No. 259

AN ACT

HB 473

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 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.

"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 of 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 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 bottom of every prescription blank shall be imprinted with the words "substitution permissible" and "do not substitute" and shall contain two signature lines for the physician's or other authorized prescriber's signature on the line immediately above the chosen option. 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.

(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 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).

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 from the formulary containing the generic names and brand names where applicable.

(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) 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," 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.

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 of prescription drugs.

Section 9. This act shall take effect immediately.

APPROVED—The 24th day of November, A. D. 1976.

MILTON J. SHAPP