

**VIRGINIA BOARD OF PHARMACY  
MINUTES OF REGULATION COMMITTEE**

July 23, 2004  
Fifth Floor  
Board Room 4

Department of Health Professions  
6603 West Broad Street  
Richmond, Virginia 23230

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**CALL TO ORDER:** A meeting of the Regulation Committee of the Board of Pharmacy was called to order at 9:03 AM.

**PRESIDING:** Michael J. Ayotte, Committee Chairman

**MEMBERS  
PRESENT:** John Beckner  
Willie Brown  
Bobby Ison  
Leo Ross

**STAFF PRESENT:** Elizabeth Scott Russell, Executive Director  
Ralph A. Orr, Deputy Executive Director  
Elaine J. Yeatts, Senior Regulatory Analyst  
Howard M. Casway, Assistant Attorney General

**REVISION OF  
PHYSICIAN  
SELLING DRUGS  
REGULATIONS** The committee reviewed regulations 18 VAC 110-30-10 et seq and determined the regulations need updating largely to conform to other Board of Pharmacy regulations. Additionally, the committee discussed who may assist the physician and may develop a survey to determine current staffing for these licenses. Other regulations requiring closer scrutiny include definitions, inactive status, acts to be performed by the licensee, expired controlled substance storage and security, and the mechanisms for the disposal of controlled substances. Staff will develop draft language for review by the committee at its next meeting.

**DICUSS  
WHOLESALE  
DISTRIBUTOR  
REGULATIONS** The committee reviewed the Model Rules for the Licensure of Wholesale Distributors from the National Association of Boards of Pharmacy (NABP), as well as a draft from Pfizer, and HDMA recommendations. Mr. Ayotte suggested separating facility licensure requirements from pedigree requirements and working on regulations for facility licensure first. FDA is expected to require electronic pedigrees as early as 2006 but there are still many issues to resolve with the technology, including privacy issues and whether the technology affects the stability of the drug products. The committee will invite wholesale distributors and manufacturers to participate in developing language for these regulations. Staff will begin drafting a working document for the committee.

**DISCUSS  
REGULATIONS ON  
OUTSOURCING OF  
DATA ENTRY AND  
DUR BY HOSPITALS  
AND OTHER  
SETTINGS**

The committee reviewed rules from Texas, Nevada, and Florida. It was suggested that the committee also review proposed regulations from Pennsylvania and Tennessee and to separate requirements for data entry in hospitals from those of retail pharmacy operations. Four processes were identified to be addressed in regulation: the receipt of the order, the entry of the order, the filling of the order and the actual dispensing of the order. Staff will develop draft language for review by the committee at its next meeting.

**NEXT MEETING**

The next meeting date was tentatively set for August 24, 2004 immediately following a formal hearing. This meeting may need to be rescheduled.

**ADJOURN:**

The meeting was adjourned at 12:40 PM.

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Elizabeth Scott Russell, Executive Director

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Michael Ayotte, Chair

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Date