

AMENDED IN ASSEMBLY JULY 19, 2001

**SENATE BILL**

**No. 293**

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**Introduced by Senator Torlakson**

February 16, 2001

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~~An act to amend Section 49452.5 of the Education Code, relating to pupil health.~~ *An act to amend Section 4123 of, to add Sections 4011.5 and 4040.7 to, 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, making an appropriation therefor.*

LEGISLATIVE COUNSEL'S DIGEST

SB 293, as amended, Torlakson. ~~Scabies screening~~ *Pharmacies: 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 this act. The bill would appropriate \$700,000 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, among other things, the pharmacy to refrain from any activity that posed an immediate threat to the public health or safety. The bill would define "sterile drug products" and would implement quality assurance methods regarding the compounding of these substances. The bill would require the board to adopt necessary regulations regarding sterile drug products. The bill*

would require a pharmacy to obtain a license from the board in order to prepare sterile drug products. 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.

The bill would provide that a violation of this act 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 sterile drug products, this bill would impose a state-mandated local program.

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.

~~Existing law requires the governing board of any school district to provide for the screening of every female pupil in grade 7 and every male pupil in grade 8 for the condition known as scoliosis.~~

~~This bill would, instead, require this screening of every female during some point when the female pupil is in grades 5 to 7, inclusive, and every male pupil during some point when the male pupil is in grades 6 to 8, inclusive.~~

Vote: ~~majority~~ <sup>2/3</sup>. Appropriation: ~~no~~ yes. Fiscal committee: ~~no~~ yes. State-mandated local program: ~~no~~ yes.

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

- 1    ~~SECTION 1. —The Legislature finds and declares that children~~
- 2    SECTION 1. *The Legislature hereby establishes six positions*
- 3    *in the California State Board of Pharmacy to implement the*
- 4    *provisions of this act. Those positions shall be apportioned as*
- 5    *follows: one supervising pharmacy inspector, two pharmacy*
- 6    *inspectors, one management services technician, and two office*
- 7    *technicians.*
- 8    *The sum of seven hundred thousand dollars (\$700,000) is*
- 9    *hereby appropriated from the Pharmacy Board Contingent Fund*
- 10   *to the California State Board of Pharmacy for the costs associated*



1 *with the implementation of this act, including, but not limited to,*  
2 *the salaries and benefits of the employees described in this section.*

3 *SEC. 2. Section 4011.5 is added to the Business and*  
4 *Professions Code, to read:*

5 *4011.5. (a) Whenever the board has a reasonable belief,*  
6 *based on information obtained during an inspection or*  
7 *investigation by the board, that activity in a pharmacy poses an*  
8 *immediate threat to the public health or safety, the executive officer*  
9 *of the board may issue an order to the pharmacy to immediately*  
10 *cease and desist from that activity. The cease and desist order may*  
11 *include the immediate closure of all or part of a pharmacy. The*  
12 *cease and desist order shall remain in effect for no more than 30*  
13 *days or the date of a hearing seeking an interim suspension order,*  
14 *whichever is earlier.*

15 *(b) Whenever the board orders the closure of a business*  
16 *pursuant to subdivision (a), the board shall immediately issue the*  
17 *owner a notice setting forth the acts or omissions with which the*  
18 *owner is charged, specifying the pertinent code section.*

19 *SEC. 3. Section 4040.7 is added to the Business and*  
20 *Professions Code, to read:*

21 *4040.7. “Sterile drug product” means any dosage form*  
22 *devoid of viable microorganisms or pyrogens, including, but not*  
23 *limited to, parenterals, injectables, and ophthalmics.*

24 *SEC. 4. Section 4123 of the Business and Professions Code is*  
25 *amended to read:*

26 *4123. Any pharmacy that contracts to compound a sterile*  
27 *drug for parenteral therapy product, pursuant to a prescription, for*  
28 *delivery to another pharmacy shall report that contractual*  
29 *arrangement to the board. That information shall be reported by*  
30 *the pharmacy performing the compounding services within 30*  
31 *days of commencing that compounding.*

32 *SEC. 5. Article 7.5 (commencing with Section 4127) is added*  
33 *to Chapter 9 of Division 2 of the Business and Professions Code,*  
34 *to read:*

35

36 *Article 7.5. Sterile Drug Products*

37

38 *4127. For the purposes of this article, “guidelines” means the*  
39 *“Guidelines on Quality Assurance for Pharmacy-Prepared Sterile*



1 *Products” approved by the American Society for Health-System*  
2 *Pharmacists on April 27, 2000.*

3 *4127.1. Sterile drug products shall be compounded in a*  
4 *manner consistent with the guidelines.*

5 *4127.2. (a) A pharmacy shall not compound sterile drug*  
6 *products in this state unless the pharmacy has obtained a license*  
7 *from the board pursuant to this section. A license shall be required*  
8 *for each location owned or operated by a specific person where*  
9 *sterile drug products are compounded. The license shall be*  
10 *renewed annually and is not transferable.*

11 *(b) A license to compound sterile drug products may only be*  
12 *issued for a location that is licensed as a pharmacy. Furthermore,*  
13 *the license to compound sterile drug products may only be issued*  
14 *to the owner of the pharmacy license at that location. A license to*  
15 *compound sterile drug products may not be issued until the*  
16 *location is inspected by the board and found in compliance with*  
17 *the guidelines and other requirements in this article and in*  
18 *regulations adopted by the board.*

19 *(c) The applicant for a license to compound sterile drug*  
20 *products shall indicate on the application the risk level or levels,*  
21 *as defined in the guidelines, of drugs to be compounded at that*  
22 *location. The location shall meet the requirements for that risk*  
23 *level indicated in the guidelines. The license issued shall indicate*  
24 *the risk level or levels that may be compounded at that location.*

25 *(d) If a pharmacy wishes to compound sterile drug products*  
26 *that are classified in a risk level, as defined by the guidelines,*  
27 *higher than that indicated on the license, then the licensee shall*  
28 *apply for a change of license from the board at least 30 days prior*  
29 *to commencing the compounding of sterile drug products of a*  
30 *higher risk level. That change of license shall not be granted until*  
31 *the location is inspected by the board and found in compliance*  
32 *with the guidelines for compounding drugs at that risk level.*

33 *(e) A license to compound sterile drug products may not be*  
34 *renewed until the location has been inspected by the board and*  
35 *found to be in compliance with the guidelines and other*  
36 *requirements in this article and in regulations adopted by the*  
37 *board.*

38 *4127.3. (a) A nonresident pharmacy may not compound*  
39 *sterile drug products for shipment into the State of California*  
40 *without a license issued by the board pursuant to this section. A*



1 license shall be required for each location owned or operated by  
2 a specific person or entity where sterile drug products are  
3 compounded. The license shall be renewed annually.

4 (b) A license to compound sterile drug products may only be  
5 issued for a location that is licensed as a nonresident pharmacy.  
6 Furthermore, the license to compound sterile drug products may  
7 only be issued to the owner of the nonresident pharmacy license at  
8 that location. A license to compound sterile drug products may not  
9 be issued until the board receives the following from the  
10 nonresident pharmacy:

11 (1) A copy of the nonresident pharmacy's most recent  
12 inspection report.

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

15 (3) An affidavit, signed by the pharmacist in charge of the  
16 nonresident pharmacy, confirming the pharmacy's compliance  
17 with the guidelines.

18 (c) The applicant for a license to compound sterile drug  
19 products shall indicate on the application the risk level or levels,  
20 as defined in the guidelines, of drugs to be compounded at that  
21 location. The location shall meet the requirements for that risk  
22 level indicated in the guidelines. The license issued shall indicate  
23 the risk level or levels that may be compounded at that location.

24 (d) If the nonresident pharmacy wishes to compound sterile  
25 drug products that are classified in a risk level, as defined by the  
26 guidelines, higher than that indicated on the license, then the  
27 nonresident pharmacy shall apply for a change of license from the  
28 board at least 30 days prior to commencing the compounding of  
29 sterile drug products of a higher risk level. That change of license  
30 shall not be granted until the nonresident pharmacy provides the  
31 board with copies of the materials required in subdivision (b)  
32 updated to reflect the increased risk level.

33 4127.4. Pharmacy technicians who participate in the  
34 compounding of sterile drug products shall maintain current  
35 certification by the Pharmacy Technician Certification Board.

36 4127.5. Pharmacies and nonresident pharmacies licensed  
37 prior to the effective date of this article who compound sterile drug  
38 products shall comply with the terms of this article on or before  
39 July 1, 2002.



1 4127.6. (a) For each batch of sterile drug product  
2 compounded, the pharmacy shall record the following  
3 information:

4 (1) Identity of all solutions and ingredients and their  
5 corresponding amounts, concentrations, or volumes.

6 (2) Manufacturer lot number and expiration date for each  
7 component.

8 (3) Component manufacturer or suitable manufacturer  
9 identification number.

10 (4) Container specifications, including, but not limited to,  
11 syringes or pump cassettes.

12 (5) Lot or control number assigned to the batch.

13 (6) Expiration date of batch-prepared products.

14 (7) Date of preparation.

15 (8) Identity of personnel involved in preparation. This may be  
16 determined by initials, codes, or signatures which divulge the  
17 identity of the preparer.

18 (b) The pharmacy shall record the lot or control number of  
19 sterile drug products provided to patients or prescribers.

20 (c) Batch records required by this section shall be retained by  
21 the pharmacy for three years.

22 4127.7. Each pharmacy issued a license to compound sterile  
23 drug products shall maintain written policies and procedures in  
24 the pharmacy governing the compounding of sterile drug  
25 products. The policies and procedures required by this section  
26 shall comply with the board guidelines and include a quality  
27 assurance process for compounding sterile drug products.

28 4127.8. Notwithstanding any other provision of law, a  
29 violation of this article may subject the person or entity that  
30 committed the violation to a fine of up to two thousand five hundred  
31 dollars (\$2,500) per occurrence pursuant to a citation issued by  
32 the board.

33 4127.9. (a) The fee for the issuance of a license, or renewal  
34 of a license, to compound sterile drug products shall be five  
35 hundred dollars (\$500) and may be increased to six hundred  
36 dollars (\$600).

37 SEC. 6. No reimbursement is required by this act pursuant to  
38 Section 6 of Article XIII B of the California Constitution because  
39 the only costs that may be incurred by a local agency or school  
40 district will be incurred because this act creates a new crime or



1 *infraction, eliminates a crime or infraction, or changes the penalty*  
2 *for a crime or infraction, within the meaning of Section 17556 of*  
3 *the Government Code, or changes the definition of a crime within*  
4 *the meaning of Section 6 of Article XIII B of the California*  
5 *Constitution.*

6 ~~are developing and maturing at earlier ages and that early detection~~  
7 ~~of scoliosis is the best way to treat the condition. Therefore, it is~~  
8 ~~the Legislature's intent to allow the required scoliosis screening~~  
9 ~~for pupils to begin at an earlier age.~~

10 SEC. 2. ~~Section 49452.5 of the Education Code is amended~~  
11 ~~to read:~~

12 ~~49452.5. The governing board of any school district shall,~~  
13 ~~subject to Section 49451 and in addition to the physical~~  
14 ~~examinations required pursuant to Sections 100275, 124035, and~~  
15 ~~124090 of the Health and Safety Code, provide for the screening~~  
16 ~~of every female pupil during some point when the female pupil is~~  
17 ~~in grades 5 to 7, inclusive, and every male pupil during some point~~  
18 ~~when the male pupil is in grades 6 to 8, inclusive, for the condition~~  
19 ~~known as scoliosis. The screening shall be in accord with standards~~  
20 ~~established by the State Department of Education. The screening~~  
21 ~~shall be supervised only by qualified supervisors of health as~~  
22 ~~specified in Sections 44871 to 44878, inclusive, and Section~~  
23 ~~49422, or by school nurses employed by the district or the county~~  
24 ~~superintendent of schools, or pursuant to contract with an agency~~  
25 ~~authorized to perform these services by the county superintendent~~  
26 ~~of schools of the county in which the district is located pursuant~~  
27 ~~to Sections 1750 to 1754, inclusive, and Section 49402 of this~~  
28 ~~code, Section 101425 of the Health and Safety Code, and~~  
29 ~~guidelines established by the State Board of Education. The~~  
30 ~~screening shall be given only by individuals who supervise, or who~~  
31 ~~are eligible to supervise, the screening, or licensed chiropractors,~~  
32 ~~or by certificated employees of the district or of the county~~  
33 ~~superintendent of schools who have received in-service training,~~  
34 ~~pursuant to rules and regulations adopted by the State Board of~~  
35 ~~Education, to qualify them to perform these screenings. It is the~~  
36 ~~intent of the Legislature that these screenings be performed, at no~~  
37 ~~additional cost to the state, the school district, or the parent or~~  
38 ~~guardian, during the regular schoolday and that any staff time~~  
39 ~~devoted to these activities be redirected from other ongoing~~  
40 ~~activities not related to the pupil's health care.~~



1 ~~In-service training may be conducted by orthopedic surgeons,~~  
2 ~~physicians, registered nurses, physical therapists, and~~  
3 ~~chiropractors, who have received specialized training in scoliosis~~  
4 ~~detection.~~

5 ~~Pupils suspected of having scoliosis during the initial screening~~  
6 ~~shall be rescreened by an orthopedic surgeon when there will be~~  
7 ~~no cost to the state, the school district, or the parent or guardian.~~

8 ~~No person screening pupils for scoliosis pursuant to this section~~  
9 ~~shall solicit, encourage, or advise treatment or consultation by that~~  
10 ~~person, or any entity in which that person has a financial interest,~~  
11 ~~for scoliosis or any other condition discovered in the course of the~~  
12 ~~screening.~~

13 ~~The governing board of any school district shall provide for the~~  
14 ~~notification of the parent or guardian of any pupil suspected of~~  
15 ~~having scoliosis. The notification shall include an explanation of~~  
16 ~~scoliosis, the significance of treating it at an early age, and the~~  
17 ~~public services available, after diagnosis, for treatment. Referral~~  
18 ~~of the pupil and the pupil's parent or guardian to appropriate~~  
19 ~~community resources shall be made pursuant to Sections 49426~~  
20 ~~and 49456.~~

21 ~~No action of any kind in any court of competent jurisdiction~~  
22 ~~shall lie against any individual, authorized by this section to~~  
23 ~~supervise or give a screening, by virtue of this section.~~

24 ~~In enacting amendments to this section, it is the intent of the~~  
25 ~~Legislature that no participating healing arts licentiate use the~~  
26 ~~screening program for the generation of referrals or for his or her~~  
27 ~~financial benefit. The Legislature does not intend to deny or limit~~  
28 ~~the freedom of choice in the selection of an appropriate health care~~  
29 ~~provider for treatment or consultation.~~

