AMENDED IN SENATE APRIL 3, 2008

SENATE BILL No. 1504

Introduced by Senator Ridley-Thomas

February 21, 2008

An act to amend Sections 4052.5 and 4073 of the Business and Professions Code, relating to pharmacies.

LEGISLATIVE COUNSEL'S DIGEST

SB 1504, as amended, Ridley-Thomas. Antiepileptic drug products: substitution.

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacists by the California State Board of Pharmacy, and makes a knowing violation of the act a crime. Existing law authorizes a pharmacist filling a prescription order for a drug product prescribed by its trade or brand name to substitute a generic drug product, subject to specified requirements. Existing law authorizes a pharmacist filling a prescription order for a drug product to substitute a drug product with a different form of medication having the same active chemical ingredients of equivalent strength and duration of therapy as the prescribed drug product, subject to specified requirements.

This bill would prohibit a pharmacist filling a prescription order for an antiepileptic drug or formulation of an antiepileptic drug, prescribed by its trade, brand, or generic name for the treatment or prevention of epileptic seizures, from substituting a drug product pursuant to those provisions without prior notification of the prescriber and the signed consent of the patient or the patient's parent, legal guardian, or spouse.

Because this bill would impose a new prohibition under the Pharmacy Law, the violation of which would be a crime, it would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. Section 4052.5 of the Business and Professions Code is amended to read:

4052.5. (a) In addition to the authority allowed under Section 4073, but subject to the express prohibition set forth in subdivision (f) of Section 4073, a pharmacist filling a prescription order for a drug product may select a different form of medication with the same active chemical ingredients of equivalent strength and duration of therapy as the prescribed drug product when the change will improve the ability of the patient to comply with the prescribed drug therapy.

(b) In no case shall a selection be made pursuant to this section if the prescriber personally indicates, either orally or in his or her own handwriting, "Do not substitute" or words of similar meaning. Nothing in this subdivision shall prohibit a prescriber from checking a box on a prescription marked "Do not substitute" if the prescriber personally initials the box or checkmark.

(c) Selection pursuant to this section is within the discretion of the pharmacist, except as provided in subdivision (b). The pharmacist who selects the drug product to be dispensed pursuant to this section shall assume the same responsibility for selecting the dispensed drug product as would be incurred in filling a prescription for a drug product using the prescribed form of medication. There shall be no liability on the prescriber for an act or omission by a pharmacist in selecting, preparing, or dispensing a drug product pursuant to this section.

(d) This section shall apply to all prescriptions, including those presented by or on behalf of persons receiving assistance from the federal government or pursuant to the California Medical Assistance Program set forth in Chapter 7 (commencing with

Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code.

(e) When a substitution is made pursuant to this section, the use of the different form of medication shall be communicated to the patient, and the name of the dispensed drug product shall be indicated on the prescription label, unless the prescriber orders otherwise.

(f) This section shall not permit substitution between long-acting and short-acting forms of a medication with the same chemical ingredients or between one drug product and two or more drug products with the same chemical ingredients.

SEC. 2. Section 4073 of the Business and Professions Code is amended to read:

4073. (a) A pharmacist filling a prescription order for a drug product prescribed by its trade or brand name may select another drug product with the same active chemical ingredients of the same strength, quantity, and dosage form, and of the same generic drug name as determined by the United States Adopted Names (USAN) and accepted by the federal Food and Drug Administration (FDA), of those drug products having the same active chemical ingredients.

(b) In no case shall a selection be made pursuant to this section if the prescriber personally indicates, either orally or in his or her own handwriting, "Do not substitute," or words of similar meaning. Nothing in this subdivision shall prohibit a prescriber from checking a box on a prescription marked "Do not substitute"; provided that the prescriber personally initials the box or checkmark. To indicate that a selection shall not be made pursuant to this section for an electronic data transmission prescription as defined in subdivision (c) of Section 4040, a prescriber may indicate "Do not substitute," or words of similar meaning, in the prescription as transmitted by electronic data, or may check a box marked on the prescription "Do not substitute." In either instance, it shall not be required that the prohibition on substitution be manually initialed by the prescriber.

(c) Selection pursuant to this section is within the discretion of the pharmacist, except as provided in subdivisions (b) and (f). The person who selects the drug product to be dispensed pursuant to this section shall assume the same responsibility for selecting the dispensed drug product as would be incurred in filling a prescription for a drug product prescribed by generic name. There

shall be no liability on the prescriber for an act or omission by a pharmacist in selecting, preparing, or dispensing a drug product pursuant to this section. In no case shall the pharmacist select a drug product pursuant to this section unless the drug product selected costs the patient less than the prescribed drug product. Cost, as used in this subdivision, is defined to include any professional fee that may be charged by the pharmacist.

(d) This section shall apply to all prescriptions, including those presented by or on behalf of persons receiving assistance from the federal government or pursuant to the California Medical Assistance Program set forth in Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code.

(e) When a substitution is made pursuant to this section, the use of the cost-saving drug product dispensed shall be communicated to the patient and the name of the dispensed drug product shall be indicated on the prescription label, except where the prescriber orders otherwise.

(f) In no case shall a pharmacist filling a prescription order for an antiepileptic drug, or formulation of an antiepileptic drug prescribed by its trade, brand, or generic name for the treatment or prevention of epileptic seizures, substitute a drug product pursuant to this section or subdivision (a) of Section 4052.5 without prior notification of the prescriber and the signed consent to the substitution from the patient or the patient's parent, legal guardian, or spouse.

For purposes of this subdivision, the following definitions apply:

(1) "Antiepileptic drug" means any drug approved by the United States Food and Drug Administration (FDA) for the treatment of epilepsy or the treatment or prevention of epileptic seizures.

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

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

(4) ~~"Substitute"~~ "*Select*," "*selection*," "*substitute*," or "substitution" means the substitution for an antiepileptic drug originally prescribed ~~of a~~ *with any other* version of the same ~~antiepileptic drug, including a generic version for the prescribed generic version, a generic version by one manufacturer for a generic version by a different manufacturer, or a different formulation of~~

~~the prescribed antiepileptic drug.~~ *antiepileptic drug, including, but not limited to, any of the following:*

(A) A generic version for the prescribed trade or brand name drug.

(B) A trade or brand name drug for the prescribed generic version.

(C) A generic drug produced by one manufacturer for a generic drug produced by a different manufacturer.

(D) Any dosage form of that prescribed antiepileptic drug that differs from the dosage form originally prescribed by the prescriber.

SEC. 3. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

O