AMENDED IN ASSEMBLY JULY 16, 2015

AMENDED IN ASSEMBLY JUNE 23, 2015

AMENDED IN SENATE MAY 5, 2015

AMENDED IN SENATE APRIL 14, 2015

SENATE BILL No. 671

Introduced by Senator Hill

February 27, 2015

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

LEGISLATIVE COUNSEL'S DIGEST

SB 671, as amended, Hill. Pharmacy: biological product.

The Pharmacy Law governs the practice of pharmacy in this state, including the permissible duties of licensed pharmacists. The Pharmacy Law authorizes a pharmacist filling a prescription order for a drug product prescribed by its trade or brand name to 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 knowing violation of the Pharmacy Law is a misdemeanor.

This bill, except as specified, would authorize a pharmacist to select an alternative biological product when filling a prescription order for a prescribed biological product if the alternative biological product is interchangeable, as defined, and the prescriber does not personally indicate in a prescribed manner that a substitution is not to be made. The bill would require a pharmacist or a designee, within a specified period following the dispensing of a biological product, to make an

electronically accessible entry in a described entry system of the specific biological product provided to the patient. The bill would provide an alternate means of communicating the name of the biological product dispensed to the prescriber if the pharmacy does not have access to one or more of the described entry systems. The bill would also require that the substitution of a biological product be communicated to the patient. The bill would prohibit a pharmacist from selecting an alternative biological product that meets the requirements of these provisions unless the cost to the patient of the alternative biological product selected is the same or less than the cost of the prescribed biological product. 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 biological products determined by the federal Food and Drug Administration to be interchangeable.

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 an alternative biological product only if all of the following:

(1) The alternative biological product is interchangeable.

(2) The prescriber does not personally indicate “Do not substitute,” or words of similar meaning, in the manner provided in subdivision (d).

(b) Within five days following the dispensing of a biological product, a dispensing pharmacist or the pharmacists’ designee shall make an entry of the specific biological product provided to the patient, including the name of the biological product and the

manufacturer. The communication shall be conveyed by making an entry that can be electronically accessed by the prescriber ~~through:~~ *through one or more of the following electronic records systems:*

(1) An interoperable electronic medical records ~~system,~~ *system*.

(2) An electronic prescribing ~~technology,~~ *technology.*

(3) A pharmacy benefit management ~~system, or~~ *system.*

(4) A pharmacy record.

(c) Entry into an electronic records system as described in subdivision (b) is presumed to provide notice to the prescriber. ~~If~~

(d) If the pharmacy does not have access to one or more of the entry systems in subdivision (b), the pharmacist or the pharmacist's designee shall communicate the name of the biological product dispensed to the prescriber using facsimile, telephone, electronic transmission, or other prevailing means, except that communication shall not be required in this instance to the prescriber when either of the following apply:

(1) There is no interchangeable biological product approved by the federal Food and Drug Administration for the product prescribed.

(2) A refill prescription is not changed from the product dispensed on the prior filling of the prescription.

~~(d)~~

(e) 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.

(1) This subdivision shall not prohibit a prescriber from checking a box on a prescription marked "Do not substitute," provided that the prescriber personally initials the box or checkmark.

(2) 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.

~~(e)~~

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

pharmacist who selects an alternative biological product to be dispensed pursuant to this section shall assume the same responsibility for substituting the biological product as would be incurred in filling a prescription for a biological product 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 select a biological product that meets the requirements of subdivision (a) unless the cost to the patient of the biological product selected is the same or less than the cost of the prescribed biological product. Cost, as used in this subdivision, includes any professional fee that may be charged by the pharmacist.

~~(f)~~

(g) 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.

~~(g)~~

(h) When a selection is made pursuant to this section, the substitution of a biological product shall be communicated to the patient.

~~(h)~~

(i) The board shall maintain on its public Internet Web site a link to the current list, if available, of biological products determined by the federal Food and Drug Administration to be interchangeable.

~~(i)~~

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

(1) "Biological product" has the same meaning that applies to that term under Section 351 of the federal Public Health Service Act (42 U.S.C. Sec. 262(i)).

(2) "Interchangeable" means a biological product that the federal Food and Drug Administration has determined meets the standards set forth in ~~42 U.S.C.~~ Section ~~262(k)(4),~~ *262(k)(4) of Title 42 of the United States Code,* or has been deemed therapeutically equivalent by the federal Food and Drug Administration as set forth in the latest addition or supplement of the Approved Drug Products with Therapeutic Equivalence Evaluations.

(3) "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)).

~~(j)~~

(k) This section shall not prohibit the administration of immunizations, as permitted in Sections 4052 and 4052.8.

~~(k)~~

(l) This section shall not prohibit 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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