HOUSE AMENDED
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THE GENERAL ASSEMBLY OF PENNSYLVANIA

SENATE BILL

No. 1111 Session of 1989

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

AS AMENDED ON THIRD CONSIDERATION, HOUSE OF REPRESENTATIVES, JUNE 30, 1990

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. 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 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 a generic drug on the drug formulary. 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 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.~~

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 [HAVING THE SAME GENERIC NAME, DOSAGE FORM AND LABELED POTENCY, MEETING

STANDARDS OF THE UNITED STATES PHARMACOPOEIA OR NATIONAL FORMULARY OR THEIR SUCCESSORS, IF APPLICABLE, AND NOT FOUND IN VIOLATION OF THE REQUIREMENTS OF THE UNITED STATES FOOD AND DRUG ADMINISTRATION OR THE PENNSYLVANIA DEPARTMENT OF HEALTH.] 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.

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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 [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) UNLESS THE PRESCRIBER INDICATES OTHERWISE.] 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 [PRODUCT] 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 [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 OF HEALTH IN ACCORDANCE WITH THE PROVISIONS OF SECTION 5(B).] <u>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.</u>

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 [FROM THE FORMULARY] CONTAINING THE

GENERIC NAMES AND BRAND NAMES WHERE APPLICABLE.

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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.] 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 SECTION 5(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 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," MAY BE WAIVED OTHERWISE THE INCLUSIONS OF ALL DRUGS IN THE FORMULARY SHALL BE IN COMPLIANCE WITH THE PROVISIONS OF THE ADMINISTRATIVE AGENCY LAW. THE FORMULARY MAY BE ADDED TO OR DELETED FROM UPON THE MOTION OF THE SECRETARY OR ON THE PETITION OF ANY INTERESTED PARTY HOWEVER BEFORE SUCH ADDITION OR DELETION THE SECRETARY SHALL REQUEST 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.] 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 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 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 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 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.