

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~~ *add Section 4076.5 of 4076.6 to the Business and Professions Code, and to add Section 1714.20 to the Civil 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 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. *A violation of that law is a crime.*

This bill would ~~remove that obsolete date~~. require a dispenser to use a standardized direction for use on the label of the prescription container from a list in existing regulations. The bill would require the board to make available translations, in a minimum of 5 languages other than English, of those standardized directions for use and post the translated standardized directions for use on its Internet Web site. The bill would require a dispenser, upon request of a patient for a translated direction for use, to select the appropriate translated standardized direction for use, if available, and append it to the label on the patient's prescription container or provide it on a supplemental document. The bill would authorize a dispenser to provide his or her

own translated directions as an alternative to the above-described procedure. By imposing new requirements on dispensers, the violation of which would be a crime, this bill would impose a state-mandated local program.

The bill would exempt from civil liability a dispenser who complies with the requirement to select the appropriate translated standardized direction for use, if available, and append it to the label, for any error that results from the inability of the dispenser to understand a translated direction for use in a language other than English.

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: ~~no~~-yes. State-mandated local program: ~~no~~-yes.

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

- 1 SECTION 1. Section 4076.6 is added to the Business and
- 2 Professions Code, to read:
- 3 4076.6. (a) For all dangerous drugs dispensed to patients in
- 4 this state, when applicable, a dispenser shall use a standardized
- 5 direction for use on the label of the prescription container from
- 6 the list in subdivision (a) of Section 1707.5 of Title 16 of the
- 7 California Code of Regulations.
- 8 (b) The board shall make available translations, in a minimum
- 9 of five languages other than English, of the standardized directions
- 10 for use that are listed in subdivision (a) of Section 1707.5 of Title
- 11 16 of the California Code of Regulations. These translations shall
- 12 be approved by qualified translators, as determined by the board.
- 13 The board shall post these translated standardized directions for
- 14 use on its Internet Web site.
- 15 (c) Upon the request of a patient for a translated direction for
- 16 use, a dispenser shall select the appropriate translated
- 17 standardized direction for use from those established in accordance
- 18 with subdivision (b), if available, and append it to the label on the
- 19 patient's prescription container or provide it on a supplemental
- 20 document. If a translated direction for use appears on a

1 *prescription container label, the English version of the direction*
2 *shall also appear on the label. The translated direction for use*
3 *shall appear in the patient-centered area of the label in accordance*
4 *with subdivision (a) of Section 1707.5 of Title 16 of the California*
5 *Code of Regulations. The English version may appear in an area*
6 *of the label outside the patient-centered area.*

7 *(d) A dispenser may provide his or her own translated directions*
8 *as an alternative to the procedure established in subdivisions (a)*
9 *to (c), inclusive. The translated directions for use shall appear in*
10 *the patient-centered area of the label in accordance with*
11 *subdivision (a) of Section 1707.5 of Title 16 of the California Code*
12 *of Regulations or a supplemental document. The English version*
13 *may appear in other areas of the label outside the patient-centered*
14 *area.*

15 *SEC. 2. Section 1714.20 is added to the Civil Code, immediately*
16 *following Section 1714.2, to read:*

17 *1714.20. A dispenser who complies with subdivision (c) of*
18 *Section 4076.6 of the Business and Professions Code shall not be*
19 *liable for civil damages for any error that results from the inability*
20 *of the dispenser to understand a translated direction for use in a*
21 *language other than English.*

22 *SEC. 3. No reimbursement is required by this act pursuant to*
23 *Section 6 of Article XIII B of the California Constitution because*
24 *the only costs that may be incurred by a local agency or school*
25 *district will be incurred because this act creates a new crime or*
26 *infraction, eliminates a crime or infraction, or changes the penalty*
27 *for a crime or infraction, within the meaning of Section 17556 of*
28 *the Government Code, or changes the definition of a crime within*
29 *the meaning of Section 6 of Article XIII B of the California*
30 *Constitution.*

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

33 ~~4076.5. (a) The board shall promulgate regulations that require~~
34 ~~a standardized, patient-centered, prescription drug label on all~~
35 ~~prescription medicine dispensed to patients in California.~~

36 ~~(b) To ensure maximum public comment, the board shall hold~~
37 ~~public meetings statewide that are separate from its normally~~
38 ~~scheduled hearings in order to seek information from groups~~
39 ~~representing consumers, seniors, pharmacists or the practice of~~

1 pharmacy, other health care professionals, and other interested
2 parties:

3 (e) ~~When developing the requirements for prescription drug~~
4 ~~labels, the board shall consider all of the following factors:~~

5 (1) ~~Medical literacy research that points to increased~~
6 ~~understandability of labels.~~

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

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

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

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

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

12 (7) ~~Technology requirements necessary to implement the~~
13 ~~standards.~~

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

28 (e) (1) ~~The board may exempt from the regulations promulgated~~
29 ~~pursuant to subdivision (a) a prescription dispensed to a patient if~~
30 ~~all of the following apply:~~

31 (A) ~~The drugs are dispensed by a JCAHO-accredited home~~
32 ~~infusion or specialty pharmacy.~~

33 (B) ~~The patient receives health-professional-directed education~~
34 ~~before the beginning of therapy by a nurse or pharmacist.~~

35 (C) ~~The patient receives weekly or more frequent followup~~
36 ~~contacts by a nurse or pharmacist.~~

37 (D) ~~Care is provided under a formal plan of care based upon a~~
38 ~~physician and surgeon's orders.~~

39 (2) ~~For purposes of paragraph (1), home infusion and specialty~~
40 ~~therapies include parenteral therapy or other forms of~~

1 ~~administration that require regular laboratory and patient~~
2 ~~monitoring.~~

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