

Introduced by Senator HillFebruary 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 introduced, 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).
- 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 a reasonable time following the dispensing of a
- 12 biological product, a dispensing pharmacist or the pharmacists’
- 13 designee shall communicate to the prescriber the specific biological
- 14 product provided to the patient, including the name of the
- 15 biological product and the manufacturer. The communication shall
- 16 be 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
- 20 shall communicate the name of the biological product dispensed
- 21 to the prescriber using facsimile, telephone, electronic transmission,
- 22 or other prevailing means, except that communication shall not be

1 required in this instance to the prescriber when either of the
2 following apply:

3 (1) There is no FDA-approved interchangeable biological
4 product, as defined in subdivision (h), for the product prescribed.

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

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

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

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

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

35 (e) This section shall apply to all prescriptions, including those
36 presented by or on behalf of persons receiving assistance from the
37 federal government or pursuant to the Medi-Cal Act set forth in
38 Chapter 7 (commencing with Section 14000) of Part 3 of Division
39 9 of the Welfare and Institutions Code.

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

4 (g) The board shall maintain on its public Internet Web site a
5 link to the current list, if available, of biological products
6 determined by the FDA to be interchangeable, as defined in
7 paragraph (2) of subdivision (h).

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

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

13 (2) “Interchangeable” means a biological product that the FDA
14 has determined meets the standards set forth in 42 U.S.C. Section
15 262(k)(4), or has been deemed therapeutically equivalent by the
16 FDA as set forth in the latest addition or supplement of the
17 Approved Drug Products with Therapeutic Equivalence
18 Evaluations.

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

22 (i) This section shall not prohibit the administration of
23 immunizations, as permitted in Section 4052.

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

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

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