AMENDED IN ASSEMBLY AUGUST 6, 2013

AMENDED IN ASSEMBLY JUNE 20, 2013

AMENDED IN SENATE APRIL 16, 2013

# SENATE BILL No. 598

**Introduced by Senator Hill**
(Coauthors: Assembly Members Gorell and Mullin)

February 22, 2013

An act to add Section 4073.5 to the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

SB 598, as amended, Hill. Biosimilars.

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, as specified, 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, in his or her discretion, except as specified, to select a biosimilar, as defined, when filling a prescription order for a prescribed biological product only if ~~certain conditions are met, including, among other conditions, the requirement that,~~ *the product has been approved by the federal Food and Drug Administration, as specified, and the prescriber does not personally indicate "Do not substitute," as specified. The bill would also require,* for prescriptions

filled prior to January 1, 2017, the pharmacy ~~notify the prescriber or enter the appropriate information in a patient record system shared by the prescriber within 5 business days of the selection~~ *to, within 5 business days of the selection of a biological product or an interchangeable biosimilar, notify the prescriber or enter in a patient record whether the prescription dispensed was a biological product or an interchangeable biosimilar, except as specified*. The bill would prohibit a pharmacist from ~~substituting a biological product pursuant to~~ *selecting a biosimilar that meets the requirements of* these provisions unless the ~~biological product~~ *cost to the patient of the biosimilar* selected ~~costs the patient~~ *is* the same or less than the *cost of the* prescribed biological product. The bill would also require that the substitution of a biosimilar be communicated to the patient. Because a knowing violation of these requirements would be a misdemeanor, the bill would create new crimes, thereby imposing a state-mandated local program.

The bill would also require the California State Board of Pharmacy to maintain on its public Internet Web site a link to the current list, if available, of biosimilar products determined by the federal Food and Drug Administration to be interchangeable, as specified.

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 4073.5 is added to the Business and Professions Code, to read:

4073.5. (a) A pharmacist filling a prescription order for a prescribed biological product may select a biosimilar only if ~~all~~ *both* of the following conditions are met:

(1) The product selected as a biosimilar has been approved by the federal Food and Drug Administration (FDA) under the 351(k) pathway of the federal Public Health Service Act (42 U.S.C. Sec. 262(k)) and has been determined to be interchangeable with the prescribed biological product.

(2) The prescriber does not personally indicate~~, either orally or in his or her own handwriting,~~ "Do not substitute," or words of similar meaning, in the manner provided in subdivision ~~(b)~~ *(c)*.

~~(3) For prescriptions filled prior to January 1, 2017, the pharmacy notifies the prescriber or enters the appropriate information in a patient record system shared by the prescriber within five business days of the selection.~~

*(b) For prescriptions filled prior to January 1, 2017, the pharmacy shall, within five business days of the selection of a biological product or an interchangeable biosimilar, approved as provided in paragraph (1) of subdivision (a), notify the prescriber whether the prescription dispensed was a biological product or an interchangeable biosimilar, approved as provided in paragraph (1) of subdivision (a), or enter the information in a patient record system shared by the prescriber. No notification is required if the prescriber indicates "Do not substitute" in the manner provided in subdivision (c), if there is no FDA-approved interchangeable biosimilar pursuant to paragraph (1) of subdivision (a), or if a refill prescription is not changed from the product originally dispensed.*

~~(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 pharmacist who selects the biosimilar to be dispensed pursuant to this section shall assume the same responsibility for substituting

the biosimilar as would be incurred in filling a prescription for a biosimilar prescribed by name. There shall be no liability on the prescriber for an act or omission by a pharmacist in selecting, preparing, or dispensing a biological product pursuant to this section. In no case shall the pharmacist ~~substitute a biological product pursuant to this section~~ *select a biosimilar that meets the requirements of paragraph (1) of subdivision (a)* unless the ~~biological product selected costs the patient~~ *cost to the patient of the biosimilar selected is* the same or less than the *cost of the* prescribed biological 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 Medi-Cal Act 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 selection is made pursuant to this section, the substitution of a biosimilar shall be communicated to the patient.

~~(f)~~

*(g)* The board shall maintain on its public Internet Web site a link to the current list, if available, of biosimilar products determined by the FDA to be interchangeable, as provided in paragraph (1) of subdivision (a).

~~(g)~~

*(h)* For purposes of this section, the following terms shall have the following meanings:

(1) "Biological product," "biosimilar," and "interchangeable" have the same meanings that apply to those terms under Section 351 of the federal Public Health Service Act (42 U.S.C. Sec. 262).

(2) "Prescription," with respect to a biological product, means *a prescription for* a product that is subject to Section 503(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 353(b)).

(3) "351(k) pathway" refers to the licensure of a biological product as a biosimilar or an interchangeable biosimilar by the FDA pursuant to Section 351(k) of the federal Public Health Service Act.

~~(h)~~

*(i)* Nothing in this section prohibits the administration of immunizations, as permitted in Section 4052.

~~(i)~~

*(j)* Nothing in this section ~~shall be interpreted to prohibit~~ *prohibits* a disability insurer or health care service plan from requiring prior authorization or imposing other appropriate utilization controls in approving coverage for any biological product.

SEC. 2. 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.

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