By Senator Rich

34-03005A-08 20082414__

A bill to be entitled

An act relating to anti-epileptic drugs; amending s. 440.13, F.S., relating to medical services and supplies; conforming a cross-reference; amending s. 465.025, F.S.; providing definitions; prohibiting a pharmacist from interchanging an anti-epileptic drug without prior notification and consent from the prescribing practitioner and the patient or the patient's parent, guardian, or spouse; amending s. 465.0251, F.S., relating to generic drugs; conforming a cross-reference; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Paragraph (m) of subsection (1) of section 440.13, Florida Statutes, is amended to read:

440.13 Medical services and supplies; penalty for violations; limitations.--

(1) DEFINITIONS.--As used in this section, the term:

(m) "Medicine" means a drug prescribed by an authorized health care provider and includes only generic drugs or single-source patented drugs for which there is no generic equivalent, unless the authorized health care provider writes or states that the brand-name drug as defined in s. 465.025 is medically necessary, or is a drug appearing on the schedule of drugs created pursuant to s. 465.025(7) ~~s. 465.025(6)~~, or is available at a cost lower than its generic equivalent.

Section 2. Section 465.025, Florida Statutes, is amended to read:

465.025 Substitution of drugs.--

(1) As used in this section:

(a) "Anti-epileptic drug" means any drug prescribed for the treatment of epilepsy or any drug used to treat or prevent seizures.

(b) ~~(a)~~ "Brand name" means the registered trademark name given to a drug product by its manufacturer, labeler, or distributor.

(c) "Epilepsy" means a neurological condition characterized by recurrent seizures.

(d) ~~(b)~~ "Generically equivalent drug product" means a drug product having ~~with~~ the same active ingredient, finished dosage form, and strength.

(e) "Interchange" means the substitution of one version of the same anti-epileptic therapeutic product, including a generic version for the prescribed brand, a brand version for the prescribed generic version, a generic version by a manufacturer for a generic version by a different manufacturer, a different formulation of the prescribed anti-epileptic drug, or a different anti-epileptic therapeutic drug product for the anti-epileptic product originally prescribed.

(f) ~~(c)~~ "Prescriber" means any practitioner licensed to prescribe medicinal drugs.

(g) "Seizure" means an acute clinical change that is secondary to a brief disturbance in the electrical activity of the brain.

(2) A pharmacist who receives a prescription for a brand name drug, except an anti-epileptic drug, shall, unless requested

otherwise by the purchaser, substitute a less expensive, generically equivalent drug product that is:

(a) Distributed by a business entity doing business, and subject to suit and service of legal process, in the United States; and

(b) Listed in the formulary of generic and brand name drug products as provided in subsection (5) for the brand name drug prescribed,

unless the prescriber writes the words "MEDICALLY NECESSARY," in her or his own handwriting, on the face of a written prescription; unless, in the case of an oral prescription, the prescriber expressly indicates to the pharmacist that the brand name drug prescribed is medically necessary; or unless, in the case of a prescription that is electronically generated and transmitted, the prescriber makes an overt act when transmitting the prescription to indicate that the brand name drug prescribed is medically necessary. When done in conjunction with the electronic transmission of the prescription, the prescriber's overt act indicates to the pharmacist that the brand name drug prescribed is medically necessary.

(3)(a) Any pharmacist who substitutes any drug as provided in subsection (2) shall notify the person presenting the prescription of such substitution, together with the existence and amount of the retail price difference between the brand name drug and the drug substituted for it, and shall inform the person presenting the prescription that such person may refuse the substitution as provided in subsection (2).

(b) Any pharmacist substituting a less expensive drug product shall pass on to the consumer the full amount of the savings realized by such substitution.

(4) Each pharmacist shall maintain a record of any substitution of a generically equivalent drug product for a prescribed brand name drug as provided in this section.

(5) A pharmacist may not interchange an anti-epileptic drug or formulation of an anti-epileptic drug, brand, or generic for the treatment of seizures or epilepsy without prior notification of, and the signed, informed consent to, such interchange from the prescribing practitioner and the patient or the patient's parent, legal guardian, or spouse.

(6) ~~(5)~~ Each community pharmacy shall establish a formulary of generic and brand name drug products which, if selected as the drug product of choice, would not pose a threat to the health and safety of patients receiving prescription medication. In compiling the list of generic and brand name drug products for inclusion in the formulary, the pharmacist shall rely on drug product research, testing, information, and formularies compiled by other pharmacies, by states, by the United States Department of Health, Education, and Welfare, by the United States Department of Health and Human Services, or by any other source which the pharmacist deems reliable. Each community pharmacy shall make such formulary available to the public, the Board of Pharmacy, or any physician requesting same. This formulary shall be revised following each addition, deletion, or modification of said formulary.

(7) ~~(6)~~ The Board of Pharmacy and the Board of Medicine shall establish by rule a formulary of generic drug type and

brand name drug products which are determined by the boards to demonstrate clinically significant biological or therapeutic inequivalence and which, if substituted, would pose a threat to the health and safety of patients receiving prescription medication.

(a) The formulary may be added to or deleted from as the Board of Pharmacy and the Board of Medicine deem appropriate. Any person who requests any inclusion, addition, or deletion of a generic drug type or brand name drug product to the formulary shall have the burden of proof to show cause why such inclusion, addition, or deletion should be made.

(b) Upon adoption of the formulary required by this subsection, and upon each addition, deletion, or modification to the formulary, the Board of Pharmacy shall mail a copy to each manager of the prescription department of each community pharmacy licensed by the state, each nonresident pharmacy registered in the state, and each board regulating practitioners licensed by the laws of the state to prescribe drugs shall incorporate such formulary into its rules. 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 drug product is included in the said formulary.

(8) ~~(7)~~ Every community pharmacy shall display in a prominent place that is in clear and unobstructed public view, at or near the place where prescriptions are dispensed, a sign in block letters not less than 1 inch in height which shall read: "CONSULT YOUR PHARMACIST CONCERNING THE AVAILABILITY OF A LESS EXPENSIVE GENERICALLY EQUIVALENT DRUG AND THE REQUIREMENTS OF FLORIDA LAW."

(9)~~(8)~~ The standard of care to be applied to the acts of any pharmacist performing professional services in compliance with this section when a substitution is made by said pharmacist shall be that which would apply to the performance of professional services in the dispensing of a prescription order prescribing a drug by generic name. In no event when a pharmacist substitutes a drug shall the prescriber be liable in any action for loss, damage, injury, or death to any person occasioned by or arising from the use or nonuse of the substituted drug, unless the original drug was incorrectly prescribed.

Section 3. Section 465.0251, Florida Statutes, is amended to read:

465.0251 Generic drugs; removal from formulary under specified circumstances.--

(1) The Board of Pharmacy and the Board of Medicine shall remove any generic named drug product from the formulary established by s. 465.025(7) ~~s. 465.025(6)~~, if every commercially marketed equivalent of that drug product is "A" rated as therapeutically equivalent to a reference listed drug or is a reference listed drug as referred to in "Approved Drug Products with Therapeutic Equivalence Evaluations" (Orange Book) published by the United States Food and Drug Administration.

(2) ~~Nothing in~~ This section does not ~~act shall~~ alter or amend s. 465.025 as to existing law providing for the authority of physicians to prohibit generic drug substitution by writing "medically necessary" on the prescription.

Section 4. This act shall take effect upon becoming a law.