AMENDED IN SENATE SEPTEMBER 1, 2015

AMENDED IN SENATE JULY 8, 2015

AMENDED IN SENATE JUNE 9, 2015

AMENDED IN ASSEMBLY APRIL 28, 2015

AMENDED IN ASSEMBLY APRIL 6, 2015

CALIFORNIA LEGISLATURE—2015–16 REGULAR SESSION

ASSEMBLY BILL No. 1073

Introduced by Assembly Member Ting

February 27, 2015

An act to amend ~~Section~~ *Sections 4076 and* 4199 of, and to add Section 4076.6 to, the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

AB 1073, as amended, Ting. Pharmacy: prescription drug labels.

The Pharmacy Law provides for the licensure and regulation of pharmacists by the California State Board of Pharmacy. That law requires *a pharmacist to dispense a prescription in a container that, among other things, is correctly labeled with the directions for use of the drug, and requires* the board to promulgate regulations that require, on or before January 1, 2011, a standardized, patient-centered, prescription drug label on all prescription medicine dispensed to patients in California. Existing regulations of the board implement that requirement, establishing standardized directions for use to be used when applicable, and requiring that the board publish on its Internet

Web site translation of those directions for use into at least 5 languages other than English. A violation of that law is a crime.

This bill would require a *pharmacist to use professional judgment in determining the content of the directions for use of a prescription. The bill would also require a* dispenser, excluding a veterinarian, upon the request of a patient or patient's representative, to provide translated directions for use as prescribed. The bill would authorize a dispenser to use translations made available by the board pursuant to those existing regulations. The bill would make a dispenser responsible for the accuracy of English-language directions for use provided to the patient. By imposing new requirements on dispensers, the violation of which would be a crime, this bill would impose a state-mandated local program.

The Pharmacy Law also provides for the licensure and regulation of veterinary food-animal drug retailers by the board. That law subjects to specific prescription drug labeling requirements any veterinary food-animal drug dispensed pursuant to a prescription from a licensed veterinarian for food-producing animals from a veterinary food-animal drug retailer pursuant to that law.

This bill would also subject any veterinary food-animal drug so dispensed to the above drug labeling requirements relating to standardized directions for use.

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:

4076. (a) A pharmacist shall not dispense any prescription except in a container that meets the requirements of state and federal law and is correctly labeled with all of the following:

(1) Except when the prescriber or the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions

pursuant to a standardized procedure described in Section 2836.1 or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to Section 4052.1, 4052.2, or 4052.6 orders otherwise, either the manufacturer's trade name of the drug or the generic name and the name of the manufacturer. Commonly used abbreviations may be used. Preparations containing two or more active ingredients may be identified by the manufacturer's trade name or the commonly used name or the principal active ingredients.

(2) The directions for the use of the drug.

(3) The name of the patient or patients.

(4) The name of the prescriber or, if applicable, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1 or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to Section 4052.1, 4052.2, or 4052.6.

(5) The date of issue.

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

(7) The strength of the drug or drugs dispensed.

(8) The quantity of the drug or drugs dispensed.

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

(10) The condition or purpose for which the drug was prescribed if the condition or purpose is indicated on the prescription.

(11) (A) Commencing January 1, 2006, the physical description of the dispensed medication, including its color, shape, and any identification code that appears on the tablets or capsules, except as follows:

(i) Prescriptions dispensed by a veterinarian.

(ii) An exemption from the requirements of this paragraph shall be granted to a new drug for the first 120 days that the drug is on

the market and for the 90 days during which the national reference file has no description on file.

(iii) Dispensed medications for which no physical description exists in any commercially available database.

(B) This paragraph applies to outpatient pharmacies only.

(C) The information required by this paragraph may be printed on an auxiliary label that is affixed to the prescription container.

(D) This paragraph shall not become operative if the board, prior to January 1, 2006, adopts regulations that mandate the same labeling requirements set forth in this paragraph.

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

(c) If a pharmacist dispenses a dangerous drug or device in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include on individual unit dose containers for a specific patient, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1 or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to Section 4052.1, 4052.2, or 4052.6.

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

(e) A pharmacist shall use professional judgment in determining the content of the directions for use.

~~SECTION 1.~~

SEC. 2. Section 4076.6 is added to the Business and Professions Code, to read:

4076.6. (a) Upon the request of a patient or patient's representative, a dispenser shall provide translated directions for use, which shall be printed on the prescription container, label, or on a supplemental document. *If translated directions for use appear on a prescription container or label, the English-language version of the directions for use shall also appear on the container or label, whenever possible, and may appear on other areas of the label outside the patient-centered area. When it is not possible for the English-language directions for use to appear on the container or label, it shall be provided on a supplemental document.*

(b) A dispenser may use translations made available by the board pursuant to subdivision (b) of Section 1707.5 of Title 16 of the California Code of Regulations to comply with this section.

(c) A dispenser shall not be required to provide translated directions for use beyond the languages that the board has made available or beyond the directions that the board has made available in translated form.

(d) ~~Nothing~~ *A dispenser may provide his or her own translated directions for use to comply with the requirements of this section, and nothing* in this section shall be construed to prohibit a dispenser from providing translated directions for use in languages beyond those that the board has made available or beyond the directions that the board has made available in translated form.

(e) A dispenser shall be responsible for the accuracy of the English-language directions for use provided to the patient. *This section shall not affect a dispenser's existing responsibility to correctly label a prescription pursuant to Section 4076.*

(f) For purposes of this section, a dispenser does not include a veterinarian.

~~SEC. 2.~~

SEC. 3. Section 4199 of the Business and Professions Code is amended to read:

4199. (a) Any veterinary food-animal drug dispensed pursuant to a prescription from a licensed veterinarian for food producing animals from a veterinary food-animal drug retailer pursuant to

this chapter is subject to the labeling requirements of Sections 4076, 4076.6, and 4077.

(b) All prescriptions filled by a veterinary food-animal drug retailer shall be kept on file and maintained for at least three years in accordance with Section 4333.

~~SEC. 3.~~

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

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