

AMENDED IN ASSEMBLY SEPTEMBER 3, 2013

AMENDED IN ASSEMBLY AUGUST 15, 2013

AMENDED IN ASSEMBLY AUGUST 5, 2013

AMENDED IN ASSEMBLY JULY 3, 2013

AMENDED IN ASSEMBLY JUNE 24, 2013

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, the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

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

(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, commencing July 1, 2014, 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, commencing July 1, 2014, would specify requirements for the board for the issuance or renewal of a license, and requirements for the pharmacy as a licensee. The bill would require the board to adopt regulations to implement these provisions, *and, on and after July 1, 2014, to review formal revisions to specified national standards relating to the compounding of sterile preparations to determine whether amendments to those regulations are necessary*, as specified. 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.

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

This bill, commencing July 1, 2014, would establish the fee for the issuance or renewal of a nonresident sterile compounding pharmacy license in the amount of \$780 and would require the applicant to deposit a reasonable amount, as determined by the board, necessary to cover the board's estimated cost of performing an inspection of the nonresident pharmacy location, as specified.

(3) *The bill would also require the board to report to the Legislature, on or before January 1, 2018, regarding the regulation of nonresident pharmacies, including, among other things, a detailed description of board activities related to the inspection and licensure of nonresident pharmacies.*

~~(3)~~

(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:

4
5 Article 7.5. Sterile Drug Products
6

7 SEC. 2. Section 4127 of the Business and Professions Code is
8 amended to read:

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

12 (b) The board shall adopt emergency regulations in accordance
13 with the Administrative Procedure Act (Chapter 3.5 (commencing
14 with Section 11340) of Part 1 of Division 3 of Title 2 of the
15 Government Code) to establish policies, guidelines, and procedures
16 to initially implement the provisions of this article that become
17 operative on July 1, 2014. The initial adoption, amendment, or
18 repeal of a regulation authorized by this section is deemed to
19 address an emergency for purposes of Sections 11346.1 and
20 11346.6 of the Government Code, and the board is hereby
21 exempted for that purpose from the requirements of subdivision
22 (b) of Section 11346.1 of the Government Code. After the initial
23 adoption, amendment, or repeal of an emergency regulation
24 pursuant to this section, the board may request approval from the
25 Office of Administrative Law to readopt the regulation as an
26 emergency regulation pursuant to Section 11346.1 of the
27 Government Code.

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

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

34 4127. (a) A pharmacy that compounds sterile drug products
35 for injection, administration into the eye, or inhalation shall possess
36 a sterile compounding pharmacy license as provided in this article.

37 (b) The board shall adopt regulations in accordance with the
38 Administrative Procedure Act (Chapter 3.5 (commencing with

1 Section 11340) of Part 1 of Division 3 of Title 2 of the Government
2 Code) to establish policies, guidelines, and procedures to
3 implement this article.

4 (c) *The board shall review any formal revision to General*
5 *Chapter 797 of the United States Pharmacopeia and The National*
6 *Formulary (USP–NF), relating to the compounding of sterile*
7 *preparations, not later than 90 days after the revision becomes*
8 *official, to determine whether amendments are necessary for the*
9 *regulations adopted by the board pursuant to subdivision (b).*

10 (e)

11 (d) This section shall become operative on July 1, 2014.

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

14 4127.1. (a) A pharmacy shall not compound injectable sterile
15 drug products in this state unless the pharmacy has obtained a
16 license from the board pursuant to this section. The license shall
17 be renewed annually and is not transferable.

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

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

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

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

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

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

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

8 SEC. 5. Section 4127.1 is added to the Business and Professions
9 Code, to read:

10 4127.1. (a) A pharmacy shall not compound sterile drug
11 products unless the pharmacy has obtained a sterile compounding
12 pharmacy license from the board pursuant to this section. The
13 license shall be renewed annually and is not transferable.

14 (b) A license to compound sterile drug products shall be issued
15 only to a location that is licensed as a pharmacy and shall be issued
16 only to the owner of the pharmacy licensed at that location.

17 (c) A license to compound sterile drug products shall not be
18 issued or renewed until the location is inspected by the board and
19 found in compliance with this article and regulations adopted by
20 the board.

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

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

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

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

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

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

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

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

1 (3) Provide to the board, within 12 hours, any recall notice
2 issued by the pharmacy for sterile drug products it has
3 compounded.

4 (f) Adverse effects reported or potentially attributable to a
5 pharmacy’s sterile drug product shall be reported to the board
6 within ~~24~~ 12 hours and immediately reported to the MedWatch
7 program of the federal Food and Drug Administration.

8 (g) The reconstitution of a sterile powder shall not require a
9 license pursuant to this section if both of the following
10 requirements are met:

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

15 (h) This section shall become operative on July 1, 2014.

16 SEC. 6. Section 4127.2 of the Business and Professions Code
17 is amended to read:

18 4127.2. (a) A nonresident pharmacy shall not compound
19 injectable sterile drug products for shipment into the State of
20 California without a license issued by the board pursuant to this
21 section. The license shall be renewed annually and shall not be
22 transferable.

23 (b) A license to compound injectable sterile drug products may
24 only be issued for a location that is licensed as a nonresident
25 pharmacy. Furthermore, the license to compound injectable sterile
26 drug products may only be issued to the owner of the nonresident
27 pharmacy license at that location. A license to compound injectable
28 sterile drug products may not be issued or renewed until the board
29 receives the following from the nonresident pharmacy:

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

35 (2) A copy of the nonresident pharmacy’s proposed policies
36 and procedures for sterile compounding.

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

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

3 *(d) On or before January 1, 2018, the board shall provide a*
4 *report to the Legislature regarding the regulation of nonresident*
5 *pharmacies. The report shall be submitted to the Legislature in*
6 *the manner required pursuant to Section 9795 of the Government*
7 *Code. At a minimum, the report shall address all of the following:*

8 *(1) A detailed description of board activities related to the*
9 *inspection and licensure of nonresident pharmacies.*

10 *(2) The status of proposed changes to federal law that are under*
11 *serious consideration and that would govern compounding*
12 *pharmacies, including legislation pending before the United States*
13 *Congress, administrative rules, regulations, or orders under*
14 *consideration by the federal Food and Drug Administration or*
15 *other appropriate federal agency, and cases pending before the*
16 *courts.*

17 *(3) If applicable, recommended modifications to the board's*
18 *statutory duties related to nonresident pharmacies as a result of*
19 *changes to federal law or any additional modifications necessary*
20 *to protect the health and safety of the public.*

21 ~~(e)~~

22 *(e) This section shall become inoperative on July 1, 2014, and,*
23 *as of January 1, 2015, is repealed, unless a later enacted statute,*
24 *that becomes operative on or before January 1, 2015, deletes or*
25 *extends the dates on which it becomes inoperative and is repealed.*

26 SEC. 7. Section 4127.2 is added to the Business and Professions
27 Code, to read:

28 4127.2. (a) A nonresident pharmacy shall not compound sterile
29 drug products for shipment into this state without a sterile
30 compounding pharmacy license issued by the board pursuant to
31 this section. The license shall be renewed annually and shall not
32 be transferable.

33 (b) A license to compound sterile drug products shall be issued
34 only to a location that is licensed as a nonresident pharmacy and
35 shall be issued only to the owner of the nonresident pharmacy
36 licensed at that location.

37 (c) A license to compound sterile drug products shall not be
38 issued or renewed until the location is inspected by the board and
39 found in compliance with this article and any regulations adopted
40 by the board. The nonresident pharmacy shall reimburse the board

1 for all actual and necessary costs incurred by the board in
2 conducting an inspection of the pharmacy at least once annually
3 pursuant to subdivision (v) of Section 4400.

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

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

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

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

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

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

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

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

24 (3) Provide to the board, within 12 hours, any recall notice
25 issued by the pharmacy for sterile drug products it has compounded
26 that have been shipped into, or dispensed in, California.

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

29 (f) Adverse effects reported or potentially attributable to a
30 nonresident pharmacy's sterile compounded drug product shall be
31 reported to the board within ~~24~~ 12 hours and immediately reported
32 to the MedWatch program of the federal Food and Drug
33 Administration.

34 (g) *On or before January 1, 2018, the board shall provide a*
35 *report to the Legislature regarding the regulation of nonresident*
36 *pharmacies. The report shall be submitted to the Legislature in*
37 *the manner required pursuant to Section 9795 of the Government*
38 *Code. At a minimum, the report shall address all of the following:*

39 (1) *A detailed description of board activities related to the*
40 *inspection and licensure of nonresident pharmacies.*

1 (2) *Whether fee revenue collected pursuant to subdivision (v)*
2 *of Section 4400 and travel cost reimbursements collected pursuant*
3 *to subdivision (c) of this section provide revenue in an amount*
4 *sufficient to support the board's activities related to the inspection*
5 *and licensure of nonresident pharmacies.*

6 (3) *The status of proposed changes to federal law that are under*
7 *serious consideration and that would govern compounding*
8 *pharmacies, including legislation pending before the United States*
9 *Congress, administrative rules, regulations, or orders under*
10 *consideration by the federal Food and Drug Administration or*
11 *other appropriate federal agency, and cases pending before the*
12 *courts.*

13 (4) *If applicable, recommended modifications to the board's*
14 *statutory duties related to nonresident pharmacies as a result of*
15 *changes to federal law or any additional modifications necessary*
16 *to protect the health and safety of the public.*

17 (h) *The requirement for submitting a report imposed under*
18 *subdivision (g) is inoperative on January 1, 2022, pursuant to*
19 *Section 10231.5 of the Government Code.*

20 ~~(g)~~

21 (i) *This section shall become operative on July 1, 2014.*

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

24 4400. The amount of fees and penalties prescribed by this
25 chapter, except as otherwise provided, is that fixed by the board
26 according to the following schedule:

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

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

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

39 (d) The fee for regrading an examination shall be ninety dollars
40 (\$90) and may be increased to one hundred fifteen dollars (\$115).

1 If an error in grading is found and the applicant passes the
2 examination, the regrading fee shall be refunded.

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

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

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

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

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

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

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

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

36 (2) For nonresident wholesalers who have 21 or more facilities
37 operating nationwide the application fees for the first 20 locations
38 shall be six hundred dollars (\$600) and may be increased to seven
39 hundred eighty dollars (\$780). The application fee for any
40 additional location after licensure of the first 20 locations shall be

1 two hundred twenty-five dollars (\$225) and may be increased to
2 three hundred dollars (\$300). A temporary license fee shall be five
3 hundred fifty dollars (\$550) and may be increased to seven hundred
4 fifteen dollars (\$715).

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

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

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

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

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

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

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

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

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

1 license shall be one hundred dollars (\$100) and may be increased
2 to one hundred thirty dollars (\$130).

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

9 (t) The fee for issuance of a retired license pursuant to Section
10 4200.5 shall be thirty-five dollars (\$35) and may be increased to
11 forty-five dollars (\$45).

12 (u) The fee for issuance or renewal of a nongovernmental license
13 to compound sterile drug products shall be six hundred dollars
14 (\$600) and may be increased to seven hundred eighty dollars
15 (\$780). The fee for a temporary license shall be five hundred fifty
16 dollars (\$550) and may be increased to seven hundred fifteen
17 dollars (\$715).

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

22 SEC. 9. Section 4400 is added to the Business and Professions
23 Code, to read:

24 4400. The amount of fees and penalties prescribed by this
25 chapter, except as otherwise provided, is that fixed by the board
26 according to the following schedule:

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

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

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

39 (d) The fee for regrading an examination shall be ninety dollars
40 (\$90) and may be increased to one hundred fifteen dollars (\$115).

1 If an error in grading is found and the applicant passes the
2 examination, the regrading fee shall be refunded.

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

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

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

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

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

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

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

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

36 (2) For nonresident wholesalers who have 21 or more facilities
37 operating nationwide the application fees for the first 20 locations
38 shall be six hundred dollars (\$600) and may be increased to seven
39 hundred eighty dollars (\$780). The application fee for any
40 additional location after licensure of the first 20 locations shall be

1 two hundred twenty-five dollars (\$225) and may be increased to
2 three hundred dollars (\$300). A temporary license fee shall be five
3 hundred fifty dollars (\$550) and may be increased to seven hundred
4 fifteen dollars (\$715).

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

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

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

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

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

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

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

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

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

1 license shall be one hundred dollars (\$100) and may be increased
2 to one hundred thirty dollars (\$130).

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

9 (t) The fee for issuance of a retired license pursuant to Section
10 4200.5 shall be thirty-five dollars (\$35) and may be increased to
11 forty-five dollars (\$45).

12 (u) The fee for issuance or renewal of a nongovernmental sterile
13 compounding pharmacy license shall be six hundred dollars (\$600)
14 and may be increased to seven hundred eighty dollars (\$780). The
15 fee for a temporary license shall be five hundred fifty dollars (\$550)
16 and may be increased to seven hundred fifteen dollars (\$715).

17 (v) The fee for the issuance or renewal of a nonresident sterile
18 compounding pharmacy license shall be seven hundred eighty
19 dollars (\$780). In addition to paying that application fee, the
20 nonresident sterile compounding pharmacy shall deposit, when
21 submitting the application, a reasonable amount, as determined by
22 the board, necessary to cover the board's estimated cost of
23 performing the inspection required by Section 4127.2. If the
24 required deposit is not submitted with the application, the
25 application shall be deemed to be incomplete. If the actual cost of
26 the inspection exceeds the amount deposited, the board shall
27 provide to the applicant a written invoice for the remaining amount
28 and shall not take action on the application until the full amount
29 has been paid to the board. If the amount deposited exceeds the
30 amount of actual and necessary costs incurred, the board shall
31 remit the difference to the applicant.

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

33 SEC. 10. No reimbursement is required by this act pursuant to
34 Section 6 of Article XIII B of the California Constitution because
35 the only costs that may be incurred by a local agency or school
36 district will be incurred because this act creates a new crime or
37 infraction, eliminates a crime or infraction, or changes the penalty
38 for a crime or infraction, within the meaning of Section 17556 of
39 the Government Code, or changes the definition of a crime within

- 1 the meaning of Section 6 of Article XIII B of the California
- 2 Constitution.

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