ASSEMBLY BILL

No. 1276

Introduced by Assembly Member Karnette

February 23, 2007

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 1276, as introduced, 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 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 if indicated 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 would be 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:

SECTION 1. Section 4076 of the Business and Professions
 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 functions

9 pursuant to a standardized procedure described in Section 2836.1,

- 10 or protocol, the physician assistant who functions pursuant to
- 11 Section 3502.1, the naturopathic doctor who functions pursuant 12 to a standardized procedure or protocol described in Section
- 13 3640.5, or the pharmacist who functions pursuant to a policy,
- procedure, or protocol pursuant to either subparagraph (D) of
- 15 paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph
- 16 (5) of, subdivision (a) of Section 4052 paragraph (4) of subdivision
- 17 (a) of Section 4052.1 or paragraph (4) of subdivision (a) of Section

18 4052.2 orders otherwise, either the manufacturer's trade name of

- 19 the drug or the generic name and the name of the manufacturer.
- 20 Commonly used abbreviations may be used. Preparations
- 21 containing two or more active ingredients may be identified by
- 22 the manufacturer's trade name or the commonly used name or the
- 23 principal active ingredients.
- 24 (2) The directions for the use of the drug.
- 25 (3) The name of the patient or patients.
- 26 (4) The name of the prescriber or, if applicable, the name of the
- 27 certified nurse-midwife who functions pursuant to a standardized

1 procedure or protocol described in Section 2746.51, the nurse

2 practitioner who functions pursuant to a standardized procedure
3 described in Section 2836.1, or protocol, the physician assistant

4 who functions pursuant to Section 3502.1, the naturopathic doctor

5 who functions pursuant to a standardized procedure or protocol

6 described in Section 3640.5, or the pharmacist who functions

7 pursuant to a policy, procedure, or protocol pursuant to either

8 subparagraph (D) of paragraph (4) of, or clause (iv) of

9 subparagraph (A) of paragraph (5) of, subdivision (a) of Section

10 4052 paragraph (4) of subdivision (a) of Section 4052.1 or

11 paragraph (4) of subdivision (a) of Section 4052.2.

12 (5) The date of issue.

(6) The name and address of the pharmacy, and prescriptionnumber or other means of identifying the prescription.

- 15 (7) The strength of the drug or drugs dispensed.
- 16 (8) The quantity of the drug or drugs dispensed.

17 (9) The expiration date of the effectiveness of the drug 18 dispensed.

19 (10) The condition for which intended purpose of the drug-was

20 prescribed if requested by the patient and the condition is or drugs,

21 if indicated on the prescription. As used in this section, "purpose"

22 *means a concise description of the symptom or symptoms that the* 23 *drug is, or the drugs are, intended to treat.*

24 (11) (A) Commencing January 1, 2006, the physical description

25 of the dispensed medication, including its color, shape, and any

26 identification code that appears on the tablets or capsules, except27 as follows:

28 (i) Prescriptions dispensed by a veterinarian.

29 (ii) An exemption from the requirements of this paragraph shall

30 be granted to a new drug for the first 120 days that the drug is on

31 the market and for the 90 days during which the national reference

32 file has no description on file.

(iii) Dispensed medications for which no physical descriptionexists 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 same

40 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 readily 7 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 Safety Code, it is not necessary to include on individual unit dose 10 containers for a specific patient, the name of the certified 11 12 nurse-midwife who functions pursuant to a standardized procedure 13 or protocol described in Section 2746.51, the nurse practitioner 14 who functions pursuant to a standardized procedure described in 15 Section 2836.1, or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions 16 17 pursuant to a standardized procedure or protocol described in 18 Section 3640.5, or the pharmacist who functions pursuant to a 19 policy, procedure, or protocol pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph 20 21 (5) of, subdivision (a) of Section 4052 paragraph (4) of subdivision 22 (a) of Section 4052.1 or paragraph (4) of subdivision (a) of Section 23 4052.2. 24 (d) If a pharmacist dispenses a prescription drug for use in a 25 facility licensed pursuant to Section 1250 Chapter 2 (commencing 26 with Section 1250) of Division 2 of the Health and Safety Code, 27 it is not necessary to include the information required in paragraph 28 (11) of subdivision (a) when the prescription drug is administered

29 to a patient by a person licensed under the Medical Practice Act

30 (Chapter 5 (commencing with Section 2000)), the Nursing Practice

31 Act (Chapter 6 (commencing with Section 2700)), or the

Vocational Nursing Practice Act (Chapter 6.5 (commencing withSection 2840)), who is acting within his or her scope of practice.

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

36 4079. A person described in paragraph (2) of subdivision (a)

37 of Section 4040 shall ask the patient, or the patient's authorized

38 representative if the patient is either incapacitated or a minor who

39 cannot provide informed consent, whether to indicate the intended

- 1 purpose of the prescription on the prescription's label. This section
- 2 does not apply to prescriptions dispensed by veterinarians.
- 3 SEC. 3. No reimbursement is required by this act pursuant to
- 4 Section 6 of Article XIIIB of the California Constitution because
- 5 the only costs that may be incurred by a local agency or school
- 6 district will be incurred because this act creates a new crime or
- 7 infraction, eliminates a crime or infraction, or changes the penalty
- 8 for a crime or infraction, within the meaning of Section 17556 of
- 9 the Government Code, or changes the definition of a crime within
- 10 the meaning of Section 6 of Article XIII B of the California
- 11 Constitution.

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