interpret the statute in this manner in its emergency regulations.

There were two other concerns discussed by the committee that

may require legislation to fix. The first is that there is no immunity from liability for persons participating in the program. Second, the language excepting drugs paid for by Medicaid and Medicare was left in the statute. For such a program to be successful, this needs to be removed. Rachel Cain, DMAS, will check with her agency and determine if there can be amendments to the statute to allow donation of drugs paid for by Medicaid or Medicare when there is no possibility of return of the drugs for credit to either of those payors. Once DHP receives a response from DMAS, staff will draft a legislative proposal to take care of these two issues.

The committee reviewed Maryland's laws and regulations for its program as well as Ohio's. Ohio does not permit donations by consumers if the donated drug has ever been in the possession of the consumer, essentially limiting donated drugs to institutional settings. It was generally decided that for such a program in Virginia to work and not put the person accepting donated drugs in a position of being in violation of federal law by accepting Schedule II-V controlled substances, that collection sites for donated drugs should be restricted to permitted pharmacies. The collecting pharmacy would need to register with the Board, but no fee would be assessed for this registration. The registration would enable the Board to be able to publish a list of collection locations. The collecting pharmacy could directly dispense donated drugs to patients of free clinics or other clinics serving the indigent, or could transfer the collected drugs to another pharmacy in a free clinic or serving a free clinic. There would be requirements for recordkeeping for accountability purposes, and requirements for separate storage within the prescription department to ensure security and proper use of these collected drugs. While such program will allow for consumers to donate drugs, it was recognized by the committee that such donations will be severely limited due to safety concerns about drug integrity. Any donated drug will still have to meet packaging requirements as set forth in the statute, and the pharmacist screening the drug for acceptability will need to determine whether the integrity can be ensured. Staff will draft proposed regulations for the committee to review at its next meeting mid-July.

**ADJOURN:**

The meeting was adjourned at approximately 2:30PM.

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Elizabeth Scott Russell  
Executive Director

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Dave Kozera, Chairman

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Date