AMENDED IN SENATE APRIL 16, 2013

# SENATE BILL No. 598

**Introduced by Senator Hill**

February 22, 2013

An act to add Sections 4052.55 and 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 requirements that, 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 and retain a written record of the biosimilar selection for a period of at least 3 years*. The bill would prohibit a pharmacist from substituting a biological product pursuant to these provisions unless the biological product selected costs the patient less than the prescribed biological

product. The bill would also require that the substitution of a biosimilar be communicated to the patient ~~and that the full name and manufacturer of the biosimilar be indicated on the prescription label~~. 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 4052.55 is added to the Business and Professions Code, to read:

4052.55. (a) In addition to the authority allowed under Section 4073.5, a pharmacist filling a prescription order for a prescribed biological product may select a biosimilar only if all 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, pursuant to subdivision (b).

(3) ~~The pharmacist~~ *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.

(4) ~~The~~ *For prescriptions filled prior to January 1, 2017, the* pharmacy retains a written record of the biosimilar selection for a period of at least three years.

(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 biosimilar to be dispensed pursuant to this section shall assume the same responsibility for substituting the dispensed biosimilar as would be incurred in filling a prescription for a biosimilar 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 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) When a selection is made pursuant to this section, the substitution of a biosimilar shall be communicated to the patient ~~and the full name and manufacturer of the dispensed biosimilar shall be indicated on the prescription label, unless where the prescriber orders otherwise~~.

(f) 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) 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 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 (42 U.S.C. Sec. 262(k)).

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

SEC. 2. 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 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).

(3) ~~The pharmacist~~ *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.

(4) ~~The~~ *For prescriptions filled prior to January 1, 2017, the* pharmacy retains a written record of the biosimilar selection for a period of at least three years.

(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 selection be manually initialed by the prescriber.

(c) Selection pursuant to this section is within the discretion of the pharmacist, except as provided in subdivision (b). The pharmacist who selects the biosimilar to be dispensed pursuant to this section shall assume the same responsibility for substituting the dispensed biological product as would be incurred in filling a prescription for a biosimilar 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 biological product pursuant to this section. In no case shall the pharmacist substitute a biological product pursuant to this section unless the biological product selected costs the patient less than 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) 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) When a selection is made pursuant to this section, the substitution of a biosimilar shall be communicated to the patient ~~and the full name and manufacturer of the dispensed biosimilar shall be indicated on the prescription label, unless where the prescriber orders otherwise~~.

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

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.

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