

AMENDED IN SENATE MARCH 24, 2011

SENATE BILL

No. 632

Introduced by Senator Emmerson

February 18, 2011

~~An act to amend Section 4037 of the Business and Professions Code,~~
An act to add Section 4052.6 to the Business and Professions Code,
relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

SB 632, as amended, Emmerson. Pharmacy.

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacists and pharmacies by the California State Board of Pharmacy. ~~Existing law defines the term "pharmacy" for the purposes of these provisions.~~ *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 make a technical, nonsubstantive change to that provision.~~ *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: ~~no~~-yes.
State-mandated local program: ~~no~~-yes.

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

1 *SECTION 1. The Legislature finds and declares all of the*
2 *following:*

3 *(a) Opioid use and abuse has increased greatly in the United*
4 *States since the 1990s and continues to rise. While the benefits of*
5 *these products in treating and managing pain are widely*
6 *recognized, the potential for misuse and abuse of these products*
7 *has long been a concern of manufacturers, federal and state law*
8 *enforcement, health care providers, legislators, and regulators.*

9 *(b) Studies show that addicts tend to crush or otherwise break*
10 *down time-released products into a form that can be snorted or*
11 *injected for a more intense high. Thus, formulations that make it*
12 *more difficult to crush or otherwise manipulate those products*
13 *may mitigate the potential for abuse.*

14 *(c) Pharmaceutical manufacturers have invested enormous*
15 *research and development resources in both creating novel*
16 *technologies that may help deter the inappropriate use of opioid*
17 *medications and testing those products against other opioid*
18 *formulations.*

19 *(d) The United States Food and Drug Administration (FDA)*
20 *has afforded priority review to new drug applications for opioids*
21 *incorporating tamper resistant technologies. However, the FDA*
22 *has been reluctant to permit claims that those products actually*
23 *mitigate the potential for abuse without additional research.*
24 *Companies continue to develop post approval data in the overall*
25 *patient population; however, that effort will take many years.*
26 *Products incorporating tamper resistant technologies can play an*
27 *important role today in offering health care providers the*

1 *opportunity to prescribe products incorporating tamper resistant*
2 *technologies that provide advantages in reducing the potential for*
3 *misuse and abuse of opioids.*

4 *(e) Given the critically important public health and law*
5 *enforcement goals of preventing the abuse and misuse of opioids,*
6 *the Legislature should approve policies that encourage*
7 *manufacturers to develop opioid products with tamper resistant*
8 *technologies and promote efficient use of scarce health care*
9 *resources.*

10 *(f) Health care providers should have the ability to write*
11 *prescriptions for opioid products incorporating tamper resistant*
12 *technologies when, in their medical judgment, those prescriptions*
13 *are medically necessary.*

14 *SEC. 2. Section 4052.6 is added to the Business and Professions*
15 *Code, to read:*

16 *4052.6. (a) For the purposes of this section, the following*
17 *definitions shall apply:*

18 *(1) "Opioid analgesic drug" means a drug in the opioid*
19 *analgesic drug class prescribed to treat moderate to severe pain*
20 *or other conditions, whether in immediate release or extended*
21 *release form and whether or not combined with other drug*
22 *substances to form a single tablet or other dosage form.*

23 *(2) "Opioid analgesic drug incorporating a tamper resistant*
24 *technology" means an opioid analgesic drug listed as such by the*
25 *board pursuant to subdivision (b).*

26 *(b) (1) For the purposes of carrying out the provisions*
27 *described in subdivision (c), the board shall create a list of opioid*
28 *analgesic drugs that incorporate a tamper resistant technology.*
29 *A drug shall not be included on the list unless the following*
30 *requirements are satisfied:*

31 *(A) The drug manufacturer or distributor submits evidence to*
32 *the board that the opioid analgesic drug incorporates a tamper*
33 *resistant technology.*

34 *(B) The opioid analgesic drug has been approved by the United*
35 *States Food and Drug Administration (FDA) pursuant to an*
36 *application that includes at least one human tampering or abuse*
37 *potential study or a laboratory study comparing the tamper or*
38 *abuse resistant properties of the drug to one or more opioid*
39 *analgesic drugs that have been approved by the FDA and serve*
40 *as a positive control.*

1 (2) *The list shall include a determination by the board as to*
2 *which opioid analgesic drugs incorporating tamper resistant*
3 *technologies provide substantially similar tamper resistant*
4 *properties, based solely upon studies submitted by the drug*
5 *manufacturer.*

6 (3) *Nothing in this subdivision shall be construed to require*
7 *that a drug included on the list bear a labeling claim with respect*
8 *to reduction of tampering, abuse, or abuse potential at the time of*
9 *listing.*

10 (c) (1) *Notwithstanding Sections 4052.5 and 4073, a pharmacist*
11 *shall not interchange or substitute an opioid analgesic drug, brand,*
12 *or generic, for an opioid analgesic drug incorporating a tamper*
13 *resistant technology unless the opioid analgesic drug that is*
14 *interchanged or substituted is included on the list described in*
15 *subdivision (b).*

16 (2) *If the opioid analgesic drug is not on the list described in*
17 *subdivision (b), the pharmacist shall obtain consent from the*
18 *prescribing physician and surgeon prior to an interchange or*
19 *substitution. The consent may be obtained by telephone or through*
20 *any other electronic communication.*

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

30 ~~SECTION 1. Section 4037 of the Business and Professions~~
31 ~~Code is amended to read:~~

32 ~~4037. (a) "Pharmacy" shall mean an area, place, or premises~~
33 ~~licensed by the board in which the profession of pharmacy is~~
34 ~~practiced and where prescriptions are compounded. "Pharmacy"~~
35 ~~includes, but is not limited to, any area, place, or premises~~
36 ~~described in a license issued by the board wherein controlled~~
37 ~~substances, dangerous drugs, or dangerous devices are stored,~~
38 ~~possessed, prepared, manufactured, derived, compounded, or~~
39 ~~repackaged, and from which the controlled substances, dangerous~~

1 ~~drugs, or dangerous devices are furnished, sold, or dispensed at~~
2 ~~retail.~~

3 (b) ~~“Pharmacy” shall not include any area in a facility licensed~~
4 ~~by the State Department of Public Health where floor supplies,~~
5 ~~ward supplies, operating room supplies, or emergency room~~
6 ~~supplies of dangerous drugs or dangerous devices are stored or~~
7 ~~possessed solely for treatment of patients registered for treatment~~
8 ~~in the facility or for treatment of patients receiving emergency care~~
9 ~~in the facility.~~

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