SENATE BILL No. 294

Introduced by Senator Emmerson

February 15, 2013

An act to amend Sections 4127.1, 4127.2, and 4400 of, to amend the heading of Article 7.5 (commencing with Section 4127) of Chapter 9 of Division 2 of, and to repeal and add Section 4127 of, the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

SB 294, as introduced, Emmerson. Sterile drug products.

The Pharmacy Law provides for the licensure and regulation of pharmacists and pharmacy corporations in this state by the California State Board of Pharmacy. Existing law requires the board to adopt regulations establishing standards for compounding injectable sterile drug products in a pharmacy. Existing law requires pharmacies to obtain a license from the board, subject to annual renewal, in order to compound injectable sterile drug products. A similar licensing requirement applies to nonresident pharmacies compounding injectable sterile drug products for shipment into California. A violation of the Pharmacy Law is a crime.

This bill would expand these provisions to prohibit a pharmacy from compounding or dispensing, and a nonresident pharmacy from compounding for shipment into this state, sterile drug products for injection, administration into the eye, or inhalation, unless the pharmacy has obtained a sterile compounding pharmacy license from the board. The bill would specify requirements for the board for issuance or renewal of a license, and requirements for the pharmacy as a licensee. By adding additional requirements to the Pharmacy Law concerning sterile drug products, the violation of which is a crime, the bill would impose a state-mandated local program.

Existing law specifies the fee for issuance or renewal of a nongovernmental license to compound sterile drug products.

This bill would provide that the fee for a nonresident sterile compounding pharmacy license shall also require payment of the travel expenses incurred by the board in inspecting the pharmacy at least once annually.

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:

SECTION 1. The heading of Article 7.5 (commencing with Section 4127) of Chapter 9 of Division 2 of the Business and Professions Code is amended to read:

Article 7.5. ~~Injectable~~ Sterile Drug Products

SEC. 2. Section 4127 of the Business and Professions Code is repealed.

~~4127. The board shall adopt regulations establishing standards for compounding injectable sterile drug products in a pharmacy.~~

SEC. 3. Section 4127 is added to the Business and Professions Code, to read:

4127. A pharmacy that compounds sterile drug products for injection, administration into the eye, or inhalation shall possess a sterile compounding pharmacy license as provided in this article before dispensing the compounded medication.

SEC. 4. Section 4127.1 of the Business and Professions Code is amended to read:

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

(b) A license to compound ~~injectable~~ sterile drug products ~~may only~~ *shall* be issued ~~for~~ *only to* a location that is licensed as a pharmacy. Furthermore, the license to compound ~~injectable~~ sterile drug products ~~may only~~ *shall* be issued *only* to the owner of the pharmacy ~~license~~ *licensed* at that location. A license to compound ~~injectable~~ sterile drug products ~~may~~ *shall* not be issued until the location is inspected by the board and found in compliance with this article and regulations adopted by the board.

(c) A license to compound ~~injectable~~ sterile drug products ~~may~~ *shall* not be *issued or* renewed until the ~~location has been inspected by the board and found to be in compliance with this article and regulations adopted by the board.~~ *board does all of the following:*

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

(1) Performs an onsite inspection of the premises, and any deficiencies noted are corrected.

(2) Reviews a current copy of the pharmacy's policies and procedures for sterile compounding.

(3) Reviews the pharmacy's completed self-assessment form required by Section 1735.2 of Title 16 of the California Code of Regulations.

(4) Is provided with copies of all inspection reports conducted of the pharmacy's premises, and any reports from a private accrediting agency, conducted in the prior 12 months documenting the pharmacy's operations.

(5) Receives a list of all sterile medications compounded by the pharmacy since the last license renewal.

(d) A pharmacy licensed pursuant to this section shall do all of the following:

(1) Provide to the board a copy of any disciplinary or other action taken by another state within 10 days of the action.

(2) Notify the board within 10 days of the suspension of any accreditation held by the pharmacy.

(3) Provide to the board, within 24 hours, any recall notice issued by the pharmacy for sterile drug products it has compounded.

(e) Adverse effects reported or potentially attributable to a pharmacy's sterile drug product shall be immediately reported to the board and the MedWatch program of the federal Food and Drug Administration.

~~(e)~~

(f) The reconstitution of a sterile powder shall not require a license pursuant to this section if both of the following are met:

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

(2) The drug is reconstituted for administration to patients by a health care professional licensed to administer drugs by injection pursuant to this division.

SEC. 5. Section 4127.2 of the Business and Professions Code is amended to read:

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

(b) A license to compound ~~injectable~~ sterile drug products ~~may only~~ *shall* be issued ~~for~~ *only to* a location that is licensed as a nonresident pharmacy. Furthermore, the license to compound ~~injectable~~ sterile drug products ~~may only~~ *shall* be issued *only* to the owner of the nonresident pharmacy ~~license~~ *licensed* at that location. A license to compound ~~injectable~~ sterile drug products ~~may~~ *shall* not be issued ~~or renewed until the board receives the following from the nonresident pharmacy:~~ *until the location is inspected by the board and found in compliance with this article and any regulations adopted by the board.*

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

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

~~(c) Nonresident pharmacies operated by entities that are licensed as a hospital, home health agency, or a skilled nursing facility and have current accreditation from the Joint Commission on Accreditation of Healthcare Organizations, or other private~~

~~accreditation agencies approved by the board, are exempt from the requirement to obtain a license pursuant to this section.~~

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

(c) A license to compound sterile drug products shall not be issued or renewed until the board does all of the following:

(1) Performs an onsite inspection of the premises, and any deficiencies noted are corrected. The nonresident pharmacy shall be responsible for payment of reasonable travel expenses incurred by the board in connection with inspecting the pharmacy at least once annually pursuant to subdivision (v) of Section 4400.

(2) Reviews a current copy of the nonresident pharmacy's policies and procedures for sterile compounding.

(3) Reviews the pharmacy's completed self-assessment form required by Section 1735.2 of Title 16 of the California Code of Regulations.

(4) Is provided with copies of all inspection reports conducted of the nonresident pharmacy's premises, and any reports from a private accrediting agency, conducted in the prior 12 months documenting the nonresident pharmacy's operations.

(5) Receives a list of all sterile drug products compounded by the pharmacy within the prior 12 months.

(d) A pharmacy licensed pursuant to this section shall do all of the following:

(1) Provide to the board a copy of any disciplinary or other action taken by its state of residence or another state within 10 days of the action.

(2) Notify the board within 10 days of the suspension of any accreditation held by the pharmacy.

(3) Provide to the board, within 24 hours, any recall notice issued by the pharmacy for sterile drug products it has compounded that have been shipped into, or dispensed in, California.

(4) Advise the board of any complaint it receives from a provider, pharmacy, or patient in California.

(e) Adverse effects reported or potentially attributable to a nonresident pharmacy's sterile compounded drug products shall be immediately reported to the board and the MedWatch program of the federal Food and Drug Administration.

SEC. 6. Section 4400 of the Business and Professions Code is amended to read:

4400. The amount of fees and penalties prescribed by this chapter, except as otherwise provided, is that fixed by the board according to the following schedule:

(a) The fee for a nongovernmental pharmacy license shall be four hundred dollars ($400) and may be increased to five hundred twenty dollars ($520). The fee for the issuance of a temporary nongovernmental pharmacy permit shall be two hundred fifty dollars ($250) and may be increased to three hundred twenty-five dollars ($325).

(b) The fee for a nongovernmental pharmacy license annual renewal shall be two hundred fifty dollars ($250) and may be increased to three hundred twenty-five dollars ($325).

(c) The fee for the pharmacist application and examination shall be two hundred dollars ($200) and may be increased to two hundred sixty dollars ($260).

(d) The fee for regrading an examination shall be ninety dollars ($90) and may be increased to one hundred fifteen dollars ($115). If an error in grading is found and the applicant passes the examination, the regrading fee shall be refunded.

(e) The fee for a pharmacist license and biennial renewal shall be one hundred fifty dollars ($150) and may be increased to one hundred ninety-five dollars ($195).

(f) The fee for a nongovernmental wholesaler license and annual renewal shall be six hundred dollars ($600), and may be increased to seven hundred eighty dollars ($780). The application fee for any additional location after licensure of the first 20 locations shall be two hundred twenty-five dollars ($225) and may be increased to three hundred dollars ($300). A temporary license fee shall be five hundred fifty dollars ($550) and may be increased to seven hundred fifteen dollars ($715).

(g) The fee for a hypodermic license and renewal shall be one hundred twenty-five dollars ($125) and may be increased to one hundred sixty-five dollars ($165).

(h) (1) The fee for application, investigation, and issuance of license as a designated representative pursuant to Section 4053 shall be two hundred fifty-five dollars ($255) and may be increased to three hundred thirty dollars ($330).

(2) The fee for the annual renewal of a license as a designated representative shall be one hundred fifty dollars ($150) and may be increased to one hundred ninety-five dollars ($195).

(i) (1) The fee for the application, investigation, and issuance of a license as a designated representative for a veterinary food-animal drug retailer pursuant to Section 4053 shall be two hundred fifty-five dollars ($255) and may be increased to three hundred thirty dollars ($330).

(2) The fee for the annual renewal of a license as a designated representative for a veterinary food-animal drug retailer shall be one hundred fifty dollars ($150) and may be increased to one hundred ninety-five dollars ($195).

(j) (1) The application fee for a nonresident wholesaler's license issued pursuant to Section 4161 shall be six hundred dollars ($600) and may be increased to seven hundred eighty dollars ($780).

(2) For nonresident wholesalers who have 21 or more facilities operating nationwide the application fees for the first 20 locations shall be six hundred dollars ($600) and may be increased to seven hundred eighty dollars ($780). The application fee for any additional location after licensure of the first 20 locations shall be two hundred twenty-five dollars ($225) and may be increased to three hundred dollars ($300). A temporary license fee shall be five hundred fifty dollars ($550) and may be increased to seven hundred fifteen dollars ($715).

(3) The annual renewal fee for a nonresident wholesaler's license issued pursuant to Section 4161 shall be six hundred dollars ($600) and may be increased to seven hundred eighty dollars ($780).

(k) The fee for evaluation of continuing education courses for accreditation shall be set by the board at an amount not to exceed forty dollars ($40) per course hour.

(*l*) The fee for an intern pharmacist license shall be ninety dollars ($90) and may be increased to one hundred fifteen dollars ($115). The fee for transfer of intern hours or verification of licensure to another state shall be twenty-five dollars ($25) and may be increased to thirty dollars ($30).

(m) The board may waive or refund the additional fee for the issuance of a license where the license is issued less than 45 days before the next regular renewal date.

(n) The fee for the reissuance of any license, or renewal thereof, that has been lost or destroyed or reissued due to a name change

shall be thirty-five dollars ($35) and may be increased to forty-five dollars ($45).

(o) The fee for the reissuance of any license, or renewal thereof, that must be reissued because of a change in the information, shall be one hundred dollars ($100) and may be increased to one hundred thirty dollars ($130).

(p) It is the intent of the Legislature that, in setting fees pursuant to this section, the board shall seek to maintain a reserve in the Pharmacy Board Contingent Fund equal to approximately one year's operating expenditures.

(q) The fee for any applicant for a nongovernmental clinic license shall be four hundred dollars ($400) and may be increased to five hundred twenty dollars ($520) for each license. The annual fee for renewal of the license shall be two hundred fifty dollars ($250) and may be increased to three hundred twenty-five dollars ($325) for each license.

(r) The fee for the issuance of a pharmacy technician license shall be eighty dollars ($80) and may be increased to one hundred five dollars ($105). The fee for renewal of a pharmacy technician license shall be one hundred dollars ($100) and may be increased to one hundred thirty dollars ($130).

(s) The fee for a veterinary food-animal drug retailer license shall be four hundred five dollars ($405) and may be increased to four hundred twenty-five dollars ($425). The annual renewal fee for a veterinary food-animal drug retailer license shall be two hundred fifty dollars ($250) and may be increased to three hundred twenty-five dollars ($325).

(t) The fee for issuance of a retired license pursuant to Section 4200.5 shall be thirty-five dollars ($35) and may be increased to forty-five dollars ($45).

(u) The fee for issuance or renewal of a nongovernmental *sterile compounding pharmacy* license ~~to compound sterile drug products~~ shall be six hundred dollars ($600) and may be increased to seven hundred eighty dollars ($780). The fee for a temporary license shall be five hundred fifty dollars ($550) and may be increased to seven hundred fifteen dollars ($715).

(v) The fee for a nonresident sterile compounding pharmacy license shall also require payment of the travel expenses incurred by the board in inspecting the pharmacy at least once annually.

Failure to pay this fee within 30 days shall result in the suspension of the nonresident sterile compounding pharmacy license.

SEC. 7. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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