# Rules of Department of Commerce and Insurance

## Division 2220—State Board of Pharmacy

### Chapter 3—Negative Generic Drug Formulary

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20 CSR 2220-3.010 Generic Drug Formulary


20 CSR 2220-3.011 Generic Drug Substitution

PURPOSE: The purpose of this rule is to establish requirements for generic drug substitution.

20 CSR 2220-3.040 Return and Reuse of Drugs and Devices

PURPOSE: This rule sets guidelines for the return and reuse of drugs and devices.

(1) Pharmacists and pharmacies shall not accept from patients or their agents for reuse or resale any drugs, prescribed medications, chemicals, poisons, or medical devices unless otherwise provided for in this regulation.

(2) A pharmacist or pharmacy may receive and reuse drugs from long-term care facilities, hospitals, and hospice facilities (as regulated by the Department of Health and Senior Services, in 19 CSR 30-35.020 Hospices Providing Direct Care in a Hospice Facility), provided that the following conditions are met:

(A) The pharmacist has assurance from a person in responsible charge of the drugs at a facility delineated in this section that the drugs being returned have been stored in accordance with the manufacturer’s recommendations and meet U.S.P. standards;

(B) The drugs were originally dispensed by the pharmacist or pharmacy to the facility delineated in section (2);

(C) There is an established mechanism to trace the expiration date and the manufacturer’s lot number of the drugs being returned;

(D) Only drug products dispensed by a licensed pharmacy utilizing one (1) of the following sources may be reused and no drug products for reuse shall be in any way subject to further repackaging:

1. Drug products in the original manufacturer’s packaging that remains sealed in tamper-evident packaging;

2. Drug products repackaged by facilities that are federally registered as a repackager of medications and the packaging remains sealed in tamper-evident packaging;
3. Drug products that have been repackaged by a licensed pharmacy and are returned unused by the facility and remain sealed in tamper-evident packaging;

4. Drug products that have been repackaged by a licensed pharmacy and are provided in unit of use packaging whereby unused portions can be separated and reused without any further repackaging processes necessary on the returned product; and

(E) Any products that are accepted for return and can be reused based on standards provided in this rule shall be re-labeled to provide accurate information concerning patient and prescription information. Original lot numbers, expiration or beyond-use dates assigned to a product that is reused by a pharmacy shall not be altered or in any way updated.

(3) Pharmacists and pharmacies may return to stock prescriptions that have not been received by or delivered to the patient and shall delete the dispensing from the pharmacy’s records and reverse the claim with the third party payor, if applicable. In order for a product to be returned to stock, it must have been stored at all times at the manufacturer’s labeled storage requirements.

(A) Except as otherwise authorized by subsection (3)(B), all drugs returned to stock that are not in the original manufacturer container must be maintained in the patient container with the dispensing date, prescription number, and name of drug visible. The expiration date of the drug shall become the lesser of one (1) year from the dispensing date on the label or the manufacturer’s original expiration date, if known.

(B) Return-to-stock medication may be returned to an automated filling system unit, cell, or cartridge containing the same medication, if—

1. The prescription/medication order is returned to the automated filling system that originally dispensed it;
2. A pharmacist verifies the return-to-stock drug is properly stocked and loaded in the automated filling system;
3. The expiration date for all drugs in the unit, cell, or cartridge where medication is returned must become the shortest expiration of any drug contained in the same unit, cell, or cartridge, including, any return-to-stock medication; and
4. Drugs from different manufacturers may not be commingled in the same unit, cell, or cartridge.
