

AMENDED IN ASSEMBLY AUGUST 19, 2013

AMENDED IN ASSEMBLY JULY 1, 2013

AMENDED IN SENATE APRIL 24, 2013

**SENATE BILL**

**No. 205**

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**Introduced by Senator Corbett**

February 8, 2013

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An act to amend, *repeal, and add* Section 4076 of the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

SB 205, as amended, Corbett. Prescription drugs: labeling.

The Pharmacy Law provides for the licensure and regulation of pharmacists by the California State Board of Pharmacy. Existing law ~~requires every~~ *defines a* prescription, ~~as defined, to include~~ *as including* a legible, clear notice of the condition or purpose for which the drug is prescribed, if requested by the patient. Existing law prohibits a pharmacist from dispensing any prescription unless it is in a specified container that is correctly labeled to include, among other information, the condition or purpose for which the drug was prescribed if the condition or purpose is indicated on the prescription. A violation of the Pharmacy Law is a crime.

This bill, *beginning January 1, 2016*, would require certain portions of the required information on the prescription label, including the name of the patient or patients, to be printed in at least a 12-point typeface. Because a violation of this requirement would be a crime, the bill 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 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,~~  
14 ~~procedure, or protocol pursuant to either Section 4052.1 or 4052.2~~  
15 ~~orders otherwise, either the manufacturer's trade name of the drug~~  
16 ~~or the generic name and the name of the manufacturer. Commonly~~  
17 ~~used abbreviations may be used. Preparations containing two or~~  
18 ~~more active ingredients may be identified by the manufacturer's~~  
19 ~~trade name or the commonly used name or the principal active~~  
20 ~~ingredients.~~

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

22 ~~(3) The name of the patient or patients.~~

23 ~~(4) The name of the prescriber or, if applicable, the name of the~~  
24 ~~certified nurse-midwife who functions pursuant to a standardized~~  
25 ~~procedure or protocol described in Section 2746.51, the nurse~~  
26 ~~practitioner who functions pursuant to a standardized procedure~~  
27 ~~described in Section 2836.1 or protocol, the physician assistant~~  
28 ~~who functions pursuant to Section 3502.1, the naturopathic doctor~~  
29 ~~who functions pursuant to a standardized procedure or protocol~~  
30 ~~described in Section 3640.5, or the pharmacist who functions~~

1 pursuant to a policy, procedure, or protocol pursuant to either  
2 Section 4052.1 or 4052.2.  
3 (5) The date of issue.  
4 (6) The name and address of the pharmacy, and prescription  
5 number or other means of identifying the prescription.  
6 (7) The strength of the drug or drugs dispensed.  
7 (8) The quantity of the drug or drugs dispensed.  
8 (9) The expiration date of the effectiveness of the drug  
9 dispensed.  
10 (10) The condition or purpose for which the drug was prescribed  
11 if the condition or purpose is indicated on the prescription.  
12 (11) (A) Commencing January 1, 2006, the physical description  
13 of the dispensed medication, including its color, shape, and any  
14 identification code that appears on the tablets or capsules, except  
15 as follows:  
16 (i) Prescriptions dispensed by a veterinarian.  
17 (ii) An exemption from the requirements of this paragraph shall  
18 be granted to a new drug for the first 120 days that the drug is on  
19 the market and for the 90 days during which the national reference  
20 file has no description on file.  
21 (iii) Dispensed medications for which no physical description  
22 exists in any commercially available database.  
23 (B) This paragraph applies to outpatient pharmacies only.  
24 (C) The information required by this paragraph may be printed  
25 on an auxiliary label that is affixed to the prescription container.  
26 (D) This paragraph shall not become operative if the board,  
27 prior to January 1, 2006, adopts regulations that mandate the same  
28 labeling requirements set forth in this paragraph.  
29 (b) The information required by paragraphs (1), (2), (3), (7),  
30 and (10) of subdivision (a) shall be printed in at least a 12-point  
31 typeface.  
32 (c) If a pharmacist dispenses a prescribed drug by means of a  
33 unit dose medication system, as defined by administrative  
34 regulation, for a patient in a skilled nursing, intermediate care, or  
35 other health care facility, the requirements of this section will be  
36 satisfied if the unit dose medication system contains the  
37 aforementioned information or the information is otherwise readily  
38 available at the time of drug administration.  
39 (d) If a pharmacist dispenses a dangerous drug or device in a  
40 health facility, as defined in Section 1250 of the Health and Safety

1 Code, it is not necessary to include on individual unit dose  
 2 containers for a specific patient, the name of the certified  
 3 nurse-midwife who functions pursuant to a standardized procedure  
 4 or protocol described in Section 2746.51, the nurse practitioner  
 5 who functions pursuant to a standardized procedure described in  
 6 Section 2836.1 or protocol, the physician assistant who functions  
 7 pursuant to Section 3502.1, the naturopathic doctor who functions  
 8 pursuant to a standardized procedure or protocol described in  
 9 Section 3640.5, or the pharmacist who functions pursuant to a  
 10 policy, procedure, or protocol pursuant to either Section 4052.1  
 11 or 4052.2.

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

22 *SECTION 1. Section 4076 of the Business and Professions*  
 23 *Code is amended to read:*

24 4076. (a) A pharmacist shall not dispense any prescription  
 25 except in a container that meets the requirements of state and  
 26 federal law and is correctly labeled with all of the following:

27 (1) ~~Except where~~ *when* the prescriber or the certified  
 28 nurse-midwife who functions pursuant to a standardized procedure  
 29 or protocol described in Section 2746.51, the nurse practitioner  
 30 who functions pursuant to a standardized procedure described in  
 31 Section 2836.1 or protocol, the physician assistant who functions  
 32 pursuant to Section 3502.1, the naturopathic doctor who functions  
 33 pursuant to a standardized procedure or protocol described in  
 34 Section 3640.5, or the pharmacist who functions pursuant to a  
 35 policy, procedure, or protocol pursuant to either Section 4052.1  
 36 or 4052.2 orders otherwise, either the manufacturer's trade name  
 37 of the drug or the generic name and the name of the manufacturer.  
 38 Commonly used abbreviations may be used. Preparations  
 39 containing two or more active ingredients may be identified by

- 1 the manufacturer's trade name or the commonly used name or the  
2 principal active ingredients.
- 3 (2) The directions for the use of the drug.
- 4 (3) The name of the patient or patients.
- 5 (4) The name of the prescriber or, if applicable, the name of the  
6 certified nurse-midwife who functions pursuant to a standardized  
7 procedure or protocol described in Section 2746.51, the nurse  
8 practitioner who functions pursuant to a standardized procedure  
9 described in Section 2836.1 or protocol, the physician assistant  
10 who functions pursuant to Section 3502.1, the naturopathic doctor  
11 who functions pursuant to a standardized procedure or protocol  
12 described in Section 3640.5, or the pharmacist who functions  
13 pursuant to a policy, procedure, or protocol pursuant to either  
14 Section 4052.1 or 4052.2.
- 15 (5) The date of issue.
- 16 (6) The name and address of the pharmacy, and prescription  
17 number or other means of identifying the prescription.
- 18 (7) The strength of the drug or drugs dispensed.
- 19 (8) The quantity of the drug or drugs dispensed.
- 20 (9) The expiration date of the effectiveness of the drug  
21 dispensed.
- 22 (10) The condition or purpose for which the drug was prescribed  
23 if the condition or purpose is indicated on the prescription.
- 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, except  
27 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.
- 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 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~~ *health facility, as defined in Section*  
10 1250 of the Health and Safety Code, it is not necessary to include  
11 on individual unit dose containers for a specific patient, the name  
12 of the certified nurse-midwife who functions pursuant to a  
13 standardized procedure or protocol described in Section 2746.51,  
14 the nurse practitioner who functions pursuant to a standardized  
15 procedure described in Section 2836.1 or protocol, the physician  
16 assistant who functions pursuant to Section 3502.1, the naturopathic  
17 doctor who functions pursuant to a standardized procedure or  
18 protocol described in Section 3640.5, or the pharmacist who  
19 functions pursuant to a policy, procedure, or protocol pursuant to  
20 either Section 4052.1 or 4052.2.

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

31 (e) *This section shall remain in effect only until January 1, 2016,*  
32 *and as of that date is repealed, unless a later enacted statute, that*  
33 *is enacted before January 1, 2016, deletes or extends that date.*

34 *SEC. 2. Section 4076 is added to the Business and Professions*  
35 *Code, to read:*

36 *4076. (a) A pharmacist shall not dispense any prescription*  
37 *except in a container that meets the requirements of state and*  
38 *federal law and is correctly labeled with all of the following:*

39 *(1) Except when the prescriber or the certified nurse-midwife*  
40 *who functions pursuant to a standardized procedure or protocol*

1 *described in Section 2746.51, the nurse practitioner who functions*  
2 *pursuant to a standardized procedure described in Section 2836.1*  
3 *or protocol, the physician assistant who functions pursuant to*  
4 *Section 3502.1, the naturopathic doctor who functions pursuant*  
5 *to a standardized procedure or protocol described in Section*  
6 *3640.5, or the pharmacist who functions pursuant to a policy,*  
7 *procedure, or protocol pursuant to either Section 4052.1 or 4052.2*  
8 *orders otherwise, either the manufacturer's trade name of the drug*  
9 *or the generic name and the name of the manufacturer. Commonly*  
10 *used abbreviations may be used. Preparations containing two or*  
11 *more active ingredients may be identified by the manufacturer's*  
12 *trade name or the commonly used name or the principal active*  
13 *ingredients.*

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

15 (3) *The name of the patient or patients.*

16 (4) *The name of the prescriber or, if applicable, the name of*  
17 *the certified nurse-midwife who functions pursuant to a*  
18 *standardized procedure or protocol described in Section 2746.51,*  
19 *the nurse practitioner who functions pursuant to a standardized*  
20 *procedure described in Section 2836.1 or protocol, the physician*  
21 *assistant who functions pursuant to Section 3502.1, the*  
22 *naturopathic doctor who functions pursuant to a standardized*  
23 *procedure or protocol described in Section 3640.5, or the*  
24 *pharmacist who functions pursuant to a policy, procedure, or*  
25 *protocol pursuant to either Section 4052.1 or 4052.2.*

26 (5) *The date of issue.*

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

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

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

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

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

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

38 (i) *Prescriptions dispensed by a veterinarian.*

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

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

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

5 *(B) This paragraph applies to outpatient pharmacies only.*

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

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

11 *(b) The information required by paragraphs (1), (2), (3), (7),*  
12 *and (10) of subdivision (a) shall be printed in at least a 12-point*  
13 *typeface.*

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

21 *(d) If a pharmacist dispenses a dangerous drug or device in a*  
22 *health facility, as defined in Section 1250 of the Health and Safety*  
23 *Code, it is not necessary to include on individual unit dose*  
24 *containers for a specific patient, the name of the certified*  
25 *nurse-midwife who functions pursuant to a standardized procedure*  
26 *or protocol described in Section 2746.51, the nurse practitioner*  
27 *who functions pursuant to a standardized procedure described in*  
28 *Section 2836.1 or protocol, the physician assistant who functions*  
29 *pursuant to Section 3502.1, the naturopathic doctor who functions*  
30 *pursuant to a standardized procedure or protocol described in*  
31 *Section 3640.5, or the pharmacist who functions pursuant to a*  
32 *policy, procedure, or protocol pursuant to either Section 4052.1*  
33 *or 4052.2.*

34 *(e) If a pharmacist dispenses a prescription drug for use in a*  
35 *facility licensed pursuant to Section 1250 of the Health and Safety*  
36 *Code, it is not necessary to include the information required in*  
37 *paragraph (11) of subdivision (a) when the prescription drug is*  
38 *administered to a patient by a person licensed under the Medical*  
39 *Practice Act (Chapter 5 (commencing with Section 2000)), the*  
40 *Nursing Practice Act (Chapter 6 (commencing with Section 2700)),*

1 *or the Vocational Nursing Practice Act (Chapter 6.5 (commencing*  
2 *with Section 2840)), who is acting within his or her scope of*  
3 *practice.*

4 *(f) This section shall become operative on January 1, 2016.*

5 ~~SEC. 2.~~

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

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