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THE GENERAL ASSEMBLY OF PENNSYLVANIA

SENATE BILL

No. 1111 Session of 1989

INTRODUCED BY GREENWOOD, DAWIDA, PORTERFIELD, SALVATORE, HELFRICK AND LEWIS, JUNE 26, 1989

REFERRED TO PUBLIC HEALTH AND WELFARE, JUNE 26, 1989

AN ACT

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 from the formulary.

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

Section 1. Section 3(a) of the act of November 24, 1976 (P.L.1163, No.259), referred to as the Generic Equivalent Drug Law, amended December 15, 1988 (P.L.1257, No.154), is amended to read:

Section 3. (a) Whenever a pharmacist receives a prescription for a brand name drug he shall, unless requested otherwise by the purchaser, substitute a less expensive generically equivalent drug product listed in the formulary of generic and brand name drug products developed by the Department of Health as provided in section 5(b) and (c) unless the prescriber indicates otherwise. 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 product shall be contingent on whether the pharmacy has the brand name or generically equivalent drug in stock.

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Section 2. Section 5 of the act is amended to read:

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) Distribute in cooperation with the Pennsylvania Board of Pharmacy periodically an updated formulary of generically equivalent drug products to all pharmacies in the Commonwealth.

(b) The Secretary of Health in cooperation with the Pennsylvania Drug, Device and Cosmetic Board shall within 180 days of the effective date of this act establish a formulary of

generically equivalent drugs and the name of their manufacturers. In compiling the list of generic and brand name drug products for inclusion in the formulary, the secretary may adopt in whole or in part formularies adopted by the United States Department of Health, Education and Welfare for their maximum allowable cost program for drug reimbursements under Title XVIII and Title XIX of the Social Security Act. In the event of an emergency, as determined by the secretary to affect the health or safety of the public, the secretary may remove a drug product from the list without public hearings. If the formulary for the maximum allowable cost program is adopted by the secretary, formal hearings as required in [the act of June 4, 1945 (P.L.1388, No.422), known as the "Administrative Agency Law,"] Title 2 of the Pennsylvania Consolidated Statutes (relating to administrative law and procedure) may be waived otherwise the inclusions of all drugs in the formulary shall be in compliance with the provisions of the [Administrative Agency Law] Title 2 of the Pennsylvania Consolidated Statutes. The formulary may be added to or deleted from upon the motion of the secretary or on the petition of any interested party [however]. However, before such addition or deletion the secretary shall [request] receive the advice in writing from the Drug, Device and Cosmetic Board whether a drug should be added or deleted. [Such advice shall be rendered to the secretary within a reasonable time. After considering the available facts, the secretary shall make a finding with respect to such drug and may issue a regulation on its substitution for a period of one year. The status of such drugs as well as the formulary shall be reviewed annually by the secretary.]

(c) A Pennsylvania Generic Drug Law Formulary Application

shall remain active for one year from the date of its notarization. The Office of Drugs, Devices and Cosmetics shall accept applications prior to a manufacturer receiving final United States Food and Drug Administration (FDA) approval. However, an application shall be accompanied by written verification from the FDA relating to the generic drug's satisfying FDA bioequivalence requirements. 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 to a consultant pharmacologist designated by the 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 to hear testimony from all parties affected by the possible inclusion of a generic drug on the drug formulary. Such notice shall be mailed to every drug company 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 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 a drug for inclusion on the formulary 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 on 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 formulary update. The status of such drugs as well as the formulary shall be reviewed annually by the secretary.

(d) For the purposes of this act, the act of July 31, 1968 (P.L.769, No.240), referred to as the "Commonwealth Documents Law," the act of October 15, 1980 (P.L.950, No.164), known as the "Commonwealth Attorneys Act," and the act of June 25, 1982 (P.L.633, No.181), known as the "Regulatory Review Act," the formulary or any addition or deletion to the formulary shall not be considered a rule or regulation.

Section 3. This act shall take effect in 60 days.