

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. Among other permitted acts, a pharmacist filling a prescription order for a drug product prescribed by its trade or brand name is authorized 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 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 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 "Do not substitute," as specified. The bill would also require a pharmacist or his or her designee when dispensing a biological product to communicate to the prescriber the specific biological product provided to the patient, including the name of the product and the manufacturer, except as specified. 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. The bill would also require that the substitution of a biological product 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 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:

1 SECTION 1. Section 4073.5 is added to the Business and
2 Professions Code, to read:
3 4073.5. (a) A pharmacist filling a prescription order for a
4 prescribed biological product may select an alternative biological
5 product only if all of the following:
6 (1) The alternative biological product is ~~interchangeable, as~~
7 ~~defined in paragraph (2) of subdivision (h):~~ *interchangeable*.
8 (2) The prescriber does not personally indicate “Do not
9 substitute,” or words of similar meaning, in the manner provided
10 in subdivision (c).
11 (b) Within five days following the dispensing of a biological
12 product, a dispensing pharmacist or the pharmacists’ designee
13 shall communicate to the prescriber the specific biological product
14 provided to the patient, including the name of the biological
15 product and the manufacturer. The communication shall be
16 conveyed by making an entry into an interoperable electronic
17 medical records system, through electronic prescribing technology,
18 or a pharmacy record that is electronically accessible by the
19 prescriber. Otherwise, the pharmacist or the pharmacist’s designee

1 shall communicate the name of the biological product dispensed
2 to the prescriber using facsimile, telephone, electronic transmission,
3 or other prevailing means, except that communication shall not be
4 required in this instance to the prescriber when either of the
5 following apply:

6 (1) There is no ~~FDA-approved~~ interchangeable biological
7 ~~product, as defined in subdivision (h);~~ *product approved by the*
8 *federal Food and Drug Administration* for the product prescribed.

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

11 (c) In no case shall a selection be made pursuant to this section
12 if the prescriber personally indicates, either orally or in his or her
13 own handwriting, “Do not substitute,” or words of similar meaning.

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

17 (2) To indicate that a selection shall not be made pursuant to
18 this section for an electronic data transmission prescription, as
19 defined in subdivision (c) of Section 4040, a prescriber may
20 indicate “Do not substitute,” or words of similar meaning, in the
21 prescription as transmitted by electronic data, or may check a box
22 marked on the prescription “Do not substitute.” In either instance,
23 it shall not be required that the prohibition on substitution be
24 manually initialed by the prescriber.

25 (d) Selection pursuant to this section is within the discretion of
26 the pharmacist, except as provided in subdivision (c). A pharmacist
27 who selects ~~the~~ *an alternative* biological product to be dispensed
28 pursuant to this section shall assume the same responsibility for
29 substituting the biological product as would be incurred in filling
30 a prescription for a biological product prescribed by name. There
31 shall be no liability on the prescriber for an act or omission by a
32 pharmacist in selecting, preparing, or dispensing a biological
33 product pursuant to this section. In no case shall the pharmacist
34 select a biological product that meets the requirements of
35 subdivision (a) unless the cost to the patient of the biological
36 product selected is the same or less than the cost of the prescribed
37 biological product. Cost, as used in this subdivision, includes any
38 professional fee that may be charged by the pharmacist.

39 (e) This section shall apply to all prescriptions, including those
40 presented by or on behalf of persons receiving assistance from the

1 federal government or pursuant to the Medi-Cal Act set forth in
2 Chapter 7 (commencing with Section 14000) of Part 3 of Division
3 9 of the Welfare and Institutions Code.

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

7 (g) The board shall maintain on its public Internet Web site a
8 link to the current list, if available, of biological products
9 determined by the ~~FDA~~ *federal Food and Drug Administration* to
10 be interchangeable, as defined in paragraph (2) of subdivision (h):
11 *interchangeable*.

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

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

17 (2) “Interchangeable” means a biological product that the ~~FDA~~
18 *federal Food and Drug Administration* has determined meets the
19 standards set forth in 42 U.S.C. Section 262(k)(4), or has been
20 deemed therapeutically equivalent by the ~~FDA~~ *federal Food and*
21 *Drug Administration* as set forth in the latest addition or
22 supplement of the Approved Drug Products with Therapeutic
23 Equivalence Evaluations.

24 (3) “Prescription,” with respect to a biological product, means
25 a prescription for a product that is subject to Section 503(b) of the
26 Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 353(b)).

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

29 (j) This section shall not prohibit a disability insurer or health
30 care service plan from requiring prior authorization or imposing
31 other appropriate utilization controls in approving coverage for
32 any biological product.

33 SEC. 2. No reimbursement is required by this act pursuant to
34 Section 6 of Article XIII B of the California Constitution because
35 the only costs that may be incurred by a local agency or school
36 district will be incurred because this act creates a new crime or
37 infraction, eliminates a crime or infraction, or changes the penalty
38 for a crime or infraction, within the meaning of Section 17556 of
39 the Government Code, or changes the definition of a crime within

1 the meaning of Section 6 of Article XIII B of the California
2 Constitution.

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