

AMENDED IN ASSEMBLY SEPTEMBER 10, 2001  
AMENDED IN ASSEMBLY SEPTEMBER 6, 2001  
AMENDED IN ASSEMBLY AUGUST 30, 2001  
AMENDED IN ASSEMBLY AUGUST 28, 2001  
AMENDED IN ASSEMBLY AUGUST 20, 2001  
AMENDED IN ASSEMBLY JULY 19, 2001

**SENATE BILL**

**No. 293**

---

---

**Introduced by Senators Torlakson and Figueroa**

February 16, 2001

---

---

An act to ~~amend Section 4123 of, and to add Article 7.5 (commencing with Section 4127) to Chapter 9 of Division 2 of, the Business and Professions Code, relating to pharmacies, and making an appropriation therefor.~~

LEGISLATIVE COUNSEL'S DIGEST

SB 293, as amended, Torlakson. Pharmacies: injectable sterile drug products.

Existing law, the Pharmacy Law, provides for the licensing and regulation of pharmacists and pharmacy corporations in this state. Existing law regulates controlled substances, dangerous drugs, and dangerous devices.

~~This bill would create new positions within the California State Pharmacy Board in order to carry out the provisions of the bill. The~~ *This* bill would appropriate \$580,000 from the Pharmacy Board Contingent Fund for purposes of the bill.

This bill would authorize the board, based on reasonable belief obtained during an investigation or pharmacy inspection, to issue a cease and desist order to a pharmacy requiring the pharmacy to refrain from compounding injectable sterile drug products if that activity poses an immediate threat to the public health or safety. The bill would implement quality assurance methods regarding the compounding of injectable sterile drug products. The bill would require the board to adopt necessary regulations regarding injectable sterile drug products. The bill would require specified pharmacies to obtain a license from the board in order to prepare injectable sterile drug products. The bill would provide that the reconstitution of a sterile powder would not require a license if specified conditions are met. By charging a fee for these licenses which would be deposited into the continuously appropriated Pharmacy Board Contingent Fund, the bill would make an appropriation.

This bill would provide that a violation of the bill or regulations adopted pursuant to it would be subject to a fine of up to \$2,500. These fines would be deposited into the continuously appropriated Pharmacy Board Contingent Fund and would thereby make an appropriation.

A violation of the Pharmacy Law is a crime. By adding additional requirements to the Pharmacy Law concerning injectable sterile drug products, this bill would impose a state-mandated local program by creating a new crime.

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: <sup>2</sup>/<sub>3</sub>. Appropriation: yes. Fiscal committee: yes. State-mandated local program: yes.

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

1 SECTION 1. ~~The Legislature hereby establishes five~~  
 2 ~~positions in the California State Board of Pharmacy to implement~~  
 3 ~~the provisions of this act. Those positions shall be apportioned as~~  
 4 ~~follows: one supervising pharmacy inspector, two pharmacy~~  
 5 ~~inspectors, one management services technician, and one office~~  
 6 ~~technician. It is the intent of the Legislature in enacting this act to~~



1 *increase the regulatory scrutiny of the compounding of sterile*  
2 *injectable drug products in pharmacies in order to improve public*  
3 *safety. The compounding of injectable sterile drug products in*  
4 *pharmacies benefits patients throughout California and is an*  
5 *essential health care service.*

6 ~~The~~

7 *Effective July 1, 2002, the sum of five hundred eighty thousand*  
8 *dollars (\$580,000) is hereby appropriated from the Pharmacy*  
9 *Board Contingent Fund to the California State Board of Pharmacy*  
10 *for the costs associated with the implementation of this act,*  
11 *including, but not limited to, the salaries and benefits of the*  
12 *employees described in this section required to implement this act.*

13 ~~SEC. 2. Section 4123 of the Business and Professions Code~~  
14 ~~is amended to read:~~

15 ~~4123. Any pharmacy that contracts to compound a sterile~~  
16 ~~drug product for delivery to another pharmacy, a prescriber's~~  
17 ~~office, or a licensed health care facility shall report that contractual~~  
18 ~~arrangement to the board. That information shall be reported by~~  
19 ~~the pharmacy performing the compounding services within 30~~  
20 ~~days of commencing that compounding.~~

21 ~~SEC. 3.~~

22 *SEC. 2. Article 7.5 (commencing with Section 4127) is added*  
23 *to Chapter 9 of Division 2 of the Business and Professions Code,*  
24 *to read:*

25

26 *Article 7.5. Injectable Sterile Drug Products*

27

28 *4127. The board shall adopt regulations establishing*  
29 *standards for compounding injectable sterile drug products in a*  
30 *pharmacy.*

31 *4127.1. (a) A pharmacy shall not compound injectable sterile*  
32 *drug products in this state unless the pharmacy has obtained a*  
33 *license from the board pursuant to this section. The license shall*  
34 *be renewed annually and is not transferable.*

35 *(b) A license to compound injectable sterile drug products may*  
36 *only be issued for a location that is licensed as a pharmacy.*  
37 *Furthermore, the license to compound injectable sterile drug*  
38 *products may only be issued to the owner of the pharmacy license*  
39 *at that location. A license to compound injectable sterile drug*  
40 *products may not be issued until the location is inspected by the*



1 board and found in compliance with this article and regulations  
2 adopted by the board.

3 (c) A license to compound injectable sterile drug products may  
4 not be renewed until the location has been inspected by the board  
5 and found to be in compliance with this article and regulations  
6 adopted by the board.

7 (d) Pharmacies operated by entities that are licensed by either  
8 the board or the State Department of Health Services and that have  
9 current accreditation from the Joint Commission on Accreditation  
10 of Healthcare Organizations, or other private accreditation  
11 agencies approved by the board, are exempt from the requirement  
12 to obtain a license pursuant to this section.

13 (e) The reconstitution of a sterile powder shall not require a  
14 license pursuant to this section if all of the following are met:

15 (1) The sterile powder was obtained from a manufacturer.

16 (2) The drug is reconstituted for administration to a specific  
17 patient by a health care professional licensed to administer drugs  
18 by injection pursuant to this division.

19 (3) The reconstituted drug is immediately administered to the  
20 patient.

21 (f) This section shall become effective on the earlier of July  
22 1, 2003, or the effective date of regulations adopted by the board  
23 pursuant to Section 4127.

24 4127.2. (a) A nonresident pharmacy may not compound  
25 injectable sterile drug products for shipment into the State of  
26 California without a license issued by the board pursuant to this  
27 section. ~~A license shall be required for each location owned or~~  
28 ~~operated by a specific person or entity where injectable sterile drug~~  
29 ~~products are compounded.~~ The license shall be renewed annually  
30 *and shall not be transferable.*

31 (b) A license to compound injectable sterile drug products may  
32 only be issued for a location that is licensed as a nonresident  
33 pharmacy. Furthermore, the license to compound injectable sterile  
34 drug products may only be issued to the owner of the nonresident  
35 pharmacy license at that location. A license to compound  
36 injectable sterile drug products may not be issued or renewed until  
37 the board receives the following from the nonresident pharmacy:

38 (1) A copy of an inspection report issued by the pharmacy's  
39 licensing agency, or a report from a private accrediting agency  
40 approved by the board, in the prior 12 months documenting the



1 pharmacy's compliance with board regulations regarding the  
2 compounding of injectable sterile drug products.

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

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

11 (d) This section shall become effective on the earlier of July 1,  
12 2003, or the effective date of regulations adopted by the board  
13 pursuant to Section 4127.

14 4127.3. (a) Whenever the board has a reasonable belief,  
15 based on information obtained during an inspection or  
16 investigation by the board, that a pharmacy compounding  
17 injectable sterile drug products poses an immediate threat to the  
18 public health or safety, the executive officer of the board may issue  
19 an order to the pharmacy to immediately cease and desist from  
20 compounding injectable sterile drug products. The cease and  
21 desist order shall remain in effect for no more than 30 days or the  
22 date of a hearing seeking an interim suspension order, whichever  
23 is earlier.

24 (b) Whenever the board issues a cease and desist order pursuant  
25 to subdivision (a), the board shall immediately issue the owner a  
26 notice setting forth the acts or omissions with which the owner is  
27 charged, specifying the pertinent code section or sections.

28 (c) The order shall provide that the owner, within 15 days of  
29 receipt of the notice, may request a hearing before the president of  
30 the board to contest the cease and desist order. Consideration of the  
31 owner's contest of the cease and desist order shall comply with the  
32 requirements of Section 11425.10 of the Government Code. The  
33 hearing shall be held no later than five days from the date the  
34 request of the owner is received by the board. The president shall  
35 render a written decision within five days of the hearing. In the  
36 absence of the president of the board, the vice president of the  
37 board may conduct the hearing permitted by this subdivision.  
38 Review of the decision of the president of the board may be sought  
39 by the owner or person in possession or control of the pharmacy  
40 pursuant to Section 1094.5 of the Code of Civil Procedure.



1 (d) Failure to comply with a cease and desist order issued  
2 pursuant to this section shall be unprofessional conduct.

3 4127.4. Notwithstanding any other provision of law, a  
4 violation of this article, or regulations adopted pursuant thereto,  
5 may subject the person or entity that committed the violation to a  
6 fine of up to two thousand five hundred dollars (\$2,500) per  
7 occurrence pursuant to a citation issued by the board.

8 4127.5. The fee for the issuance of a license, or renewal of a  
9 license, to compound sterile drug products shall be five hundred  
10 dollars (\$500) and may be increased to six hundred dollars (\$600).

11 *4127.6. This article shall become operative upon the*  
12 *allocation of positions to the board for the implementation of the*  
13 *provisions of this article in the annual Budget Act.*

14 ~~SEC. 4.~~

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

