

AMENDED IN SENATE JUNE 19, 2013

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 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 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 *as soon as possible* within ~~24~~ 12 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 *anceled*, 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 *anceled*, 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 4127.9 is added to the Business and
- 2 Professions Code, to read:
- 3 4127.9. (a) A pharmacy licensed pursuant to Section 4127.1
- 4 or 4127.2, including a pharmacy that is exempt from licensure
- 5 pursuant to subdivision (d) of Section 4127.1 and subdivision (c)
- 6 of Section 4127.2, that issues a recall notice regarding a sterile
- 7 compounded drug shall, in addition to any other duties, contact
- 8 the recipient pharmacy, prescriber, or patient of the recalled drug
- 9 and the board *as soon as possible* within ~~24~~ 12 hours of the recall
- 10 notice if both of the following apply:
- 11 (1) Use of or exposure to the recalled drug may cause serious
- 12 adverse health consequences or death.
- 13 (2) The recalled drug was dispensed, or is intended for use, in
- 14 this state.

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

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

5 (2) If the recalled drug was dispensed directly to the prescriber,
6 the notice shall be made to the prescriber, who shall ensure the
7 patient is notified.

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

12 SEC. 2. Section 4303 of the Business and Professions Code is
13 amended to read:

14 4303. (a) The board may report any violation by a nonresident
15 pharmacy of the laws and regulations of this state, any other state,
16 or of the United States, including, but not limited to, any violation
17 of this chapter or of the regulations established by the board, to
18 any appropriate state or federal regulatory or licensing agency,
19 including, but not limited to, the regulatory or licensing agency of
20 the state in which the nonresident pharmacy is a resident or in
21 which the pharmacist is licensed.

22 (b) The board may *cancel*, deny, revoke, or suspend a
23 nonresident pharmacy registration, issue a citation or letter of
24 admonishment to a nonresident pharmacy, or take any other action
25 against a nonresident pharmacy that the board may take against a
26 resident pharmacy license, on any of the same grounds upon which
27 such action might be taken against a resident pharmacy, provided
28 that the grounds for the action are also grounds for action in the
29 state in which the nonresident pharmacy is permanently located.

30 (c) If the home state pharmacy license of a nonresident pharmacy
31 is *canceled*, revoked, or suspended for any reason, any license
32 issued pursuant to Section 4112 or 4127.2 shall be immediately
33 *canceled*, revoked, or suspended by operation of law.

34 SEC. 3. No reimbursement is required by this act pursuant to
35 Section 6 of Article XIII B of the California Constitution because
36 the only costs that may be incurred by a local agency or school
37 district will be incurred because this act creates a new crime or
38 infraction, eliminates a crime or infraction, or changes the penalty
39 for a crime or infraction, within the meaning of Section 17556 of
40 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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