

AMENDED IN ASSEMBLY AUGUST 23, 2011

AMENDED IN SENATE MAY 10, 2011

AMENDED IN SENATE APRIL 11, 2011

**SENATE BILL**

**No. 431**

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**Introduced by Senator Emmerson**  
*(Coauthor: Assembly Member Fuentes)*

February 16, 2011

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An act to amend Sections 4081, 4104, 4105, and 4112 of, ~~and to add Section 4126.7 to,~~ the Business and Professions Code, relating to pharmacies.

LEGISLATIVE COUNSEL'S DIGEST

SB 431, as amended, 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. ~~Under existing law, a reverse distributor is any person who acts as an agent for a pharmacy, drug wholesaler, manufacturer, or other entity by receiving, inventorying, and managing the disposition of outdated or nonsalable dangerous drugs.~~ A knowing violation of the Pharmacy Law is a crime.

~~This bill would, except as specified, prohibit a reverse distributor from accepting the return of dangerous drugs that have been dispensed to a patient that are later returned by the patient or patient's agent to a pharmacy, as specified.~~

Existing 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 every pharmacy report to the board within 30 days of the receipt or development of certain information affecting the ability of those individuals to practice the profession or occupation authorized by their license, as specified. Existing law requires an entity licensed by the board to retain records of the acquisition and disposition of dangerous drugs and devices in a specified manner. Existing federal law requires registrants distributing specified controlled substances to conduct an inventory of controlled substances every 2 years.

This bill would instead require a pharmacy to report and provide to the board, within 14 days of the receipt or development thereof, the information described above regarding the ability of licensed individuals employed by or with the pharmacy to practice the profession or occupation authorized by their license. The bill would require the report to include specified detailed information, including the date of the last controlled substances inventory, and would require the pharmacy to prepare and submit an audit relating to the report upon the request of the board. The bill would also require an entity licensed by the board to provide records to designated persons within 3 business days of the time of the request, unless that timeframe is extended by the board, as specified. The bill would prohibit a pharmacist whose license was revoked by the board to perform pharmacy duties, as specified, for a nonresident pharmacy.

Existing law requires all records of manufacture and of sale, acquisition, or disposition of dangerous drugs or dangerous devices to be at all times during business hours open to inspection by authorized officers of the law and preserved at least 3 years from the date of making. Existing law requires every person or entity who maintains a stock of dangerous drugs or dangerous devices to keep a current inventory.

This bill would require that any record pertaining to the return of dangerous drugs to a wholesaler, ~~reverse distributor~~, or hazardous waste hauler include specified information, including the quantity or weight of the drugs returned.

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 4081 of the Business and Professions  
2 Code is amended to read:

3 4081. (a) All records of manufacture and of sale, acquisition,  
4 or disposition of dangerous drugs or dangerous devices shall be  
5 at all times during business hours open to inspection by authorized  
6 officers of the law, and shall be preserved for at least three years  
7 from the date of making. A current inventory shall be kept by every  
8 manufacturer, wholesaler, pharmacy, veterinary food-animal drug  
9 retailer, physician, dentist, podiatrist, veterinarian, laboratory,  
10 clinic, hospital, institution, or establishment holding a currently  
11 valid and unrevoked certificate, license, permit, registration, or  
12 exemption under Division 2 (commencing with Section 1200) of  
13 the Health and Safety Code or under Part 4 (commencing with  
14 Section 16000) of Division 9 of the Welfare and Institutions Code  
15 who maintains a stock of dangerous drugs or dangerous devices.

16 (b) The owner, officer, and partner of a pharmacy, wholesaler,  
17 or veterinary food-animal drug retailer shall be jointly responsible,  
18 with the pharmacist-in-charge or designated  
19 representative-in-charge, for maintaining the records and inventory  
20 described in this section.

21 (c) The pharmacist-in-charge or designated  
22 representative-in-charge shall not be criminally responsible for  
23 acts of the owner, officer, partner, or employee that violate this  
24 section and of which the pharmacist-in-charge or designated  
25 representative-in-charge had no knowledge, or in which he or she  
26 did not knowingly participate.

27 (d) Any record pertaining to the return of dangerous drugs to a  
28 wholesaler ~~or provided to a reverse distributor~~ shall document the  
29 quantity or weight of the drugs returned, the date the drugs were

1 returned, and the name of the ~~reverse distributor or wholesaler~~ to  
2 whom the drugs were provided.

3 (e) Any record pertaining to the return of dangerous drugs to a  
4 hazardous waste hauler, as described in Section 117660 of the  
5 Health and Safety Code, shall list the volume in weight or  
6 measurement of the pharmaceutical waste returned, the date the  
7 waste was returned, and the name of the hazardous waste hauler  
8 to whom the waste was provided.

9 SEC. 2. Section 4104 of the Business and Professions Code is  
10 amended to read:

11 4104. (a) Every pharmacy shall have in place procedures for  
12 taking action to protect the public when a licensed individual  
13 employed by or with the pharmacy is discovered or known to be  
14 chemically, mentally, or physically impaired to the extent it affects  
15 his or her ability to practice the profession or occupation authorized  
16 by his or her license, or is discovered or known to have engaged  
17 in the theft, diversion, or self-use of dangerous drugs.

18 (b) Every pharmacy shall have written policies and procedures  
19 for addressing chemical, mental, or physical impairment, as well  
20 as theft, diversion, or self-use of dangerous drugs, among licensed  
21 individuals employed by or with the pharmacy.

22 (c) Every pharmacy shall report and provide to the board, within  
23 14 days of the receipt or development thereof, the following  
24 information with regard to any licensed individual employed by  
25 or with the pharmacy:

26 (1) Any admission by a licensed individual of chemical, mental,  
27 or physical impairment affecting his or her ability to practice.

28 (2) Any admission by a licensed individual of theft, diversion,  
29 or self-use of dangerous drugs.

30 (3) Any video or documentary evidence demonstrating chemical,  
31 mental, or physical impairment of a licensed individual to the  
32 extent it affects his or her ability to practice.

33 (4) Any video or documentary evidence demonstrating theft,  
34 diversion, or self-use of dangerous drugs by a licensed individual.

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

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

1 (d) The report required in subdivision (c) shall include sufficient  
2 detail to inform the board of the facts upon which the report is  
3 based, including an estimate of the type and quantity of all  
4 dangerous drugs involved, the timeframe over which the losses  
5 are suspected, and the date of the last controlled substances  
6 inventory. Upon request of the board, the pharmacy shall prepare  
7 and submit an audit involving the dangerous drugs suspected to  
8 be missing.

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

15 SEC. 3. Section 4105 of the Business and Professions Code is  
16 amended to read:

17 4105. (a) All records or other documentation of the acquisition  
18 and disposition of dangerous drugs and dangerous devices by any  
19 entity licensed by the board shall be retained on the licensed  
20 premises in a readily retrievable form.

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

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

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

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

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

4 (f) When requested by an authorized officer of the law or by an  
5 authorized representative of the board, the owner, corporate officer,  
6 or manager of an entity licensed by the board shall provide the  
7 board with the requested records within three business days of the  
8 time the request was made. The entity may request in writing an  
9 extension of this timeframe for a period not to exceed 14 calendar  
10 days from the date the records were requested. A request for an  
11 extension of time is subject to the approval of the board. An  
12 extension shall be deemed approved if the board fails to deny the  
13 extension request within two business days of the time the  
14 extension request was made directly to the board.

15 SEC. 4. Section 4112 of the Business and Professions Code is  
16 amended to read:

17 4112. (a) Any pharmacy located outside this state that ships,  
18 mails, or delivers, in any manner, controlled substances, dangerous  
19 drugs, or dangerous devices into this state shall be considered a  
20 nonresident pharmacy.

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

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

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

1 nonresident pharmacy shall submit a copy of the most recent  
2 inspection report resulting from an inspection conducted by the  
3 regulatory or licensing agency of the state in which it is located.

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

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

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

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

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

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

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

4 ~~SEC. 5. Section 4126.7 is added to the Business and Professions  
5 Code, to read:~~

6 ~~4126.7. (a) A reverse distributor shall not accept the return of  
7 dangerous drugs that have been dispensed to a patient and returned  
8 to the pharmacy unless the dangerous drugs were dispensed in a  
9 sealed or tamper-evident package and there is no evidence that the  
10 package was opened, damaged, or otherwise tampered with prior  
11 to its return to the pharmacy. Records of these returned dangerous  
12 drugs shall be kept by the pharmacy.~~

13 ~~(b) For purposes of this section, “dispensed” means that the  
14 dangerous drugs have been provided to the patient or patient’s  
15 agent and taken from a pharmacy.~~

16 ~~SEC. 6.~~

17 ~~SEC. 5. No reimbursement is required by this act pursuant to  
18 Section 6 of Article XIII B of the California Constitution because  
19 the only costs that may be incurred by a local agency or school  
20 district will be incurred because this act creates a new crime or  
21 infraction, eliminates a crime or infraction, or changes the penalty  
22 for a crime or infraction, within the meaning of Section 17556 of  
23 the Government Code, or changes the definition of a crime within  
24 the meaning of Section 6 of Article XIII B of the California  
25 Constitution.~~

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