

AMENDED IN SENATE MAY 28, 2013

SENATE BILL

No. 294

Introduced by Senator Emmerson

February 15, 2013

An act to amend the heading of Article 7.5 (commencing with Section 4127) of Chapter 9 of Division 2 of, and to amend, repeal, and add Sections 4127, 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 amended, Emmerson. Sterile drug products.

The

(1) *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 *the* 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

(2) *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~~ *require the board to establish, by regulation, the fee for the issuance or renewal of a nonresident sterile compounding pharmacy license, in an amount not to exceed the reasonable regulatory costs of issuing and renewing the license, or \$2,800, whichever is less. The bill would also require the nonresident sterile compounding pharmacy to reimburse the board for all costs incurred by the board in conducting an inspection of the pharmacy at least once annually, including, but not limited to, travel expenses, meals, lodging, and other actual and necessary costs incurred by the board in connection with the inspection. The failure to reimburse the board for these costs within 30 days of the inspection would result in the suspension of the nonresident sterile compounding pharmacy license.*

(3) *The provisions of the bill would become operative on July 1, 2014.*

The

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

1 Article 7.5. Sterile Drug Products

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4 ~~repealed.~~

5 *SEC. 2. Section 4127 of the Business and Professions Code is*
6 *amended to read:*

7 4127. (a) The board shall adopt regulations establishing
8 standards for compounding injectable sterile drug products in a
9 pharmacy.

10 (b) *This section shall become inoperative on July 1, 2014, and,*
11 *as of January 1, 2015, is repealed, unless a later enacted statute,*
12 *that becomes operative on or before January 1, 2015, deletes or*
13 *extends the dates on which it becomes inoperative and is repealed.*

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

16 4127. (a) A pharmacy that compounds sterile drug products
17 for injection, administration into the eye, or inhalation shall possess
18 a sterile compounding pharmacy license as provided in this article
19 before dispensing the compounded medication.

20 (b) *This section shall become operative on July 1, 2014.*

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

23 ~~4127.1. (a) A pharmacy shall not compound sterile drug~~
24 ~~products unless the pharmacy has obtained a sterile compounding~~
25 ~~pharmacy license from the board pursuant to this section. The~~
26 ~~license shall be renewed annually and is not transferable.~~

27 ~~(b) A license to compound sterile drug products shall be issued~~
28 ~~only to a location that is licensed as a pharmacy. Furthermore, the~~
29 ~~license to compound sterile drug products shall be issued only to~~
30 ~~the owner of the pharmacy licensed at that location. A license to~~
31 ~~compound sterile drug products shall not be issued until the~~
32 ~~location is inspected by the board and found in compliance with~~
33 ~~this article and regulations adopted by the board.~~

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

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

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

- 1 ~~(3) Reviews the pharmacy's completed self-assessment form~~
2 ~~required by Section 1735.2 of Title 16 of the California Code of~~
3 ~~Regulations.~~
- 4 ~~(4) Is provided with copies of all inspection reports conducted~~
5 ~~of the pharmacy's premises, and any reports from a private~~
6 ~~accrediting agency, conducted in the prior 12 months documenting~~
7 ~~the pharmacy's operations.~~
- 8 ~~(5) Receives a list of all sterile medications compounded by the~~
9 ~~pharmacy since the last license renewal.~~
- 10 ~~(d) A pharmacy licensed pursuant to this section shall do all of~~
11 ~~the following:~~
- 12 ~~(1) Provide to the board a copy of any disciplinary or other~~
13 ~~action taken by another state within 10 days of the action.~~
- 14 ~~(2) Notify the board within 10 days of the suspension of any~~
15 ~~accreditation held by the pharmacy.~~
- 16 ~~(3) Provide to the board, within 24 hours, any recall notice~~
17 ~~issued by the pharmacy for sterile drug products it has~~
18 ~~compounded.~~
- 19 ~~(e) Adverse effects reported or potentially attributable to a~~
20 ~~pharmacy's sterile drug product shall be immediately reported to~~
21 ~~the board and the MedWatch program of the federal Food and~~
22 ~~Drug Administration.~~
- 23 ~~(f) The reconstitution of a sterile powder shall not require a~~
24 ~~license pursuant to this section if both of the following are met:~~
- 25 ~~(1) The sterile powder was obtained from a manufacturer.~~
- 26 ~~(2) The drug is reconstituted for administration to patients by~~
27 ~~a health care professional licensed to administer drugs by injection~~
28 ~~pursuant to this division.~~
- 29 ~~SEC. 5. Section 4127.2 of the Business and Professions Code~~
30 ~~is amended to read:~~
- 31 ~~4127.2. (a) A nonresident pharmacy shall not compound sterile~~
32 ~~drug products for shipment into this state without a sterile~~
33 ~~compounding pharmacy license issued by the board pursuant to~~
34 ~~this section. The license shall be renewed annually and shall not~~
35 ~~be transferable.~~
- 36 ~~(b) A license to compound sterile drug products shall be issued~~
37 ~~only to a location that is licensed as a nonresident pharmacy.~~
38 ~~Furthermore, the license to compound sterile drug products shall~~
39 ~~be issued only to the owner of the nonresident pharmacy licensed~~
40 ~~at that location. A license to compound sterile drug products shall~~

1 not be issued until the location is inspected by the board and found
2 in compliance with this article and any regulations adopted by the
3 board.

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

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

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

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

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

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

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

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

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

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

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

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

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

1 4400. ~~The amount of fees and penalties prescribed by this~~
2 ~~chapter, except as otherwise provided, is that fixed by the board~~
3 ~~according to the following schedule:~~

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

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

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

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

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

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

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

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

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

- 1 (i) (1) ~~The fee for the application, investigation, and issuance~~
2 ~~of a license as a designated representative for a veterinary~~
3 ~~food-animal drug retailer pursuant to Section 4053 shall be two~~
4 ~~hundred fifty-five dollars (\$255) and may be increased to three~~
5 ~~hundred thirty dollars (\$330).~~
6 (2) ~~The fee for the annual renewal of a license as a designated~~
7 ~~representative for a veterinary food-animal drug retailer shall be~~
8 ~~one hundred fifty dollars (\$150) and may be increased to one~~
9 ~~hundred ninety-five dollars (\$195).~~
10 (j) (1) ~~The application fee for a nonresident wholesaler's license~~
11 ~~issued pursuant to Section 4161 shall be six hundred dollars (\$600)~~
12 ~~and may be increased to seven hundred eighty dollars (\$780).~~
13 (2) ~~For nonresident wholesalers who have 21 or more facilities~~
14 ~~operating nationwide the application fees for the first 20 locations~~
15 ~~shall be six hundred dollars (\$600) and may be increased to seven~~
16 ~~hundred eighty dollars (\$780). The application fee for any~~
17 ~~additional location after licensure of the first 20 locations shall be~~
18 ~~two hundred twenty-five dollars (\$225) and may be increased to~~
19 ~~three hundred dollars (\$300). A temporary license fee shall be five~~
20 ~~hundred fifty dollars (\$550) and may be increased to seven hundred~~
21 ~~fifteen dollars (\$715).~~
22 (3) ~~The annual renewal fee for a nonresident wholesaler's license~~
23 ~~issued pursuant to Section 4161 shall be six hundred dollars (\$600)~~
24 ~~and may be increased to seven hundred eighty dollars (\$780).~~
25 (k) ~~The fee for evaluation of continuing education courses for~~
26 ~~accreditation shall be set by the board at an amount not to exceed~~
27 ~~forty dollars (\$40) per course hour.~~
28 (l) ~~The fee for an intern pharmacist license shall be ninety dollars~~
29 ~~(\$90) and may be increased to one hundred fifteen dollars (\$115).~~
30 ~~The fee for transfer of intern hours or verification of licensure to~~
31 ~~another state shall be twenty-five dollars (\$25) and may be~~
32 ~~increased to thirty dollars (\$30).~~
33 (m) ~~The board may waive or refund the additional fee for the~~
34 ~~issuance of a license where the license is issued less than 45 days~~
35 ~~before the next regular renewal date.~~
36 (n) ~~The fee for the reissuance of any license, or renewal thereof,~~
37 ~~that has been lost or destroyed or reissued due to a name change~~
38 ~~shall be thirty-five dollars (\$35) and may be increased to forty-five~~
39 ~~dollars (\$45).~~

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

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

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

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

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

26 ~~(t) The fee for issuance of a retired license pursuant to Section~~
27 ~~4200.5 shall be thirty-five dollars (\$35) and may be increased to~~
28 ~~forty-five dollars (\$45).~~

29 ~~(u) The fee for issuance or renewal of a nongovernmental sterile~~
30 ~~compounding pharmacy license shall be six hundred dollars (\$600)~~
31 ~~and may be increased to seven hundred eighty dollars (\$780). The~~
32 ~~fee for a temporary license shall be five hundred fifty dollars (\$550)~~
33 ~~and may be increased to seven hundred fifteen dollars (\$715).~~

34 ~~(v) The fee for a nonresident sterile compounding pharmacy~~
35 ~~license shall also require payment of the travel expenses incurred~~
36 ~~by the board in inspecting the pharmacy at least once annually.~~
37 ~~Failure to pay this fee within 30 days shall result in the suspension~~
38 ~~of the nonresident sterile compounding pharmacy license.~~

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

1 4127.1. (a) A pharmacy shall not compound injectable sterile
2 drug products in this state unless the pharmacy has obtained a
3 license from the board pursuant to this section. The license shall
4 be renewed annually and is not transferable.

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

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

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

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

- 25 (1) The sterile powder was obtained from a manufacturer.
26 (2) The drug is reconstituted for administration to patients by
27 a health care professional licensed to administer drugs by injection
28 pursuant to this division.

29 (f) *This section shall become inoperative on July 1, 2014, and,
30 as of January 1, 2015, is repealed, unless a later enacted statute,
31 that becomes operative on or before January 1, 2015, deletes or
32 extends the dates on which it becomes inoperative and is repealed.*

33 *SEC. 5. Section 4127.1 is added to the Business and Professions
34 Code, to read:*

35 *4127.1. (a) A pharmacy shall not compound sterile drug
36 products unless the pharmacy has obtained a sterile compounding
37 pharmacy license from the board pursuant to this section. The
38 license shall be renewed annually and is not transferable.*

39 *(b) A license to compound sterile drug products shall be issued
40 only to a location that is licensed as a pharmacy. Furthermore,*

1 *the license to compound sterile drug products shall be issued only*
2 *to the owner of the pharmacy licensed at that location. A license*
3 *to compound sterile drug products shall not be issued until the*
4 *location is inspected by the board and found in compliance with*
5 *this article and regulations adopted by the board.*

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

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

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

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

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

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

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

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

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

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

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

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

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

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

40 *(g) This section shall become operative on July 1, 2014.*

1 *SEC. 6. Section 4127.2 of the Business and Professions Code*
2 *is amended to read:*

3 4127.2. (a) A nonresident pharmacy ~~may~~ *shall* not compound
4 injectable sterile drug products for shipment into the State of
5 California without a license issued by the board pursuant to this
6 section. The license shall be renewed annually and shall not be
7 transferable.

8 (b) A license to compound injectable sterile drug products may
9 only be issued for a location that is licensed as a nonresident
10 pharmacy. Furthermore, the license to compound injectable sterile
11 drug products may only be issued to the owner of the nonresident
12 pharmacy license at that location. A license to compound injectable
13 sterile drug products may not be issued or renewed until the board
14 receives the following from the nonresident pharmacy:

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

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

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

28 ~~(d) This section shall become effective on the earlier of July 1,~~
29 ~~2003, or the effective date of regulations adopted by the board~~
30 ~~pursuant to Section 4127.~~

31 *(d) This section shall become inoperative on July 1, 2014, and,*
32 *as of January 1, 2015, is repealed, unless a later enacted statute,*
33 *that becomes operative on or before January 1, 2015, deletes or*
34 *extends the dates on which it becomes inoperative and is repealed.*

35 *SEC. 7. Section 4127.2 is added to the Business and Professions*
36 *Code, to read:*

37 4127.2. (a) A nonresident pharmacy shall not compound sterile
38 drug products for shipment into this state without a sterile
39 compounding pharmacy license issued by the board pursuant to

1 *this section. The license shall be renewed annually and shall not*
2 *be transferable.*

3 *(b) A license to compound sterile drug products shall be issued*
4 *only to a location that is licensed as a nonresident pharmacy.*
5 *Furthermore, the license to compound sterile drug products shall*
6 *be issued only to the owner of the nonresident pharmacy licensed*
7 *at that location. A license to compound sterile drug products shall*
8 *not be issued until the location is inspected by the board and found*
9 *in compliance with this article and any regulations adopted by the*
10 *board.*

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

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

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

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

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

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

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

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

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

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

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

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

5 (f) This section shall become operative on July 1, 2014.

6 SEC. 8. Section 4400 of the Business and Professions Code is
7 amended to read:

8 4400. The amount of fees and penalties prescribed by this
9 chapter, except as otherwise provided, is that fixed by the board
10 according to the following schedule:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

4 (n) The fee for the reissuance of any license, or renewal thereof,
5 that has been lost or destroyed or reissued due to a name change
6 shall be thirty-five dollars (\$35) and may be increased to forty-five
7 dollars (\$45).

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

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

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

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

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

33 (t) The fee for issuance of a retired license pursuant to Section
34 4200.5 shall be thirty-five dollars (\$35) and may be increased to
35 forty-five dollars (\$45).

36 (u) The fee for issuance or renewal of a nongovernmental license
37 to compound sterile drug products shall be six hundred dollars
38 (\$600) and may be increased to seven hundred eighty dollars
39 (\$780). The fee for a temporary license shall be five hundred fifty

1 dollars (\$550) and may be increased to seven hundred fifteen
2 dollars (\$715).

3 (v) *This section shall become inoperative on July 1, 2014, and,*
4 *as of January 1, 2015, is repealed, unless a later enacted statute,*
5 *that becomes operative on or before January 1, 2015, deletes or*
6 *extends the dates on which it becomes inoperative and is repealed.*

7 SEC. 9. *Section 4400 is added to the Business and Professions*
8 *Code, to read:*

9 4400. *The amount of fees and penalties prescribed by this*
10 *chapter, except as otherwise provided, is that fixed by the board*
11 *according to the following schedule:*

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

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

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

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

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

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

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

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

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

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

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

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

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

32 (3) *The annual renewal fee for a nonresident wholesaler's*
33 *license issued pursuant to Section 4161 shall be six hundred dollars*
34 *(\$600) and may be increased to seven hundred eighty dollars*
35 *(\$780).*

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

39 (l) *The fee for an intern pharmacist license shall be ninety*
40 *dollars (\$90) and may be increased to one hundred fifteen dollars*

1 (\$115). The fee for transfer of intern hours or verification of
2 licensure to another state shall be twenty-five dollars (\$25) and
3 may be increased to thirty dollars (\$30).

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

7 (n) The fee for the reissuance of any license, or renewal thereof,
8 that has been lost or destroyed or reissued due to a name change
9 shall be thirty-five dollars (\$35) and may be increased to forty-five
10 dollars (\$45).

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

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

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

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

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

36 (t) The fee for issuance of a retired license pursuant to Section
37 4200.5 shall be thirty-five dollars (\$35) and may be increased to
38 forty-five dollars (\$45).

39 (u) The fee for issuance or renewal of a nongovernmental sterile
40 compounding pharmacy license shall be six hundred dollars (\$600)

1 *and may be increased to seven hundred eighty dollars (\$780). The*
2 *fee for a temporary license shall be five hundred fifty dollars (\$550)*
3 *and may be increased to seven hundred fifteen dollars (\$715).*

4 *(v) The board shall establish, by regulation, the fee for a*
5 *nonresident sterile compounding pharmacy license in an amount*
6 *not to exceed the reasonable regulatory costs of issuing and*
7 *renewing the license, or two thousand eight hundred dollars*
8 *(\$2,800), whichever is less. In addition to paying the license fee,*
9 *the nonresident sterile compounding pharmacy shall reimburse*
10 *the board for all costs incurred by the board in conducting an*
11 *inspection of the pharmacy at least once annually, including, but*
12 *not limited to, travel expenses, meals, lodging, and other actual*
13 *and necessary costs incurred by the board in connection with the*
14 *inspection. Failure to reimburse the board for all costs associated*
15 *with the annual inspection, as authorized by this subdivision, within*
16 *30 days of the inspection shall result in the suspension of the*
17 *nonresident sterile compounding pharmacy license.*

18 *(w) This section shall become operative on July 1, 2014.*

19 ~~SEC. 7.~~

20 *SEC. 10.* No reimbursement is required by this act pursuant to
21 Section 6 of Article XIII B of the California Constitution because
22 the only costs that may be incurred by a local agency or school
23 district will be incurred because this act creates a new crime or
24 infraction, eliminates a crime or infraction, or changes the penalty
25 for a crime or infraction, within the meaning of Section 17556 of
26 the Government Code, or changes the definition of a crime within
27 the meaning of Section 6 of Article XIII B of the California
28 Constitution.