

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. ~~Among other permitted acts,~~ *The Pharmacy Law authorizes* 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~~ *knowing violation of* the Pharmacy Law is ~~guilty of a misdemeanor, as specified.~~ *a misdemeanor.*

~~This bill~~ *bill, except as specified,* would authorize a ~~pharmacist, in his or her discretion, except as specified,~~ *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 ~~“Do not substitute,” as specified.~~ *in a prescribed manner that a substitution is not to be made.* The bill would ~~also~~ require a pharmacist

~~or his or her designee when dispensing a biological product to communicate to the prescriber 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, including the name of the product and the manufacturer, except as specified. 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. ~~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.

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

4 (b) Within five days following the dispensing of a biological
5 product, a dispensing pharmacist or the pharmacists’ designee
6 shall ~~communicate to the prescriber~~ *make an entry of* the specific
7 biological product provided to the patient, including the name of
8 the biological product and the manufacturer. The communication
9 shall be conveyed by making an entry ~~into an interoperable~~
10 ~~electronic medical records system, through electronic prescribing~~
11 ~~technology, or a pharmacy record that is electronically accessible~~
12 ~~by the prescriber. Otherwise, that can be electronically accessed~~
13 *by the prescriber through:*

14 (1) *An interoperable electronic medical records system,*

15 (2) *An electronic prescribing technology,*

16 (3) *A pharmacy benefit management system, or*

17 (4) *A pharmacy record.*

18 (c) *Entry into an electronic records system as described in*
19 *subdivision (b) is presumed to provide notice to the prescriber. If*
20 *the pharmacy does not have access to one or more of the entry*
21 *systems in subdivision (b), the pharmacist or the pharmacist’s*
22 *designee shall communicate the name of the biological product*
23 *dispensed to the prescriber using facsimile, telephone, electronic*
24 *transmission, or other prevailing means, except that communication*
25 *shall not be required in this instance to the prescriber when either*
26 *of the following apply:*

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

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

32 ~~(e)~~

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

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

39 (2) *To indicate that a selection shall not be made pursuant to*
40 *this section for an electronic data transmission prescription, as*

1 defined in subdivision (c) of Section 4040, a prescriber may
2 indicate “Do not substitute,” or words of similar meaning, in the
3 prescription as transmitted by electronic data, or may check a box
4 marked on the prescription “Do not substitute.” In either instance,
5 it shall not be required that the prohibition on substitution be
6 manually initialed by the prescriber.

7 ~~(d)~~

8 (e) Selection pursuant to this section is within the discretion of
9 the pharmacist, except as provided in subdivision ~~(e)~~: (d). A
10 pharmacist who selects an alternative biological product to be
11 dispensed pursuant to this section shall assume the same
12 responsibility for substituting the biological product as would be
13 incurred in filling a prescription for a biological product prescribed
14 by name. There shall be no liability on the prescriber for an act or
15 omission by a pharmacist in selecting, preparing, or dispensing a
16 biological product pursuant to this section. In no case shall the
17 pharmacist select a biological product that meets the requirements
18 of subdivision (a) unless the cost to the patient of the biological
19 product selected is the same or less than the cost of the prescribed
20 biological product. Cost, as used in this subdivision, includes any
21 professional fee that may be charged by the pharmacist.

22 ~~(e)~~

23 (f) This section shall apply to all prescriptions, including those
24 presented by or on behalf of persons receiving assistance from the
25 federal government or pursuant to the Medi-Cal Act set forth in
26 Chapter 7 (commencing with Section 14000) of Part 3 of Division
27 9 of the Welfare and Institutions Code.

28 ~~(f)~~

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

32 ~~(g)~~

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

37 ~~(h)~~

38 (i) For purposes of this section, the following terms shall have
39 the following meanings:

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

4 (2) “Interchangeable” means a biological product that the federal
5 Food and Drug Administration has determined meets the standards
6 set forth in 42 U.S.C. Section 262(k)(4), or has been deemed
7 therapeutically equivalent by the federal Food and Drug
8 Administration as set forth in the latest addition or supplement of
9 the Approved Drug Products with Therapeutic Equivalence
10 Evaluations.

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

14 (i)

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

17 (j)

18 (k) This section shall not prohibit a disability insurer or health
19 care service plan from requiring prior authorization or imposing
20 other appropriate utilization controls in approving coverage for
21 any biological product.

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