HOUSE BILL NO. 2352

Offered January 14, 2009 Prefiled January 14, 2009

A BILL to amend and reenact § 54.1-3411.1 of the Code of Virginia, relating to donation of prescription medication; liability of pharmaceutical manufacturers.

Patron—Landes

Referred to Committee on Health, Welfare and Institutions

Be it enacted by the General Assembly of Virginia:

1. That § 54.1-3411.1 of the Code of Virginia is amended and reenacted as follows:

§ 54.1-3411.1. Prohibition on returns, exchanges, or re-dispensing of drugs; exceptions.

- A. Drugs dispensed to persons pursuant to a prescription shall not be accepted for return or exchange for the purpose of re-dispensing by any pharmacist or pharmacy after such drugs have been removed from the pharmacy premises from which they were dispensed except:
- 1. In a hospital with an on-site hospital pharmacy wherein drugs may be returned to the pharmacy in accordance with practice standards;
- 2. In such cases where official compendium storage requirements are assured and the drugs are in manufacturers' original sealed containers or in sealed individual dose or unit dose packaging that meets official compendium class A or B container requirements, or better, and such return or exchange is consistent with federal law; or
 - 3. When a dispensed drug has not been out of the possession of a delivery agent of the pharmacy.
- B. (For contingent expiration see Editor's note) Pursuant to a voluntary agreement between a nursing home or a hospital and a pharmacy, drugs may be transferred in accordance with subdivision A 2 between the nursing home or the hospital and the pharmacy for re-dispensing to patients of clinics organized in whole or in part for the delivery of health care services without charge, or to the indigent, free of charge, if the following procedures are satisfied:
 - 1. The physical transfer shall be accomplished by a person authorized to do so by the pharmacy;
- 2. The person or his authorized representative from whom the prescription medication was obtained shall provide written consent for the donation and such consent shall be maintained on file at the licensed nursing home or hospital;
- 3. The person's name, prescription number, and any other patient identifying information, shall be obliterated from the packaging prior to removal from the licensed nursing home or hospital;
- 4. The drug name, strength, and expiration date or beyond-use date shall remain on the medication package label;
- 5. An inventory list of the drugs shall accompany the drugs being transferred that shall include, but not be limited to, the medication names, strengths, expiration dates, and quantities; and
- 6. Outdated drugs shall not be transferred and shall be destroyed in accordance with regulations adopted by the Board.

The pharmacist-in-charge at the pharmacy shall be responsible for determining the suitability of the product for re-dispensing. A re-dispensed prescription shall not be assigned an expiration date beyond the expiration date or beyond-use date on the label from the first dispensing and no product shall be re-dispensed more than one time. No product shall be accepted for re-dispensing by the pharmacist where integrity cannot be assured.

- B. (For contingent effective date see Editor's note) The Board of Pharmacy shall promulgate regulations to establish a Prescription Drug Donation Program for accepting unused previously dispensed prescription drugs that meet the criteria set forth in subdivision A2, for the purpose of re-dispensing such drugs to patients of clinics organized in whole or in part for the delivery of health care services to the indigent. Such program shall not authorize the donation of Schedule II-V controlled substances if so prohibited by federal law. No drugs shall be re-dispensed unless the integrity of the drug can be assured.
- C. Nothing in this section shall authorize the donation of unused 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 pursuant to this section unless such donation is prohibited.
- D. A pharmaceutical manufacturer shall not be liable for any claim or injury arising from the transfer of any prescription or any consumer information regarding the transferred prescription medication pursuant to this section. Nothing in this section shall be construed to create any new or additional liability, or to abrogate any liability that may exist, applicable to a pharmaceutical manufacturer for the storage, donation, acceptance, or dispensing of any drug in accordance with this section.

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