

ASSEMBLY BILL

No. 2144

Introduced by Assembly Member Rodriguez

February 17, 2016

An act to amend Sections 4073.5 and 4074 of the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

AB 2144, as introduced, Rodriguez. Pharmacy: prescriptions.

The Pharmacy Law provides for the licensure and regulation of pharmacists by the California State Board of Pharmacy. That law establishes requirements for the substitution of an alternative biological product when a pharmacist is filling a prescription order for a prescribed biological product. That law requires a pharmacist to inform the patient orally or in writing of harmful effects of a drug dispensed by prescription, if the drug poses substantial risk to the person consuming the drug when taken in combination with alcohol, or if the drug may impair a person's ability to drive a motor vehicle, whichever is applicable, and the board requires by regulation that warning is to be given.

This bill would make nonsubstantive changes to those substitution and warning provisions.

Vote: majority. Appropriation: no. Fiscal committee: no.
State-mandated local program: no.

The people of the State of California do enact as follows:

- 1 SECTION 1. Section 4073.5 of the Business and Professions
- 2 Code is amended to read:

1 4073.5. (a) A pharmacist filling a prescription order for a
2 prescribed biological product may select an alternative biological
3 product only if all of the following: *following apply*:

4 (1) The alternative biological product is interchangeable.

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

8 (b) Within five days following the dispensing of a biological
9 product, a dispensing pharmacist or the pharmacists’ designee
10 shall make an entry of the specific biological product provided to
11 the patient, including the name of the biological product and the
12 manufacturer. The communication shall be conveyed by making
13 an entry that can be electronically accessed by the prescriber
14 through one or more of the following electronic records systems:

15 (1) An interoperable electronic medical records system.

16 (2) An electronic prescribing technology.

17 (3) A pharmacy benefit management system.

18 (4) A pharmacy record.

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

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

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

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

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

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

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

9 (f) Selection pursuant to this section is within the discretion of
10 the pharmacist, except as provided in subdivision (e). A pharmacist
11 who selects an alternative biological product to be dispensed
12 pursuant to this section shall assume the same responsibility for
13 substituting the biological product as would be incurred in filling
14 a prescription for a biological product prescribed by name. There
15 shall be no liability on the prescriber for an act or omission by a
16 pharmacist in selecting, preparing, or dispensing a biological
17 product pursuant to this section. ~~In no case shall the~~ *The* pharmacist
18 *shall not* select a biological product that meets the requirements
19 of subdivision (a) unless the cost to the patient of the biological
20 product selected is the same or less than the cost of the prescribed
21 biological product. ~~Cost,~~ “*Cost*,” as used in this subdivision,
22 includes any professional fee that may be charged by the
23 pharmacist.

24 (g) This section shall apply to all prescriptions, including those
25 presented by or on behalf of persons receiving assistance from the
26 federal government or pursuant to the Medi-Cal Act set forth in
27 Chapter 7 (commencing with Section 14000) of Part 3 of Division
28 9 of the Welfare and Institutions Code.

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

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

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

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

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

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

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

13 (l) This section shall not prohibit a disability insurer or health
14 care service plan from requiring prior authorization or imposing
15 other appropriate utilization controls in approving coverage for
16 any biological product.

17 SEC. 2. Section 4074 of the Business and Professions Code is
18 amended to read:

19 4074. (a) A pharmacist shall inform a patient orally or in
20 writing of the harmful effects of a drug dispensed by prescription
21 if both of the following apply:

22 (1) The drug poses substantial risk to the person consuming the
23 drug when taken in combination with alcohol or the drug may
24 impair a person’s ability to drive a motor vehicle, whichever is
25 applicable.

26 (2) The drug is determined by the board pursuant to subdivision
27 (c) to be a drug or drug type for which this warning shall be given.

28 (b) In addition to the requirement described in subdivision (a),
29 on and after July 1, 2014, if a pharmacist exercising his or her
30 professional judgment determines that a drug may impair a person’s
31 ability to operate a vehicle or vessel, the pharmacist shall include
32 a written label on the drug container indicating that the drug may
33 impair a person’s ability to operate a vehicle or vessel. The label
34 required by this subdivision may be printed on an auxiliary label
35 that is affixed to the prescription container.

36 (c) ~~The board may by regulation~~ *board, by regulation, may*
37 require additional information or labeling.

38 (d) This section shall not apply to a drug furnished to a patient
39 in conjunction with treatment or emergency services provided in

1 a health facility or, except as provided in subdivision (e), to a drug
2 furnished to a patient pursuant to subdivision (a) of Section 4056.
3 (e) A health facility shall establish and implement a written
4 policy to ensure that each patient shall receive information
5 regarding each drug given at the time of discharge and each drug
6 given pursuant to subdivision (a) of Section 4056. This information
7 shall include the use and storage of each drug, the precautions and
8 relevant warnings, and the importance of compliance with
9 directions. This information shall be given by a pharmacist or
10 registered nurse, unless already provided by a patient's prescriber,
11 and the written policy shall be developed in collaboration with a
12 physician, a pharmacist, and a registered nurse. The written policy
13 shall be approved by the medical staff. Nothing in this subdivision
14 or any other law shall be construed to require that only a pharmacist
15 provide this consultation.

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