

AMENDED IN SENATE JANUARY 4, 2012

AMENDED IN SENATE MARCH 24, 2011

**SENATE BILL**

**No. 632**

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**Introduced by Senator Emmerson**

February 18, 2011

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An act to ~~add~~ *amend* Section ~~4052.6 to~~ 4980.42 of the Business and Professions Code, relating to ~~pharmacy~~ *marriage and family therapists*.

LEGISLATIVE COUNSEL'S DIGEST

SB 632, as amended, Emmerson. ~~Pharmacy~~ *Marriage and family therapists*.

*Existing law provides for the licensing and regulation of marriage and family therapists by the Board of Behavioral Sciences. Existing law specifies the education required for licensure, which includes, for specified applicants, a requirement for a practicum that involves direct client contact and hours of experience relating to client-centered advocacy, as defined. Existing law authorizes trainees to perform activities and services in certain work settings provided that these constitute part of the trainee's supervised course of study and the person is designated as a trainee. Existing law also authorizes trainees to gain hours of experience outside the required practicum under certain conditions, but requires trainees who gain experience outside the required practicum to be enrolled in a practicum in order to counsel clients, except that trainees may counsel clients while not enrolled in a practicum if the period of lapsed enrollment is less than 90 calendar days, and if that period is immediately preceded and immediately followed by enrollment in a practicum course.*

*This bill would provide that the exception described above applies to specified trainees.*

~~Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacists and pharmacies by the California State Board of Pharmacy. A violation of the law is a crime. Existing law authorizes a pharmacist filling a prescription order for a drug product prescribed by the trade or brand name to substitute a generic drug product, subject to specified requirements. Existing law also authorizes a pharmacist filling a prescription order for a drug product to select a different form of medication with the same active chemical ingredients, as specified, if certain requirements are met.~~

~~This bill would prohibit a pharmacist from interchanging or substituting an opioid analgesic drug, as defined, for an opioid analgesic drug incorporating a tamper resistant technology, as defined, unless the opioid analgesic drug to be interchanged or substituted is described on a list to be prepared by the board. In those situations where the drug is not on the board's list, the bill would require the pharmacist to obtain consent from the prescriber prior to an interchange or substitution. The bill would make findings and declarations in that regard. Because a violation of these requirements by a pharmacist would constitute 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-no. State-mandated local program: yes-no.~~

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

- 1     *SECTION 1. Section 4980.42 of the Business and Professions*
- 2     *Code is amended to read:*
- 3     4980.42. (a) Trainees performing services in any work setting
- 4     specified in subdivision (e) of Section 4980.43 may perform those
- 5     activities and services as a trainee, provided that the activities and
- 6     services constitute part of the trainee's supervised course of study
- 7     and that the person is designated by the title "trainee."
- 8     (b) Trainees may gain hours of experience outside the required
- 9     practicum but must be enrolled in a practicum course to counsel
- 10    clients, as set forth in clause (iii) of subparagraph (B) of paragraph

1 (1) of subdivision (d) of Section 4980.36, except as provided in  
2 subdivision (c).

3 (c) Trainees *subject to clause (iii) of subparagraph (B) of*  
4 *paragraph (1) of subdivision (d) of Section 4980.36* may counsel  
5 clients while not enrolled in a practicum course if the period of  
6 lapsed enrollment is less than 90 calendar days, and if that period  
7 is immediately preceded and immediately followed by enrollment  
8 in a practicum course.

9 (d) All hours of experience gained pursuant to subdivisions (b)  
10 and (c) shall be subject to the requirements of subdivision (b) and  
11 to the other requirements of this chapter.

12 ~~(e) On and after January 1, 1995, all~~ All hours of experience  
13 gained as a trainee shall be coordinated between the school and  
14 the site where the hours are being accrued. The school shall  
15 approve each site and shall have a written agreement with each  
16 site that details each party's responsibilities, including the methods  
17 by which supervision shall be provided. The agreement shall  
18 provide for regular progress reports and evaluations of the student's  
19 performance at the site. If an applicant has gained hours of  
20 experience while enrolled in an institution other than the one that  
21 confers the qualifying degree, it shall be the applicant's  
22 responsibility to provide to the board satisfactory evidence that  
23 those hours of trainee experience were gained in compliance with  
24 this section.

25 ~~SECTION 1. The Legislature finds and declares all of the~~  
26 ~~following:~~

27 ~~(a) Opioid use and abuse has increased greatly in the United~~  
28 ~~States since the 1990s and continues to rise. While the benefits of~~  
29 ~~these products in treating and managing pain are widely recognized,~~  
30 ~~the potential for misuse and abuse of these products has long been~~  
31 ~~a concern of manufacturers, federal and state law enforcement,~~  
32 ~~health care providers, legislators, and regulators.~~

33 ~~(b) Studies show that addicts tend to crush or otherwise break~~  
34 ~~down time-released products into a form that can be snorted or~~  
35 ~~injected for a more intense high. Thus, formulations that make it~~  
36 ~~more difficult to crush or otherwise manipulate those products~~  
37 ~~may mitigate the potential for abuse.~~

38 ~~(c) Pharmaceutical manufacturers have invested enormous~~  
39 ~~research and development resources in both creating novel~~  
40 ~~technologies that may help deter the inappropriate use of opioid~~

1 medications and testing those products against other opioid  
2 formulations:

3 (d) The United States Food and Drug Administration (FDA)  
4 has afforded priority review to new drug applications for opioids  
5 incorporating tamper resistant technologies. However, the FDA  
6 has been reluctant to permit claims that those products actually  
7 mitigate the potential for abuse without additional research.  
8 Companies continue to develop post approval data in the overall  
9 patient population; however, that effort will take many years.  
10 Products incorporating tamper resistant technologies can play an  
11 important role today in offering health care providers the  
12 opportunity to prescribe products incorporating tamper resistant  
13 technologies that provide advantages in reducing the potential for  
14 misuse and abuse of opioids.

15 (e) Given the critically important public health and law  
16 enforcement goals of preventing the abuse and misuse of opioids,  
17 the Legislature should approve policies that encourage  
18 manufacturers to develop opioid products with tamper resistant  
19 technologies and promote efficient use of scarce health care  
20 resources.

21 (f) Health care providers should have the ability to write  
22 prescriptions for opioid products incorporating tamper resistant  
23 technologies when, in their medical judgment, those prescriptions  
24 are medically necessary.

25 SEC. 2. Section 4052.6 is added to the Business and Professions  
26 Code, to read:

27 4052.6. (a) For the purposes of this section, the following  
28 definitions shall apply:

29 (1) "Opioid analgesic drug" means a drug in the opioid analgesic  
30 drug class prescribed to treat moderate to severe pain or other  
31 conditions, whether in immediate release or extended release form  
32 and whether or not combined with other drug substances to form  
33 a single tablet or other dosage form.

34 (2) "Opioid analgesic drug incorporating a tamper resistant  
35 technology" means an opioid analgesic drug listed as such by the  
36 board pursuant to subdivision (b).

37 (b) (1) For the purposes of carrying out the provisions described  
38 in subdivision (c), the board shall create a list of opioid analgesic  
39 drugs that incorporate a tamper resistant technology. A drug shall

1 not be included on the list unless the following requirements are  
2 satisfied:

3 (A) ~~The drug manufacturer or distributor submits evidence to~~  
4 ~~the board that the opioid analgesic drug incorporates a tamper~~  
5 ~~resistant technology.~~

6 (B) ~~The opioid analgesic drug has been approved by the United~~  
7 ~~States Food and Drug Administration (FDA) pursuant to an~~  
8 ~~application that includes at least one human tampering or abuse~~  
9 ~~potential study or a laboratory study comparing the tamper or abuse~~  
10 ~~resistant properties of the drug to one or more opioid analgesic~~  
11 ~~drugs that have been approved by the FDA and serve as a positive~~  
12 ~~control.~~

13 (2) ~~The list shall include a determination by the board as to~~  
14 ~~which opioid analgesic drugs incorporating tamper resistant~~  
15 ~~technologies provide substantially similar tamper resistant~~  
16 ~~properties, based solely upon studies submitted by the drug~~  
17 ~~manufacturer.~~

18 (3) ~~Nothing in this subdivision shall be construed to require that~~  
19 ~~a drug included on the list bear a labeling claim with respect to~~  
20 ~~reduction of tampering, abuse, or abuse potential at the time of~~  
21 ~~listing.~~

22 (e) (1) ~~Notwithstanding Sections 4052.5 and 4073, a pharmacist~~  
23 ~~shall not interchange or substitute an opioid analgesic drug, brand,~~  
24 ~~or generic, for an opioid analgesic drug incorporating a tamper~~  
25 ~~resistant technology unless the opioid analgesic drug that is~~  
26 ~~interchanged or substituted is included on the list described in~~  
27 ~~subdivision (b).~~

28 (2) ~~If the opioid analgesic drug is not on the list described in~~  
29 ~~subdivision (b), the pharmacist shall obtain consent from the~~  
30 ~~prescribing physician and surgeon prior to an interchange or~~  
31 ~~substitution. The consent may be obtained by telephone or through~~  
32 ~~any other electronic communication.~~

33 ~~SEC. 3. No reimbursement is required by this act pursuant to~~  
34 ~~Section 6 of Article XIII B of the California Constitution because~~  
35 ~~the only costs that may be incurred by a local agency or school~~  
36 ~~district will be incurred because this act creates a new crime or~~  
37 ~~infraction, eliminates a crime or infraction, or changes the penalty~~  
38 ~~for a crime or infraction, within the meaning of Section 17556 of~~  
39 ~~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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