

AMENDED IN SENATE JUNE 21, 2005

AMENDED IN ASSEMBLY MAY 9, 2005

AMENDED IN ASSEMBLY APRIL 13, 2005

AMENDED IN ASSEMBLY APRIL 5, 2005

CALIFORNIA LEGISLATURE—2005—06 REGULAR SESSION

ASSEMBLY BILL

No. 657

Introduced by Assembly Member Karnette
(Coauthor: Assembly Member Mountjoy)

February 17, 2005

An act to amend Section 4076 of, and to add Section 4079 to, the Business and Professions Code, relating to pharmacies.

LEGISLATIVE COUNSEL'S DIGEST

AB 657, as amended, Karnette. Pharmacies: prescription containers: labels.

Existing law, the Pharmacy Law makes the California State Board of Pharmacy responsible for the regulation of the practice of pharmacy. Existing law generally makes it a misdemeanor to knowingly violate the Pharmacy Law.

The Pharmacy Law prohibits a pharmacist from dispensing a prescription except in a container that meets the requirements of state and federal law and is correctly labeled with, among other things, the condition for which the drug was prescribed if requested by the patient and if the condition is indicated on the prescription.

This bill would eliminate the requirement of the labeling requirement pertaining to the condition for which the drug was prescribed, and would instead require the container to be labeled with the intended purpose, as defined, of the drug, as set forth on the

prescription, and would require that the purpose be listed on the prescription.

The bill would, *except for veterinarians*, require a person who is authorized to write or issue a prescription to ask the patient or his or her authorized representative whether to indicate the intended purpose of the prescription on the prescription’s label.

Because the bill would specify additional requirements under the Pharmacy Law, the violation of which is a crime, it would impose a state-mandated local program.

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 4076 of the Business and Professions
 2 Code is amended to read:
 3 4076. (a) A pharmacist shall not dispense any prescription
 4 except in a container that meets the requirements of state and
 5 federal law and is correctly labeled with all of the following:
 6 (1) Except where the prescriber or the certified nurse-midwife
 7 who functions pursuant to a standardized procedure or protocol
 8 described in Section 2746.51, the nurse practitioner who
 9 functions pursuant to a standardized procedure described in
 10 Section 2836.1, or protocol, the physician assistant who functions
 11 pursuant to Section 3502.1, or the pharmacist who functions
 12 pursuant to a policy, procedure, or protocol pursuant to either
 13 subparagraph (D) of paragraph (4) of, or clause (iv) of
 14 subparagraph (A) of paragraph (5) of, subdivision (a) of Section
 15 4052 orders otherwise, either the manufacturer’s trade name of
 16 the drug or the generic name and the name of the manufacturer.
 17 Commonly used abbreviations may be used. Preparations
 18 containing two or more active ingredients may be identified by
 19 the manufacturer’s trade name or the commonly used name or
 20 the principal active ingredients.

- 1 (2) The directions for the use of the drug.
- 2 (3) The name of the patient or patients.
- 3 (4) The name of the prescriber or, if applicable, the name of
4 the certified nurse-midwife who functions pursuant to a
5 standardized procedure or protocol described in Section 2746.51,
6 the nurse practitioner who functions pursuant to a standardized
7 procedure described in Section 2836.1, or protocol, the physician
8 assistant who functions pursuant to Section 3502.1, or the
9 pharmacist who functions pursuant to a policy, procedure, or
10 protocol pursuant to either subparagraph (D) of paragraph (4) of,
11 or clause (iv) of subparagraph (A) of paragraph (5) of,
12 subdivision (a) of Section 4052.
- 13 (5) The date of issue.
- 14 (6) The name and address of the pharmacy, and prescription
15 number or other means of identifying the prescription.
- 16 (7) The strength of the drug or drugs dispensed.
- 17 (8) The quantity of the drug or drugs dispensed.
- 18 (9) The expiration date of the effectiveness of the drug
19 dispensed.
- 20 (10) The intended purpose of the drug or drugs, if indicated on
21 the prescription. As used in this section, “purpose” means a
22 concise description of the symptom or symptoms that the drug is,
23 or drugs are, intended to treat.
- 24 (11) (A) Commencing January 1, 2006, the physical
25 description of the dispensed medication, including its color,
26 shape, and any identification code that appears on the tablets or
27 capsules, except as follows:
 - 28 (i) Prescriptions dispensed by a veterinarian.
 - 29 (ii) An exemption from the requirements of this paragraph
30 shall be granted to a new drug for the first 120 days that the drug
31 is on the market and for the 90 days during which the national
32 reference file has no description on file.
 - 33 (iii) Dispensed medications for which no physical description
34 exists in any commercially available database.
- 35 (B) This paragraph applies to outpatient pharmacies only.
- 36 (C) The information required by this paragraph may be printed
37 on an auxiliary label that is affixed to the prescription container.
- 38 (D) This paragraph shall not become operative if the board,
39 prior to January 1, 2006, adopts regulations that mandate the
40 same labeling requirements set forth in this paragraph.

1 (b) If a pharmacist dispenses a prescribed drug by means of a
2 unit dose medication system, as defined by administrative
3 regulation, for a patient in a skilled nursing, intermediate care, or
4 other health care facility, the requirements of this section will be
5 satisfied if the unit dose medication system contains the
6 aforementioned information or the information is otherwise
7 readily available at the time of drug administration.

8 (c) If a pharmacist dispenses a dangerous drug or device in a
9 facility licensed pursuant to Section 1250 of the Health and
10 Safety Code, it is not necessary to include on individual unit dose
11 containers for a specific patient, the name of the certified
12 nurse-midwife who functions pursuant to a standardized
13 procedure or protocol described in Section 2746.51, the nurse
14 practitioner who functions pursuant to a standardized procedure
15 described in Section 2836.1, or protocol, the physician assistant
16 who functions pursuant to Section 3502.1, or the pharmacist who
17 functions pursuant to a policy, procedure, or protocol pursuant to
18 either subparagraph (D) of paragraph (4) of, or clause (iv) of
19 subparagraph (A) of paragraph (5) of, subdivision (a) of Section
20 4052.

21 (d) If a pharmacist dispenses a prescription drug for use in a
22 facility licensed pursuant to Section 1250 of the Health and
23 Safety Code, it is not necessary to include the information
24 required in paragraph (11) of subdivision (a) when the
25 prescription drug is administered to a patient by a person licensed
26 under the Medical Practice Act (Chapter 5 (commencing with
27 Section 2000)), the Nursing Practice Act (Chapter 6
28 (commencing with Section 2700)), or the Vocational Nursing
29 Practice Act (Chapter 6.5 (commencing with Section 2840)),
30 who is acting within his or her scope of practice.

31 SEC. 2. Section 4079 is added to the Business and
32 Professions Code, to read:

33 4079. A person described in paragraph (2) of subdivision (a)
34 of Section 4040 shall ask the patient or the patient's authorized
35 representative, if the patient is either incapacitated or a minor
36 who can not provide informed consent, whether to indicate the
37 intended purpose of the prescription on the prescription's label.
38 *This section does not apply to prescriptions dispensed by*
39 *veterinarians.*

1 SEC. 3. No reimbursement is required by this act pursuant to
2 Section 6 of Article XIII B of the California Constitution
3 because the only costs that may be incurred by a local agency or
4 school district will be incurred because this act creates a new
5 crime or infraction, eliminates a crime or infraction, or changes
6 the penalty for a crime or infraction, within the meaning of
7 Section 17556 of the Government Code, or changes the
8 definition of a crime within the meaning of Section 6 of Article
9 XIII B of the California Constitution.

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