

Virginia Board of Pharmacy

Re-dispensing Drugs Previously Dispensed in Compliance Packaging

Subsection A, 2 of 54.1-3411.1 of the *Code of Virginia* states:

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:

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;

The board interprets “sealed individual dose” to include drugs packaged in compliance packaging, e.g., bingo cards, when the following conditions are met:

- the compliance packaging meets official compendium class A or B container requirements, or better;
- only one drug is contained in the sealed dose; and,
- an appropriately assigned expiration date for the package is known.

Drug may only be re-dispensed when official compendium storage requirements are assured. Drug removed from a sealed individual dose may not be returned to a manufacturer stock bottle. Drug that has exceeded its expiration date or in packaging that was not assigned an expiration date at the time of the original dispensing may not be re-dispensed. Sealed doses containing more than one type of drug may not be re-dispensed. Drugs in Schedule II-V may not be returned to a pharmacy for re-dispensing unless authorized under federal law.

Drug removed from the sealed individual dose for re-dispensing may be repackaged in accordance with §54.1-3411.1. When repackaging in advance of dispensing the drug, the repackaging records required in Regulation 18VAC110-20-355 should include the original lot number from which the drug was first dispensed or if unknown, the originally assigned prescription number; the assigned expiration date may not exceed the originally assigned expiration date when first dispensed.

Reference from Code of Virginia:

§ 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 indigent patients, either through hospitals, or through 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 indigent patients, either through hospitals, or through 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. 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 storage, donation, acceptance, transfer, or dispensing of any drug provided to a patient, or any other activity undertaken in accordance with a drug distribution program established pursuant to this section.

E. 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 its products separately from the storage, donation, acceptance, transfer, or dispensing of any drug provided to a patient in accordance with a drug distribution program established pursuant to this section.