Original Sponsors: Bradley, Bradner and Gardiner

Offered: 4/28/76
Referred: Rules

IN THE HOUSE BY THE JUDICIARY COMMITTEE

SENATE CS FOR CS FOR HOUSE BILL NO. 584 am S

IN THE LEGISLATURE OF THE STATE OF ALASKA

NINTH LEGISLATURE - SECOND SESSION

A BILL

For an Act entitled: "An Act relating to the Pharmacy Act."

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF ALASKA:

* Section 1. AS 08.80.030(3) is amended to read:

(3) investigate [,] individually, [OR] collectively, or through its agent, for [ALL ALLEGED] violations of this chapter, or of any other state or federal statute relating to the practice of pharmacy;

* Sec. 2. AS 08.80.295 is repealed and re-enacted to read:

Sec. 08.80.295. SUBSTITUTION. (a) Except as limited by (b) and (c) of this section, with the consent of the purchaser, the pharmacist may substitute 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 and meets the standards of (e) of this section. Upon substitution the pharmacist shall notify the purchaser and the person who prescribed the drug of the substitution and of the drug substituted.

(b) A person authorized to prescribe drugs shall specify in writing or by oral communication whether or not the pharmacist may substitute a drug under (a) of this section. Written specification may be accomplished by checking a box on the prescription order labeled "DISPENSE AS WRITTEN" or "SUBSTITUTION ALLOWED" if the physician personally initials the box or check mark; in the event the physician fails or neglects to initial the box or check mark, the prescription shall be dispensed as written. Written specification may also be by handwriting. If the person communicating the specification does so orally, the

pharmacist shall indicate that fact in handwriting on the written copy of the prescription order.

(c) A pharmacist shall substitute a drug product under (a) of this section only when there will be a savings in cost to the purchaser.

(d) If a person authorized to prescribe drugs is temporarily unavailable, the pharmacist may, if he cannot supply the drug requested, substitute a drug or preparation of approximately equal therapeutic value so long as he notifies the author of the prescription at an early opportunity. The pharmacist in all cases of substitution, except when specifically indicated to the contrary by the prescriber, shall relate the nature of the change to the purchaser.

(e) The manufacturer of products substituted under the provisions of this section shall comply with the following minimum good manufacturing standards and practices:

(1) maintain quality control standards equal to those of the Food and Drug Administration;

(2) comply with regulations promulgated by the Food and Drug Administration;

(3) mark products with identification code or monogram;

(4) label products with expiration date;

(5) provide services to accept return goods;

(6) maintain twenty-four hour resources for product information;

(7) maintain drug recall capabilities;

(8) provide documentation of compliance with Department of Defense (DOD) standard of purchases.

(9) shall not refuse to sell to any properly licensed pharmacy.

(f) As used in this section, unless the context requires other-

wise,

(1) "brand name" means 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" means the official title of a drug or drug ingredients published in the latest edition of a Pharmacopoeia, Homeopathic Pharmacopoeia or Formulary;

(3) "reference or trade standard product" means the original or patented product of the original manufacturer;

(4) "substitute" means to dispense without prescriber's express authorization a different drug product in place of the drug ordered or prescribed;

(5) "therapeutically equivalent" means drugs that will provide essentially the same efficacy and toxicity when administered to an individual in the same dosage regimen.

* Sec. 3. AS 08.80 is amended by adding a new section to read:

Sec. 08.80.297. PRESCRIPTION PRICES AVAILABLE TO CONSUMER. A pharmacist shall disclose the price of filling any prescription before filling it, when requested by the consumer.

* Sec. 4. AS 08.80.460 is amended by adding a new subsection to read:

(b) A person who violates the provisions of sec. 295 of this chapter is punishable by a civil fine in an amount established by the board in a schedule or schedules establishing the amount of civil fine for a particular violation. The schedule or schedules shall be adopted by the board by regulation. Any civil fine imposed under this section may be appealed in the manner provided for appeals in the Administrative Procedure Act (AS 44.62).