

**Introduced by Senator Emmerson**February 16, 2011

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An act to amend Sections 4104, 4105, and 4112 of the Business and Professions Code, relating to pharmacies.

## LEGISLATIVE COUNSEL'S DIGEST

SB 431, as introduced, Emmerson. Pharmacies: regulation.

Existing law, the Pharmacy Law, creates the California State Board of Pharmacy and makes it responsible for administering and enforcing the provisions of that law, including the licensure of pharmacies, as defined, and nonresident pharmacies that ship, mail, or deliver controlled substances or dangerous drugs or devices, as defined, into this state. The law requires that each pharmacy establish procedures for addressing the theft, diversion, or self-use of dangerous drugs by a licensed individual employed by or with the pharmacy, and that an entity licensed by the board retain records of the acquisition and disposition of dangerous drugs and devices in a specified manner. The law makes a knowing violation of its provisions a misdemeanor.

This bill would require a pharmacy to conduct an audit of the theft, diversion, or self-use of dangerous drugs by a licensed individual employed by or with the pharmacy and provide, as specified, the board with a certified copy of the audit and its results. The bill would also require an entity licensed by the board to provide records to designated persons within 72 hours of the time of the request, unless that timeframe is extended by the board. The bill would prohibit a pharmacist whose license was revoked by the board to perform pharmacy duties, as specified, for a nonresident pharmacy.

Because this bill would specify additional requirements under the Pharmacy Law, a violation of which is a crime, it would impose a state-mandated local program by creating additional crimes.

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.

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

- 1 SECTION 1. Section 4104 of the Business and Professions
- 2 Code is amended to read:
- 3 4104. (a) Every pharmacy shall have in place procedures for
- 4 taking action to protect the public when a licensed individual
- 5 employed by or with the pharmacy is discovered or known to be
- 6 chemically, mentally, or physically impaired to the extent it affects
- 7 his or her ability to practice the profession or occupation authorized
- 8 by his or her license, or is discovered or known to have engaged
- 9 in the theft, diversion, or self-use of dangerous drugs.
- 10 (b) Every pharmacy shall have written policies and procedures
- 11 for addressing chemical, mental, or physical impairment, as well
- 12 as theft, diversion, or self-use of dangerous drugs, among licensed
- 13 individuals employed by or with the pharmacy.
- 14 (c) Every pharmacy shall report *and provide* to the board, within
- 15 30 days of the receipt or development of the following information
- 16 with regard to any licensed individual employed by or with the
- 17 pharmacy:
- 18 (1) Any admission by a licensed individual of chemical, mental,
- 19 or physical impairment affecting his or her ability to practice.
- 20 (2) Any admission by a licensed individual of theft, diversion,
- 21 or self-use of dangerous drugs.
- 22 (3) Any video or documentary evidence demonstrating chemical,
- 23 mental, or physical impairment of a licensed individual to the
- 24 extent it affects his or her ability to practice.
- 25 (4) Any video or documentary evidence demonstrating theft,
- 26 diversion, or self-use of dangerous drugs by a licensed individual.

1 (5) Any termination based on chemical, mental, or physical  
2 impairment of a licensed individual to the extent it affects his or  
3 her ability to practice.

4 (6) Any termination of a licensed individual based on theft,  
5 diversion, or self-use of dangerous drugs.

6 *(d) The pharmacy shall conduct an audit to determine the*  
7 *quantity and type of dangerous drugs stolen, diverted, or used by*  
8 *a licensed individual employed by or with the pharmacy. The*  
9 *pharmacy shall submit to the board a certified copy of the audit*  
10 *within 30 days of the receipt or development of information*  
11 *described in paragraph (4) of subdivision (c).*

12 ~~(e)~~

13 (e) Anyone making a report authorized or required by this  
14 section shall have immunity from any liability, civil or criminal,  
15 that might otherwise arise from the making of the report. Any  
16 participant shall have the same immunity with respect to  
17 participation in any administrative or judicial proceeding resulting  
18 from the report.

19 SEC. 2. Section 4105 of the Business and Professions Code is  
20 amended to read:

21 4105. (a) All records or other documentation of the acquisition  
22 and disposition of dangerous drugs and dangerous devices by any  
23 entity licensed by the board shall be retained on the licensed  
24 premises in a readily retrievable form.

25 (b) The licensee may remove the original records or  
26 documentation from the licensed premises on a temporary basis  
27 for license-related purposes. However, a duplicate set of those  
28 records or other documentation shall be retained on the licensed  
29 premises.

30 (c) The records required by this section shall be retained on the  
31 licensed premises for a period of three years from the date of  
32 making.

33 (d) Any records that are maintained electronically shall be  
34 maintained so that the pharmacist-in-charge, the pharmacist on  
35 duty if the pharmacist-in-charge is not on duty, or, in the case of  
36 a veterinary food-animal drug retailer or wholesaler, the designated  
37 representative on duty, shall, at all times during which the licensed  
38 premises are open for business, be able to produce a hard copy  
39 and electronic copy of all records of acquisition or disposition or  
40 other drug or dispensing-related records maintained electronically.

1 (e) (1) Notwithstanding subdivisions (a), (b), and (c), the board,  
2 may upon written request, grant to a licensee a waiver of the  
3 requirements that the records described in subdivisions (a), (b),  
4 and (c) be kept on the licensed premises.

5 (2) A waiver granted pursuant to this subdivision shall not affect  
6 the board's authority under this section or any other provision of  
7 this chapter.

8 ~~(f) This section shall become operative on January 1, 2006.~~

9 *(f) When requested by an authorized officer of the law or by an*  
10 *authorized representative of the board, the owner, corporate*  
11 *officer, or manager of an entity licensed by the board shall provide*  
12 *the board with the requested records within 72 hours of the time*  
13 *the request was made. The entity may request in writing an*  
14 *extension of this timeframe for a period not to exceed 14 days from*  
15 *the date the records were requested. A request for an extension of*  
16 *time is subject to the approval of the board.*

17 SEC. 3. Section 4112 of the Business and Professions Code is  
18 amended to read:

19 4112. (a) Any pharmacy located outside this state that ships,  
20 mails, or delivers, in any manner, controlled substances, dangerous  
21 drugs, or dangerous devices into this state shall be considered a  
22 nonresident pharmacy.

23 (b) A person may not act as a nonresident pharmacy unless he  
24 or she has obtained a license from the board. The board may  
25 register a nonresident pharmacy that is organized as a limited  
26 liability company in the state in which it is licensed.

27 (c) A nonresident pharmacy shall disclose to the board the  
28 location, names, and titles of (1) its agent for service of process in  
29 this state, (2) all principal corporate officers, if any, (3) all general  
30 partners, if any, and (4) all pharmacists who are dispensing  
31 controlled substances, dangerous drugs, or dangerous devices to  
32 residents of this state. A report containing this information shall  
33 be made on an annual basis and within 30 days after any change  
34 of office, corporate officer, partner, or pharmacist.

35 (d) All nonresident pharmacies shall comply with all lawful  
36 directions and requests for information from the regulatory or  
37 licensing agency of the state in which it is licensed as well as with  
38 all requests for information made by the board pursuant to this  
39 section. The nonresident pharmacy shall maintain, at all times, a  
40 valid unexpired license, permit, or registration to conduct the

1 pharmacy in compliance with the laws of the state in which it is a  
2 resident. As a prerequisite to registering with the board, the  
3 nonresident pharmacy shall submit a copy of the most recent  
4 inspection report resulting from an inspection conducted by the  
5 regulatory or licensing agency of the state in which it is located.

6 (e) All nonresident pharmacies shall maintain records of  
7 controlled substances, dangerous drugs, or dangerous devices  
8 dispensed to patients in this state so that the records are readily  
9 retrievable from the records of other drugs dispensed.

10 (f) Any pharmacy subject to this section shall, during its regular  
11 hours of operation, but not less than six days per week, and for a  
12 minimum of 40 hours per week, provide a toll-free telephone  
13 service to facilitate communication between patients in this state  
14 and a pharmacist at the pharmacy who has access to the patient's  
15 records. This toll-free telephone number shall be disclosed on a  
16 label affixed to each container of drugs dispensed to patients in  
17 this state.

18 (g) *A nonresident pharmacy shall not permit a pharmacist whose*  
19 *license has been revoked by the board to manufacture, compound,*  
20 *furnish, sell, dispense, or initiate the prescription of a dangerous*  
21 *drug or dangerous device, or to provide any pharmacy-related*  
22 *service, to a person residing in California.*

23 ~~(g)~~

24 (h) The board shall adopt regulations that apply the same  
25 requirements or standards for oral consultation to a nonresident  
26 pharmacy that operates pursuant to this section and ships, mails,  
27 or delivers any controlled substances, dangerous drugs, or  
28 dangerous devices to residents of this state, as are applied to an  
29 in-state pharmacy that operates pursuant to Section 4037 when the  
30 pharmacy ships, mails, or delivers any controlled substances,  
31 dangerous drugs, or dangerous devices to residents of this state.  
32 The board shall not adopt any regulations that require face-to-face  
33 consultation for a prescription that is shipped, mailed, or delivered  
34 to the patient. The regulations adopted pursuant to this subdivision  
35 shall not result in any unnecessary delay in patients receiving their  
36 medication.

37 ~~(h)~~

38 (i) The registration fee shall be the fee specified in subdivision  
39 (a) of Section 4400.

40 ~~(i)~~

1 (j) The registration requirements of this section shall apply only  
2 to a nonresident pharmacy that ships, mails, or delivers controlled  
3 substances, dangerous drugs, and dangerous devices into this state  
4 pursuant to a prescription.

5 (j)

6 (k) Nothing in this section shall be construed to authorize the  
7 dispensing of contact lenses by nonresident pharmacists except as  
8 provided by Section 4124.

9 SEC. 4. No reimbursement is required by this act pursuant to  
10 Section 6 of Article XIII B of the California Constitution because  
11 the only costs that may be incurred by a local agency or school  
12 district will be incurred because this act creates a new crime or  
13 infraction, eliminates a crime or infraction, or changes the penalty  
14 for a crime or infraction, within the meaning of Section 17556 of  
15 the Government Code, or changes the definition of a crime within  
16 the meaning of Section 6 of Article XIII B of the California  
17 Constitution.