Senate Bill 677

Sponsored by COMMITTEE ON HEALTH POLICY AND PUBLIC AFFAIRS

SUMMARY

The following summary is not prepared by the sponsors of the measure and is not a part of the body thereof subject to consideration by the Legislative Assembly. It is an editor's brief statement of the essential features of the measure **as introduced.**

Prohibits pharmacist from substituting certain drugs for specific antiepileptic drug prescribed for patient without consent of prescriber and patient.

A BILL FOR AN ACT

Relating to substitution of prescription drugs by pharmacist; amending ORS 689.515.

Be It Enacted by the People of the State of Oregon:

SECTION 1. ORS 689.515 is amended to read:

689.515. (1) As used in this section unless the context requires otherwise:

(a) "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.

(b) "Dosage form" means the physical formulation or medium in which the product is intended, manufactured and made available for use, including but not limited to tablets, capsules, oral solutions, aerosols, ointments, inhalers and suppositories, and the particular form of which utilizes a specific technology or mechanism to control, enhance or direct the release, targeting, systemic absorption or other delivery of a dosage regimen in the body.

(c) "Generic name" means the official title of a drug or drug ingredients published in the latest edition of the official Pharmacopoeia, Homeopathic Pharmacopoeia or Formulary.

(d) "Substitute" means to dispense without the prescriber's express authorization a different drug product in place of the drug ordered or prescribed.

(e) "Therapeutically equivalent" means drugs that are approved by the United States Food and Drug Administration for interstate distribution and the Food and Drug Administration has determined that the drugs will provide essentially the same efficacy and toxicity when administered to an individual in the same dosage regimen.

(2) Except as limited by subsections (3) and (5) of this section, unless the purchaser instructs otherwise, the pharmacist may substitute as follows:

(a) 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.

(b) When the prescriber is not reasonably available for consultation and the prescribed drug does not utilize a unique delivery system technology, an oral tablet, capsule or liquid form of the prescribed drug so long as the form dispensed or administered has the same strength, dose and dose schedule and is therapeutically equivalent to the drug prescribed.

(3) A practitioner may specify in writing, by a telephonic communication or by electronic transmission that there shall be no substitution for the specified brand name drug in any pre-

NOTE: Matter in **boldfaced** type in an amended section is new; matter [*italic and bracketed*] is existing law to be omitted. New sections are in **boldfaced** type.

scription. The phrase "no substitution" or the notation "N.S." must be in the practitioner's handwriting or, if the prohibition was communicated by telephonic communication or electronic transmission, in the pharmacist's handwriting and shall not be preprinted or stamped or initialed on the prescription form.

(4) Every pharmacy shall post a sign in a location easily seen by patrons at the counter where prescriptions are dispensed or administered stating that, "This pharmacy may be able to substitute a less expensive drug which is therapeutically equivalent to the one prescribed by your doctor unless you do not approve." The printing on the sign shall be in block letters not less than one inch in height. If the pharmacist has reasonable cause to believe that the purchaser cannot read the sign or comprehend its content, the pharmacist shall endeavor to explain the meaning of the sign.

(5) A pharmacist shall substitute a drug product under this section only when there will be a savings in or no increase in cost to the purchaser.

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

(7) Except as provided in subsection (8) of this section, when a pharmacist dispenses a substituted drug as authorized by subsection (2) of this section, the pharmacist must label the prescription container with the name of the dispensed drug. If the dispensed drug does not have a brand name, the prescription label shall indicate the generic name of the drug dispensed along with the name of the drug manufacturer.

(8) A prescription dispensed by a pharmacist shall bear upon the label the name of the medication in the container or shall be labeled as intended by the prescriber.

(9) The substitution of any drug by a licensed pharmacist or the pharmacist's employer pursuant to this section does not constitute the practice of medicine.

(10) No substitution of drugs made by a pharmacist or the pharmacist's employer in accordance with this section and any rules that the State Board of Pharmacy may adopt thereunder shall constitute evidence of negligence if the substitution was made within reasonable and prudent practice of pharmacy or if the substituted drug was accepted in a generally recognized formulary or government list.

(11) Failure of a practitioner to specify that no substitution is authorized does not constitute evidence of negligence unless the practitioner knows that the health condition of the patient for whom the practitioner is prescribing warrants the use of the brand name drug product and not the substituted drug.

(12) Notwithstanding subsections (2) to (11) of this section, a pharmacist may not substitute any antiepileptic drug, formulation of an antiepileptic drug, brand name drug or generic name equivalent drug for the specified antiepileptic drug that has been prescribed for the treatment of seizures of a patient without the prior consent of the prescriber and the patient or the parent, guardian or spouse of the patient.
