Guidance document: 110-46 Adopted: December 11, 2017

Board of Pharmacy

Delivery of Dispensed Drugs

Pursuant to § 314.170 of the Code of Federal Regulations, "All drugs, including those the Food and Drug Administration approves under section 505 of the act and this part, are subject to the adulteration and misbranding provisions in sections 501, 502, and 503 of the act." § 54.1.3457 of the Code of Virginia prohibits the delivery of any drug that is adulterated and § 54.1.3461 describes an adulterated drug as one that "purports to be or is represented as a drug the name of which is recognized in an official compendium." Thus, there is a legal expectation that all pharmacies, both resident and nonresident, must deliver drugs in a manner that ensures appropriate temperature ranges or else they may be in violation of possibly delivering an adulterated drug. In addition to guidance provided by the United States Pharmacopeia on temperature storage requirements and excursions, the Board provides the following guidelines:

During delivery of a dispensed drug to a patient at a location other than the pharmacy, the pharmacist shall ensure that the drug is packaged in a manner that maintains appropriate storage temperature requirements, in accordance with the manufacturer's recommendations. The packaging may include the use of a temperature monitoring device, particularly for drugs that are temperature-sensitive. If cold packs are used in the packaging materials, the pharmacist shall ensure that the cold packs are placed appropriately in the container to avoid freezing and to ensure the appropriate temperature range is maintained during delivery.

A pharmacist who delivers a prescription drug order by mail, common carrier, or delivery service, when the drug order is not personally hand delivered directly, to the patient or his agent at the person's residence or other designated location shall also comply with the requirements of § 54.1-3420.2.

Code of Virginia:

§ 54.1-3420.2. Delivery of prescription drug order.

- A. Whenever any pharmacy permitted to operate in this Commonwealth or nonresident pharmacy registered to conduct business in the Commonwealth delivers a prescription drug order by mail, common carrier, or delivery service, when the drug order is not personally hand delivered directly, to the patient or his agent at the person's residence or other designated location, the following conditions shall be required:
- 1. Written notice shall be placed in each shipment alerting the consumer that under certain circumstances chemical degradation of drugs may occur; and
- 2. Written notice shall be placed in each shipment providing a toll-free or local consumer access telephone number which is designed to respond to consumer questions pertaining to chemical degradation of drugs.