LEGISLATIVE BILL 103

Approved by the Governor March 21, 1977

Introduced by Moylan, 6; Fowler, 27

AN ACT to amend section 71-1,147.10, Reissue Revised Statutes of Nebraska, 1943, relating to pharmacy; to harmonize provisions with the Nebraska Drug Product Selection Act; to adopt the Nebraska Drug Product Selection Act; and to repeal the original section.

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

Section 1. The Legislature declares it to be the public policy of this state that its citizens receive chemically and therapeutically equivalent drug products at the most reasonable price consistent with a high standard of pharmacy practice.

Sec. 2. As used in this act, unless the context otherwise requires:

(1) Brand name shall mean the proprietary or trade name selected by the manufacturer and placed upon a drug, its container, label, or wrapping at the time of packaging;

(2) Generic name shall mean the official title of a drug or drug combination as determined by the United States Adopted Names and accepted by the federal Food and Drug Administration of those drug products having exactly the same active chemical ingredients in exactly the same strength and quantity;

(3) Drug product select shall mean to dispense, without the duly licensed prescriber's express authorization, a chemically and therapeutically equivalent drug product in place of the drug ordered or prescribed;

(4) Chemically equivalent shall mean drug products that contain amounts of the identical therapeutically active ingredients in the identical strength, quantity, and dosage form and that meet present compendial standards;

(5) Therapeutically equivalent shall mean drugs that are approved by the Food and Drug Administration for interstate distribution and that will provide essentially the same efficacy and toxicity, as determined by the pharmacist in his professional judgment, when administered to an individual in the same dosage regimen.

No drug shall be considered therapeutically equivalent if such drug has been determined by the Food and Drug Administration or the Department of Health not to provide the same demonstrated and documented efficacy or toxicity as the brand name drug prescribed. The department shall be required to publish such list, either federal or state, wherein such nonequivalency has been demonstrated and documented, to all duly certified pharmacies and duly licensed physicians practicing in the State of Nebraska at the time of publication of such a list;

(6) Pharmacist shall mean a pharmacist duly licensed in accordance with the provisions of licensure of Chapter 71, article 1;

(7) Medical practitioner shall mean a duly licensed physician, physician and surgeon, practitioner of osteopathic medicine, dentist, podiatrist, or veterinarian licensed in accordance with the provisions of Chapter 71, article 1; and

(8) Department shall mean the Department of Health.

Sec. 3. (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 4 of this act, 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, therapeutically equivalent, except that products designated as controlled substances as listed in Schedule I or II of section 28-4,117 shall not be interchanged. It shall be the responsibility of the purchaser or the ultimate user to advise or instruct the pharmacist that he does not desire drug product selection, and it shall not be mandatory for the pharmacist to drug product select against his professional judgment.

(2) The department may 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 drug product select a less expensive drug product which is therapeutically equivalent 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 has been marked with an identification code or monogram; (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.

Sec. 4. (1) A pharmacist may drug product select a drug product pursuant to subsection (1) of section 3 of this act only when there will be a savings in cost to the purchaser, except that, if a pharmacy does not have in stock the prescribed drug product and the medical practitioner has not indicated N.D.P.S., and the only equivalent drug product in stock is the same or higher priced, the pharmacist, with the consent of the purchaser, may substitute the same or the higher priced drug product. Any savings resulting from drug product selection shall be reflected in the price charged the purchaser by the pharmacist.

(2) Whenever a drug product has been prescribed with the notation that no drug product selection is permitted for a patient who has a contract whereunder he is reimbursed for the cost of health care, directly or indirectly, the party that has contracted to reimburse the patient, directly or indirectly, shall make reimbursements on the basis of the brand name price and

not on the basis of the generic, chemical, or therapeutically equivalent drug price, unless the contract specifically requires generic reimbursement under the Code of Federal Regulations.

(3) If the physician prescribes a drug by its generic name, the pharmacist shall, consistent with reasonable professional judgment, dispense an effective brand which is the lowest retail cost brand in stock.

(4) All prescriptions dispensed shall bear upon the label the name of the medication in the container unless the prescriber writes do not label or words of similar import on the prescription or so designates in an oral transmission of the prescription.

(5) Nothing in this section shall require a pharmacy, which prices prescriptions upon a professional fee basis, to charge less than its established minimum price for the filling of any prescription.

Sec. 5. (1) The drug product selection of any drug by a pharmacist pursuant to this act shall not constitute the practice of medicine.

(2) Drug product selection of drugs made by a pharmacist in accordance with this act, and any rules that the department may adopt under this act, shall not constitute evidence of negligence if the drug product selection was made within reasonable and prudent practice of pharmacy.

(3) When drug product selection by a pharmacist is permissible in accordance with the provisions of this act, such drug product selection shall not constitute evidence of negligence on the part of the prescribing medical practitioner. In order to promote drug product selection to the fullest extent, it is declared to be in the public interest that failure of a prescribing medical practitioner to provide that there shall be no drug product selection in any case shall not constitute evidence of negligence or malpractice on the part of such prescribing medical practitioner, and it is hereby so provided.

Sec. 6. The manufacturer, packager, or distributor of any human use legend drug sold, delivered, or offered for sale in the State of Nebraska after January 1, 1978, shall have printed on the label on the immediate container of the drug the name and address of the manufacturer of the finished dosage form of the drug. Whenever a duly authorized agent of the department finds or has probable cause to believe that any drug or

medicine is without such labeling, he shall affix thereto an appropriate marking, giving notice that the article is, or is suspected of being sold, delivered, or offered for gain in violation of this act and has been embargoed, and warning that it is unlawful for any person to remove or dispose of the embargoed article by sale or otherwise without permission from the agent or a court of competent jurisdiction.

Sec. 7. (1) In addition to any other penalties provided by law, any person who shall violate the provisions of this act or any rule promulgated under this act shall, upon conviction thereof, be punished by a fine of not more than two hundred fifty dollars for each violation.

(2) It shall be unlawful for any employer or such an employer's agent to coerce a pharmacist to dispense a prescription drug against the professional judgment of the pharmacist or as ordered by the prescribing medical practitioner.

Sec. 8. Sections 1 to 8 of this act shall be known and may be cited as the Nebraska Drug Product Selection Act.

Sec. 9. That section 71-1,147.10, Reissue Revised Statutes of Nebraska, 1943, be amended to read as follows:

71-1,147.10. The Department of Health shall, upon the recommendation and findings of the Board of Examiners in Pharmacy, deny an application for a permit to conduct a pharmacy, or revoke or suspend a permit or an application for renewal thereof, following proper hearing by the Department of Health, should the applicant or permittee be found guilty of any of the following acts or omissions:

(1) Conviction of any crime involving moral turpitude;

(2) Obtaining a pharmacy permit by false representation or fraud;

(3) Operating a pharmacy without a registered pharmacist responsible for the practice of pharmacy;

(4) The compounding and dispensing of drugs and medicines or the filling of a prescription by a person other than a registered pharmacist or by an intern in pharmacy, without the presence of and the immediate personal supervision of a registered pharmacist;

(5) A conviction of a violation of any of the provisions of this act or of a felony, or, if a natural person, the revocation or suspension of a license to practice pharmacy in this state;

(6) Unprofessional conduct, which is hereby defined to include: (a) Misrepresentation or fraud in the conduct of a pharmacy; (b) aiding or abetting an unlicensed person to practice pharmacy; (c) the dispensing over the counter without a prescription of a drug which under state or federal law or regulation is prohibited from being dispensed without a prescription or the renewal of such a prescription without the authorization of the prescriber; ~~or~~ (d) the dispensing of a different drug ~~or brand of drug~~ in place of the drug ~~or brand of drug~~ ordered or prescribed without the express permission of the person ordering or prescribing the same; or (e) any fraudulent act in drug product selection whereby the purchaser is charged for the prescribed brand rather than the selected product which is deemed to be chemically and therapeutically equivalent;

(7) Violation of the rules and regulations governing the practice of pharmacy as promulgated under authority of section 71-1,147.09 by the Department of Health;

(8) Suggesting, soliciting, ordering, assisting or abetting a pharmacist in the violation of any of the offenses set forth in sections 71-147 and 71-148; and

(9) Nothing contained in this section shall be construed to prohibit any hospital, licensed by the Department of Health, from establishing rules and regulations regarding the method by which medical staff members shall agree to order or prescribe drugs and medicines for patients of such hospitals. ~~Hospitals shall not be subject to the provisions of subdivision (d) of subsection (6) of this section.~~

Sec. 10. That original section 71-1,147.10, Reissue Revised Statutes of Nebraska, 1943, is repealed.