

REVISED Meeting Notice
Missouri Board of Pharmacy
Conference Call

July 29, 2016 11:30 a.m.
Missouri Division of Professional Registration
3605 Missouri Blvd
Jefferson City, MO 65109

Except to the extent disclosure is otherwise required by law, the Missouri Board of Pharmacy is authorized to close meetings, records and votes pursuant to Section 610.021(1).

The Board may go into closed session at any time during the meeting pursuant to § 610.021(1) for purposes of legal advice. If the meeting is closed, the appropriate section will be announced to the public with the motion and vote recorded in open session minutes.

If any member of the public wishes to attend the conference call, s/he should be present at the Division of Professional Registration, 3605 Missouri Blvd, Jefferson City, Missouri, at 11:30 a.m. on July 29, 2016. Notification of special needs as addressed by the Americans with Disabilities Act should be forwarded to the Missouri Board of Pharmacy, P O Box 625, 3605 Missouri Blvd., Jefferson City, Missouri 65102, or by calling (573) 751-0091 to ensure available accommodations. The text telephone for the hearing impaired is (800) 735-2966.

Please see the attached tentative agenda for this meeting.

TENTATIVE AGENDA
July 29, 2016 11:30 a.m.
Missouri Board of Pharmacy
Conference Call

Missouri Division of Professional Registration
3605 Missouri Boulevard
Jefferson City, MO 65102

- 1 Call to Order
- 2 Roll Call
- 3 2017 legislation
 - a. Civil Penalties
 - b. Fund Proposal
 - c. Pharmacist CE
 - d. Third-Party Logistics Providers
 - e. Prescription format Requirements
 - f. New Decision Items
- 4 Future topics/meeting dates
- 5 The Board may go into closed session at any point during the meeting and all votes, to the extent permitted by law, pertaining to and/or resulting from this closed meeting will be closed under Section 610.021(1), (5), (7), and (14) and under Section 324.001.8, RSMo. The Board will return to open session at the conclusion of discussion of closed session items.
- 6 Adjournment

Missouri Revised Statutes

Chapter 338

Pharmacists and Pharmacies

Equipment required--manner of operation of pharmacy--compliance with state and federal laws required.

338.250. **1.** No pharmacy shall be licensed under the provisions of this chapter unless it is equipped with proper pharmaceutical equipment and reference manuals, so that the practice of pharmacy may be accurately and properly performed. The board shall prescribe the minimum of technical equipment which the pharmacy shall at all times possess. Such requirements may vary, depending upon the population served, but shall be consistently and uniformly enforced. No permit shall be issued or renewed for the operation of a pharmacy unless the pharmacy shall be operated in a manner and according to the rules and regulations prescribed by law and by the Missouri board of pharmacy with respect to obtaining and maintaining such a permit. Any pharmacy that receives or possesses drugs or devices shall be held responsible for compliance with all laws within this chapter as well as state and federal drug laws on all drugs received or possessed, including but not limited to drugs and devices received or possessed pursuant to a consignment arrangement.

2. The Board may issue a temporary charitable pharmacy permit to a Missouri licensed pharmacy or pharmacist to operate a charitable pharmacy at a specified location, provided a temporary charitable permit shall not be issued for more than a seven (7) day period and may not be renewed or reissued more than twice per calendar year.

(L. 1951 p. 734 § 6, A.L. 1990 H.B. 1287, A.L. 1998 S.B. 940)

CIVIL PENALTIES

338.055. 1. The board may refuse to issue any certificate of registration or authority, permit or license required pursuant to this chapter for one or any combination of causes stated in subsection 2 of this section or if the designated pharmacist-in-charge, manager-in-charge, or any officer, owner, manager, or controlling shareholder of the applicant has committed any act or practice in subsection 2 of this section. The board shall notify the applicant in writing of the reasons for the refusal and shall advise the applicant of his or her right to file a complaint with the administrative hearing commission as provided by chapter 621.

2. The board may cause a complaint to be filed with the administrative hearing commission as provided by chapter 621 against any holder of any certificate of registration or authority, permit or license required by this chapter or any person who has failed to renew or has surrendered his or her certificate of registration or authority, permit or license for any one or any combination of the following causes:

(1) Use of any controlled substance, as defined in chapter 195, or alcoholic beverage to an extent that such use impairs a person's ability to perform the work of any profession licensed or regulated by this chapter;

(2) The person has been finally adjudicated and found guilty, or entered a plea of guilty or nolo contendere, in a criminal prosecution under the laws of any state or of the United States, for any offense reasonably related to the qualifications, functions or duties of any profession licensed or regulated under this chapter, for any offense an essential element of which is fraud, dishonesty or an act of violence, or for any offense involving moral turpitude, whether or not sentence is imposed;

(3) Use of fraud, deception, misrepresentation or bribery in securing any certificate of registration or authority, permit or license issued pursuant to this chapter or in obtaining permission to take any examination given or required pursuant to this chapter;

(4) Obtaining or attempting to obtain any fee, charge, tuition or other compensation by fraud, deception or misrepresentation;

(5) Incompetence, misconduct, gross negligence, fraud, misrepresentation or dishonesty in the performance of the functions or duties of any profession licensed or regulated by this chapter;

(6) Violation of, or assisting or enabling any person to violate, any provision of this chapter, or of any lawful rule or regulation adopted pursuant to this chapter;

(7) Impersonation of any person holding a certificate of registration or authority, permit or license or allowing any person to use his or her certificate of registration or authority, permit, license, or diploma from any school;

(8) Denial of licensure to an applicant or disciplinary action against an applicant or the holder of a license or other right to practice any profession regulated by this chapter granted by another state, territory, federal agency, or country whether or not voluntarily agreed to by the licensee or applicant, including, but not limited to, surrender of the license upon grounds for which denial or discipline is authorized in this state;

(9) A person is finally adjudged incapacitated by a court of competent jurisdiction;

(10) Assisting or enabling any person to practice or offer to practice any profession licensed or regulated by this chapter who is not registered and currently eligible to practice under this chapter;

(11) Issuance of a certificate of registration or authority, permit or license based upon a material mistake of fact;

(12) Failure to display a valid certificate or license if so required by this chapter or any rule promulgated hereunder;

(13) Violation of any professional trust or confidence;

(14) Use of any advertisement or solicitation which is false, misleading or deceptive to the general public or persons to whom the advertisement or solicitation is primarily directed;

(15) Violation of the drug laws or rules and regulations of this state, any other state or the federal government;

(16) The intentional act of substituting or otherwise changing the content, formula or brand of any drug prescribed by written or oral prescription without prior written or oral approval from the prescriber for the respective change in each prescription; provided, however, that nothing contained herein shall prohibit a pharmacist from substituting or changing the brand of any drug as provided under section [338.056](#), and any such substituting or changing of the brand of any drug as provided for in section [338.056](#) shall not be deemed unprofessional or dishonorable conduct unless a violation of section [338.056](#) occurs;

(17) Personal use or consumption of any controlled substance unless it is prescribed, dispensed, or administered by a health care provider who is authorized by law to do so.

3. After the filing of such complaint, the proceedings shall be conducted in accordance with the provisions of chapter 621. Upon a finding by the administrative hearing commission that the grounds, provided in subsection 2 of this section, for disciplinary action are met, the board may, singly or in combination, assess an administrative civil penalty, require satisfactory completion of a continuing professional education program as the board may specify, censure or place the person named in the complaint on probation on such terms and conditions as the board deems appropriate for a period not to exceed five years, or may suspend, for a period not to exceed three years, or revoke the license, certificate, or permit. The board may impose additional discipline on a licensee, registrant, or permittee found to have violated any disciplinary terms previously imposed under this section or by agreement. The additional discipline may include, singly or in combination, an administrative civil penalty, require satisfactory completion of a continuing professional education program, censure, placing the licensee, registrant, or permittee named in the complaint on additional probation on such terms and conditions as the board deems appropriate, which additional probation shall not exceed five years, or suspension for a period not to exceed three years, or revocation of the license, certificate, or permit.

4. If the board concludes that a licensee or registrant has committed an act or is engaging in a course of conduct which would be grounds for disciplinary action which constitutes a clear and present danger to the public health and safety, the board may file a complaint before the administrative hearing commission requesting an expedited hearing and specifying the activities which give rise to the danger and the nature of the proposed restriction or suspension of the licensee's or registrant's license. Within fifteen days after service of the complaint on the licensee or registrant, the administrative hearing commission shall conduct a preliminary hearing to determine whether the alleged activities of the licensee or registrant appear to constitute a clear and present danger to the public health and safety which justify that the licensee's or registrant's license or registration be immediately restricted or suspended. The burden of proving that the actions of a licensee or registrant constitute a clear and present danger to the public health and safety shall be upon the state board of pharmacy. The administrative hearing commission shall issue its decision immediately after the hearing and shall either grant to the board the authority to suspend or restrict the license or dismiss the action.

5. If the administrative hearing commission grants temporary authority to the board to restrict or suspend the licensee's or registrant's license, such temporary authority of the board shall become final authority if there is no request by the licensee or registrant for a full hearing within thirty days of the preliminary hearing. The administrative hearing commission shall, if requested by the licensee or registrant named in the complaint, set a date to hold a full hearing under the provisions of chapter 621 regarding the activities alleged in the initial complaint filed by the board.

6. If the administrative hearing commission dismisses the action filed by the board pursuant to subsection 4 of this section, such dismissal shall not bar the board from initiating a subsequent action on the same grounds.

7. Any civil penalty imposed by the board under subsection 3 of this section shall not exceed two thousand five hundred dollars for each offense. Each day of a continued violation constitutes a separate offense, with a maximum penalty of twenty-five thousand dollars. In determining the amount of penalty to be imposed, the Board may consider any of the following:

- (1) Whether the amount imposed will be a substantial deterrent to the violation;
- (2) The circumstances leading to the violation;
- (3) The severity of the violation and the risk of harm to the public;
- (4) The economic benefits gained by the violator as a result of noncompliance; and
- (5) The interest of the public.

8. Any disciplinary order imposing a civil penalty is subject to judicial review upon the filing of a petition under section 536.100 by any person subject to the penalty.

9. Failure to pay a civil penalty shall be grounds for denying, disciplining or refusing to renew or reinstate a license, registration or permit. If the penalty is not timely paid, the board may notify the attorney general. The attorney general may commence an action to recover the amount of the penalty, including reasonable attorney fees and costs. In such action, the validity and appropriateness of the final order imposing the civil penalty shall not be subject to review.

10. Penalties collected under this section shall be handled in accordance with Section 7 of Article IX of the Missouri Constitution. Such penalties shall not be considered a charitable contribution for tax purposes.

BOARD FUND PROPOSAL

338.700.1. As used in sections 338.700 to 338.710, the following terms shall mean:

- (1) “Board”- the Missouri board of pharmacy;
- (2) “Department”- the Missouri department of health and senior services, and;
- (3) “Program”- the Rx Cares for Missouri Program.

338.710.1. There is hereby created in the Missouri board of pharmacy the “Rx Cares for Missouri Program”. The goal of the program shall be to promote medication safety and to prevent prescription drug abuse, misuse and diversion in Missouri.

2. The board of pharmacy, in consultation with the Missouri department of health and senior services, shall be authorized to expend, allocate or award funds appropriated to the board to develop or provide programs or education to promote medication safety or to suppress or prevent prescription drug abuse, misuse and diversion in the state of Missouri. Funds disbursed to a state agency under this section may enhance, but shall not supplant, funds otherwise appropriated to such state agency.

3. The board shall be the administrative agency responsible for implementing the program in consultation with the department. The board of pharmacy and the department of health and senior services may enter into interagency agreements between themselves to allow the department to assist in the management or operation of the program. The board may award funds directly to the department to implement, manage, develop or provide programs or education pursuant to the program.

4. After a full year of program operation, the board shall prepare and submit an evaluation report to the Governor and the general assembly describing the operation of the program and the funds allocated. Unless otherwise authorized by the general assembly, the program shall sunset on August 28, 20120.

5. Any rule or portion of a rule, as that term is defined in section [536.010](#), that is created under the authority delegated in this section shall become effective only if it complies with and is subject to all of the provisions of chapter 536 and, if applicable, section [536.028](#). This section and chapter 536 are nonseverable and if any of the powers vested with the general assembly pursuant to chapter 536 to review, to delay the effective date, or to disapprove and annul a rule

- 1 are subsequently held unconstitutional, then the grant of rulemaking authority and any rule
- 2 proposed or adopted after August 28, 2017, shall be invalid and void.

CONTINUING EDUCATION

Renewal of license or permit--late renewal or failure to renew, effect--continuing education requirements--inactive license issued when--changed to active, procedure.

338.060. 1. Every licensed pharmacist or permit holder who desires to continue in the practice of this profession shall ~~, within thirty days before the license expiration date,~~ file an application for the renewal before the license expiration date, which application shall be accompanied by the fee prescribed in sections 338.010 to 338.198.

2. If any pharmacist fails, after the expiration of the pharmacist's license, to make application to the board for its renewal, the pharmacist's name shall be removed from the register of licensed pharmacists, and such person, in order to again become registered as a licensed pharmacist, shall be required to pay all delinquent fees. Any pharmacist who fails to renew the pharmacist's license within two years of its expiration and then desires to be preregistered shall be treated in the same manner as a person who has never been licensed. Any registered pharmacist whose certificate of registration has expired while the pharmacist has been engaged in active duty with the United States Army, United States Navy, United States Air Force, the Marine Corps, Coast Guard, or any other branch of the armed services or the state militia called into the service or training of the United States of America, or in training or education under the supervision of the United States preliminary to induction into the military services may have the pharmacist's certificate of registration renewed without paying any lapse, renewal or registration fee or without passing any examination, if within one year after the termination of such service, training or education, other than by dishonorable discharge, the pharmacist furnishes the board with an affidavit to the effect that the pharmacist has been so engaged and that the pharmacist's service, training or education has terminated.

3. Except as provided in subsection 5 of this section, when applying for a renewal of the license as required by the provisions of this section, each licensed pharmacist shall submit proof of the completion of at least ~~fifteen~~ thirty hours of board-approved continuing education courses during ~~each twelve-month~~ the biennial renewal period immediately preceding the date of the application for renewal of the license. The board shall prescribe the form to be completed. No

license shall be renewed unless the holder thereof has complied with the provisions of this subsection.

4. The proof of completion of such continuing education shall be in such form as the board may require. The approved courses shall include those offered by correspondence, but the board shall approve all courses of instruction which may be used to satisfy the education requirements of subsection 3 of this section.

5. Each licensed pharmacist may, instead of submitting proof of the completion of the required continuing education courses, apply for an inactive license at the time the pharmacist makes application for the renewal of the pharmacist's license and pay the required renewal fee. An inactive license shall then be issued, and may be renewed biennially. While the inactive license is in effect the pharmacist shall not practice pharmacy. The inactive license may be changed to a regular license without other examination whenever the pharmacist submits proof of the completion of the total number of continuing education courses ~~for the total amount of such courses not completed~~ required for each biennial renewal period since the pharmacist was last licensed on an active basis.

(RSMo 1939 § 10009, A.L. 1943 p. 521, A.L. 1947 V. I p. 277, A. 1949 H.B. 2075, A.L. 1951 p. 737, A.L. 1981 S.B. 16, A.L. 1984 S.B. 478, A.L. 1997 S.B. 141, A.L. 1999 H.B. 343)

Prior revisions: 1929 § 13145; 1919 § 4717; 1909 § 5769

THIRD-PARTY LOGISTIC PROVIDERS

(Submitted but not approved for 2015-2016 session)

Receipt of drugs from unlicensed distributor or pharmacy, unlawful--penalty--pharmacy-to-pharmacy transfers, limit--legend drugs, inventories and records--rulemaking authority

338.315. 1. Except as otherwise provided by the board by rule, it shall be unlawful for any pharmacist, pharmacy owner or person employed by a pharmacy to knowingly purchase or receive any legend drugs under 21 U.S.C. Section 353 from other than a licensed or registered drug distributor, [third party logistics provider](#) or licensed pharmacy. Any person who violates the provisions of this section shall, upon conviction, be adjudged guilty of a class A misdemeanor. Any subsequent conviction shall constitute a class D felony.

2. Notwithstanding any other provision of law to the contrary, the sale, purchase, or trade of a prescription drug by a pharmacy to other pharmacies is permissible if the total dollar volume of such sales, purchases, or trades are in compliance with the rules of the board and do not exceed five percent of the pharmacy's total annual prescription drug sales.

3. Pharmacies shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of legend drugs. Such records shall be maintained for two years and be readily available upon request by the board or its representatives.

4. The board shall promulgate rules to implement the provisions of this section. Any rule or portion of a rule, as that term is defined in section 536.010, that is created under the authority delegated in this section shall become effective only if it complies with and is subject to all of the provisions of chapter 536 and, if applicable, section 536.028. This section and chapter 536 are nonseverable and if any of the powers vested with the general assembly pursuant to chapter 536 to review, to delay the effective date, or to disapprove and annul a rule are subsequently held unconstitutional, then the grant of rulemaking authority and any rule proposed or adopted after August 28, 2012, shall be invalid and void.

Definitions.

338.330. As used in sections 338.300 to 338.370, the following terms mean:

(1) "Legend drug":

(a) Any drug or biological product:

a. Subject to Section 503(b) of the Federal Food, Drug and Cosmetic Act, including finished dosage forms and active ingredients subject to such Section 503(b); or

b. Required under federal law to be labeled with one of the following statements prior to being dispensed or delivered:

(i) "Caution: Federal law prohibits dispensing without prescription";

(ii) "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian";
or

(iii) "Rx Only"; or

c. Required by any* applicable federal or state law or regulation to be dispensed by prescription only or that is restricted to use or dispensed by practitioners only; and

(b) The term "drug", "prescription drug", or "legend drug" shall not include:

a. An investigational new drug, as defined by 21 CFR 312.3(b), that is being utilized for the purposes of conducting a clinical trial or investigation of such** drug or product that is governed by, and being conducted under and pursuant to, 21 CFR 312, et. seq.;

b. Any drug product being utilized for the purposes of conducting a clinical trial or investigation that is governed by, and being conducted under and pursuant to, 21 CFR 312, et. seq.; or

c. Any drug product being utilized for the purposes of conducting a clinical trial or investigation that is governed or approved by an institutional review board subject to 21 CFR Part 56 or 45 CFR Part 46;

(2) "Out-of-state wholesale drug distributor", a wholesale drug distributor with no physical facilities located in the state;

(3) "Pharmacy distributor", any licensed pharmacy, as defined in section 338.210, engaged in the delivery or distribution of legend drugs to any other licensed pharmacy where such delivery or distribution constitutes at least five percent of the total gross sales of such pharmacy;

(4) "Wholesale drug distributor", anyone engaged in the delivery or distribution of legend drugs from any location and who is involved in the actual, constructive or attempted transfer of a drug

or drug-related device in this state, other than to the ultimate consumer. This shall include, but not be limited to, drug wholesalers, repackagers and manufacturers which are engaged in the delivery or distribution of drugs in this state, with facilities located in this state or in any other state or jurisdiction. A wholesale drug distributor shall not include any common carrier or individual hired solely to transport legend drugs. Any locations where drugs are delivered on a consignment basis, as defined by the board, shall be exempt from licensure as a drug distributor, and those standards of practice required of a drug distributor but shall be open for inspection by board of pharmacy representatives as provided for in section 338.360-;

(5) “Third-party Logistics Provider”, an entity that provides or coordinates warehousing, or other logistics services of a product on behalf of a drug manufacturer, wholesale distributor, or dispenser of a legend drug, but does not take ownership of the product, nor have responsibility to direct the sale or disposition of the product.

License required, temporary licenses may be granted--out-of-state distributors, reciprocity allowed, when.

338.333. 1. Except as otherwise provided by the board of pharmacy by rule in the event of an emergency or to alleviate a supply shortage, no person or distribution outlet shall act as a wholesale drug distributor, ~~or~~ pharmacy distributor or third party logistics provider -without first obtaining license to do so from the Missouri board of pharmacy and paying the required fee. The board may grant temporary licenses when the wholesale drug distributor, ~~or~~ pharmacy distributor or third party logistics provider first applies for a license to operate within the state. Temporary licenses shall remain valid until such time as the board shall find that the applicant meets or fails to meet the requirements for regular licensure. No license shall be issued or renewed for a wholesale drug distributor, ~~or~~ pharmacy distributor or third party logistics provider to operate unless the same shall be operated in a manner prescribed by law and according to the rules and regulations promulgated by the board of pharmacy with respect thereto. Separate licenses shall be required for each distribution or third party logistics -site owned or operated by a wholesale drug distributor, ~~or~~ pharmacy distributor or third party logistics provider unless such drug distributor, ~~or~~ pharmacy distributor or third party logistics provider meets the requirements of section 338.335.

2. An agent or employee of any licensed or registered wholesale drug distributor, ~~or~~ pharmacy distributor or third party logistics provider need not seek licensure under this section and may lawfully possess pharmaceutical drugs, if ~~he~~ the agent or employee is acting in the usual course of his or her business or employment.

3. The board may permit out-of-state wholesale drug distributors, third party logistics provider or out-of-state pharmacy distributors to be licensed as required by sections 338.210 to 338.370 on the basis of reciprocity to the extent that ~~-an out-of-state wholesale drug distributor or out-of-state pharmacy distributor~~ the entity both:

(1) Possesses a valid license granted by another state pursuant to legal standards comparable to those which must be met by a wholesale drug distributor, ~~or~~ pharmacy distributor or third party logistics provider of this state as prerequisites for obtaining a license under the laws of this state; and

(2) Distributes into Missouri from a state which would extend reciprocal treatment under its own laws to a wholesale drug distributor, ~~or~~ pharmacy distributor or third party logistics provider of this state.

Out-of-state distributors, licenses required, exception.

338.337. It shall be unlawful for any out-of-state wholesale drug distributor, ~~or~~ out-of-state pharmacy acting as a distributor or out-of-state third party logistics provider to do business in this state without first obtaining a license to do so from the board of pharmacy and paying the required fee, except as otherwise provided by section 338.335 and this section. Application for an out-of-state wholesale drug distributor's or out-of-state third party logistics provider's license under this section shall be made on a form furnished by the board. The issuance of a license under sections 338.330 to 338.370 shall not change or affect tax liability imposed by the Missouri department of revenue on any ~~out-of-state wholesale drug distributor or out-of-state pharmacy - entity.~~ Any out-of-state wholesale drug distributor that is a drug manufacturer and which produces and distributes from a facility which has been inspected and approved by the Food and Drug Administration, maintains current approval by the federal Food and Drug Administration, and has provided a copy of the most recent Food and Drug Administration Establishment Inspection Report to the board, and which is licensed by the state in which the distribution facility is located, or, if located within a foreign jurisdiction, is authorized and in good standing to operate as a drug manufacturer within such jurisdiction, need not be licensed as provided in this section but such out-of-state distributor shall register its business name and address with the board of pharmacy and pay a filing fee in an amount established by the board.

Sale of drugs, out-of-state distributor, license required.

338.340. No person acting as principal or agent for any out-of-state wholesale drug distributor, ~~or~~ out-of-state pharmacy distributor or out-of-state third party logistics provider shall sell or distribute drugs in this state unless the ~~wholesale drug distributor or pharmacy distributor~~ entity has obtained a license pursuant to the provisions of sections 338.330 to 338.370.

Rx Format

Generic substitutions may be made, when, form required for prescription blanks, exception--penalty.

338.056. 1. Except as provided in subsection 2 of this section*, the pharmacist filling prescription orders for drug products prescribed by trade or brand name may select another drug product with the same active chemical ingredients of the same strength, quantity and dosage form, and of the same generic drug type, as determined by the United States Adopted Names and accepted by the Federal Food and Drug Administration. Selection pursuant to this section is within the discretion of the pharmacist, except as provided in subsection 2 of this section*. The pharmacist who selects the drug product to be dispensed pursuant to this section shall assume the same responsibility for selecting the dispensed drug product as would be incurred in filling a prescription for a drug product prescribed by generic name. The pharmacist shall not select a drug product pursuant to this section unless the product selected costs the patient less than the prescribed product.

2. ~~[A pharmacist who receives a prescription for a brand name drug may, unless requested otherwise by the purchaser, select a less expensive generically equivalent product under the following circumstances:~~

~~(1) If a written prescription is involved, the prescription form used shall have two signature lines at opposite ends at the bottom of the form. Under the line at the right side shall be clearly printed the words: "Dispense as Written". Under the line at the left side shall be clearly printed the words "Substitution Permitted". The prescriber shall communicate the instructions to the pharmacist by signing the appropriate line. No prescription shall be valid without the signature of the prescriber on one of these lines;]~~ A pharmacist who receives a prescription for a brand name drug may select a less expensive generically equivalent product unless requested otherwise by the purchaser or the prescribing practitioner indicates that substitution is prohibited or clearly displays "brand medically necessary", "DAW", "do not substitute" or words of similar import on the prescription. No prescription shall be valid without the signature of the prescriber

~~[(2)]~~**3.** If an oral prescription is involved, the practitioner or the practitioner's agent, communicating the instructions to the pharmacist, shall instruct the pharmacist as to whether or not a therapeutically equivalent generic drug may be substituted. The pharmacist shall note the instructions on the file copy of the prescription.

~~[3. All prescriptions written in the state of Missouri by practitioners authorized to write prescriptions shall be on forms which comply with subsection 2 hereof.]~~

4. Notwithstanding the provisions of subsection 2 of this section to the contrary, a pharmacist may fill a prescription for a brand name drug by substituting a generically equivalent drug when generic substitution is allowed in accordance with the laws of the state where the prescribing practitioner is located.

5. Violations of this section are infractions.

ALABAMA

No person shall dispense or cause to be dispensed a different drug or brand of drug in lieu of that ordered or prescribed without the express permission in each case of the person ordering or prescribing such drug, except as provided below:

(1) A licensed pharmacist in this state shall be permitted to select for the brand name drug product prescribed by a licensed physician or other practitioner who is located in this state and authorized by law to write prescriptions, hereinafter referred to as "practitioner," a less expensive pharmaceutically and therapeutically equivalent drug product containing the same active ingredient, or ingredients, and of the same dosage form strength, in all cases where the practitioner expressly authorizes such selection in accordance with subdivision (4) of this section.

(2) A licensed pharmacist located in this state shall be permitted to select for the brand name drug product prescribed by a practitioner who is located in another state or licensing jurisdiction and who is authorized by the laws of that state or jurisdiction to write prescriptions, a less expensive pharmaceutically and therapeutically equivalent drug product containing the same active ingredient or ingredients, and of the same dosage form strength, in all cases where the out-of-state licensed physician or other practitioner does not expressly prohibit a substitution.

(3) A pharmacist shall record on the prescription form the name and manufacturer or distributor of any drug product dispensed as herein authorized.

(4) Every written prescription issued in this state by a licensed practitioner shall contain two signature lines. Under one signature line shall be printed clearly the words "dispense as written." Under the other signature line shall be printed clearly the words "product selection permitted." The practitioner shall communicate instructions to the pharmacist by signing on the appropriate line. The State Board of Pharmacy shall not promulgate any rule or regulation affecting the subject matter of this subdivision. An oral prescription from the practitioner shall instruct the pharmacist whether or not a less expensive pharmaceutically and therapeutically equivalent drug product may be dispensed. The pharmacist shall note instructions on the file copy of the prescription and retain the prescription form for the period specified by law.

(5) Unless otherwise indicated by the practitioner, the prescription label on the dispensing container shall indicate the actual drug product dispensed, either the brand name, or if none, the generic name; and the name of the manufacturer or a reasonable abbreviation of the name of the manufacturer.

(6) This shall not be interpreted to exclude the use of a formulary or drug list as adopted and approved by a medical staff in a licensed hospital with drugs provided thereunder by procedures established for use within that licensed hospital.(7) Any person who violates the provisions of this section shall be punished by a fine of up to \$1,000 - See more at: <http://codes.lp.findlaw.com/alcode/34/23/1/34-23-8#sthash.jFU5TeYe.dpuf>

Alaska

12 AAC 52.510. SUBSTITUTION. (a) A pharmacist may dispense an equivalent drug product instead of the prescribed drug if

(1) the prescribing practitioner does not hand write or electronically note on the prescription drug order that a specific brand must be dispensed, using language such as “brand medically necessary” or similar wording;

(2) the patient is notified and consents to the substitution;

(3) the equivalent drug product costs the patient less than the prescribed drug product; and

(4) for the drug product actually dispensed, the pharmacist notes on the prescription drug order one of the following:

(A) the drug product’s manufacturer or distributor;

(B) national drug code number;

(C) short name code; or

(D) trade name.

(b) The determination of the drug product to be dispensed for a prescription drug order is a professional responsibility of the pharmacist. A pharmacist may not dispense any product that in the pharmacist’s professional opinion is not an equivalent drug product as the term “equivalent drug product” is defined in AS 08.80.480.

ARIZONA

32-1963.01. Substitution for prescription drugs; requirements; label; definitions

A. If a medical practitioner prescribes a brand name drug and does not indicate an intent to prevent substitution as prescribed in subsection D of this section, a pharmacist may fill the prescription with a generic equivalent drug.

B. Any pharmacy personnel shall notify the person presenting the prescription of the amount of the price difference between the brand name drug prescribed and the generic equivalent drug, if both of the following apply:

1. The medical practitioner does not indicate an intent to prevent substitution with a generic equivalent drug.

2. The transaction is not subject to third-party reimbursement.

C. The pharmacist shall place on the container the name of the drug dispensed followed by the words "generic equivalent for" followed by the brand or trade name of the product that is being replaced by the generic equivalent. The pharmacist shall include the brand or trade name on the container or label of any contact lenses dispensed pursuant to this chapter.

D. A prescription generated in this state must be dispensed as written only if the prescriber writes or clearly displays "DAW", "dispense as written", "do not substitute", "medically necessary" or any statement by the prescriber that clearly indicates an intent to prevent substitution on the face of the prescription form. A prescription from out of state or from agencies of the United States

government must be dispensed as written only if the prescriber writes or clearly displays "do not substitute", "dispense as written" or "medically necessary" or any statement by the prescriber that clearly indicates an intent to prevent substitution on the face of the prescription form.

E. This section applies to all prescriptions, including those presented by or on behalf of persons receiving state or federal assistance payments.

F. An employer or agent of an employer of a pharmacist shall not require the pharmacist to dispense any specific generic equivalent drug or substitute any specific generic equivalent drug for a brand name drug against the professional judgment of the pharmacist or the order of the prescriber.

G. The liability of a pharmacist in substituting according to this section shall be no greater than that which is incurred in the filling of a generically written prescription. This subsection does not limit or diminish the responsibility for the strength, purity or quality of drugs provided in section 32-1963. The failure of a prescriber to specify that no substitution is authorized does not constitute evidence of negligence.

H. A pharmacist may not make a substitution pursuant to this section unless the manufacturer or distributor of the generic drug has shown that:

1. All products dispensed have an expiration date on the original package.
2. The manufacturer or distributor maintains recall and return capabilities for unsafe or defective drugs.

I. The labeling and oral notification requirements of this section do not apply to pharmacies serving patients in a health care institution as defined in section 36-401. However, in order for this exemption to apply to hospitals, the hospital must have a formulary to which all medical practitioners of that hospital have agreed and that is available for inspection by the board.

J. For the purposes of this section:

1. "Brand name drug" means a drug with a proprietary name assigned to it by the manufacturer or distributor.
2. "Formulary" means a list of medicinal drugs.
3. "Generic equivalent" or "generically equivalent" means a drug that has an identical amount of the same active chemical ingredients in the same dosage form, that meets applicable standards of strength, quality and purity according to the United States pharmacopeia or other nationally recognized compendium and that, if administered in the same amounts, will provide comparable therapeutic effects. Generic equivalent or generically equivalent does not include a drug that is listed by the federal food and drug administration as having unresolved bioequivalence concerns according to the administration's most recent publication of approved drug products with therapeutic equivalence evaluations.

Arkansas

07-00-0007—A PHARMACIST SHALL NOT DISPENSE A GENERICALLY EQUIVALENT DRUG PRODUCT UNDER ACA § 17-92-503 (a) AND (b) OF THE GENERIC SUBSTITUTION ACT IF:

(a) In the case of a written prescription, on the prescription the prescriber writes in his or her own handwriting words that specify that no substitution shall be made and then also signs the prescription.

(b) The prescriber, in the case of a prescription other than one in writing signed by the prescriber, expressly states at the time the prescription is given, that it is to be dispensed as communicated, and same is either entered into the pharmacy's electronic prescription system or reduced to writing on the prescription by the pharmacist, or

(c) The person for whom the drug product is prescribed indicates the prescription is to be dispensed as written or communicated. (4/07/89, Amended 5/31/2014)

California

11162.1. Prescription Forms for Controlled Substances; Requirements

(a) The prescription forms for controlled substances shall be printed with the following features:

(1) A latent, repetitive "void" pattern shall be printed across the entire front of the prescription blank; if a prescription is scanned or photocopied, the word "void" shall appear in a pattern across the entire front of the prescription.

(2) A watermark shall be printed on the backside of the prescription blank; the watermark shall consist of the words "California Security Prescription."

(3) A chemical void protection that prevents alteration by chemical washing.

(4) A feature printed in thermochromic ink.

(5) An area of opaque writing so that the writing disappears if the prescription is lightened.

(6) A description of the security features included on each prescription form.

(7) (A) Six quantity check off boxes shall be printed on the form so that the prescriber may indicate the quantity by checking the applicable box where the following quantities shall appear:

1–24

25–49

50–74

75–100

101–150

151 and over.

(B) In conjunction with the quantity boxes, a space shall be provided to designate the units referenced in the quantity boxes when the drug is not in tablet or capsule form.

(8) Prescription blanks shall contain a statement printed on the bottom of the prescription blank that the "Prescription is void if the number of drugs prescribed is not noted."

(9) The preprinted name, category of licensure, license number, federal controlled substance registration number, and address of the prescribing practitioner.

(10) Check boxes shall be printed on the form so that the prescriber may indicate the number of refills ordered.

(11) The date of origin of the prescription.

(12) A check box indicating the prescriber's order not to substitute.

(13) An identifying number assigned to the approved security printer by the Department of Justice.

(14) (A) A check box by the name of each prescriber when a prescription form lists multiple prescribers.

(B) Each prescriber who signs the prescription form shall identify himself or herself as the prescriber by checking the box by his or her name.

(b) Each batch of controlled substance prescription forms shall have the lot number printed on the form and each form within that batch shall be numbered sequentially beginning with the numeral one.

(c) (1) A prescriber designated by a licensed health care facility, a clinic specified in Section 1200, or a clinic specified in subdivision (a) of Section 1206 that has 25 or more physicians or surgeons may order controlled substance prescription forms for use by prescribers when treating patients in that facility without

4073. Substitution of Generic Drug —Requirements and Exceptions

(a) A pharmacist filling a prescription order for a drug product prescribed by its trade or brand name may select another drug product with the same active chemical ingredients of the same strength, quantity, and dosage form, and of the same generic drug name as determined by the United States Adopted Names (USAN) and accepted by the federal Food and Drug Administration (FDA), of those drug products having the same active chemical ingredients.

(a) In no case shall a selection be made pursuant to this section if the prescriber personally indicates, either orally or in his or her own handwriting, "Do not substitute," or words of similar meaning.

Nothing in this subdivision shall prohibit a prescriber from checking a box on a prescription marked "Do not substitute"; provided that the prescriber personally initials the box or checkmark.

To indicate that a selection shall not be made pursuant to this section for an electronic data transmission prescription as defined in subdivision (c) of Section 4040, a prescriber may indicate "Do not substitute," or words of similar meaning, in the prescription as transmitted by electronic data, or may check a box marked on the prescription "Do not substitute." In either instance, it shall not be required that the prohibition on substitution be manually initialed by the prescriber.

(b) Selection pursuant to this section is within the discretion of the pharmacist, except as provided in subdivision (b). The person who selects the drug product to be dispensed pursuant to this section shall assume the same responsibility for selecting the dispensed drug product as would be incurred in filling a prescription for a drug product prescribed by generic name. There shall be no liability on the prescriber for an act or omission by a pharmacist in selecting, preparing, or dispensing a drug product pursuant to this section. In no case shall the pharmacist select a drug product pursuant to this section

unless the drug product selected costs the patient less than the prescribed drug product. Cost, as used in this subdivision, is defined to include any professional fee that may be charged by the pharmacist.

(c) This section shall apply to all prescriptions, including those presented by or on behalf of persons receiving assistance from the federal government or pursuant to the California Medical Assistance Program set forth in Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code.

(d) When a substitution is made pursuant to this section, the use of the cost-saving drug product dispensed shall be communicated to the patient and the name of the dispensed drug product shall be indicated on the prescription label, except where the prescriber orders otherwise.

Connecticut

Sec. 20-619. (Formerly Sec. 20-185a). Substitution of generic drugs. Regulations. (a) For the purposes of section 20-579 and this section:

(b) Except as limited by subsections (c), (e) and (i) of this section, unless the purchaser instructs otherwise, the pharmacist may substitute a generic drug product with the same strength, quantity, dose and dosage form as the prescribed drug product which is, in the pharmacist's professional opinion, therapeutically equivalent. When the prescribing practitioner is not reasonably available for consultation and the prescribed drug does not use a unique delivery system technology, the pharmacist may substitute an oral tablet, capsule or liquid form of the prescribed drug as long as the form dispensed has the same strength, dose and dose schedule and is therapeutically equivalent to the drug prescribed. The pharmacist shall inform the patient or a representative of the patient, and the practitioner of the substitution at the earliest reasonable time.

(c) A prescribing practitioner may specify in writing or by a telephonic or other electronic communication that there shall be no substitution for the specified brand name drug product specified on any prescription form, provided (1) for written prescriptions, **the practitioner shall specify on the prescription form that the drug product is "brand medically necessary" or "no substitution"**, (2) for prescriptions transmitted by telephonic means, the pharmacist shall specify "brand medically necessary" or "no substitution" on the prescription form in the pharmacist's handwriting or in the electronic prescription record and shall record on the prescription form the time the telephonic authorization was received and the name of the person who communicated the telephonic authorization to the pharmacist, and (3) for prescriptions transmitted by any other electronic communication, the practitioner shall select the dispense as written code on the certified electronic prescription form to indicate that a substitution is not allowed by the practitioner. No prescription form for written prescriptions, and no prescription form for prescriptions transmitted pursuant to subdivision (2) or (3) of this subsection, may default to "brand medically necessary" or "no substitution".

(d) Each pharmacy shall post a sign in a location easily seen by patrons at the counter where prescriptions are dispensed stating that, "THIS PHARMACY MAY BE ABLE TO SUBSTITUTE A LESS EXPENSIVE DRUG PRODUCT WHICH IS THERAPEUTICALLY EQUIVALENT TO THE ONE PRESCRIBED BY YOUR DOCTOR UNLESS YOU DO NOT APPROVE." The printing on the sign shall be in block letters not less than one inch in height.

(e) A pharmacist may substitute a drug product under subsection (b) of this section only when there will be a savings in cost passed on to the purchaser. The pharmacist shall disclose the amount of the savings at the request of the patient.

Delaware

§ 2549 Substitution of drugs.

(a) When a pharmacist receives a prescription drug order from a practitioner for a brand or trade name drug, the pharmacist may dispense a therapeutically equivalent drug if the following conditions are met:

(1) The practitioner, in the case of a written prescription, places that practitioner's own signature on the signature line along side or above the words "substitution permitted" pursuant to subsection (c) of this section; or, in the case of a verbal prescription or a verbal prescription reduced to writing, the practitioner states that the substitution may be made; or, in the case of an order written in an institution licensed by the Department of Health and Social Services pursuant to Chapter 10 or Chapter 11 of Title 16, the practitioner has given written authorization to fill all prescription drug orders with therapeutically equivalent drugs unless otherwise indicated;

(2) The pharmacist informs the patient or the patient's adult representative that a therapeutically equivalent drug has been dispensed;

(3) The pharmacist indicates on the prescription and on the prescription label the name of the manufacturer or distributor of the therapeutically equivalent drug substituted unless the practitioner indicates otherwise.

(b) Unauthorized dispensing of a therapeutically equivalent drug in violation of this section is punishable by a fine of not less than \$500 nor more than \$1,000 or by a term of imprisonment of not less than 30 days nor more than 1 year, or both a fine and a term of imprisonment.

(c) Every prescription written in this State by a practitioner must be on a prescription form containing a line for the practitioner's signature. Alongside or beneath the signature line the words "Substitution Permitted" must be clearly printed. Beneath the signature line the following statement must be clearly printed:

"In order for a brand name product to be dispensed, the prescriber must handwrite 'Brand Necessary' or 'Brand Medically Necessary' in the space below."

A second line to accommodate the above-mentioned wording must be provided beneath the statement. Prescription forms containing the appropriate signature line and statement must be used by every practitioner in this State who prescribes drugs.

Florida

465.025 Substitution of drugs.—

(1) As used in this section:

(a) “Brand name” means the registered trademark name given to a drug product by its manufacturer, labeler, or distributor.

(b) “Generically equivalent drug product” means a drug product with the same active ingredient, finished dosage form, and strength.

(c) “Prescriber” means any practitioner licensed to prescribe medicinal drugs.

(2) A pharmacist who receives a prescription for a brand name drug shall, unless requested otherwise by the purchaser, substitute a less expensive, generically equivalent drug product that is:

(a) Distributed by a business entity doing business, and subject to suit and service of legal process, in the United States; and

(b) Listed in the formulary of generic and brand name drug products as provided in subsection (5) for the brand name drug prescribed, unless the prescriber writes the words “MEDICALLY NECESSARY,” in her or his own handwriting, on the face of a written prescription; unless, in the case of an oral prescription, the prescriber expressly indicates to the pharmacist that the brand name drug prescribed is medically necessary; or unless, in the case of a prescription that is electronically generated and transmitted, the prescriber makes an overt act when transmitting the prescription to indicate that the brand name drug prescribed is medically necessary. When done in conjunction with the electronic transmission of the prescription, the prescriber’s overt act indicates to the pharmacist that the brand name drug prescribed is medically necessary.

(3)(a) Any pharmacist who substitutes any drug as provided in subsection (2) shall notify the person presenting the prescription of such substitution, together with the existence and amount of the retail price difference between the brand name drug and the drug substituted for it, and shall inform the person presenting the prescription that such person may refuse the substitution as provided in subsection (2).

(b) Any pharmacist substituting a less expensive drug product shall pass on to the consumer the full amount of the savings realized by such substitution.

(4) Each pharmacist shall maintain a record of any substitution of a generically equivalent drug product for a prescribed brand name drug as provided in this section.

Illinois

225 ILCS 85/25) (from Ch. 111, par. 4145) (Section scheduled to be repealed on January 1, 2018)

Sec. 25. No person shall compound, or sell or offer for sale, or cause to be compounded, sold or offered for sale any medicine or preparation under or by a name recognized in the United States Pharmacopoeia National Formulary, for internal or external use, which differs from the standard of strength, quality or purity as determined by the test laid down in the United States Pharmacopoeia National Formulary official at the time of such compounding, sale or offering for sale. Nor shall any person compound, sell or offer for sale, or cause to be compounded, sold, or offered for sale, any drug, medicine, poison, chemical or pharmaceutical preparation, the strength or purity of which shall fall below the professed standard of strength or purity under which it is sold. Except as set forth in Section 26 of this Act, if the physician or other authorized prescriber, when transmitting an oral or written prescription, does not prohibit drug product selection, a different brand name or nonbrand name drug product of the same generic name may be dispensed by the pharmacist, provided that the selected drug has a unit price less than the drug product specified in the prescription. A generic drug determined to be therapeutically equivalent by the United States Food and Drug Administration (FDA) shall be available for substitution in Illinois in accordance with this Act and the Illinois Food, Drug and Cosmetic Act, provided that each manufacturer submits to the Director of the Department of Public Health a notification containing product technical bioequivalence information as a prerequisite to product substitution when they have completed all required testing to support FDA product approval and, in any event, the information shall be submitted no later than 60 days prior to product substitution in the State. On the prescription forms of prescribers, shall be placed a signature line and the words "may not substitute". The prescriber, in his or her own handwriting, shall place a mark beside "may not substitute" to direct the pharmacist in the dispensing of the prescription. Preprinted or rubber stamped marks, or other deviations from the above prescription format shall not be permitted. The prescriber shall sign the form in his or her own handwriting to authorize the issuance of the prescription.

In every case in which a selection is made as permitted by the Illinois Food, Drug and Cosmetic Act, the pharmacist shall indicate on the pharmacy record of the filled prescription the name or other identification of the manufacturer of the drug which has been dispensed.

The selection of any drug product by a pharmacist shall not constitute evidence of negligence if the selected nonlegend drug product was of the same dosage form and each of its active ingredients did not vary by more than 1 percent from the active ingredients of the prescribed, brand name, nonlegend drug product. Failure of a prescribing physician to specify that drug product selection is prohibited does not constitute evidence of negligence unless that practitioner has reasonable cause to believe that the health condition of the patient for whom the physician is prescribing warrants the use of the brand name drug product and not another.

The Department is authorized to employ an analyst or chemist of recognized or approved standing whose duty it shall be to examine into any claimed adulteration, illegal substitution, improper selection, alteration, or other violation hereof, and report the result of his investigation, and if such report justify such action the Department shall cause the offender to be prosecuted.

(Source: P.A. 94-936, eff. 6-26-06; 95-689, eff. 10-29-07.)

Iowa

155A.32 DRUG PRODUCT SELECTION -- RESTRICTIONS.

1. If an authorized prescriber prescribes, in writing, electronically, by facsimile, or orally, a drug by its brand or trade name, the pharmacist may exercise professional judgment in the economic interest of the patient by selecting a drug product with the same generic name and demonstrated bioavailability as the one prescribed for dispensing and sale to the patient. If the cost of the prescription or any part of it will be paid by expenditure of public funds authorized under chapter 249A, the pharmacist shall exercise professional judgment by selecting a drug product with the same generic name and demonstrated bioavailability as the one prescribed for dispensing and sale. If the pharmacist exercises drug product selection, the pharmacist shall inform the patient of the savings which the patient will obtain as a result of the drug product selection and pass on to the patient no less than fifty percent of the difference in actual acquisition costs between the drug prescribed and the drug substituted.

2. The pharmacist shall not exercise the drug product selection described in this section if either of the following is true:

- a. The prescriber specifically indicates that no drug product selection shall be made.
- b. The person presenting the prescription indicates that only the specific drug product prescribed should be dispensed. However, this paragraph does not apply if the cost of the prescription or any part of it will be paid by expenditure of public funds authorized under chapter 249A.

3. If selection of a generically equivalent product is made under this section, the pharmacist making the selection shall note that fact and the name of the manufacturer of the selected drug on the prescription presented by the patient or the patient's adult representative or transmitted by the prescriber or the prescriber's authorized agent.

Kansas

65-1637. Pharmacist required to be in charge of pharmacy; compounding, filling and refilling of prescriptions; refusal to fill; brand exchange. [See Revisor's Note] In every store, shop or other place defined in this act as a "pharmacy" there shall be a pharmacist in charge and, except as otherwise provided by law, the compounding and dispensing of prescriptions shall be limited to pharmacists only. Except as otherwise provided by the pharmacy act of this state, when a pharmacist is not in attendance at a pharmacy, the premises shall be enclosed and secured. Prescription orders may be written, oral, telephonic or by electronic transmission unless prohibited by law. Blank forms for written prescription orders may have two signature lines. If

there are two lines, one signature line shall state: "Dispense as written" and the other signature line shall state: "Brand exchange permissible." Prescriptions shall only be filled or refilled in accordance with the following requirements:

(a) All prescriptions shall be filled in strict conformity with any directions of the prescriber, except:

(1) That a pharmacist may provide up to three-month supply of a prescription drug that is not a controlled substance or psychotherapeutic drug when a practitioner has written a drug order to be filled with a smaller supply but included sufficient numbers of refills for a three-month supply; and

(2) that a pharmacist who receives a prescription order for a brand name drug product may exercise brand exchange with a view toward achieving a lesser cost to the purchaser unless:

(A) The prescriber, in the case of a prescription signed by the prescriber and written on a blank form containing two signature lines, signs the signature line following the statement "dispense as written,"

(B) the prescriber, in the case of a prescription signed by the prescriber, writes in the prescriber's own handwriting "dispense as written" on the prescription,

(C) the prescriber, in the case of a prescription other than one in writing signed by the prescriber, expressly indicates the prescription is to be dispensed as communicated, or

(D) the federal food and drug administration has determined that a drug product of the same generic name is not bioequivalent to the prescribed brand name prescription medication.

(b) Prescription orders shall be recorded in writing by the pharmacist and the record so made by the pharmacist shall constitute the original prescription to be dispensed by the pharmacist. This record, if telephoned by other than the physician shall bear the name of the person so telephoning. Nothing in this paragraph shall be construed as altering or affecting in any way laws of this state or any federal act requiring a written prescription order.

(c) (1) Except as provided in paragraph (2), no prescription shall be refilled unless authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filled by the pharmacist.

Kentucky

217.822 Substitution of equivalent drug -- Substitute must be lower in price than prescribed drug -- Selection by pharmacist not practice of medicine -- Liability of pharmacist -- Duty of pharmacist.

(1) When a pharmacist receives a prescription for a brand name drug which is not listed by generic name in the nonequivalent drug product formulary prepared by the board, he shall select a lower priced therapeutically equivalent drug which he has in stock, unless otherwise instructed by the purchaser or his physician, provided however that if such selection is made, the label on the container of the drug shall show the name of the drug dispensed.

(2) When an equivalent drug product is dispensed in lieu of a brand name drug prescribed, the price of the equivalent drug product dispensed shall be lower in price to the purchaser than the drug product prescribed.

(3) If, in the opinion of a practitioner, it is to the best interest of his patient that an equivalent drug should not be dispensed, he may indicate in the manner of his choice on the prescription "Do Not Substitute," except that the indication shall not be preprinted on a prescription.

(4) The selection of any drug by a pharmacist under the provisions of this section shall not constitute the practice of medicine.

(5) A pharmacist who selects an equivalent drug product pursuant to KRS 217.815 to 217.826 assumes no greater liability for selecting the dispensed drug product than would be incurred in dispensing a prescription for a drug product prescribed by its generic name.

(6) When a pharmacist receives a generically written prescription for a multiple source drug product, he shall dispense an equivalent drug product in accordance with the provisions of KRS 217.815 to 217.826.

Effective: July 15, 1982

History: Amended 1982 Ky. Acts ch. 399, sec. 4, effective July 15, 1982. -- Amended 1976 Ky. Acts ch. 274, sec. 2. -- Created 1972 Ky. Acts ch. 126, sec. 8.

Louisiana

NRS 639.2583 General requirements governing substitution; procedure; limitations; applicability.

1. Except as otherwise provided in this section, if a practitioner has prescribed a drug by brand name and the practitioner has not indicated, by a method set forth in subsection 5, that a substitution is prohibited, the pharmacist who fills or refills the prescription shall dispense, in substitution, another drug which is available to him or her if the other drug:

- (a) Is less expensive than the drug prescribed by brand name;
- (b) Is biologically equivalent to the drug prescribed by brand name;
- (c) Has the same active ingredient or ingredients of the same strength, quantity and form of dosage as the drug prescribed by brand name; and
- (d) Is of the same generic type as the drug prescribed by brand name.

2. If the pharmacist has available to him or her more than one drug that may be substituted for the drug prescribed by brand name, the pharmacist shall dispense, in substitution, the least expensive of the drugs that are available to him or her for substitution.

3. Before a pharmacist dispenses a drug in substitution for a drug prescribed by brand name, the pharmacist shall:

- (a) Advise the person who presents the prescription that the pharmacist intends to dispense a drug in substitution; and
- (b) Advise the person that he or she may refuse to accept the drug that the pharmacist intends to dispense in substitution, unless the pharmacist is being paid for the drug by a governmental agency.

4. If a person refuses to accept the drug that the pharmacist intends to dispense in substitution, the pharmacist shall dispense the drug prescribed by brand name, unless the pharmacist is being paid for the drug by a governmental agency, in which case the pharmacist shall dispense the drug in substitution.

5. A pharmacist shall not dispense a drug in substitution for a drug prescribed by brand name if the practitioner has indicated that a substitution is prohibited using one or more of the following methods:

- (a) By oral communication to the pharmacist at any time before the drug is dispensed.

(b) By handwriting the words “Dispense as Written” on the form used for the prescription, including, without limitation, any form used for transmitting the prescription from a facsimile machine to another facsimile machine. The pharmacist shall disregard the words “Dispense as Written” if they have been placed on the form used for the prescription by preprinting or other mechanical process or by any method other than handwriting.

(c) By including the words “Dispense as Written” in any prescription that is given to the pharmacist by electronic transmission pursuant to the regulations of the Board or in accordance with [NRS 439.581](#) to [439.595](#), inclusive, and the regulations adopted pursuant thereto, including, without limitation, an electronic transmission from a computer equipped with a facsimile modem to a facsimile machine or from a computer to another computer pursuant to the regulations of the Board.

6. The provisions of this section also apply to a prescription issued to a person by a practitioner from outside this State if the practitioner has not indicated, by a method set forth in subsection 5, that a substitution is prohibited.

7. The provisions of this section do not apply to:

(a) A prescription drug that is dispensed to any inpatient of a hospital by an inpatient pharmacy which is associated with that hospital;

(b) A prescription drug that is dispensed to any person by mail order or other common carrier by an Internet pharmacy which is certified by the Board pursuant to [NRS 639.23288](#) and authorized to provide service by mail order or other common carrier pursuant to the provisions of this chapter; or

(c) A prescription drug that is dispensed to any person by a pharmacist if the substitution:

(1) Would violate the terms of a health care plan that maintains a mandatory, exclusive or closed formulary for its coverage for prescription drugs; or

(2) Would otherwise make the transaction ineligible for reimbursement by a third party.

(Added to NRS by [1979, 1348](#); A [1981, 393, 1374](#); [1985, 2005](#); [2003, 1213](#); [2011, 1764](#))

MAINE

§13781. Generic and therapeutically equivalent substitution

A written prescription issued by a practitioner in this State may contain a box in the lower right-hand corner of the prescription form. The following words must appear to the left of this box: "Any drug which is the generic and therapeutic equivalent of the drug specified above in this prescription must be dispensed, provided that no check mark () has been handwritten in the box in the lower right-hand corner." [2003, c. 384, §1 (AMD).]

Except with regard to a patient who is paying for a drug with the patient's own resources, any pharmacist receiving a prescription in which no handwritten check mark () is found in the box provided shall substitute a generic and therapeutically equivalent drug for the drug specified on the prescription if the substituted drug is distributed by a business entity doing business in the United States that is subject to suit and the service of legal process in the United States and the price of the substituted drug does not exceed the price of the drug specified by the practitioner; except that, when the cost of a prescription is to be reimbursed under the MaineCare program pursuant to Title 22, chapter 855, the pharmacist shall substitute a generic and therapeutically equivalent drug only when the Department of Health and Human Services has determined that

the substitute drug would be a more cost-effective alternative than the drug prescribed by the practitioner. Except for prescribed drugs listed under the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 United States Code, Section 812, as amended, as Schedule II drugs, with regard to a patient who is paying for a drug with the patient's own resources, a pharmacist shall inquire about the patient's preference for either the brand-name drug or generic and therapeutically equivalent drug and dispense the drug that the patient prefers. [2007, c. 85, §1 (AMD).]

Except with regard to a patient who is paying for a drug with the patient's own resources, if a written prescription issued by a practitioner in this State does not contain the box described in this section, a pharmacist shall substitute a generic and therapeutically equivalent drug for the drug specified on the prescription if the substituted drug is distributed by a business entity doing business in the United States that is subject to suit and the service of legal process in the United States and the price of the substituted drug does not exceed the price of the drug specified by the practitioner, unless a practitioner has handwritten on the prescription form, along with the practitioner's signature, "dispense as written," "DAW," "brand," "brand necessary" or "brand medically necessary"; except that, when the cost of a prescription is to be reimbursed under the MaineCare program pursuant to Title 22, chapter 855, the pharmacist shall substitute a generic and therapeutically equivalent drug only when the Department of Health and Human Services has determined that the substitute drug would be a more cost-effective alternative than the drug prescribed by the practitioner. Except for prescribed drugs listed under the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 United States Code, Section 812, as amended, as Schedule II drugs, with regard to a patient who is paying for a drug with the patient's own resources, a pharmacist shall inquire about the patient's preference for either the brand-name drug or generic and therapeutically equivalent drug and dispense the drug that the patient prefers. [2007, c. 85, §2 (AMD).]

Any pharmacist who substitutes a generic and therapeutically equivalent drug under this section shall inform the person to whom the drug is dispensed of the substitution. When any substitution is made under this section, the pharmacist shall cause the name of the generic and therapeutically equivalent drug, the name or abbreviation of the drug manufacturer or distributor of that substitute drug and all other information as required by section 13794 to appear on the container label of the drug dispensed. [1987, c. 710, §5 (NEW).]

This section does not apply to prescriptions ordered by practitioners for patients in hospitals when those prescriptions are filled by a hospital pharmacy or in any institution where a formulary system is established. [1987, c. 710, §5 (NEW).]

Maryland

§ 12-504. Substitution of generic equivalent for brand name drug products.

(c) Substitutions.- A pharmacist may substitute a generically equivalent drug or device product, of the same dosage form and strength, for any brand name drug or device product prescribed, if:

(1) The authorized prescriber does not state expressly that the prescription is to be dispensed only as directed;

(2) The substitution is recognized in the United States Food and Drug Administration's current list of approved drug or device products with therapeutic equivalence evaluations; and

(3) The consumer is charged less for the substituted drug or device than the price of the brand name drug or device.

(d) Requirements on substitution.- If a drug or device product is substituted under this section, the pharmacist shall:

(1) Notify the patient in writing that the drug or device product dispensed is a generic equivalent of the prescribed drug or device product; and

(2) Record on the prescription and keep a record of the name and manufacturer of the substituted drug or device product.

Massachusetts

721.020: Prescription Formats Every prescription written in the Commonwealth must be in a prescription format that conforms to the following requirements:

(A) a prescription must permit the practitioner to instruct the pharmacist to dispense a brand name drug product by indicating “no substitution”, provided that:

(1) the indication of “no substitution” is not the default indication;

(2) the prescription indicates that “Interchange is mandated unless the practitioner indicates ‘no substitution’ in accordance with the law”; and

(3) the indication of “no substitution” is a unique element in the prescription and shall not be satisfied by use of any other element, including the signature;

(B) if the prescription is paper-based, including but not limited to a prescription that is transmitted via facsimile or similar technology, or reduced to writing by a pharmacist, the prescription must be on a form that contains a signature line for the practitioner's signature on the lower portion of the form. Hospital and clinic prescription forms shall contain a line directly below the signature line for the practitioner to print or type his or her name. Below the signature line, or in the case of hospital and clinic prescription forms, below the line provided for the practitioner to print or type his or her name, there shall be a space in which the practitioner may indicate "no substitution". Below this space shall be printed the words "Interchange is mandated unless the practitioner indicates 'no substitution' in accordance with the law”;

(C) if the prescription is transmitted electronically, the practitioner shall generate and transmit the prescription in a format that can be read and stored by a pharmacy in a retrievable and readable form;

(D) the name and address of the practitioner shall be clearly indicated on the prescription. A hospital or clinic prescription shall have the name and address of the hospital or clinic clearly indicated on the prescription;

Mississippi

§ 73-21-117. Substitution of generic equivalent drug [Repealed effective July 1, 2016] (1) A pharmacist may select a generic equivalent drug product only when such selection results in lower cost to the purchaser, unless product selection is expressly prohibited by the prescriber. (2) A pharmacist shall select a generic equivalent drug product when: (a) The purchaser requests the selection of a generic equivalent drug product; (b) The prescriber has not expressly prohibited product selection; and (c) Product selection will result in lower cost to the purchaser. Before product selection is made, the pharmacist shall advise the purchaser of his prerogatives under this subsection. (3) When requested by the purchaser to dispense the drug product as ordered by the prescriber, a pharmacist shall not select a generic equivalent drug product. **HISTORY:** SOURCES: Laws, 1983, ch. 414, § 24; reenacted without change, Laws, 1991, ch. 527, § 24; reenacted without change, Laws, 1993, ch. 416, § 25 (approved March 18, 1993); reenacted without change, Laws, 1998, ch. 511, § 26; reenacted without change, Laws, 2002, ch. 501, § 26; reenacted without change, Laws, 2006, ch. 533, § 25; reenacted without change, Laws, 2011, ch. 546, § 24, eff from and after passage (approved Apr. 26, 2011.)

NEW YORK

§6810. Prescriptions.

6.

- a. Every prescription written in this state by a person authorized to issue such prescription shall be on prescription forms containing one line for the prescriber's signature. The prescriber's signature shall validate the prescription. Every electronic prescription shall provide for the prescriber's electronic signature, which shall validate the electronic prescription. Imprinted conspicuously on every prescription written in this state in eight point upper case type immediately below the signature line shall be the words: "THIS PRESCRIPTION WILL BE FILLED GENERICALLY UNLESS PRESCRIBER WRITES 'd a w' IN THE BOX BELOW". Unless the prescriber writes d a w in such box in the prescriber's own handwriting or, in the case of electronic prescriptions, inserts an electronic direction to dispense the drug as written, the prescriber's signature or electronic signature shall designate approval of substitution by a pharmacist of a drug product pursuant to paragraph (o) of subdivision one of section two hundred six of the public health law. No other letters or marks in such box shall prohibit substitution. No prescription forms used or intended to be used by a person authorized to

issue a prescription shall have 'd a w' preprinted in such box. Such box shall be placed directly under the signature line and shall be three-quarters inch in length and one-half inch in height, or in comparable form for an electronic prescription as may be specified by regulation of the commissioner. Immediately below such box shall be imprinted in six point type the words "Dispense As Written". Notwithstanding any other provision of law, no state official, agency, board or other entity shall promulgate any regulation or guideline modifying those elements of the prescription form's contents specified in this subdivision. To the extent otherwise permitted by law, a prescriber may modify only those elements of the prescription form's contents not specified in this subdivision. Notwithstanding any other provision of this section or any other law, when a generic drug is not available and the brand name drug originally prescribed is available and the pharmacist agrees to dispense the brand name product for a price that will not exceed the price that would have been charged for the generic substitute had it been available, substitution of a generic drug product will not be required. If the generic drug product is not available and a medical emergency situation, which for purposes of this section is defined as any condition requiring alleviation of severe pain or which threatens to cause disability or take life if not promptly treated, exists, then the pharmacist may dispense the brand name product at his regular price. In such instances the pharmacist must record the date, hour and nature of the medical emergency on the back of the prescription and keep a copy of all such prescriptions.

North Dakota

19-02.1-14.1. Definitions - Label of prescription drugs - Selecting and dispensing generic name drugs - Identification of prescription drugs.

3. If a practitioner prescribes a drug by its brand name, the pharmacist may exercise professional judgment in the economic interest of the patient by selecting a drug product with the same generic name and demonstrated therapeutical equivalency as the one prescribed for dispensing and sale to the patient unless the practitioner specifically indicates in the practitioner's own handwriting "brand medically necessary" on a written prescription or expressly indicates that an oral prescription is to be dispensed as communicated. If the prescription is created electronically by the prescriber, the required legend must appear on the practitioner's screen. The practitioner must take a specific overt action to include the "brand medically necessary" language with the electronic transmission. The pharmacist shall note the instructions on the file copy of the prescription, or maintain the digital record as transmitted if it is an electronic prescription. A reminder legend must be placed on all

prescription forms or appear on the computer screen of the electronic prescribing system. The legend must state "In order to require that a brand name product be dispensed, the practitioner must handwrite the words 'brand medically necessary'".

The legend printed on the prescription form or appearing on the prescriber's computer screen must be in at least six-point uppercase print or font. The pharmacist may not substitute a generic name drug product unless its price to the purchaser is less than the price of the prescribed drug product. In addition, a pharmacist may not substitute drug products in the following dosage forms: enteric coated tablets, controlled release products, injectable suspensions other than antibiotics, suppositories containing active ingredients for which systemic absorption is necessary for therapeutic activity, and different delivery systems for aerosol and nebulizer drugs. In the event that any drug listed above is, subsequent to January 1, 1982, determined to be therapeutically equivalent, then the previously mentioned substitution ban is automatically removed for that drug. The pharmacist shall inform the person receiving the drug when a prescription for a brand name drug product does not require that the prescribed drug be dispensed and of the person's right to refuse a generic name drug product selected by the pharmacist. The pharmacy file copy of every prescription must include the brand name, if any, or the name of the manufacturer, packer, or distributor of the generic name drug dispensed. A pharmacist who selects and dispenses a therapeutically equivalent generic name drug product shall assume no greater liability for selecting the dispensed drug product than would be incurred in filling a prescription for a drug product prescribed by its generic name. The practitioner is not liable for the substitution made by a pharmacist.

4. In the case of a prescription for which a maximum allowable cost program for purposes of reimbursement has been established under title XIX of the federal Social Security Act, the following also apply:

a. If the practitioner has instructed the pharmacist to dispense as written, the words "brand medically necessary" must also be written on the prescription in the practitioner's own handwriting, or appear as part of the electronic prescription as noted in subsection 3. The pharmacist may dispense a therapeutically equivalent generic name drug product if this handwritten or electronic instruction does not appear on the prescription.

b. If the pharmacist is instructed orally to dispense a brand name drug as prescribed, the pharmacist shall reduce the prescription to writing and shall note the instructions on the file copy of the prescription.

c. If the practitioner has not instructed the pharmacist to dispense a brand name drug or medicine and the patient specifically requests a brand name drug or

medicine, the patient shall pay the difference between the price to the patient of the brand name drug or medicine and the therapeutically equivalent generic name drug or medicine if the price of the brand name drug or medicine is higher.

Ohio

38-28,111. Drug product selection; when.

(1) A pharmacist may drug product select except when:

(a) A practitioner designates that drug product selection is not permitted by specifying in the written, oral, or electronic prescription that there shall be no drug product selection. For written or electronic prescriptions, the practitioner shall specify "no drug product selection", "dispense as written", "brand medically necessary", or "no generic substitution" or the notation "N.D.P.S.", "D.A.W.", or "B.M.N." or words or notations of similar import to indicate that drug product selection is not permitted. The pharmacist shall note "N.D.P.S.", "D.A.W.", "B.M.N.", "no drug product selection", "dispense as written", "brand medically necessary", "no generic substitution", or words or notations of similar import on the prescription to indicate that drug product selection is not permitted if such is communicated orally by the prescribing practitioner; or

(b) A patient or designated representative or caregiver of such patient instructs otherwise.

(2) A pharmacist shall not drug product select a drug product unless:

(a) The drug product, if it is in solid dosage form, has been marked with an identification code or monogram directly on the dosage unit;

(b) The drug product has been labeled with an expiration date;

(c) The manufacturer, distributor, or packager of the drug product provides reasonable services, as determined by the board, to accept the return of drug products that have reached their expiration date; and

(d) The manufacturer, distributor, or packager maintains procedures for the recall of unsafe or defective drug products.

OREGON

32-1963.01. Substitution for prescription drugs; requirements; label; definitions

A. If a medical practitioner prescribes a brand name drug and does not indicate an intent to prevent substitution as prescribed in subsection D of this section, a pharmacist may fill the prescription with a generic equivalent drug.

B. Any pharmacy personnel shall notify the person presenting the prescription of the amount of the price difference between the brand name drug prescribed and the generic equivalent drug, if both of the following apply:

1. The medical practitioner does not indicate an intent to prevent substitution with a generic equivalent drug.

2. The transaction is not subject to third-party reimbursement.

C. The pharmacist shall place on the container the name of the drug dispensed followed by the words "generic equivalent for" followed by the brand or trade name of the product that is being replaced by the generic equivalent. The pharmacist shall include the brand or trade name on the container or label of any contact lenses dispensed pursuant to this chapter.

D. A prescription generated in this state must be dispensed as written only if the prescriber writes or clearly displays "DAW", "dispense as written", "do not substitute", "medically necessary" or any statement by the prescriber that clearly indicates an intent to prevent substitution on the face of the prescription form. A prescription from out of state or from agencies of the United States government must be dispensed as written only if the prescriber writes or clearly displays "do not substitute", "dispense as written" or "medically necessary" or any statement by the prescriber that clearly indicates an intent to prevent substitution on the face of the prescription form.

E. This section applies to all prescriptions, including those presented by or on behalf of persons receiving state or federal assistance payments.

F. An employer or agent of an employer of a pharmacist shall not require the pharmacist to dispense any specific generic equivalent drug or substitute any specific generic equivalent drug for a brand name drug against the professional judgment of the pharmacist or the order of the prescriber.

G. The liability of a pharmacist in substituting according to this section shall be no greater than that which is incurred in the filling of a generically written prescription. This subsection does not limit or diminish the responsibility for the strength, purity or quality of drugs provided in section 32-1963. The failure of a prescriber to specify that no substitution is authorized does not constitute evidence of negligence.

H. A pharmacist may not make a substitution pursuant to this section unless the manufacturer or distributor of the generic drug has shown that:

1. All products dispensed have an expiration date on the original package.
2. The manufacturer or distributor maintains recall and return capabilities for unsafe or defective drugs.

I. The labeling and oral notification requirements of this section do not apply to pharmacies serving patients in a health care institution as defined in section 36-401. However, in order for this exemption to apply to hospitals, the hospital must have a formulary to which all medical practitioners of that hospital have agreed and that is available for inspection by the board.

J. For the purposes of this section:

1. "Brand name drug" means a drug with a proprietary name assigned to it by the manufacturer or distributor.
2. "Formulary" means a list of medicinal drugs.

3. "Generic equivalent" or "generically equivalent" means a drug that has an identical amount of the same active chemical ingredients in the same dosage form, that meets applicable standards of strength, quality and purity according to the United States pharmacopeia or other nationally recognized compendium and that, if administered in the same amounts, will provide comparable therapeutic effects. Generic equivalent or generically equivalent does not include a drug that is listed by the federal food and drug administration as having unresolved bioequivalence concerns according to the administration's most recent publication of approved drug products with therapeutic equivalence evaluations.

South Dakota

36-11-46.2. Written prescription to prohibit substitution--Notation by pharmacist. A practitioner may prohibit a pharmacist from selecting an equivalent drug product by handwriting on the prescription drug order the words "brand necessary" or words of similar meaning. The prohibition may not be preprinted or stamped on the prescription drug order. This selection does not preclude a reminder of the procedure required for the practitioner to prohibit selection by a pharmacist from being preprinted on the prescription drug order. If an oral prescription is given to a pharmacist, the practitioner or practitioner's authorized agent shall instruct the pharmacist if selection of an equivalent drug product is prohibited. The pharmacist shall note the instructions on the file copy of the prescription drug order.

Tennessee

53-10-204. Substitution authorized Instructions of prescriber.

(a) The prescriber shall allow for substitution with a generic equivalent of a brand name drug or drug product under all circumstances, unless:

(1) The prescriber determines the medical necessity of a brand name drug or drug product due to:

(A) An adverse reaction previously experienced by the patient to a generic equivalent;

(B) A generic equivalent has previously been demonstrated as ineffective for the patient; or

(C) Any other clinically based prescriber determined need;

(2) A generic equivalent is not available; or

(3) Section 53-10-210 concerning notification to the patient and the prescriber have not been complied with in instances involving an anti-epileptic drug.

(b) If the prescriber determines a brand name drug or drug product is medically necessary for a patient, the prescriber shall, in the prescriber's own handwriting, place the instruction showing intent upon the prescription at the time it is prepared and issued. For the purposes of this subsection (b), instructions showing intent may include, but not be limited to, the following language:

(1) Brand name medically necessary , dispense as written , medically necessary , brand name , no generic ;

(2) Any abbreviation of the language in subdivision (b)(1); or
(3) Any other prescriber handwritten notation, such as circling a preprinted instruction to dispense as written on the prescription order, that clearly conveys the intent that a brand name is necessary for this patient.

(c) If the prescriber determines a brand name drug or drug product is medically necessary for a patient and that prescription order is issued verbally, the prescriber shall alert the pharmacist that use of the brand name drug or drug product is medically necessary for the patient.

(d) If the prescriber determines a brand name drug or drug product is medically necessary for a patient and that prescription order is issued by the prescriber in the form of an electronic prescription order or facsimile prescription order, the prescriber shall place, or cause to be placed, the proper instruction on the electronic prescription order or facsimile prescription order prior to it being transmitted to the pharmacist.

(e) Nothing in this section shall be construed to prevent a prescriber from informing a patient of the prescriber's professional opinion as to the capabilities, effectiveness and acceptability of any drug.

Washington

RCW 69.41.120 Prescriptions to contain instruction as to whether or not a therapeutically equivalent generic drug or interchangeable biological product may be substituted—Out-of-state prescriptions—Form—Contents—Procedure.

(1) Every drug prescription shall contain an instruction on whether or not a therapeutically equivalent generic drug or interchangeable biological product may be substituted in its place, unless substitution is permitted under a prior-consent authorization.

If a written prescription is involved, the prescription must be legible and the form shall have two signature lines at opposite ends on the bottom of the form. Under the line at the right side shall be clearly printed the words "DISPENSE AS WRITTEN." Under the line at the left side shall be clearly printed the words "SUBSTITUTION PERMITTED." The practitioner shall communicate the instructions to the pharmacist by signing the appropriate line. No prescription shall be valid without the signature of the practitioner on one of these lines. In the case of a prescription issued by a practitioner in another state that uses a one-line prescription form or variation thereof, the pharmacist may substitute a therapeutically equivalent generic drug or interchangeable biological product unless otherwise instructed by the practitioner through the use of the words "dispense as written," words of similar meaning, or some other indication.

(2) If an oral prescription is involved, the practitioner or the practitioner's agent shall instruct the pharmacist as to whether or not a therapeutically equivalent generic drug or interchangeable

biological product may be substituted in its place. The pharmacist shall note the instructions on the file copy of the prescription.

(3) The pharmacist shall note the manufacturer of the drug dispensed on the file copy of a written or oral prescription.

(4) The pharmacist shall retain the file copy of a written or oral prescription for the same period of time specified in RCW [18.64.245](#) for retention of prescription records.

West Virginia

§30-5-12b. Definitions; selection of generic drug products; exceptions; records; labels; manufacturing standards; rules; notice of substitution; complaints; notice and hearing; immunity.

(a) As used in this section:

(1) "Brand name" means the proprietary or trade name selected by the manufacturer and placed upon a drug or drug product, its container, label or wrapping at the time of packaging.

(2) "Generic name" means the official title of a drug or drug combination for which a new drug application, or an abbreviated new drug application, has been approved by the United States Food and Drug Administration and is in effect.

(3) "Substitute" means to dispense without the prescriber's express authorization a therapeutically equivalent generic drug product in the place of the drug ordered or prescribed.

(4) "Equivalent" means drugs or drug products which are the same amounts of identical active ingredients and same dosage form and which will provide the same therapeutic efficacy and toxicity when administered to an individual and is approved by the United States Food and Drug Administration.

(b) A pharmacist who receives a prescription for a brand name drug or drug product shall substitute a less expensive equivalent generic name drug or drug product unless in the exercise of his or her professional judgment the pharmacist believes that the less expensive drug is not suitable for the particular patient: *Provided*, That no substitution may be made by the pharmacist where the prescribing practitioner indicates that, in his or her professional judgment, a specific brand name drug is medically necessary for a particular patient.

(c) A written prescription order shall permit the pharmacist to substitute an equivalent generic name drug or drug product except where the prescribing practitioner has indicated in his or her own handwriting the words "Brand Medically Necessary". The following sentence shall be printed on the prescription form. "This prescription may be filled with a generically equivalent drug product unless the words 'Brand Medically Necessary' are written, in the practitioner's own handwriting, on this prescription form.": *Provided*, That "Brand Medically Necessary" may be indicated on the prescription order other than in the prescribing practitioner's own handwriting unless otherwise required by federal mandate.

(d) A verbal prescription order shall permit the pharmacist to substitute an equivalent generic name drug or drug product except where the prescribing practitioner shall indicate to the pharmacist that the prescription is "Brand Necessary" or "Brand Medically Necessary". The pharmacist shall note the instructions on the file copy of the prescription or chart order form.

(e) No person may by trade rule, work rule, contract or in any other way prohibit, restrict, limit or attempt to prohibit, restrict or limit the making of a generic name substitution under the provisions of this section. No employer or his or her agent may use coercion or other means to interfere with the professional judgment of the pharmacist in deciding which generic name drugs or drug products shall be stocked or substituted: *Provided*, That this section shall not be construed to permit the pharmacist to generally refuse to substitute less expensive therapeutically equivalent generic drugs for brand name drugs and that any pharmacist so refusing shall be subject to the penalties prescribed in section twenty-two of this article.

(f) A pharmacist may substitute a drug pursuant to the provisions of this section only where there will be a savings to the buyer. Where substitution is proper, pursuant to this section, or where the practitioner prescribes the drug by generic name, the pharmacist shall, consistent with his or her professional judgment, dispense the lowest retail cost, effective brand which is in stock.

(g) All savings in the retail price of the prescription shall be passed on to the purchaser; these savings shall be equal to the difference between the retail price of the brand name product and the customary and usual price of the generic product substituted therefor: *Provided*, That in no event shall such savings be less than the difference in acquisition cost of the brand name product prescribed and the acquisition cost of the substituted product.

Wisconsin

(1) DRUG PRODUCT OR EQUIVALENT TO BE USED. Except as provided in sub. [\(2\)](#), a pharmacist shall dispense every prescription using either the drug product prescribed or its drug product equivalent, if its drug product equivalent is lower in price to the consumer than the drug product prescribed, and shall inform the consumer of the options available in dispensing the prescription. In this section, "drug product equivalent" means a drug product that is designated the therapeutic equivalent of another drug product by the federal food and drug administration.

(2) EXCEPTION. A prescriber may indicate, by writing on the face of the prescription order or, with respect to a prescription order transmitted electronically, by designating in electronic format the phrase "No substitutions" or words of similar meaning or the initials "N.S.", that no substitution of the drug product prescribed may be made under sub. [\(1\)](#). If such indication is made, the pharmacist shall dispense the prescription with the specific drug product prescribed. No preprinted statement regarding drug product substitution may appear on the face of the prescription order.

[450.13\(3\)](#) **(3)** RENEWED PRESCRIPTIONS. Prescriptions dispensed with a drug product equivalent may be renewed with a different drug product equivalent only if the pharmacist informs the consumer of the change.

(4) **LIMITATION ON LIABILITY.** A pharmacist who dispenses a prescription with a drug product equivalent under this section assumes no greater liability than would be incurred had the pharmacist dispensed the prescription with the drug product prescribed.

(5) **USE OF DRUG PRODUCT EQUIVALENT IN HOSPITALS.** Subsections (1) to (4) do not apply to a pharmacist who dispenses a drug product equivalent that is prescribed for a patient in a hospital if the pharmacist dispenses the drug product equivalent in accordance with written guidelines or procedures previously established by a pharmacy and therapeutics committee of the hospital and approved by the hospital's medical staff and use of the drug product equivalent has been approved for a patient during the period of the patient's stay within the hospital by any of the following:

(a) The patient's individual physician.

(b) The patient's advanced practice nurse prescriber, if the advanced practice nurse prescriber has entered into a written agreement to collaborate with a physician.

(c) The patient's physician assistant.

Wyoming

33-24-149. Drug substitution procedures.

(a) A pharmacist who receives a prescription for a brand name dangerous drug may dispense any generically equivalent drug of the brand name dangerous drug prescribed, unless the prescribing practitioner has clearly indicated substitution is not permitted, if the drug to be dispensed has a lower, regular and customary retail price than the brand name dangerous drug prescribed, as provided in W.S. 33-24-148.

(b) If a physician prescribes a dangerous drug by its generic name, the pharmacist shall dispense the lowest retail cost brand in stock which is generically equivalent as defined in this act.

(c) Except as provided in subsection (e) of this section, when a pharmacist dispenses a substituted drug as authorized by this act, he shall label the prescription container with the name of the dispensed drug. If the dispensed drug does not have a brand name, the prescription label shall indicate the generic name of the drug dispensed.

(d) The national drug code number or the name of the manufacturer or distributor of the generic drug dispensed shall be noted on the prescription memorandum by the pharmacist.

(e) A prescription dispensed by a pharmacist shall bear upon the label the name of the medication in the container except if the prescriber writes "do not label", or words of similar import, on the prescription memorandum or so designates in an oral transmission of the prescription.

GENERIC EQUIVALENT DRUG LAW

Act of 1976, P.L. 1163, No. 259

AN ACT

Relating to the prescribing and dispensing of generic equivalent drugs.

The General Assembly of the Commonwealth of Pennsylvania hereby enacts as follows:

Section 1. It is the purpose of this act to permit consumers to secure necessary drugs at the most economical cost consistent with the professional discretion of the purchaser's physician and pharmacist.

Section 2. As used in this act:

"Department" means the Department of Health.

"Drug" shall have the same meaning as drug in the act of April 14, 1972 (P.L. 233, No. 64), known as "The Controlled Substance, Drug, Device and Cosmetic Act."

"Generically equivalent drug" means a drug product that the Commissioner of Food and Drugs of the United States Food and Drug Administration has approved as safe and effective and has determined to be therapeutically equivalent, as listed in "The Approved Drug Products with Therapeutic Equivalence Evaluations" (Food and Drug Administration "Orange Book"), provided, however, that drug products found by the United States Food and Drug Administration to have a narrow therapeutic range shall not be considered generically equivalent for the purposes of this act. (Def. amended July 11, 1990. P.L. 509, No. 121)

"Pharmacist" shall have the same meaning as pharmacist in the act of September 27, 1961 (P.L. 1700, No. 699), known as the "Pharmacy Act."

"Prescriber" means any duly licensed physician, dentist, veterinarian or other practitioner licensed to write prescriptions intended for the treatment or prevention of disease in man or animals.

"Secretary" means the Secretary of Health.

Section 3. (a) Whenever a pharmacist receives a prescription for a brand name drug, the pharmacist shall substitute a less expensive generically equivalent drug unless requested otherwise by the purchaser or indicated otherwise by the prescriber. The bottom of every prescription blank shall be imprinted with the words "substitution permissible" and shall contain one signature line for the physician's or other authorized prescriber's signature. The prescriber's signature shall validate the prescription and, unless the prescriber handwrites "brand necessary" or "brand medically necessary," shall designate approval of substitution of a drug by a pharmacist pursuant to this act.

Imprinted conspicuously on the prescription blanks shall be the words: "In order for a brand name product to be dispensed, the prescriber must handwrite 'brand necessary' or 'brand medically necessary' in the space below." All information printed on the prescription blank shall be in eight-point uppercase print. In the case of an oral prescription, there will be no substitution if the prescriber expressly indicates to the pharmacist that the brand name drug is necessary and substitution is not allowed. Substitution of a less expensive generically equivalent drug shall be contingent on whether the pharmacy has the brand name or generically equivalent drug in stock. ((a) amended July 11, 1990, P.L. 509, No. 121)

(b) Any pharmacist who substitutes any drug shall notify the person presenting the prescription of such substitution together with the amount of the retail price difference between the brand name and the drug substituted for it and shall inform the person presenting the prescription that they may refuse the substitution.

(c) Any pharmacist substituting a less expensive drug product shall charge the purchaser the regular and customary retail price for the generically equivalent drug.

(d) Each pharmacist shall maintain a record of any substitution of a generically equivalent drug product for a prescribed brand name drug.

(e) Unless the prescriber directs otherwise, the label on all drugs dispensed by a pharmacist shall indicate the generic name using abbreviations if necessary and the name of the manufacturer. The same notation shall be made on the original prescription retained by the pharmacist.

(f) No pharmacist shall substitute a generically equivalent drug for a prescribed brand name drug unless the generically equivalent drug meets the definition of generically equivalent drug set forth in this act and the secretary has not prohibited the use of the drug in accordance with section 5. (f) amended July 11, 1990, P.L. 509, No. 121)

Section 4. (a) Every pharmacy shall post in a prominent place that is in clear and unobstructed public view, at or near the place where prescriptions are dispensed, a sign which shall read: "Pennsylvania law permits pharmacists to substitute a less expensive generically equivalent drug for a brand name drug unless you or your physician direct otherwise."

(b) Every pharmacy shall post in a conspicuous place, easily accessible to the general public, a list of commonly used generically equivalent drugs containing the generic names and brand names where applicable. ((b) amended July 11, 1990, P.L. 509, No. 121)

(c) Each pharmacy shall have available to the public a price listing of brand name and generic equivalent drug products available at the pharmacy for selection by the purchaser.

Section 5. (a) The Department of Health shall have the power and its duty shall be to:

- (1) Administer and enforce the provisions of this act.
- (2) Adopt necessary regulations consistent with this act.
- (3) Publicize the provisions of this act.
- (4) Publish by notice in the Pennsylvania Bulletin the addition or

Title 22. Examining Boards
Part 15. Texas State Board of Pharmacy
Chapter 309. Generic Substitution

§309.3. Generic Substitution.

(a) General requirements.

(1) In accordance with Chapter 562 of the Act, a pharmacist may dispense a generically equivalent drug product if:

- (A) the generic product costs the patient less than the prescribed drug product;
- (B) the patient does not refuse the substitution; and
- (C) the practitioner does not certify on the prescription form that a specific prescribed brand is medically necessary as specified in a dispensing directive described in subsection (c) of this section.

(2) If the practitioner has prohibited substitution through a dispensing directive in compliance with subsection (c) of this section, a pharmacist shall not substitute a generically equivalent drug product unless the pharmacist obtains verbal or written authorization from the practitioner and notes such authorization on the original prescription drug order.

(b) Prescription format for written prescription drug orders.

(1) A written prescription drug order issued in Texas may:

- (A) be on a form containing a single signature line for the practitioner; and
- (B) contain the following reminder statement on the face of the prescription: “A

generically equivalent drug product may be dispensed unless the practitioner hand writes the words ‘Brand Necessary’ or ‘Brand Medically Necessary’ on the face of the prescription.”

(2) A pharmacist may dispense a prescription that is not issued on the form specified in paragraph (1) of this subsection, however, the pharmacist may dispense a generically equivalent drug product unless the practitioner has prohibited substitution through a dispensing directive in compliance with subsection (c)(1) of this section.

(3) The prescription format specified in paragraph (1) of this subsection does not apply to the following types of prescription drug orders:

- (A) prescription drug orders issued by a practitioner in a state other than Texas;
- (B) prescriptions for dangerous drugs issued by a practitioner in the United Mexican States or the Dominion of Canada; or

(C) prescription drug orders issued by practitioners practicing in a federal facility provided they are acting in the scope of their employment.

(4) In the event of multiple prescription orders appearing on one prescription form, the practitioner shall clearly identify to which prescription(s) the dispensing directive(s) apply. If the practitioner does not clearly indicate to which prescription(s) the dispensing directive(s) apply, the pharmacist may substitute on all prescriptions on the form.

(c) Dispensing directive.

(1) *Written prescriptions.*

(A) A practitioner may prohibit the substitution of a generically equivalent drug product for a brand name drug product by writing across the face of the written prescription, in the practitioner’s own handwriting, the phrase “brand necessary” or “brand medically necessary.”

(B) The dispensing directive shall:

(i) be in a format that protects confidentiality as required by the Health Insurance Portability and Accountability Act of 1996 (29 U.S.C. Section 1181 et seq.) and its subsequent amendments; and

(ii) comply with federal and state law, including rules, with regard to formatting and security requirements.

(C) The dispensing directive specified in this paragraph may not be preprinted, rubber stamped, or otherwise reproduced on the prescription form.

(D) After, June 1, 2002, a practitioner may prohibit substitution on a written prescription only by following the dispensing directive specified in this paragraph. Two-line prescription forms, check boxes, or other notations on an original prescription drug order which indicate “substitution instructions” are not valid methods to prohibit substitution, and a pharmacist may substitute on

these types of written prescriptions.

(E) A written prescription drug order issued prior to June 1, 2002, but presented for dispensing on or after June 1, 2002, shall follow the substitution instructions on the prescription.

(2) *Verbal Prescriptions.*

(A) If a prescription drug order is transmitted to a pharmacist orally, the practitioner or practitioner's agent shall prohibit substitution by specifying "brand necessary" or "brand medically necessary." The pharmacists shall note any substitution instructions by the practitioner or practitioner's agent, on the file copy of the prescription drug order. Such file copy may follow the one-line format indicated in subsection (b)(1) of this section, or any other format that clearly indicates the substitution instructions.

(B) If the practitioner's or practitioner's agent does not clearly indicate that the brand name is medically necessary, the pharmacist may substitute a generically equivalent drug product.

(C) To prohibit substitution on a verbal prescription reimbursed through the medical assistance program specified in 42 C.F.R., Section 447.331:

(i) the practitioner or the practitioner's agent shall verbally indicate that the brand is medically necessary; and

(ii) the practitioner shall mail or fax a written prescription to the pharmacy which complies with the dispensing directive for written prescriptions specified in paragraph (1) of this subsection within 30 days.

(3) *Electronic prescription drug orders.*

(A) To prohibit substitution, the practitioner or practitioner's agent shall note "brand necessary" or "brand medically necessary" in the electronic prescription drug order.

(B) If the practitioner or practitioner's agent does not clearly indicate in the electronic prescription drug order that the brand is medically necessary, the pharmacist may substitute a generically equivalent drug product.

(C) To prohibit substitution on an electronic prescription drug order reimbursed through the medical assistance program specified in 42 C.F.R., Section 447.331, the practitioner shall fax a copy of the original prescription drug order which complies with the requirements of a written prescription drug order specified in paragraph (1) of this subsection within 30 days.

(4) *Prescriptions issued by out-of-state, Mexican, Canadian, or federal facility practitioners.*

(A) The dispensing directive specified in this subsection does not apply to the following types of prescription drug orders:

(i) prescription drug orders issued by a practitioner in a state other than Texas;

(ii) prescriptions for dangerous drugs issued by a practitioner in the United Mexican States or the Dominion of Canada; or

(iii) prescription drug orders issued by practitioners practicing in a federal facility provided they are acting in the scope of their employment.

(B) A pharmacist may not substitute on prescription drug orders identified in subparagraph (A) of this paragraph unless the practitioner has authorized substitution on the prescription drug order. If the practitioner has not authorized substitution on the written prescription drug order, a pharmacist shall not substitute a generically equivalent drug product unless:

(i) the pharmacist obtains verbal or written authorization from the practitioner (such authorization shall be noted on the original prescription drug order); or

(ii) the pharmacist obtains written documentation regarding substitution requirements from the State Board of Pharmacy in the state, other than Texas, in which the prescription drug order was issued. The following is applicable concerning this documentation.

(I) The documentation shall state that a pharmacist may substitute on a prescription drug order issued in such other state unless the practitioner prohibits substitution on the original prescription drug order.

(II) The pharmacist shall note on the original prescription drug order the fact that documentation from such other state board of pharmacy is on file.

(III) Such documentation shall be updated yearly.

(d) *Substitution of dosage form.*

(1) As specified in Section 562.012 of the Act, a pharmacist may dispense a dosage form of a drug product different from that prescribed, such as tablets instead of capsules or liquid instead of

tablets, provided:

- (A) the patient consents to the dosage form substitution;
- (B) the pharmacist notifies the practitioner of the dosage form substitution; and
- (C) the dosage form so dispensed:

(i) contains the identical amount of the active ingredients as the dosage prescribed for the patient;

(ii) is not an enteric-coated or time release product; and

(iii) does not alter desired clinical outcomes;

(2) Substitution of dosage form may not include the substitution of a product that has been compounded by the pharmacist unless the pharmacist contacts the practitioner prior to dispensing and obtains permission to dispense the compounded product.

(e) *Refills.*

(1) *Original substitution instructions.*

(A) All refills, shall follow the original substitution instructions, unless otherwise indicated by the practitioner or practitioner's agent

(B) Prescriptions issued prior to June 1, 2002, on the two-line form shall follow the substitution instructions on the form.

(2) *Narrow therapeutic index drugs.*

(A) The board, in consultation with the Texas State Board of Medical Examiners, has determined that no drugs shall be included on a list of narrow therapeutic index drugs as defined in §562.013, Occupations Code. The board has specified in §309.7 of this title (relating to dispensing responsibilities) that pharmacist shall use as a basis for determining generic equivalency, Approved Drug Products with Therapeutic Equivalence Evaluations and current supplements published by the Federal Food and Drug Administration, within the limitations stipulated in that publication.

(i) Pharmacists may only substitute products that are rated therapeutically equivalent in the Approved Drug Products with Therapeutic Equivalence Evaluations and current supplements.

(ii) Practitioners may prohibit substitution through a dispensing directive in compliance with subsection (c) of this section.

(B) The board shall reconsider the contents of the list if the Federal Food and Drug Administration determines a new equivalence classification which indicates that certain drug products are equivalent but special notification to the patient and practitioner is required when substituting these products.