

**COMMONWEALTH OF PENNSYLVANIA
GENERIC DRUG EQUIVALENCY/SUBSTITUTION
LAWS & REGULATIONS**

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

deletion of generically equivalent drugs and any determination by the secretary to not recognize a generically equivalent drug in accordance with subsection (b). The department shall also provide notice that a complete list of generically equivalent drugs may be obtained from the United States Food and Drug Administration. This notice shall be published at least every three months.

(b) The secretary, with the advice of the Pennsylvania Drug, Device and Cosmetic Board, may determine that a drug shall not be recognized as a generically equivalent drug for purposes of substitution in Pennsylvania and the time after which recognition shall be restored.

(c) Whenever the United States Food and Drug Administration has determined a drug product as having a narrow therapeutic range, the manufacturer may submit an application for review of generic equivalence with the Office of Drugs, Devices and Cosmetics. Within 14 days of receiving a complete application and information, the representative of the Office of Drugs, Devices and Cosmetics shall forward any pertinent clinical information or bioequivalence studies to a consultant pharmacologist designated by the Pennsylvania Drug, Device and Cosmetic Board for review. The consultant pharmacologist shall have a total of 60 days to review any clinical information after he has received all of the data needed for review from the drug manufacturer. The consultant pharmacologist shall then make his recommendation in writing to the Technical Advisory Committee (TAC). After at least 30 days' notice, but no longer than 60 days' notice, from the pharmacologist, a public hearing shall be held by the TAC, or by personnel of the department designated by the secretary, to hear testimony from all parties affected by the possible inclusion of such a drug as a generically equivalent drug for purposes of substitution in Pennsylvania. Such notice shall be mailed to every drug manufacturer that is authorized to do business in this Commonwealth and to all persons who have made a timely request of the TAC for advance notice of its public hearings and shall be published in the Pennsylvania Bulletin. The TAC shall meet quarterly and at that time shall review the recommendations of the consultant pharmacologist and the information provided at the public hearing and make its recommendation to the Pennsylvania Drug, Device and Cosmetic Board within ten working days after the quarterly meeting. The board shall have 14 days to make its recommendation to the secretary. Any decision to reject or to recognize such a drug as generically equivalent for purposes of substitution in Pennsylvania must be accompanied by a written explanation of the basis for the decision. A manufacturer may not resubmit an application after it has been rejected unless additional information is included which responds to the written explanation of the basis for rejection of the original application. After considering the available facts, the secretary shall make a finding with respect to such drug and one year, within 14 working days. The date of this determination shall be the date such drug shall be legally substitutable in this Commonwealth. The department shall issue a quarterly update. The status of such drugs shall be reviewed annually by the secretary.

(d) Any drug product having been previously included in the Pennsylvania Generic Drug Formulary, which the United States Food and Drug Administration has determined as having a narrow therapeutic range, shall be considered generically equivalent for the purposes of this act unless the secretary, with the advice of the Pennsylvania Drug, Device and Cosmetic Board, makes an independent determination

that such a product is not generically equivalent in accordance with the provisions of subsection (c).

(5 amended July 11, 1990, P.L. 509, 121)

Section 6. (a) No pharmacist complying with the provisions of this act shall be liable in any way for the dispensing of a generically equivalent drug unless the generically equivalent drug was incorrectly substituted.

(b) In no event when a pharmacist substitutes a drug shall the prescriber be liable in any action for loss, damage, injury or death or any person occasioned by or arising from the use of the substituted drug unless the original drug was incorrectly prescribed.

(c) Nothing in this act shall affect hospitals or other health care facilities licensed or approved by the Department of Health with the development and/or maintenance of a hospital formulary system in accordance with that institution's policies and procedures that pertain to its drug distribution system developed by the medical staff in cooperation with the hospital's pharmacist and administration.

Section 7. Whoever violates any provisions of this act shall be guilty of a summary offense.

Section 8. (a) Section 5(a)(8), act of September 27, 1961 (P.L. 1700, No. 699), known as the "Pharmacy Act" is repealed insofar as it is inconsistent with the provisions of this act.

(b) The act of September 27, 1961 (P.L. 1700, No. 699), known as the "Pharmacy Act" is repealed insofar as it prohibits advertising or prescription drugs.

Section 9. This act shall take effect immediately.

GENERIC EQUIVALENT DRUG LAW – AMEND
Act of 1990, P.L. 509, No. 121

Session of 1990
No. 1990-121

AN ACT

SB 1111

Amending the act of November 24, 1976 (P.L. 1163, No.259), entitled “An act relating to the prescribing and dispensing of generic equivalent drugs,” further providing for the addition and deletion of generic drugs.

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

Section 1. The definition of “generically equivalent drug” in section 2 of the act of November 24, 1976 (P.L.1163, No.259), referred to as the Generic Equivalent Drug Law, is amended to read:

Section 2. As used in this 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.

Section 2. Section 3(a) and (f) of the act, amended December 15, 1988 (P.L.1257, No.154), are amended to read:

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.

(f) No pharmacist shall substitute a generically equivalent drug for a prescribed brand 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.

Section 3. Sections 4(b) and 5 of the act are amended to read:

Section 4.

(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.

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 deletion of generically equivalent drugs and any determination by the secretary to not recognize a generically equivalent drug in accordance with subsection (b). The department shall also provide notice that a complete list of generically equivalent drugs may be obtained from the United States Food and Drug Administration. This notice shall be published at least every three months.
 - (b) The secretary, with the advice of the Pennsylvania Drug, Device and Cosmetic Board, may determine that a drug shall not be recognized as a generically equivalent drug for purposes of substitution in Pennsylvania and the time after which recognition shall be restored.
 - (c) Whenever the United States Food and Drug Administration has determined a drug product as having a narrow therapeutic range, the manufacturer may submit an application for review of generic equivalence with the Office of Drugs, Devices and Cosmetics. Within 14 days of receiving a complete application and information, the representative of the Office of Drugs, Devices and Cosmetics shall forward an pertinent clinical information or bioequivalence studies to a consultant pharmacologist designated by the Pennsylvania Drug, Device and Cosmetic Board for review. The consultant pharmacologist shall have a total of 60 days to review any clinical information after he has received all of the data needed for review from the drug manufacturer. The consultant pharmacologist shall then make his recommendation in writing to the Technical Advisory Committee (TAC).

After at least 30 days' notice, but no longer than 60 days' notice, from the time the TAC receives the recommendation on a drug from the pharmacologist, a public hearing shall be held by the TAC, or by personnel of the department designated by the secretary, to hear testimony from all parties affected by the possible inclusion of such a drug as a generically equivalent drug for purposes of substitution in Pennsylvania. Such notice shall be mailed to every drug manufacturer that is authorized to do business in this Commonwealth and to all persons who have made a timely request of the TAC for advance notice of its public hearings and shall be published in the Pennsylvania Bulletin. The TAC shall meet quarterly and at that time shall review the recommendations of the consultant pharmacologist and the information provided at the public hearing and make its recommendation to the Pennsylvania Drug, Device and Cosmetic Board within ten working days after the quarterly meeting. The board shall have 14 days to make its recommendation to the secretary. Any decision to reject or to recognize such a drug as generically equivalent for purposes of substitution in Pennsylvania must be accompanied by a written explanation of the basis for the decision. A manufacturer may not resubmit an application after it has been rejected unless additional information is included which responds to the written explanation of the basis for rejection of the original application. After considering the available facts, the secretary shall make a finding with respect to such drug and shall issue a determination of its substitution for a period of one year, within 14 working days. The date of this determination shall be the date such drug shall be legally substitutable in this Commonwealth. The department shall issue a quarterly update. The status of such drugs shall be reviewed annually by the secretary.

(d) Any drug product having been previously included in the Pennsylvania Generic Drug Formulary, which the United States Food and Drug Administration has determined as having a narrow therapeutic range, shall be considered generically equivalent for the purposes of this act unless the secretary, with the advice of the Pennsylvania Drug, Device and Cosmetic Board, makes an independent determination that such a product is not generically equivalent in accordance with the provisions of subsection (c).

Section 4. This act shall take effect in 60 days.

Approved—The 11th day of July, A. D. 1990.

Pennsylvania Code of Regulations

Title 28. Health & Safety

CHAPTER 25 CONTROLLED SUBSTANCES, DRUGS, DEVICES, AND COSMETICS

§ 25.53. Prescription orders.

(a) Prescription orders may be written on prescription blanks or may be oral, if allowed by law.

(b) If prescriptions are issued in writing, 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 the 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.” Information printed on the prescription blank shall be in 8 point, upper-case print. The following example would be acceptable:

SUBSTITUTION PERMISSIBLE M.D.*

IN ORDER FOR A BRAND NAME PRODUCT TO BE DISPENSED, THE PRESCRIBER MUST HANDWRITE “BRAND NECESSARY” OR “BRAND MEDICALLY NECESSARY” IN THE SPACE BELOW.

*as appropriate

(c) If prescription orders are given orally, substitution is permissible unless the prescriber expressly indicates to the pharmacist that the brand name drug is necessary and that substitution is not allowed.

(d) Prescriptions for controlled substances shall be written in indelible ink, indelible pencil or typewriter and shall include the following information:

(1) The date of issue.

(2) The name and address of the patient, or if the patient is an animal, the name and address of the owner and the species of the animal.

- (3) Directions for administration.
- (4) The name, address and Federal Drug Enforcement Administration registration number of the prescribing practitioner.
- (5) The signature of the prescribing practitioner in the manner described in subsection (b).
- (e) The Federal Drug Enforcement Administration registration number cannot be preprinted on the prescription form.

Authority

The provisions of this § 25.53 issued under section 5(a) of the act of November 24, 1976 (P. L. 1163, No. 259) (35 P. S. § 960.5); amended under section 3 of the act of November 24, 1976 (P. L. 1163, No. 259) (35 P. S. § 960.5); and section 2102(g) of The Administrative Code of 1929 (71 P. S. § 532(g)).

Source

The provisions of this § 25.53 amended through June 24, 1977, 7 Pa.B. 1815; amended October 26, 1990, effective October 27, 1990, 20 Pa.B. 5426. Immediately preceding text appears at serial pages (116446) to (116447).

Cross References

This section cited in 28 Pa. Code § 551.3 (relating to definitions); and 49 Pa. Code § 18.158 (relating to prescribing and dispensing drugs).

§ 25.54. Posting notice.

- (a) Every pharmacy shall post a sign which shall read as follows:
“PENNSYLVANIA LAW PERMITS PHARMACISTS TO SUBSTITUTE A LESS EXPENSIVE GENERICALLY EQUIVALENT DRUG FOR A BRAND NAME **DRUG** UNLESS YOU OR YOUR PHYSICIAN DIRECT OTHERWISE.” This sign will be printed in boldface letters not less than one inch or 2.54 centimeters in height on a white background and posted in a prominent place that is in clear and unobstructed public view at or near the place where prescriptions are dispensed.
- (b) Every pharmacy shall post in a conspicuous place, easily accessible to the general public, a list of commonly used generically equivalent drug products from the Department Formulary or in “Approved Drug Products with Therapeutic Equivalence Evaluations”, (Food and Drug Administration “Orange Book”) Publication containing brand names, names of the manufacturers, and generic names. This list shall be alphabetized by brand name, each of which shall be followed by the generic name, and printed in boldface type clearly legible and accessible to the general public.
- (c) Every pharmacy shall have available to the public a listing of the regular and customary

retail prices of that pharmacy for brand name and generic equivalent drug products, with the name of the manufacturer, available for selection by the person presenting the prescription.

Authority

The provisions of this § 25.54 issued under section 5(a) of the act of November 24, 1976 (P. L. 1163, No. 259) (35 P. S. § 960.5).

Source

The provisions of this § 25.54 amended June 24, 1977, 7 Pa.B. 1742. Immediately preceding text appears at serial page (17641).

Cross References

This section cited in 28 Pa. Code § 551.3 (relating to definitions); and 49 Pa. Code § 18.158 (relating to prescribing and dispensing drugs).

§ 25.55. Dispensing.

(a) Where the pharmacist is to substitute a less expensive generically equivalent drug for a brand name drug at the pharmacy, notification to the person presenting the prescription shall be made by the pharmacist, either directly or through a pharmacy intern or other person under the supervision of the pharmacist authorized to assist the pharmacist by the State Board of Pharmacy. Such notification shall be limited to advising the person presenting the prescription that substitution is possible, to advising the person of the amount of the retail price difference between the brand name and the generically equivalent drug product substituted for it, and to informing the person that he may refuse the substitution. Questions by the person presenting the prescription for drug product information shall be answered only by the pharmacist or pharmacy intern. The notification described in this subsection of a possible substitution and retail price difference may be oral or may be in a written statement similar to the following: "Your physician has indicated that this prescription, identified as _____, may be filled with one of the generic drug products listed in the Pennsylvania Department of Health Formulary or in "Approved Drug Products with Therapeutic Equivalence Evaluations", (Food and Drug Administration "Orange Book") Publication. This lower cost generically equivalent product has been selected by our pharmacy in order to save you, the purchaser, a total of \$_____. Please indicate whether you do ! or do not wish to have the lower priced drug. Signed _____."

(b) Where the pharmacist is to substitute a less expensive generically equivalent drug product for a brand name drug by mail, the following provisions must be complied with:

(1) The mail order pharmacy, in all communications in connection with the solicitations of mail order customers, whether by direct mailings, general advertising, or on order forms, shall include notice in upper case letters and in boldface type as follows:

PENNSYLVANIA LAW PERMITS PHARMACISTS TO SUBSTITUTE A LESS EXPENSIVE GENERICALLY EQUIVALENT DRUG FOR A BRAND NAME DRUG UNLESS YOU OR YOUR PHYSICIAN DIRECT OTHERWISE CHECK HERE IF YOU DO NOT WISH A LESS EXPENSIVE BRAND OR GENERIC DRUG "PRODUCT"

(2) After receiving a prescription order by mail, a mail order pharmacy shall substitute a less expensive generically equivalent drug product listed in the Formulary or in "Approved Drug Products with Therapeutic Equivalence Evaluations", (Food and Drug Administration "Orange Book") Publication unless expressly directed otherwise by the person presenting the prescription or the prescribing physician.

(3) When a generically equivalent drug product is dispensed by mail, the pharmacy shall notify the person presenting the prescription of the substitution and shall indicate the retail price difference between the brand name drug and the generic equivalent drug product substituted for it.

(c) Any pharmacist substituting a less expensive drug product shall charge the person presenting the prescription the regular and customary retail price of that pharmacy for the generically equivalent drug.

(d) No pharmacist shall substitute a generically equivalent drug product for a prescribed brand name drug product if the brand name drug product or the generic drug type is not included in the Formulary developed by the Department or in "Approved Drug Products with Therapeutic Equivalence Evaluations", (Food and Drug Administration "Orange Book") Publication 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.

(e) Prescription refills, where permitted by the practitioner, shall be completed using the identical product (same distributor and manufacturer) as dispensed on the original, unless the person presenting the prescription and the practitioner authorize in advance a different manufacturer's generic equivalent product. Advance authorization is not required in an emergency, but the physician shall be notified by the pharmacist as soon as possible thereafter.

Authority

The provisions of this § 25.55 issued under section 5(a) of the act of November 24, 1976 (P. L. 1163, No. 259) (35 P. S. § 960.5)

Source

The provisions of this § 25.55 amended June 24, 1977, effective June 25, 1977, 7 Pa.B. 1742. Immediately preceding text appears at serial pages (17641) and (17642).

Cross References

This section cited in 28 Pa. Code § 551.3 (relating to definitions); 49 Pa. Code § 18.158 (relating to prescribing and dispensing drugs); and 49 Pa. Code § 43a.9 (relating to schedule of civil penalties pharmacists/pharmacies).