Rules of
Department of Commerce and Insurance
Division 2220—State Board of Pharmacy
Chapter 3—Negative Generic Drug Formulary

Title 20—DEPARTMENT OF COMMERCE AND INSURANCE

Division 2220—State Board of Pharmacy

Chapter 3—Negative Generic Drug Formulary

20 CSR 2220-3.010 Generic Drug Formulary

This rule originally filed as 4 CSR 220-3.010. Emergency rule filed Dec. 28, 1978, effective Jan. 7, 1979, expired April 30, 1979. Moved to 20 CSR 2220-3.010, effective Aug. 28, 2006.

20 CSR 2220-3.011 Generic Drug Substitution

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

PUBLISHER'S NOTE: The secretary of state has determined that the publication of the entire text of the material which is incorporated by reference as a portion of this rule would be unduly cumbersome or expensive. This material as incorporated by reference in this rule shall be maintained by the agency at its headquarters and shall be made available to the public for inspection and copying at no more than the actual cost of reproduction. This note applies only to the reference material. The entire text of the rule is printed here.

(1) Except as otherwise provided by Chapter 338, RSMo, a pharmacist who receives a prescription for a brand name drug or biological product may select a less expensive generically equivalent or interchangeable biological product unless the patient requests a brand named drug or biological product or the prescribing practitioner indicates that substitution is prohibited or displays "brand medically necessary", "dispense as written", "do not substitute", "DAW", or words of similar import on the prescription.

(2) All pharmacists and dispensing physicians should be warned that any drug product not holding an approved New Drug Application or Abbreviated New Drug Application may not be used as a substitute in the state of Missouri without the dispenser assuming some personal liability.

(3) A pharmacist shall not substitute drug products that are rated as therapeutically inequivalent to other pharmaceutically equivalent products as listed in the latest edition or cumulative supplement of *The Approved Drug Products with Therapeutic Equivalence Evaluations* published by the United States Government, Department of Health and Human Services.

AUTHORITY: section 338.280, RSMo 2016, and section 338.140, RSMo Supp. 2019. This rule originally filed as 4 CSR 220-3.011. Emergency rule filed April 26, 1979, effective May 6, 1979, expired Aug. 12, 1979. Original rule filed April 26, 1979, effective Aug. 13, 1979. Emergency amendment filed April 14, 1982, effective April 24, 1982, expired Aug. 22, 1982. Amended: Filed April 14, 1982, effective July 11, 1982. Emergency amendment filed June 14, 1982, effective July 15, 1982, expired Oct. 12, 1982. Amended: Filed June 14, 1982, effective Sept. 11, 1982. Emergency amendment filed Dec. 6, 1982, effective Jan. 1, 1983, expired March 10, 1983. Amended: Filed Dec. 6, 1982, effective March 11, 1983. Emergency amendment filed June 14, 1983, effective July 15, 1983, expired Sept. 15, 1983. Amended: Filed June 14, 1983, effective Sept. 11, 1983. Emergency amendment filed Dec. 12, 1983, effective Jan. 1, 1984, expired March 14, 1984. Amended: Filed Dec. 12, 1983, effective May 11, 1984. Emergency amendment filed Feb. 3, 1984, effective Feb. 13, 1984, expired June 12, 1984. Emergency amendment filed June 20, 1984, effective June 30, 1984, expired Oct. 28, 1984. Amended: Filed July 9, 1984, effective Oct. 11, 1984. Emergency amendment filed Dec. 10, 1984, effective Dec. 20, 1984, expired April 19, 1985. Amended: Filed Dec. 11, 1984, effective March 11, 1985. Emergency amendment filed Jan. 18, 1985, effective Jan. 28, 1985, expired May 28, 1985. Emergency amendment filed June 14, 1985, effective June 24, 1985, expired Oct. 12, 1985. Amended: Filed June 14, 1985, effective Sept. 27, 1985. Emergency amendment filed Dec. 23, 1985, effective Jan. 2, 1986, expired June 2, 1986. Amended: Filed Dec. 23, 1985, effective May 11, 1986. Emergency amendment filed June 21, 1986, effective July 1, 1986, expired Oct. 28, 1986. Amended: Filed June 23, 1986, effective Sept. 26, 1986. Emergency amendment filed Dec. 10, 1986, effective Dec. 20, 1986, expired April 19, 1987. Amended: Filed Dec. 10, 1986, effective April 11, 1987. Emergency amendment filed July 5, 1987, effective July 20, 1987, expired Nov. 17, 1987. Amended: Filed July 7, 1987, effective Oct. 25, 1987. Emergency amendment filed Jan. 19, 1988, effective Feb. 1, 1988, expired May 30, 1988. Amended: Filed Jan. 19, 1988, effective April 28, 1988. Amended: Filed April 15, 1988, effective Jan. 1, 1989. Emergency amendment filed July 5, 1988, effective July 15, 1988, expired Nov. 12, 1988. Amended: Filed July 5, 1988, effective Nov. 11, 1988. Emergency amendment filed Jan. 19, 1989, effective Feb. 10, 1989, expired May 19, 1989. Amended: Filed Jan. 19, 1989, effective May 11, 1989. Amended: Filed March 31, 1989, effective Sept. 1, 1989. Amended: Filed Aug. 25, 1995, effective April 30, 1996. Moved to 20 CSR 2220-3.011, effective Aug. 28, 2006. Amended: Filed April 15, 2019, effective Nov. 30, 2019. ***

**Original authority: 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011, 2019 and 338.280, RSMo 1951, amended 1971, 1981.*

***Pursuant to Executive Order 21-09, 20 CSR 2220-3.011, section (3) was suspended from April 16, 2020 through December 31, 2021.*

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.

AUTHORITY: section 338.280, RSMo 2016. This rule originally filed as 4 CSR 220-3.040. Original rule filed Dec. 12, 1983, effective May 11, 1984. Amended: Filed July 5, 1988, effective Nov. 11, 1988. Amended: Filed Sept. 2, 1997, effective April 30, 1998. Amended: Filed April 5, 2002, effective Nov. 30, 2002. Amended: Filed May 17, 2004, effective Dec. 30, 2004. Moved to 20 CSR 2220-3.040, effective Aug. 28, 2006. Amended: Filed Feb. 6, 2008, effective Aug. 30, 2008. Amended: Filed May 13, 2020, effective Nov. 30, 2020.*

**Original authority: 338.280, RSMo 1951, amended 1971, 1981.*