ASSEMBLY BILL No. 1139

Introduced by Assembly Member Lowenthal
(Principal coauthor: Senator DeSaulnier)

February 22, 2013

An act to amend Section 4073 of the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

AB 1139, as introduced, Lowenthal. Prescriptions: biosimilar products.

The Pharmacy Law governs the practice of pharmacy in this state, including the permissible duties of licensed pharmacists. Among other permitted acts, 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 a specified federal entity, of those drug products having the same active chemical ingredients. A person who knowingly violates the Pharmacy Law is guilty of a misdemeanor, as specified.

This bill would authorize a pharmacist filling a prescription order for a biological product subject to the Federal Food, Drug, and Cosmetic Act, as specified, to select a biosimilar product, as defined by federal statute, provided that product is deemed by the federal Food and Drug Administration (FDA) to be interchangeable with the prescribed product.

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

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

SECTION 1. 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) A pharmacist filling a prescription order for a biological product subject to Section 503(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 353(b)), may select a biosimilar product, as defined by Section 351 of the federal Public Health Service Act (42 U.S.C. Sec. 262), provided that product is deemed by the FDA to be interchangeable with the prescribed product.

~~(b)~~

(c) 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)~~

(d) Selection pursuant to this section is within the discretion of the pharmacist, except as provided in subdivision ~~(b)~~ *(c)*. 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)~~

(e) 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)~~

(f) 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.

O