

AMENDED IN ASSEMBLY MARCH 18, 2016

CALIFORNIA LEGISLATURE—2015–16 REGULAR SESSION

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 amended, 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. A knowing violation of the Pharmacy Law is a crime.~~

The Pharmacy Law requires a health facility to establish and implement a written policy to ensure that each patient receives information regarding drugs given to the patient at the time of discharge or under certain other circumstances, including the use and storage of each drug, the precautions and relevant warnings, and the importance of compliance with directions.

This bill would revise that patient information provision to require that a health facility require each patient to acknowledge in writing

that the patient has received this information. Because a violation of this requirement would be a crime under certain circumstances, the bill would impose a state-mandated local program.

The Pharmacy Law establishes requirements for the substitution of an alternative biological product when a pharmacist is filling a prescription order for a prescribed biological product.

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

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: ~~no~~-yes.
State-mandated local program: ~~no~~-yes.

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:
- 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 apply:
- 6 (1) The alternative biological product is interchangeable.
- 7 (2) The prescriber does not personally indicate “Do not
- 8 substitute,” or words of similar meaning, in the manner provided
- 9 in subdivision (e).
- 10 (b) Within five days following the dispensing of a biological
- 11 product, a dispensing pharmacist or the pharmacists’ designee
- 12 shall make an entry of the specific biological product provided to
- 13 the patient, including the name of the biological product and the
- 14 manufacturer. The communication shall be conveyed by making
- 15 an entry that can be electronically accessed by the prescriber
- 16 through one or more of the following electronic records systems:
- 17 (1) An interoperable electronic medical records system.
- 18 (2) An electronic prescribing technology.
- 19 (3) A pharmacy benefit management system.
- 20 (4) A pharmacy record.

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

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

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

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

15 (e) A selection shall not be made pursuant to this section if the
16 prescriber personally indicates, either orally or in his or her own
17 handwriting, "Do not substitute," or words of similar meaning.

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

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

29 (f) Selection pursuant to this section is within the discretion of
30 the pharmacist, except as provided in subdivision (e). A pharmacist
31 who selects an alternative biological product to be dispensed
32 pursuant to this section shall assume the same responsibility for
33 substituting the biological product as would be incurred in filling
34 a prescription for a biological product prescribed by name. There
35 shall be no liability on the prescriber for an act or omission by a
36 pharmacist in selecting, preparing, or dispensing a biological
37 product pursuant to this section. The pharmacist shall not select a
38 biological product that meets the requirements of subdivision (a)
39 unless the cost to the patient of the biological product selected is
40 the same or less than the cost of the prescribed biological product.

1 “Cost,” as used in this subdivision, includes any professional fee
2 that may be charged by the pharmacist.

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

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

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

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

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

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

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

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

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

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

38 4074. (a) A pharmacist shall inform a patient orally or in
39 writing of the harmful effects of a drug dispensed by prescription
40 if both of the following apply:

1 (1) The drug poses substantial risk to the person consuming the
2 drug when taken in combination with alcohol or the drug may
3 impair a person's ability to drive a motor vehicle, whichever is
4 applicable.

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

7 (b) In addition to the requirement described in subdivision (a),
8 on and after July 1, 2014, if a pharmacist exercising his or her
9 professional judgment determines that a drug may impair a person's
10 ability to operate a vehicle or vessel, the pharmacist shall include
11 a written label on the drug container indicating that the drug may
12 impair a person's ability to operate a vehicle or vessel. The label
13 required by this subdivision may be printed on an auxiliary label
14 that is affixed to the prescription container.

15 (c) The board, by regulation, may require additional information
16 or labeling.

17 (d) This section shall not apply to a drug furnished to a patient
18 in conjunction with treatment or emergency services provided in
19 a health facility or, except as provided in subdivision (e), to a drug
20 furnished to a patient pursuant to subdivision (a) of Section 4056.

21 (e) A health facility shall establish and implement a written
22 policy to ensure that each patient shall receive information
23 regarding each drug given at the time of discharge and each drug
24 given pursuant to subdivision (a) of Section 4056. This information
25 shall include the use and storage of each drug, the precautions and
26 relevant warnings, and the importance of compliance with
27 directions. *The health facility shall require each patient to*
28 *acknowledge in writing that the patient has received this*
29 *information.* This information shall be given by a pharmacist or
30 registered nurse, unless already provided by a patient's prescriber,
31 and the written policy shall be developed in collaboration with a
32 physician, a pharmacist, and a registered nurse. The written policy
33 shall be approved by the medical staff. Nothing in this subdivision
34 or any other law shall be construed to require that only a pharmacist
35 provide this consultation.

36 *SEC. 3. No reimbursement is required by this act pursuant to*
37 *Section 6 of Article XIII B of the California Constitution because*
38 *the only costs that may be incurred by a local agency or school*
39 *district will be incurred because this act creates a new crime or*
40 *infraction, eliminates a crime or infraction, or changes the penalty*

1 *for a crime or infraction, within the meaning of Section 17556 of*
2 *the Government Code, or changes the definition of a crime within*
3 *the meaning of Section 6 of Article XIII B of the California*
4 *Constitution.*

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