LEGISLATIVE BILL 363

Approved by the Governor March 29, 1991

Introduced by Wesely, 26; Byars, 30

AN ACT relating to health; to amend section 71-5403, Reissue Revised Statutes of Nebraska, 1943; to change provisions relating to drug product selection as prescribed; and to repeal the original section.

Be it enacted by the people of the State of Nebraska,

Section 1. That section 71-5403, Reissue Revised Statutes of Nebraska, 1943, be amended to read as follows:

71-5403. (1) Except as limited (a) by this section, when a medical practitioner designates that no drug product selection is permitted, and (b) by subsection (1) of section 71-5404, unless the purchaser instructs otherwise, the pharmacist may drug product select a drug product with the same generic name in the same strength, quantity, dose, and dosage form as the prescribed drug which is, in the pharmacist's professional opinion, bioequivalent, except that products designated as controlled substances as listed in Schedule I of section 28-405 shall not be interchanged. It shall be the responsibility of the purchaser or the ultimate user to advise or instruct the pharmacist that he or she does not desire drug product selection, and it shall not be mandatory for the pharmacist to drug product select against his or her professional judgment.

(2) The department may adopt and promulgate necessary rules and regulations, upon the joint recommendation of the Board of Examiners in Medicine and Surgery and the Board of Examiners in Pharmacy, relating to (a) bioavailability, (b) fraudulent or misleading advertising pertaining to drug product selection, and (c) the control of conditions in which the prescribing practitioner or purchaser should be advised when drug product selection has been made by the pharmacist.

(3) A medical practitioner duly authorized to prescribe drugs, medicinal substances, or controlled substances may specify in writing or by telephonic communication on each prescription that there shall be no drug product selection for the specified brand name drug in any prescription. The phrase no drug product

selection or the notation N.D.P.S. shall be specified on the prescription form or orally communicated by the medical practitioner. The pharmacist shall note N.D.P.S. on the face of the prescription if such is communicated orally by the prescribing medical practitioner.

(4) 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 select a less expensive drug product which is bioequivalent to the one prescribed by the prescriber unless the purchaser does not approve. The sign shall be provided by the department, at a cost to the pharmacy which shall not exceed the actual cost of printing to the department, and the printing on the sign shall be in block letters not less than one inch in height.

(5) A pharmacist shall not drug product select a product under the provisions of this section unless: (a) The product, if it is in solid dosage form, has been marked with an identification code or monogram directly on the dosage unit; (b) the product has been labeled with an expiration date; (c) the manufacturer provides reasonable services to accept return products that have reached their expiration date; and (d) the manufacturer maintains recall capabilities for unsafe or defective drugs.

(6)(a) Except as provided in subdivision (b) of this subsection, a A pharmacist shall not drug product select a product under this section that is:

~~(a)~~ (i) An enteric-coated tablet or capsule;

~~(b)~~ (ii) An injectable suspension other than an antibiotic or insulin;

~~(c)~~ (iii) A controlled-release product;

~~(d)~~ (iv) A suppository containing active ingredients for which systemic absorption is necessary; or

~~(e)~~ (v) A different delivery system for aerosol and nebulizer drugs.

(b) A pharmacist may drug product select a product set forth in subdivision (a) of this subsection if such product has been determined by the Food and Drug Administration to be bioequivalent and therapeutically equivalent to the prescribed drug.

(7) The department shall maintain a list of drug products for which bioequivalency has been demonstrated and documented either federally or by the state.

Sec. 2. That original section 71-5403,

Reissue Revised Statutes of Nebraska, 1943, is repealed.