

AMENDED IN ASSEMBLY SEPTEMBER 6, 2013

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 defines a prescription 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.

*This bill would incorporate additional changes in Section 4076 of the Business and Professions Code proposed by SB 493, that would*

*become operative only if SB 493 and this bill are both chaptered and become effective on or before January 1, 2014, and this bill is chaptered last.*

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 when 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

1 who functions pursuant to Section 3502.1, the naturopathic doctor  
2 who functions pursuant to a standardized procedure or protocol  
3 described in Section 3640.5, or the pharmacist who functions  
4 pursuant to a policy, procedure, or protocol pursuant to either  
5 Section 4052.1 or 4052.2.

6 (5) The date of issue.

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

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

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

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

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

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

19 (i) Prescriptions dispensed by a veterinarian.

20 (ii) An exemption from the requirements of this paragraph shall  
21 be granted to a new drug for the first 120 days that the drug is on  
22 the market and for the 90 days during which the national reference  
23 file has no description on file.

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

26 (B) This paragraph applies to outpatient pharmacies only.

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

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

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

25 *SEC. 1.5. Section 4076 of the Business and Professions Code*  
 26 *is amended to read:*

27 4076. (a) A pharmacist shall not dispense any prescription  
 28 except in a container that meets the requirements of state and  
 29 federal law and is correctly labeled with all of the following:

30 (1) Except—~~where~~ *when* the prescriber or the certified  
 31 nurse-midwife who functions pursuant to a standardized procedure  
 32 or protocol described in Section 2746.51, the nurse practitioner  
 33 who functions pursuant to a standardized procedure described in  
 34 Section 2836.1 or protocol, the physician assistant who functions  
 35 pursuant to Section 3502.1, the naturopathic doctor who functions  
 36 pursuant to a standardized procedure or protocol described in  
 37 Section 3640.5, or the pharmacist who functions pursuant to a  
 38 policy, procedure, or protocol pursuant to ~~either~~ Section ~~4052.1~~  
 39 ~~or~~ 4052.1, 4052.2, *or* 4052.6 orders otherwise, either the  
 40 manufacturer's trade name of the drug or the generic name and

1 the name of the manufacturer. Commonly used abbreviations may  
2 be used. Preparations containing two or more active ingredients  
3 may be identified by the manufacturer's trade name or the  
4 commonly used name or the principal active ingredients.

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

6 (3) The name of the patient or patients.

7 (4) The name of the prescriber or, if applicable, the name of the  
8 certified nurse-midwife who functions pursuant to a standardized  
9 procedure or protocol described in Section 2746.51, the nurse  
10 practitioner who functions pursuant to a standardized procedure  
11 described in Section 2836.1 or protocol, the physician assistant  
12 who functions pursuant to Section 3502.1, the naturopathic doctor  
13 who functions pursuant to a standardized procedure or protocol  
14 described in Section 3640.5, or the pharmacist who functions  
15 pursuant to a policy, procedure, or protocol pursuant to either  
16 Section ~~4052.1~~ or 4052.1, 4052.2, or 4052.6.

17 (5) The date of issue.

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

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

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

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

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

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

30 (i) Prescriptions dispensed by a veterinarian.

31 (ii) An exemption from the requirements of this paragraph shall  
32 be granted to a new drug for the first 120 days that the drug is on  
33 the market and for the 90 days during which the national reference  
34 file has no description on file.

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

37 (B) This paragraph applies to outpatient pharmacies only.

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

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

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

11 (c) If a pharmacist dispenses a dangerous drug or device in a  
12 ~~facility licensed pursuant to~~ *health facility, as defined in* Section  
13 1250 of the Health and Safety Code, it is not necessary to include  
14 on individual unit dose containers for a specific patient, the name  
15 of the certified nurse-midwife who functions pursuant to a  
16 standardized procedure or protocol described in Section 2746.51,  
17 the nurse practitioner who functions pursuant to a standardized  
18 procedure described in Section 2836.1 or protocol, the physician  
19 assistant who functions pursuant to Section 3502.1, the naturopathic  
20 doctor who functions pursuant to a standardized procedure or  
21 protocol described in Section 3640.5, or the pharmacist who  
22 functions pursuant to a policy, procedure, or protocol pursuant to  
23 ~~either Section 4052.1 or~~ *4052.1, 4052.2, or 4052.6.*

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

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

37 SEC. 2. Section 4076 is added to the Business and Professions  
38 Code, to read:

1 4076. (a) A pharmacist shall not dispense any prescription  
2 except in a container that meets the requirements of state and  
3 federal law and is correctly labeled with all of the following:

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

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

20 (3) The name of the patient or patients.

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

31 (5) The date of issue.

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

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

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

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

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

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

5 (i) Prescriptions dispensed by a veterinarian.

6 (ii) An exemption from the requirements of this paragraph shall  
7 be granted to a new drug for the first 120 days that the drug is on  
8 the market and for the 90 days during which the national reference  
9 file has no description on file.

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

12 (B) This paragraph applies to outpatient pharmacies only.

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

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

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

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

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

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

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

12 *SEC. 2.5. Section 4076 is added to the Business and Professions*  
13 *Code, to read:*

14 *4076. (a) A pharmacist shall not dispense any prescription*  
15 *except in a container that meets the requirements of state and*  
16 *federal law and is correctly labeled with all of the following:*

17 *(1) Except when the prescriber or the certified nurse-midwife*  
18 *who functions pursuant to a standardized procedure or protocol*  
19 *described in Section 2746.51, the nurse practitioner who functions*  
20 *pursuant to a standardized procedure described in Section 2836.1*  
21 *or protocol, the physician assistant who functions pursuant to*  
22 *Section 3502.1, the naturopathic doctor who functions pursuant*  
23 *to a standardized procedure or protocol described in Section*  
24 *3640.5, or the pharmacist who functions pursuant to a policy,*  
25 *procedure, or protocol pursuant to Section 4052.1, 4052.2, or*  
26 *4052.6 orders otherwise, either the manufacturer's trade name of*  
27 *the drug or the generic name and the name of the manufacturer.*  
28 *Commonly used abbreviations may be used. Preparations*  
29 *containing two or more active ingredients may be identified by the*  
30 *manufacturer's trade name or the commonly used name or the*  
31 *principal active ingredients.*

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

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

34 *(4) The name of the prescriber or, if applicable, the name of*  
35 *the certified nurse-midwife who functions pursuant to a*  
36 *standardized procedure or protocol described in Section 2746.51,*  
37 *the nurse practitioner who functions pursuant to a standardized*  
38 *procedure described in Section 2836.1 or protocol, the physician*  
39 *assistant who functions pursuant to Section 3502.1, the*  
40 *naturopathic doctor who functions pursuant to a standardized*

1 *procedure or protocol described in Section 3640.5, or the*  
2 *pharmacist who functions pursuant to a policy, procedure, or*  
3 *protocol pursuant to Section 4052.1, 4052.2, or 4052.6.*

4 *(5) The date of issue.*

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

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

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

9 *(9) The expiration date of the effectiveness of the drug 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*  
28 *same 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,*  
35 *or other health care facility, the requirements of this section will*  
36 *be 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 Section 4052.1, 4052.2,  
11 or 4052.6.

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

23 SEC. 3. Sections 1.5 and 2.5 of this bill incorporate  
24 amendments to Section 4076 of the Business and Professions Code  
25 proposed by both this bill and Senate Bill 493. They shall only  
26 become operative if (1) both bills are enacted and become effective  
27 on or before January 1, 2014, (2) each bill amends Section 4076  
28 of the Business and Professions Code, and (3) this bill is enacted  
29 after Senate Bill 493, in which case Sections 1 and 2 of this bill  
30 shall not become operative.

31 ~~SEC. 3.~~

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

- 1 the meaning of Section 6 of Article XIII B of the California
- 2 Constitution.

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