

AMENDED IN SENATE JUNE 6, 2013  
AMENDED IN ASSEMBLY APRIL 22, 2013  
CALIFORNIA LEGISLATURE—2013–14 REGULAR SESSION

**ASSEMBLY BILL**

**No. 1045**

---

---

**Introduced by Assembly Member Quirk-Silva**

February 22, 2013

---

---

An act to amend ~~Sections 4112 and 4127.2~~ *Section 4303* of, and to add Section 4127.9 to, the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

AB 1045, as amended, Quirk-Silva. Sterile compounding *and nonresident* pharmacies.

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacies in this state by the California State Board of Pharmacy. A violation of these provisions is a crime.

Existing law provides that a pharmacy located outside this state that ships, mails, or delivers, in any manner, controlled substances, dangerous drugs, or dangerous devices into this state shall be considered a nonresident pharmacy. Existing law prohibits a person from acting as a nonresident pharmacy unless he or she has obtained a license from the board, and authorizes the board to register a nonresident pharmacy that is organized as a limited liability company in the state in which it is licensed. The law also prohibits a resident or nonresident pharmacy from compounding injectable sterile drug products for shipment into this state without a license issued by the board, and authorizes a license to compound injectable sterile drug products to be issued only for a location that is licensed as a *resident or nonresident* pharmacy.

~~This bill would provide that if the home state pharmacy license of a nonresident pharmacy is revoked or suspended for any reason, any license issued pursuant to provisions governing the licensing and registration of nonresident pharmacies and authorizing a nonresident pharmacy to compound injectable sterile drug products shall be immediately revoked or suspended by operation of law.~~

The

~~This bill would also require a resident or a nonresident pharmacy that issues a recall notice regarding a sterile compounded drug to contact the recipient pharmacy, prescriber, or patient of the recalled drug and the board within 24 hours of the recall notice if use of or exposure to the recalled drug may cause serious adverse health consequences or death and if the recalled drug was dispensed or is intended for use in this state. Because a violation of these requirements would be a crime, the bill would impose a state-mandated local program.~~

~~The bill would also provide that if the home state pharmacy license of a nonresident pharmacy is revoked or suspended for any reason, any license issued pursuant to the provisions governing the licensing and registration of nonresident pharmacies or authorizing a nonresident pharmacy to compound injectable sterile drug products shall be immediately revoked or suspended by operation of law.~~

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 4112 of the Business and Professions~~
- 2 ~~Code is amended to read:~~
- 3 4112. ~~(a) Any pharmacy located outside this state that ships,~~
- 4 ~~mails, or delivers, in any manner, controlled substances, dangerous~~
- 5 ~~drugs, or dangerous devices into this state shall be considered a~~
- 6 ~~nonresident pharmacy.~~
- 7 (b) ~~A person may not act as a nonresident pharmacy unless he~~
- 8 ~~or she has obtained a license from the board. The board may~~

1 register a nonresident pharmacy that is organized as a limited  
2 liability company in the state in which it is licensed.

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

11 (d) All nonresident pharmacies shall comply with all lawful  
12 directions and requests for information from the regulatory or  
13 licensing agency of the state in which it is licensed as well as with  
14 all requests for information made by the board pursuant to this  
15 section. The nonresident pharmacy shall maintain, at all times, a  
16 valid unexpired license, permit, or registration to conduct the  
17 pharmacy in compliance with the laws of the state in which it is a  
18 resident. As a prerequisite to registering with the board, the  
19 nonresident pharmacy shall submit a copy of the most recent  
20 inspection report resulting from an inspection conducted by the  
21 regulatory or licensing agency of the state in which it is located.  
22 If the home state pharmacy license of a nonresident pharmacy is  
23 revoked or suspended for any reason, any license issued pursuant  
24 to this section shall be immediately revoked or suspended by  
25 operation of law.

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

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

38 (g) A nonresident pharmacy shall not permit a pharmacist whose  
39 license has been revoked by the board to manufacture, compound,  
40 furnish, sell, dispense, or initiate the prescription of a dangerous

1 ~~drug or dangerous device, or to provide any pharmacy-related~~  
2 ~~service, to a person residing in California.~~

3 ~~(h) The board shall adopt regulations that apply the same~~  
4 ~~requirements or standards for oral consultation to a nonresident~~  
5 ~~pharmacy that operates pursuant to this section and ships, mails,~~  
6 ~~or delivers any controlled substances, dangerous drugs, or~~  
7 ~~dangerous devices to residents of this state, as are applied to an~~  
8 ~~in-state pharmacy that operates pursuant to Section 4037 when the~~  
9 ~~pharmacy ships, mails, or delivers any controlled substances,~~  
10 ~~dangerous drugs, or dangerous devices to residents of this state.~~  
11 ~~The board shall not adopt any regulations that require face-to-face~~  
12 ~~consultation for a prescription that is shipped, mailed, or delivered~~  
13 ~~to the patient. The regulations adopted pursuant to this subdivision~~  
14 ~~shall not result in any unnecessary delay in patients receiving their~~  
15 ~~medication.~~

16 ~~(i) The registration fee shall be the fee specified in subdivision~~  
17 ~~(a) of Section 4400.~~

18 ~~(j) The registration requirements of this section shall apply only~~  
19 ~~to a nonresident pharmacy that ships, mails, or delivers controlled~~  
20 ~~substances, dangerous drugs, and dangerous devices into this state~~  
21 ~~pursuant to a prescription.~~

22 ~~(k) Nothing in this section shall be construed to authorize the~~  
23 ~~dispensing of contact lenses by nonresident pharmacists except as~~  
24 ~~provided by Section 4124.~~

25 ~~SEC. 2. Section 4127.2 of the Business and Professions Code~~  
26 ~~is amended to read:~~

27 ~~4127.2. (a) A nonresident pharmacy may not compound~~  
28 ~~injectable sterile drug products for shipment into the State of~~  
29 ~~California without a license issued by the board pursuant to this~~  
30 ~~section. The license shall be renewed annually and shall not be~~  
31 ~~transferable.~~

32 ~~(b) A license to compound injectable sterile drug products may~~  
33 ~~only be issued for a location that is licensed as a nonresident~~  
34 ~~pharmacy. Furthermore, the license to compound injectable sterile~~  
35 ~~drug products may only be issued to the owner of the nonresident~~  
36 ~~pharmacy license at that location. If the home state pharmacy~~  
37 ~~license of a nonresident pharmacy is revoked or suspended for any~~  
38 ~~reason, any license issued pursuant to Section 4112 or this section~~  
39 ~~shall be immediately revoked or suspended by operation of law.~~  
40 ~~A license to compound injectable sterile drug products may not~~

1 be issued or renewed until the board receives the following from  
2 the nonresident pharmacy:

3 (1) A copy of an inspection report issued by the pharmacy's  
4 licensing agency, or a report from a private accrediting agency  
5 approved by the board, in the prior 12 months documenting the  
6 pharmacy's compliance with board regulations regarding the  
7 compounding of injectable sterile drug products.

8 (2) A copy of the nonresident pharmacy's proposed policies  
9 and procedures for sterile compounding.

10 (e) Nonresident pharmacies operated by entities that are licensed  
11 as a hospital, home health agency, or a skilled nursing facility and  
12 have current accreditation from the Joint Commission on  
13 Accreditation of Healthcare Organizations, or other private  
14 accreditation agencies approved by the board, are exempt from  
15 the requirement to obtain a license pursuant to this section.

16 (d) This section shall become effective on the earlier of July 1,  
17 2003, or the effective date of regulations adopted by the board  
18 pursuant to Section 4127.

19 ~~SEC. 3.~~

20 *SECTION 1.* Section 4127.9 is added to the Business and  
21 Professions Code, to read:

22 4127.9. (a) A pharmacy licensed pursuant to Section 4127.1  
23 or 4127.2, including a pharmacy that is exempt from licensure  
24 pursuant to subdivision (d) of Section 4127.1 and subdivision (c)  
25 of Section 4127.2, that issues a recall notice regarding a sterile  
26 compounded drug shall, in addition to any other duties, contact  
27 the recipient pharmacy, prescriber, or patient of the recalled drug  
28 and the board within 24 hours of the recall notice if both of the  
29 following apply:

30 (1) Use of or exposure to the recalled drug may cause serious  
31 adverse health consequences or death.

32 (2) The recalled drug was dispensed, or is intended for use, in  
33 this state.

34 (b) A recall notice issued pursuant to subdivision (a) shall be  
35 made as follows:

36 (1) If the recalled drug was dispensed directly to the patient,  
37 the notice shall be made to the patient.

38 (2) If the recalled drug was dispensed directly to the prescriber,  
39 the notice shall be made to the prescriber, who shall ensure the  
40 patient is notified.

1 (3) If the recalled drug was dispensed directly to a pharmacy,  
2 the notice shall be made to the pharmacy, who shall notify the  
3 prescriber or patient, as appropriate. If the pharmacy notifies the  
4 prescriber, the prescriber shall ensure the patient is notified.

5 *SEC. 2. Section 4303 of the Business and Professions Code is*  
6 *amended to read:*

7 4303. (a) The board may report any violation by a nonresident  
8 pharmacy of the laws and regulations of this state, any other state,  
9 or of the United States, including, but not limited to, any violation  
10 of this chapter or of the regulations established by the board, to  
11 any appropriate state or federal regulatory or licensing agency,  
12 including, but not limited to, the regulatory or licensing agency of  
13 the state in which the nonresident pharmacy is a resident or in  
14 which the pharmacist is licensed.

15 (b) The board may deny, revoke, or suspend a nonresident  
16 pharmacy registration, issue a citation or letter of admonishment  
17 to a nonresident pharmacy, or take any other action against a  
18 nonresident pharmacy that the board may take against a resident  
19 pharmacy license, on any of the same grounds upon which such  
20 action might be taken against a resident pharmacy, provided that  
21 the grounds for the action are also grounds for action in the state  
22 in which the nonresident pharmacy is permanently located.

23 (c) *If the home state pharmacy license of a nonresident*  
24 *pharmacy is revoked or suspended for any reason, any license*  
25 *issued pursuant to Section 4112 or 4127.2 shall be immediately*  
26 *revoked or suspended by operation of law.*

27 ~~SEC. 4.~~

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