

AMENDED IN ASSEMBLY JUNE 15, 2010

AMENDED IN SENATE APRIL 26, 2010

AMENDED IN SENATE APRIL 5, 2010

SENATE BILL

No. 1390

Introduced by Senator Corbett

February 19, 2010

An act to ~~amend~~ *add Sections 4076.7 and 4076.9 to, and to repeal and add Section 4076.5 of, the Business and Professions Code, relating to pharmacy.*

LEGISLATIVE COUNSEL'S DIGEST

SB 1390, as amended, Corbett. Prescription drug labels.

Existing law, the Pharmacy Law, provides for the licensure and regulation of the practice of pharmacy by the California State Board of Pharmacy. Existing law requires the board to promulgate regulations that require, on or before January 1, 2011, a standardized, patient-centered, prescription drug label on all prescription medication dispensed to patients in California. *A knowing violation of the Pharmacy Law is a crime.*

~~This bill would authorize the board to exempt from these regulatory requirements certain prescriptions dispensed to patients in a health facility, as defined.~~ *repeal that provision and would instead, on and after January 1, 2012, require prescription drug labels on all prescription drugs dispensed to patients in California to conform to a specified standardized, patient-centered format including that certain elements of the label be printed in a specified typeface and that, when applicable, directions for use utilize certain phrases and be translated into non-English languages, as specified. The bill would exempt from*

these requirements certain prescription drugs dispensed to patients in a health facility, as defined.

The bill would require the board, by January 1, 2012, to develop, collect, and publish on its Internet Web site (1) translations of the directions for use into certain languages and (2) examples of labels meeting the standardized, patient-centered format requirements.

The bill would require a pharmacy, by January 1, 2012, during its hours of operation, to provide interpreter services, as specified, to non-English-speaking patients at no charge to help the patient understand the information on his or her prescription drug label. The bill would also, by January 1, 2013, require a pharmacy to provide these non-English patients with any other written information relevant to the prescription drug in the patient's language. The bill would require these pharmacies to develop written policies and procedures by certain specified dates in order to carry out these requirements.

Because a knowing violation of these requirements 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: ~~no~~-yes.

The people of the State of California do enact as follows:

- 1 SECTION 1. *The Legislature hereby finds and declares all of*
- 2 *the following:*
- 3 (a) *Health care costs and spending in the United States are*
- 4 *rising dramatically and are expected to continue to rise. Overall,*
- 5 *national health care spending grew an estimated 5.7 percent in*
- 6 *2009, reaching \$2.5 trillion and accounting for 17.3 percent of*
- 7 *the nation's gross domestic product.*
- 8 (b) *In 2009, spending on prescription drugs in the United States*
- 9 *totaled over \$300 billion dollars, a 5-percent increase from the*
- 10 *previous year.*

1 (c) *The cost of prescription drugs continues to be among the*
2 *most significant cost factors in California’s overall spending on*
3 *health care.*

4 (d) *According to the Institute of Medicine of the National*
5 *Academies, medication errors are among the most common medical*
6 *errors, harming at least 1.5 million people every year.*

7 (e) *Up to one-half of all medications are taken incorrectly or*
8 *mixed with other medications that cause dangerous reactions that*
9 *can lead to injury and death.*

10 (f) *Approximately 46 percent of American adults cannot*
11 *understand the label on their prescription drugs.*

12 (g) *Ninety percent of Medicare patients take medications for*
13 *chronic conditions and nearly one-half of them take five or more*
14 *different medications each day.*

15 (h) *Nearly six out of 10 adults in the United States have taken*
16 *prescription medications incorrectly.*

17 (i) *According to the 2006 American Community Survey of the*
18 *United States Census Bureau, over 42 percent of Californians*
19 *speak a language other than English at home, which is significantly*
20 *above the national figure of 19.7 percent. Of these, 47 percent*
21 *could be considered limited-English proficient and represents just*
22 *over 20 percent of all Californians.*

23 (j) *Numerous articles and studies, including a study by the*
24 *Institute of Medicine entitled *Unequal Treatment: Confronting**
25 *Racial and Ethnic Disparities in Health* (2002), *highlight the*
26 *language barriers faced by patients who do not speak English and*
27 *show that providing adequate language services improves health*
28 *outcomes and patient satisfaction, comports with existing federal*
29 *and state requirements, and achieves long-term cost savings.*

30 (k) *Title VI of the Federal Civil Rights Act of 1964 (42 U.S.C.*
31 *Sec. 1981 et seq.) prohibits recipients of federal financial*
32 *assistance from discriminating against persons based on race,*
33 *color, or national origin. This has been interpreted to mean that*
34 *a limited-English proficient (LEP) individual is entitled to*
35 *meaningful access and participation in federally funded programs*
36 *through the provision of language assistance services. Any*
37 *recipient of federal funding, including a pharmacy operating in*
38 *California that participates in the Medi-Cal, Healthy Families, or*
39 *Medicare programs, is subject to the Title VI requirements.*

1 (l) According to the Policy Guidance on the Prohibition Against
 2 National Origin Discrimination as it Affects Persons with Limited
 3 English Proficiency published by the Office for Civil Rights within
 4 the United States Department of Health and Human Services on
 5 August 8, 2003 (68 Fed. Reg. 47311-23), providers of health care
 6 and social services that receive federal financial assistance,
 7 including pharmacies, must take adequate steps to ensure that
 8 LEP persons receive language assistance free of charge necessary
 9 to afford them meaningful access to the provider’s services.

10 (m) Current regulations of the California State Board of
 11 Pharmacy (16 Cal Code Regs. 1707.2), require pharmacists to
 12 provide oral consultation to all patients in all care settings where
 13 the patient is present in the pharmacy for a new prescription and
 14 a prescription of the same dosage, form, strength, or with the same
 15 directions has not been previously dispensed to the patient.

16 (n) The people of the State of California recognize the
 17 importance of reducing medication-related errors and increasing
 18 health care literacy regarding prescription drugs and prescription
 19 container labeling, which can increase consumer protection and
 20 improve the health, safety, and well-being of consumers.

21 (o) The Legislature affirms the importance of identifying
 22 deficiencies in, and opportunities for improving, patient
 23 prescription drug safety systems in order to identify and encourage
 24 the adoption of structural safeguards related to prescription drug
 25 container labels.

26 SEC. 2. Section 4076.5 of the Business and Professions Code
 27 is repealed.

28 ~~4076.5. (a) The board shall promulgate regulations that require,~~
 29 ~~on or before January 1, 2011, a standardized, patient-centered,~~
 30 ~~prescription drug label on all prescription medicine dispensed to~~
 31 ~~patients in California.~~

32 ~~(b) To ensure maximum public comment, the board shall hold~~
 33 ~~public meetings statewide that are separate from its normally~~
 34 ~~scheduled hearings in order to seek information from groups~~
 35 ~~representing consumers, seniors, pharmacists or the practice of~~
 36 ~~pharmacy, other health care professionals, and other interested~~
 37 ~~parties.~~

38 ~~(c) When developing the requirements for prescription drug~~
 39 ~~labels, the board shall consider all of the following factors:~~

- 1 ~~(1) Medical literacy research that points to increased~~
- 2 ~~understandability of labels.~~
- 3 ~~(2) Improved directions for use.~~
- 4 ~~(3) Improved font types and sizes.~~
- 5 ~~(4) Placement of information that is patient-centered.~~
- 6 ~~(5) The needs of patients with limited English proficiency.~~
- 7 ~~(6) The needs of senior citizens.~~
- 8 ~~(7) Technology requirements necessary to implement the~~
- 9 ~~standards.~~

10 ~~(d) (1) On or before January 1, 2010, the board shall report to~~
11 ~~the Legislature on its progress under this section as of the time of~~
12 ~~the report.~~

13 ~~(2) On or before January 1, 2013, the board shall report to the~~
14 ~~Legislature the status of implementation of the prescription drug~~
15 ~~label requirements adopted pursuant to this section.~~

16 *SEC. 3. Section 4076.5 is added to the Business and Professions*
17 *Code, to read:*

18 *4076.5. (a) The board shall promulgate any regulations*
19 *necessary to clarify the provisions in this section and in Sections*
20 *4076.7 and 4076.9.*

21 *(b) On or before January 1, 2012, the board shall develop,*
22 *collect, and publish on its Internet Web site the following:*

23 *(1) Translations for the directions for use described in*
24 *subparagraphs (A) to (P), inclusive, in a minimum of 14 languages,*
25 *to include all of the non-English languages identified by the*
26 *Medi-Cal Managed Care Division within the State Department of*
27 *Health Care Services for translation in vital documents, as well*
28 *as any other primary languages for groups of 10,000 or more with*
29 *limited-English-proficient persons in California, to facilitate the*
30 *use of those directions for use by pharmacies in California.*

31 *(A) Take 1 [insert appropriate dosage form] at bedtime.*

32 *(B) Take 2 [insert appropriate dosage form] at bedtime.*

33 *(C) Take 3 [insert appropriate dosage form] at bedtime.*

34 *(D) Take 1 [insert appropriate dosage form] in the morning.*

35 *(E) Take 2 [insert appropriate dosage form] in the morning.*

36 *(F) Take 3 [insert appropriate dosage form] in the morning.*

37 *(G) Take 1 [insert appropriate dosage form] in the morning,*
38 *and 1 [insert appropriate dosage form] at bedtime.*

39 *(H) Take 2 [insert appropriate dosage form] in the morning,*
40 *and 2 [insert appropriate dosage form] at bedtime.*

1 (I) Take 3 [insert appropriate dosage form] in the morning, and
2 3 [insert appropriate dosage form] at bedtime.

3 (J) Take 1 [insert appropriate dosage form] in the morning, 1
4 [insert appropriate dosage form] at noon, and 1 [insert appropriate
5 dosage form] in the evening.

6 (K) Take 2 [insert appropriate dosage form] in the morning, 2
7 [insert appropriate dosage form] at noon, and 2 [insert appropriate
8 dosage form] in the evening.

9 (L) Take 3 [insert appropriate dosage form] in the morning, 3
10 [insert appropriate dosage form] at noon, and 3 [insert appropriate
11 dosage form] in the evening.

12 (M) Take 1 [insert appropriate dosage form] in the morning, 1
13 [insert appropriate dosage form] at noon, 1 [insert appropriate
14 dosage form] in the evening, and 1 [insert appropriate dosage
15 form] at bedtime.

16 (N) Take 2 [insert appropriate dosage form] in the morning, 2
17 [insert appropriate dosage form] at noon, 2 [insert appropriate
18 dosage form] in the evening, and 2 [insert appropriate dosage
19 form] at bedtime.

20 (O) Take 3 [insert appropriate dosage form] in the morning, 3
21 [insert appropriate dosage form] at noon, 3 [insert appropriate
22 dosage form] in the evening, and 3 [insert appropriate dosage
23 form] at bedtime.

24 (P) If you have pain, take [insert appropriate dosage form] at
25 a time. Wait at least ___ hours before taking again. Do not take
26 more than [appropriate dosage form] in one day.

27 (2) Examples of labels conforming to the requirements described
28 in Section 4076.7 to aid pharmacies in label design and
29 compliance.

30 SEC. 4. Section 4076.7 is added to the Business and Professions
31 Code, to read:

32 4076.7. (a) On and after January 1, 2012, all prescription
33 drug labels on all prescription drugs dispensed to patients in
34 California shall conform to the following standardized,
35 patient-centered format:

36 (1) Each of the following elements shall be clustered into one
37 area of the label that comprises at least 50 percent of the label.
38 Each item shall be printed in at least a 12-point sans serif typeface,
39 and listed in the following order:

40 (A) Name of the patient.

- 1 (B) Name of the drug and strength of the drug. For the purposes
2 of this section, “name of the drug” means the generic name of the
3 drug and, if applicable, the manufacturer’s trade name.
- 4 (C) Directions for use.
- 5 (D) Purpose or condition, if entered on the prescription by the
6 prescriber or otherwise known to the pharmacy.
- 7 (2) For added emphasis, the label shall also highlight in bold
8 typeface or color, or use a blank space to set off, the items listed
9 in paragraph (1).
- 10 (3) The remaining elements required for the label as described
11 in Section 4076, as well as any other items of information
12 appearing on the label or the container, shall be printed so as not
13 to interfere with the legibility or emphasis of the primary elements
14 specified in paragraph (1). These remaining elements may appear
15 in any style, font, and size typeface.
- 16 (4) When applicable, directions for use shall utilize one of the
17 following phrases and, when appropriate shall be in the language
18 of the patient as translated pursuant to Section 4076.5:
- 19 (A) Take 1 [insert appropriate dosage form] at bedtime.
- 20 (B) Take 2 [insert appropriate dosage form] at bedtime.
- 21 (C) Take 3 [insert appropriate dosage form] at bedtime.
- 22 (D) Take 1 [insert appropriate dosage form] in the morning.
- 23 (E) Take 2 [insert appropriate dosage form] in the morning.
- 24 (F) Take 3 [insert appropriate dosage form] in the morning.
- 25 (G) Take 1 [insert appropriate dosage form] in the morning,
26 and 1 [insert appropriate dosage form] at bedtime.
- 27 (H) Take 2 [insert appropriate dosage form] in the morning,
28 and 2 [insert appropriate dosage form] at bedtime.
- 29 (I) Take 3 [insert appropriate dosage form] in the morning, and
30 3 [insert appropriate dosage form] at bedtime.
- 31 (J) Take 1 [insert appropriate dosage form] in the morning, 1
32 [insert appropriate dosage form] at noon, and 1 [insert appropriate
33 dosage form] in the evening.
- 34 (K) Take 2 [insert appropriate dosage form] in the morning, 2
35 [insert appropriate dosage form] at noon, and 2 [insert appropriate
36 dosage form] in the evening.
- 37 (L) Take 3 [insert appropriate dosage form] in the morning, 3
38 [insert appropriate dosage form] at noon, and 3 [insert appropriate
39 dosage form] in the evening.

1 (M) Take 1 [insert appropriate dosage form] in the morning, 1
2 [insert appropriate dosage form] at noon, 1 [insert appropriate
3 dosage form] in the evening, and 1 [insert appropriate dosage
4 form] at bedtime.

5 (N) Take 2 [insert appropriate dosage form] in the morning, 2
6 [insert appropriate dosage form] at noon, 2 [insert appropriate
7 dosage form] in the evening, and 2 [insert appropriate dosage
8 form] at bedtime.

9 (O) Take 3 [insert appropriate dosage form] in the morning, 3
10 [insert appropriate dosage form] at noon, 3 [insert appropriate
11 dosage form] in the evening, and 3 [insert appropriate dosage
12 form] at bedtime.

13 (P) If you have pain, take [insert appropriate dosage form] at
14 a time. Wait at least ____ hours before taking again. Do not take
15 more than [insert appropriate dosage form] in one day.

16 (b) As used in this section, “appropriate dosage form” means
17 the prescribed form of the prescription medication and includes
18 a pill, caplet, capsule, or tablet.

19 (c) This section shall not apply to prescriptions dispensed to a
20 patient in a health facility, as defined in Section 1250 of the Health
21 and Safety Code, if the prescriptions are administered by a licensed
22 health care professional. Prescriptions dispensed to a patient in
23 a health facility that will not be administered by a licensed health
24 care professional or that are provided to the patient upon discharge
25 from the facility shall be subject to the requirements of this section.
26 Nothing in this subdivision shall alter or diminish existing statutory
27 and regulatory informed consent, patients’ rights, or
28 pharmaceutical labeling and storage requirements, including, but
29 not limited to, the requirements of Section 1418.9 of the Health
30 and Safety Code or Section 72357, 72527, or 72528 of Title 22 of
31 the California Code of Regulations.

32 SEC. 5. Section 4076.9 is added to the Business and Professions
33 Code, to read:

34 4076.9. (a) For the purposes of this section, “limited-English
35 proficient” or “LEP,” means a person who does not speak English
36 as his or her primary language, and who has a limited ability to
37 read, write, speak, or understand English and who can read, speak,
38 or understand a language other than English.

39 (b) (1) On and after January 1, 2012, a pharmacy shall provide,
40 during all hours when the pharmacy is open, competent interpreter

1 services to each LEP patient in the LEP patient’s language at no
2 charge in order to help an LEP understand the information on his
3 or her prescription drug label. The interpreter services may be
4 provided in person by pharmacy staff, in person by a third-party
5 interpreter service, or by telephone or video conference using a
6 third-party interpreter service.

7 (2) On or before January 1, 2012, each pharmacy shall develop
8 written policies and procedures to help an LEP patient orally
9 understand the information on his or her prescription drug label,
10 including the directions for use, as described in Section 4076.7.
11 The policies and procedures shall include, at a minimum, the means
12 to (A) identify and record the patient’s oral and written language,
13 (B) provide language assistance services, including interpreter
14 services pursuant to paragraph (1) and translation services, (c)
15 train pharmacy staff on these policies and procedures, (d) provide
16 clear and prominent notice to LEP patients about the availability
17 of free language assistance services, and (e) monitor and update
18 the relevant policies and procedures.

19 (C) (1) On and after January 1, 2013, in addition to providing
20 the required information on the prescription drug label in the
21 language of an LEP patient a pharmacy shall provide an LEP
22 patient with any other written information relevant to the
23 prescription drug in the language of the LEP patient.

24 (2) On or before January 1, 2013, each pharmacy shall develop
25 written policies and procedures to carry out the requirement in
26 paragraph (1).

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

36 SECTION 1. ~~Section 4076.5 of the Business and Professions~~
37 ~~Code is amended to read:~~

38 ~~4076.5. (a) The board shall promulgate regulations that require,~~
39 ~~on or before January 1, 2011, a standardized, patient-centered,~~

1 prescription drug label on all prescription medicine dispensed to
2 patients in California.

3 ~~(b) To ensure maximum public comment, the board shall hold~~
4 ~~public meetings statewide that are separate from its normally~~
5 ~~scheduled hearings in order to seek information from groups~~
6 ~~representing consumers, seniors, pharmacists or the practice of~~
7 ~~pharmacy, other health care professionals, and other interested~~
8 ~~parties.~~

9 ~~(c) When developing the requirements for prescription drug~~
10 ~~labels, the board shall consider all of the following factors:~~

11 ~~(1) Medical literacy research that points to increased~~
12 ~~understandability of labels.~~

13 ~~(2) Improved directions for use.~~

14 ~~(3) Improved font types and sizes.~~

15 ~~(4) Placement of information that is patient-centered.~~

16 ~~(5) The needs of patients with limited English proficiency.~~

17 ~~(6) The needs of senior citizens.~~

18 ~~(7) Technology requirements necessary to implement the~~
19 ~~standards.~~

20 ~~(d) The board may exempt from the requirements of regulations~~
21 ~~promulgated pursuant to subdivision (a) prescriptions dispensed~~
22 ~~to a patient in a health facility, as defined in Section 1250 of the~~
23 ~~Health and Safety Code, if the prescriptions are administered by~~
24 ~~a licensed health care professional. Prescriptions dispensed to a~~
25 ~~patient in a health facility that will not be administered by a~~
26 ~~licensed health care professional or that are provided to the patient~~
27 ~~upon discharge from the facility shall be subject to the requirements~~
28 ~~of this section and the associated regulations. Nothing in this~~
29 ~~subdivision shall alter or diminish existing statutory and regulatory~~
30 ~~informed consent, patients' rights, or pharmaceutical labeling and~~
31 ~~storage requirements, including, but not limited to, the requirements~~
32 ~~of Section 1418.9 of the Health and Safety Code or Section 72357,~~
33 ~~72527, or 72528 of Title 22 of the California Code of Regulations.~~

34 ~~(e) (1) On or before January 1, 2010, the board shall report to~~
35 ~~the Legislature on its progress under this section as of the time of~~
36 ~~the report.~~

1 ~~(2) On or before January 1, 2013, the board shall report to the~~
2 ~~Legislature the status of implementation of the prescription drug~~
3 ~~label requirements adopted pursuant to this section.~~

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