

AMENDED IN ASSEMBLY JUNE 10, 2014

AMENDED IN ASSEMBLY JUNE 27, 2013

AMENDED IN SENATE MAY 23, 2013

AMENDED IN SENATE APRIL 24, 2013

**SENATE BILL**

**No. 204**

---

---

**Introduced by Senator Corbett**

February 8, 2013

---

---

An act to add *and repeal* Section 4076.3-~~to~~ of the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

SB 204, 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 prohibits a pharmacist from dispensing any prescription unless it is in a specified container that is correctly labeled to include, among other information, the directions for the use of the drug. ~~A violation of the Pharmacy Law is a crime.~~ Existing regulations of the board provide standardized directions for use that are required to be used on drug container labels, as specified.

*This bill would require the board to conduct a survey of a representative sample of licensed pharmacists to determine the usage of the directions for use described above. The bill would require this survey to address certain issues, including, but not limited to, whether and how often the pharmacist utilizes the directions for use, barriers to utilizing the directions for use, and other directions for use utilized by the pharmacist. The bill would also require the board to conduct a similar survey of vendors that provide electronic health records (EHR)*

*to pharmacies and prescribers to determine the type of directions for use included in the vendor's EHR programming, as specified. The bill would authorize these surveys to be conducted with other routine surveys conducted by the board during its regular course of business. The bill would require the board to report the survey findings at its July 2016 board meeting and to publish the findings on the board's Internet Web site, as specified.*

~~This bill would, commencing January 1, 2016, require translations of the directions for use in non-English languages published on the board's Internet Web site to be used, as applicable, when labeling a prescription container. The bill would, notwithstanding these provisions, authorize a pharmacy to use its own translations of the board's English language directions for use, as specified, if a trained and qualified translator or translation service, as defined, is utilized to complete the additional translations. The bill would authorize the directions for use, as specified, to be translated into additional non-English languages if a trained and qualified translator or translation service, as defined, is utilized to complete the additional translations. The bill would authorize a pharmacist to use the English language directions for use, as specified, if he or she reasonably believes a translation of the directions for use contains an error due to software or equipment malfunction. The bill would also provide that a pharmacist that reasonably uses the translations of the directions for use in non-English languages published on the board's Internet Web site has not breached his or her legal duty if the published translations contain an error and the pharmacist did not know, or did not have reason to know, of the error. The bill would require that the board's English language directions for use be provided in each instance in which a non-English translation of the directions for use is used. Because a violation of this requirement would be a crime, the bill would impose a state-mandated local program.~~

~~This bill would define "translation" and "trained and qualified translator or translation service" for purposes of the provisions described above.~~

~~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-no*.

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

1     *SECTION 1. Section 4076.3 is added to the Business and*  
2 *Professions Code, to read:*

3     4076.3. (a) *The board shall conduct a survey of a*  
4 *representative sample of licensed pharmacists to determine the*  
5 *utilization of the standardized directions for use provided in*  
6 *paragraph (4) of subdivision (a) of Section 1707.5 of Article 2 of*  
7 *Division 17 of Title 16 of the California Code of Regulations. The*  
8 *survey shall address, but not be limited to, all of the following*  
9 *issues:*

10     (1) *Whether the pharmacist utilizes the standardized directions*  
11 *for use.*

12     (2) *How often the pharmacist utilizes the standardized directions*  
13 *for use.*

14     (3) *Challenges or barriers to utilizing the standardized*  
15 *directions for use.*

16     (4) *Other directions for use utilized by the pharmacist.*

17     (b) *The board shall conduct a survey of vendors that provide*  
18 *electronic health records (EHR) to pharmacies and prescribers*  
19 *to determine the type of directions for use included in the vendor's*  
20 *EHR programming. The survey shall address, but not be limited*  
21 *to, all of the following issues:*

22     (1) *Whether the standardized directions for use described in*  
23 *subdivision (a) are included in the vendor's EHR programming.*

24     (2) *Challenges or barriers to utilizing the standardized*  
25 *directions for use in the vendor's EHR programming.*

26     (3) *Other directions for use utilized by the vendor in its EHR*  
27 *programming.*

28     (c) *The surveys required by this section may be conducted with*  
29 *other routine surveys conducted by the board during its regular*  
30 *course of business.*

31     (d) *The board shall report the findings of the surveys required*  
32 *by this section in the aggregate at its July 2016 board meeting and*  
33 *publish these findings on its Internet Web site.*

34     *This section shall remain in effect only until January 1, 2020,*  
35 *and as of that date is repealed, unless a later enacted statute, that*  
36 *is enacted before January 1, 2020, deletes or extends that date.*

37     ~~SECTION 1. Section 4076.3 is added to the Business and~~  
38 ~~Professions Code, to read:~~

1     ~~4076.3. (a) Translations of the directions for use in non-English~~  
2 ~~languages published on the board’s Internet Web site shall be used,~~  
3 ~~as applicable, when labeling a prescription container pursuant to~~  
4 ~~Section 4076.~~  
5     ~~(b) The English language directions for use established by~~  
6 ~~regulation of the board may be translated into additional~~  
7 ~~non-English languages if a trained and qualified translator or~~  
8 ~~translation service is utilized to complete the additional translations.~~  
9     ~~(c) Notwithstanding subdivision (a), a pharmacy may use its~~  
10 ~~own translations of the directions for use established by regulation~~  
11 ~~of the board in the non-English languages published on the board’s~~  
12 ~~Internet Web site when labeling a prescription container pursuant~~  
13 ~~to Section 4076 if a trained and qualified translator or translation~~  
14 ~~service is utilized.~~  
15     ~~(d) If a pharmacist reasonably believes that a translation of the~~  
16 ~~directions for use contains an error due to software or equipment~~  
17 ~~malfunction, he or she may use the English language directions~~  
18 ~~for use established by regulation of the board when labeling a~~  
19 ~~prescription container pursuant to Section 4076.~~  
20     ~~(e) A pharmacist that reasonably uses the translations of the~~  
21 ~~directions for use in non-English languages published on the~~  
22 ~~board’s Internet Web site has not breached his or her legal duty if~~  
23 ~~the published translations contain an error and the pharmacist did~~  
24 ~~not know, or did not have reason to know, of the error.~~  
25     ~~(f) The English language directions for use established by~~  
26 ~~regulation of the board shall be provided in each instance in which~~  
27 ~~a non-English translation of the directions for use is used pursuant~~  
28 ~~to this section.~~  
29     ~~(g) For purposes of this section, “translation” means the~~  
30 ~~conversion of written text to the corresponding written text in a~~  
31 ~~different language.~~  
32     ~~(h) For purposes of this section, “trained and qualified translator~~  
33 ~~or translation service” means any of the following:~~  
34     ~~(1) An individual certified by the American Translators~~  
35 ~~Association or any other nationally accredited or state-approved~~  
36 ~~program the board deems satisfactory.~~  
37     ~~(2) An individual trained in translation who has been assessed~~  
38 ~~as competent by a company specializing in translation that employs,~~  
39 ~~or has a contractual relationship with, the individual.~~

1 ~~(3) An individual employed by a pharmacy who meets all of~~  
2 ~~the following requirements:~~

3 ~~(A) He or she has written proficiency in both English and a~~  
4 ~~non-English language.~~

5 ~~(B) He or she commits to abide by the American Translators~~  
6 ~~Association's Code of Professional Conduct and Business~~  
7 ~~Practices.~~

8 ~~(C) He or she exhibits sufficient knowledge and understanding~~  
9 ~~of required health care vocabulary and terminology related to the~~  
10 ~~practice of pharmacy.~~

11 ~~A pharmacy shall establish internal policies to determine and~~  
12 ~~document an individual's qualifications pursuant to subparagraphs~~

13 ~~(A) to (C), inclusive, of this paragraph.~~

14 ~~(i) This section shall become operative on January 1, 2016.~~

15 ~~SEC. 2. No reimbursement is required by this act pursuant to~~  
16 ~~Section 6 of Article XIII B of the California Constitution because~~  
17 ~~the only costs that may be incurred by a local agency or school~~  
18 ~~district will be incurred because this act creates a new crime or~~  
19 ~~infraction, eliminates a crime or infraction, or changes the penalty~~  
20 ~~for a crime or infraction, within the meaning of Section 17556 of~~  
21 ~~the Government Code, or changes the definition of a crime within~~  
22 ~~the meaning of Section 6 of Article XIII B of the California~~  
23 ~~Constitution.~~