

AMENDED IN SENATE MAY 31, 2016

AMENDED IN SENATE APRIL 13, 2016

**SENATE BILL**

**No. 1193**

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**Introduced by Senator Hill**

(Principal coauthor: Assembly Member Salas)

February 18, 2016

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An act to amend Sections 4001, 4003, *4107, 4110, 4119.1, 4127, 4127.3, 4127.7, 4127.8, 4127.9, 4128.6, 4161, 4180, 4400, and 4400 4406* of, to add Sections 4034, *4126.9, 4203.5, and 4316* to, and to add Article 7.7 (commencing with Section 4129) to Chapter 9 of Division 2 of, the Business and Professions Code, ~~and to amend Section 13401.5 of the Corporations Code, and to amend Sections 1261.6 and 11164.5 of the Health and Safety Code,~~ relating to healing arts, and making an appropriation therefor.

LEGISLATIVE COUNSEL'S DIGEST

SB 1193, as amended, Hill. Pharmacy: ~~outsourcing facilities.~~ *Law.*

The Pharmacy Law provides for the licensure and regulation of the practice of pharmacy by the California State Board of Pharmacy, which is within the Department of Consumer Affairs, and authorizes the board to appoint, with the approval of the Director of Consumer Affairs, an executive officer, as specified. That law repeals the provisions establishing the board and authorizing the board to appoint an executive officer as of January 1, 2017. Under existing law, the board is subject to evaluation by the Joint Sunset Review Committee upon its repeal. ~~That~~

*This bill would extend the operation of the board and the board's authorization to appoint an executive officer until January 1, 2021.*

*The Pharmacy Law authorizes the board to issue a temporary permit to own or operate a pharmacy when the ownership of a pharmacy is transferred from one person to another, as specified.*

*The bill would authorize the board to issue a temporary permit, as specified, regardless of whether the ownership of a pharmacy is transferred from one person to another.*

*The Pharmacy law authorizes a pharmacy to provide pharmacy services to specified licensed health facilities through the use of an automated drug delivery system. That law also provides for*

*This bill would require a pharmacy to register use of an automated drug delivery system with the board, including the address and location of use.*

*Existing law, until January 1, 2012, permitted access by licensed personnel to multiple drugs that are not patient specific only if an automated drug delivery system had both electronic and mechanical safeguards in place to ensure that the only drugs delivered to the patient were specific to that patient. Existing law, until January 1, 2012, required each facility using an automated drug delivery system to notify the State Department of Health Care Services in writing prior to utilization of the system, as provided. Existing law, until January 1, 2012, required the department, as part of its oversight of those facilities, to review a facility's medication training, storage, and security and its administration procedures related to its use of an automated drug delivery system.*

*This bill would make these provisions operative by repealing the provision that made them inoperative on January 1, 2012.*

*The Pharmacy Law requires the board to issue a license, after an investigation to determine whether the applicant and the premises qualify for a license, that authorizes specified clinics to purchase drugs at wholesale for administration or dispensing, under the direction of a physician and surgeon, to patients registered for care at the clinic. Existing law makes a violation of any provision of the Pharmacy Law punishable as an infraction if no other penalty is provided.*

*This bill would extend the operation of the board and the board's authorization to appoint an executive officer until January 1, 2021. The bill would require a pharmacy to register use of an automated drug delivery system with the board, including the address and location of use. The bill would require the board, when a clinic applicant submits specified types of applications, to issue a license or incorporate changes to an existing license within 30 days of receipt of a completed*

application and payment of fees. The bill would *require that this provision not be construed to limit the board's authority to investigate to determine whether the applicant and the premises qualify for a license. By placing new requirements on a pharmacy, this bill would expand an existing crime and would, therefore, impose a state-mandated local program.*

The Pharmacy Law prohibits a pharmacy from compounding sterile drug products unless the pharmacy has obtained a sterile compounding pharmacy license from the board and prohibits the board from issuing or renewing that license until the board has, among other things, reviewed a current copy of the pharmacy's procedures and policies for sterile compounding. ~~Existing law provides that fees collected on behalf of the board are credited to the Pharmacy Board Contingent Fund, which continuously appropriates fees in the fund. That law prohibits the board from issuing more than one site license to a single premises with specified exceptions, including issuing a license to compound sterile injectable drugs to a resident pharmacy.~~

*This bill would expand the exception under which the board may issue more than one site license to a single premises to include issuing a license to compound sterile drugs to a pharmacy, regardless of whether those drugs are injectable and regardless of whether the pharmacy is a nonresident pharmacy.*

*The Pharmacy Law requires a pharmacy that compounds sterile drug products for injection, administration into the eye, or inhalation to possess a sterile compounding pharmacy license.*

*This bill would require a pharmacy that compounds any sterile drug products to possess a sterile compounding pharmacy license.*

*The Pharmacy Law authorizes the executive officer of the board, based on a reasonable belief obtained during an investigation or pharmacy inspection by the board, to issue a cease and desist order to a pharmacy requiring the pharmacy to refrain from compounding injectable sterile drug products if that activity poses an immediate threat to the public health or safety.*

*This bill would expand the authorization of the executive officer of the board to issue a cease and desist order to include requiring the pharmacy to refrain from compounding any sterile drug products if that activity poses an immediate threat to public health or safety.*

*The Pharmacy Law requires a pharmacy to compound injectable sterile products from one or more nonsterile ingredients in a specified environment.*

*This bill would require a pharmacy to compound any sterile products from one or more nonsterile ingredients in a specified environment.*

*The Pharmacy Law authorizes the board to issue a temporary license to compound injectable sterile drug products when the ownership of a pharmacy that is licensed to compound injectable sterile drug products is transferred from one person to another, as specified.*

*This bill would authorize the board to issue a temporary permit to compound sterile drug products, as specified, regardless of whether the drug product is injectable and regardless of whether the ownership of the pharmacy is transferred from one person to another.*

*The Pharmacy Law requires a resident or a nonresident pharmacy that issues a recall notice regarding a sterile compounded drug to contact the recipient pharmacy, prescriber, or patient of the recalled drug and the board as soon as possible within 12 hours of the recall notice, if use of or exposure to the recalled drug may cause serious adverse health consequences or death and if the recalled drug was dispensed or is intended for use in this state.*

*The bill would make a technical correction to this provision and would require a pharmacy that issues a recall notice regarding a nonsterile compounded drug to contact the recipient pharmacy, prescriber, or patient of the recalled drug and the board within 12 hours of the recall notice, if use of or exposure to the recalled drug may cause serious adverse health consequences or death and if the recalled drug was dispensed or is intended for use in this state. The bill would also require a pharmacy that has been advised that a patient has been harmed by using a nonsterile compounded product potentially attributable to the pharmacy to report the event to the MedWatch program of the federal Food and Drug Administration within 72 hours.*

~~The~~

*This bill would require the board to license an outsourcing facility, as defined, and would prohibit an outsourcing facility to be concurrently licensed with the board as a sterile compounding pharmacy at the same location. The bill would require an outsourcing facility to be licensed with the board before doing business within or into the state and would require an outsourcing facility to, among other things, notify the board of any disciplinary or other action taken by another state or the federal Food and Drug Administration within 10 days of the action. The bill would require the board to, among other things, inspect the location of an outsourcing facility to ensure that the outsourcing facility is in compliance with all laws and regulations before issuing or renewing*

an outsourcing facility's license. The bill would make a violation of any of these provisions or regulations adopted thereto punishable by a fine of up to \$5,000 per occurrence. The bill would, on or after January 1, 2018, require the board to provide a report, as specified, to the Legislature regarding the regulation of nonresident outsourcing facilities. ~~The~~

*Existing law authorizes specified clinics to purchase drugs at wholesale for administration or dispensing, under the direction of a physician and surgeon, to the clinic's patients. Existing law requires each clinic location to have a separate license.*

*This bill would require the board to synchronize license renewal dates and aggregate fees for multiple clinics under common nonprofit ownership at the request of the parent organization.*

*Existing law requires that fees collected on behalf of the board be credited to the Pharmacy Board Contingent Fund. Existing law continuously appropriates fees in the fund.*

*This bill would ~~also~~ authorize the board to collect a fee of \$780 for the issuance and renewal of an outsourcing license and a fee of \$715 for a temporary license, as specified. ~~By increasing the amount of money deposited into a continuously appropriated fund, the bill would make an appropriation.~~ This bill would provide that the Pharmacy Board Contingent Fund is available for expenditure only upon an appropriation by the Legislature.*

Existing law authorizes specified healing arts licensees to be shareholders, officers, directors, or professional employees of a designated professional corporation, subject to certain limitations relating to ownership of shares.

This bill would additionally authorize licensed pharmacists to be shareholders, officers, directors, or professional employees of a designated professional corporation, subject to certain limitations relating to ownership of shares.

*Existing law authorizes, with the approval of the board and the Department of Justice, a pharmacy or hospital to receive electronic data transmission prescriptions and computer entry prescriptions or orders for controlled substances in Schedule II, III, IV, or V, if authorized by federal law and in accordance with regulations promulgated by the federal Drug Enforcement Administration. Existing law requires the board to maintain a list of all requests and approvals granted. Existing law prohibits an approved pharmacy or hospital receiving an electronic transmission prescription or a computer entry*

*prescription or order for a controlled substance in Schedule II, III, IV, or V from being required to reduce that prescription or order to writing or to hard copy form as long as the pharmacy or hospital is able to immediately produce a specified hard copy upon request.*

*This bill would remove these provisions.*

*By placing new requirements on a pharmacy, this bill would expand an existing crime and would, therefore, impose a state-mandated local program.*

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: ~~yes~~-no. Fiscal committee: yes. State-mandated local program: yes.

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

- 1 SECTION 1. Section 4001 of the Business and Professions
- 2 Code is amended to read:
- 3 4001. (a) There is in the Department of Consumer Affairs a
- 4 California State Board of Pharmacy in which the administration
- 5 and enforcement of this chapter is vested. The board consists of
- 6 13 members.
- 7 (b) The Governor shall appoint seven competent pharmacists
- 8 who reside in different parts of the state to serve as members of
- 9 the board. The Governor shall appoint four public members, and
- 10 the Senate Committee on Rules and the Speaker of the Assembly
- 11 shall each appoint a public member who shall not be a licensee of
- 12 the board, any other board under this division, or any board referred
- 13 to in Section 1000 or 3600.
- 14 (c) At least five of the seven pharmacist appointees to the board
- 15 shall be pharmacists who are actively engaged in the practice of
- 16 pharmacy. Additionally, the membership of the board shall include
- 17 at least one pharmacist representative from each of the following
- 18 practice settings: an acute care hospital, an independent community
- 19 pharmacy, a chain community pharmacy, and a long-term health
- 20 care or skilled nursing facility. The pharmacist appointees shall
- 21 also include a pharmacist who is a member of a labor union that
- 22 represents pharmacists. For the purposes of this subdivision, a

1 “chain community pharmacy” means a chain of 75 or more stores  
2 in California under the same ownership, and an “independent  
3 community pharmacy” means a pharmacy owned by a person or  
4 entity who owns no more than four pharmacies in California.

5 (d) Members of the board shall be appointed for a term of four  
6 years. No person shall serve as a member of the board for more  
7 than two consecutive terms. Each member shall hold office until  
8 the appointment and qualification of his or her successor or until  
9 one year shall have elapsed since the expiration of the term for  
10 which the member was appointed, whichever first occurs.  
11 Vacancies occurring shall be filled by appointment for the  
12 unexpired term.

13 (e) Each member of the board shall receive a per diem and  
14 expenses as provided in Section 103.

15 (f) This section shall remain in effect only until January 1, 2021,  
16 and as of that date is repealed. Notwithstanding any other law, the  
17 repeal of this section renders the board subject to review by the  
18 appropriate policy committees of the Legislature.

19 SEC. 2. Section 4003 of the Business and Professions Code is  
20 amended to read:

21 4003. (a) The board, with the approval of the director, may  
22 appoint a person exempt from civil service who shall be designated  
23 as an executive officer and who shall exercise the powers and  
24 perform the duties delegated by the board and vested in him or her  
25 by this chapter. The executive officer may or may not be a member  
26 of the board as the board may determine.

27 (b) The executive officer shall receive the compensation as  
28 established by the board with the approval of the Director of  
29 Finance. The executive officer shall also be entitled to travel and  
30 other expenses necessary in the performance of his or her duties.

31 (c) The executive officer shall maintain and update in a timely  
32 fashion records containing the names, titles, qualifications, and  
33 places of business of all persons subject to this chapter.

34 (d) The executive officer shall give receipts for all money  
35 received by him or her and pay it to the department, taking its  
36 receipt therefor. Besides the duties required by this chapter, the  
37 executive officer shall perform other duties pertaining to the office  
38 as may be required of him or her by the board.

39 (e) This section shall remain in effect only until January 1, 2021,  
40 and as of that date is repealed.

1 SEC. 3. Section 4034 is added to the Business and Professions  
2 Code, to read:

3 4034. “Outsourcing facility” means a facility that meets all of  
4 the following:

5 (a) Is located within the United States of America at one address  
6 that is engaged in the compounding of sterile drugs and nonsterile  
7 drugs.

8 (b) Has registered as an outsourcing facility with the federal  
9 Food and Drug Administration under Section 503B of the Federal  
10 Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 353b).

11 (c) Is doing business within or into California.

12 (d) Is licensed with the board as an outsourcing facility pursuant  
13 to Article 7.7 (commencing with Section 4129).

14 SEC. 4. Section 4107 of the Business and Professions Code is  
15 amended to read:

16 4107. (a) The board ~~may~~ shall not issue more than one site  
17 license to a single premises except as follows:

18 (1) To issue a veterinary food-animal drug retailer license to a  
19 wholesaler pursuant to Section 4196.

20 (2) To issue a license to compound sterile ~~injectable~~ drugs to a  
21 pharmacy pursuant to Section ~~4127.1, 4127.1 or 4127.2.~~

22 (3) To issue a centralized hospital packaging license pursuant  
23 to Section 4128.

24 (b) For the purposes of this subdivision, “premises” means a  
25 location with its own address and an independent means of ingress  
26 and egress.

27 SEC. 5. Section 4110 of the Business and Professions Code is  
28 amended to read:

29 4110. (a) No person shall conduct a pharmacy in the State of  
30 California unless he or she has obtained a license from the board.  
31 A license shall be required for each pharmacy owned or operated  
32 by a specific person. A separate license shall be required for each  
33 of the premises of any person operating a pharmacy in more than  
34 one location. The license shall be renewed annually. The board  
35 may, by regulation, determine the circumstances under which a  
36 license may be transferred.

37 (b) The board may, at its discretion, issue a temporary ~~permit,~~  
38 ~~when the ownership of a pharmacy is transferred from one person~~  
39 ~~to another,~~ permit upon the conditions and for any periods of time  
40 as the board determines to be in the public interest. A temporary

1 permit fee shall be required in an amount established by the board  
2 as specified in subdivision (a) of Section 4400. When needed to  
3 protect public safety, a temporary permit may be issued for a period  
4 not to exceed 180 days, and may be issued subject to terms and  
5 conditions the board deems necessary. If the board determines a  
6 temporary permit was issued by mistake or denies the application  
7 for a permanent license or registration, the temporary license or  
8 registration shall terminate upon either personal service of the  
9 notice of termination upon the permitholder or service by certified  
10 mail, return receipt requested, at the permitholder's address of  
11 record with the board, whichever comes first. Neither for purposes  
12 of retaining a temporary permit nor for purposes of any disciplinary  
13 or license denial proceeding before the board shall the temporary  
14 permitholder be deemed to have a vested property right or interest  
15 in the permit.

16 (c) The board may allow the temporary use of a mobile  
17 pharmacy when a pharmacy is destroyed or damaged, the mobile  
18 pharmacy is necessary to protect the health and safety of the public,  
19 and the following conditions are met:

20 (1) The mobile pharmacy shall provide services only on or  
21 immediately contiguous to the site of the damaged or destroyed  
22 pharmacy.

23 (2) The mobile pharmacy is under the control and management  
24 of the pharmacist-in-charge of the pharmacy that was destroyed  
25 or damaged.

26 (3) A licensed pharmacist is on the premises while drugs are  
27 being dispensed.

28 (4) Reasonable security measures are taken to safeguard the  
29 drug supply maintained in the mobile pharmacy.

30 (5) The pharmacy operating the mobile pharmacy provides the  
31 board with records of the destruction of, or damage to, the  
32 pharmacy and an expected restoration date.

33 (6) Within three calendar days of restoration of the pharmacy  
34 services, the board is provided with notice of the restoration of the  
35 permanent pharmacy.

36 (7) The mobile pharmacy is not operated for more than 48 hours  
37 following the restoration of the permanent pharmacy.

38 ~~SEC. 4.~~

39 *SEC. 6.* Section 4119.1 of the Business and Professions Code  
40 is amended to read:

1 4119.1. (a) A pharmacy may provide pharmacy services to a  
2 health facility licensed pursuant to subdivision (c), (d), or both, of  
3 Section 1250 of the Health and Safety Code, through the use of  
4 an automated drug delivery system that need not be located at the  
5 same location as the pharmacy.

6 (b) Drugs stored in an automated drug delivery system shall be  
7 part of the inventory of the pharmacy providing pharmacy services  
8 to that facility, and drugs dispensed from the pharmacy system  
9 shall be considered to have been dispensed by that pharmacy.

10 (c) (1) The pharmacy shall maintain records of the acquisition  
11 and disposition of dangerous drugs and dangerous devices stored  
12 in the automated drug delivery system separate from other  
13 pharmacy records.

14 (2) The pharmacy shall own and operate the automated drug  
15 delivery system.

16 (3) The pharmacy shall provide training regarding the operation  
17 and use of the automated drug delivery system to both pharmacy  
18 and health facility personnel using the system.

19 (4) The pharmacy shall operate the automated drug delivery  
20 system in compliance with Section 1261.6 of the Health and Safety  
21 Code.

22 (d) The operation of the automated drug delivery system shall  
23 be under the supervision of a licensed pharmacist. To qualify as a  
24 supervisor for an automated drug delivery system, the pharmacist  
25 need not be physically present at the site of the automated drug  
26 delivery system and may supervise the system electronically.

27 (e) The pharmacy shall register use of an automated drug  
28 delivery system with the board, including the address and location  
29 of use.

30 (f) This section shall not be construed to revise or limit the use  
31 of automated drug delivery systems as permitted by the board in  
32 any licensed health facility other than a facility defined in  
33 subdivision (c) or (d), or both, of Section 1250 of the Health and  
34 Safety Code.

35 *SEC. 7. Section 4126.9 is added to the Business and Professions*  
36 *Code, to read:*

37 *4126.9. (a) A pharmacy that issues a recall notice regarding*  
38 *a nonsterile compounded drug product shall, in addition to any*  
39 *other duties, contact the recipient pharmacy, prescriber, or patient*

1 of the recalled drug and the board within 12 hours of the recall  
2 notice if both of the following apply:

3 (1) Use of or exposure to the recalled drug may cause serious  
4 adverse health consequences or death.

5 (2) The recalled drug was dispensed, or is intended for use, in  
6 this state.

7 (b) A recall notice issued pursuant to subdivision (a) shall be  
8 made as follows:

9 (1) If the recalled drug was dispensed directly to the patient,  
10 the notice shall be made to the patient.

11 (2) If the recalled drug was dispensed directly to the prescriber,  
12 the notice shall be made to the prescriber, who shall ensure the  
13 patient is notified.

14 (3) If the recalled drug was dispensed directly to a pharmacy,  
15 the notice shall be made to the pharmacy, which shall notify the  
16 prescriber or patient, as appropriate. If the pharmacy notifies the  
17 prescriber, the prescriber shall ensure the patient is notified.

18 (c) In cases where patient harm has occurred resulting from  
19 use of the compounded product, the event shall be reported to  
20 MedWatch within 72 hours of the pharmacy being advised.

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

23 4127. (a) A pharmacy that compounds sterile drug products  
24 ~~for injection, administration into the eye, or inhalation~~ shall possess  
25 a sterile compounding pharmacy license as provided in this article.

26 (b) The board shall adopt regulations in accordance with the  
27 Administrative Procedure Act (Chapter 3.5 (commencing with  
28 Section 11340) of Part 1 of Division 3 of Title 2 of the Government  
29 Code) to establish policies, guidelines, and procedures to  
30 implement this article.

31 (c) The board shall review any formal revision to General  
32 Chapter 797 of the United States Pharmacopeia and The National  
33 Formulary (USP–NF), relating to the compounding of sterile  
34 preparations, not later than 90 days after the revision becomes  
35 official, to determine whether amendments are necessary for the  
36 regulations adopted by the board pursuant to subdivision (b).

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

38 SEC. 9. Section 4127.3 of the Business and Professions Code  
39 is amended to read:

1 4127.3. (a) Whenever the board has a reasonable belief, based  
2 on information obtained during an inspection or investigation by  
3 the board, that a pharmacy compounding ~~injectable~~ sterile drug  
4 products poses an immediate threat to the public health or safety,  
5 the executive officer of the board may issue an order to the  
6 pharmacy to immediately cease and desist from compounding  
7 ~~injectable~~ sterile drug products. The cease and desist order shall  
8 remain in effect for no more than 30 days or the date of a hearing  
9 seeking an interim suspension order, whichever is earlier.

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

14 (c) The order shall provide that the owner, within 15 days of  
15 receipt of the notice, may request a hearing before the president  
16 of the board to contest the cease and desist order. Consideration  
17 of the owner's contest of the cease and desist order shall comply  
18 with the requirements of Section 11425.10 of the Government  
19 Code. The hearing shall be held no later than five days from the  
20 date the request of the owner is received by the board. The  
21 president shall render a written decision within five days of the  
22 hearing. In the absence of the president of the board, the vice  
23 president of the board may conduct the hearing permitted by this  
24 subdivision. Review of the decision of the president of the board  
25 may be sought by the owner or person in possession or control of  
26 the pharmacy pursuant to Section 1094.5 of the Code of Civil  
27 Procedure.

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

30 *SEC. 10. Section 4127.7 of the Business and Professions Code*  
31 *is amended to read:*

32 ~~4127.7. On and after July 1, 2005, a~~ A pharmacy shall  
33 compound sterile ~~injectable~~ products from one or more nonsterile  
34 ingredients in one of the following environments:

35 (a) An ISO class 5 laminar airflow hood within an ISO class 7  
36 cleanroom. The cleanroom must have a positive air pressure  
37 differential relative to adjacent areas.

38 (b) An ISO class 5 cleanroom.

39 (c) A barrier isolator that provides an ISO class 5 environment  
40 for compounding.

1     *SEC. 11. Section 4127.8 of the Business and Professions Code*  
2 *is amended to read:*

3     4127.8. The board may, at its discretion, issue a temporary  
4 license to compound injectable sterile drug ~~products, when the~~  
5 ~~ownership of a pharmacy that is licensed to compound injectable~~  
6 ~~sterile drug products is transferred from one person to another,~~  
7 *products* upon the conditions and for any periods of time as the  
8 board determines to be in the public interest. A temporary license  
9 fee shall be required in an amount established by the board as  
10 specified in subdivision (u) of Section 4400. When needed to  
11 protect public safety, a temporary license may be issued for a  
12 period not to exceed 180 days, and may be issued subject to terms  
13 and conditions the board deems necessary. If the board determines  
14 a temporary license was issued by mistake or denies the application  
15 for a permanent license, the temporary license shall terminate upon  
16 either personal service of the notice of termination upon the  
17 licenseholder or service by certified mail, return receipt requested  
18 at the licenseholder's address of record with the board, whichever  
19 comes first. Neither for purposes of retaining a temporary license  
20 nor for purposes of any disciplinary or license denial proceeding  
21 before the board shall the temporary licenseholder be deemed to  
22 have a vested property right or interest in the license.

23     *SEC. 12. Section 4127.9 of the Business and Professions Code*  
24 *is amended to read:*

25     4127.9. (a) A pharmacy licensed pursuant to Section 4127.1  
26 ~~or 4127.2, including a pharmacy that is exempt from licensure~~  
27 ~~pursuant to subdivision (d) of Section 4127.1 and subdivision (e)~~  
28 ~~of Section 4127.2; 4127.2~~ that issues a recall notice regarding a  
29 sterile compounded drug shall, in addition to any other duties,  
30 contact the recipient pharmacy, prescriber, or patient of the recalled  
31 drug and the board as soon as possible within 12 hours of the recall  
32 notice if both of the following apply:

33         (1) Use of or exposure to the recalled drug may cause serious  
34 adverse health consequences or death.

35         (2) The recalled drug was dispensed, or is intended for use, in  
36 this state.

37     (b) A recall notice issued pursuant to subdivision (a) shall be  
38 made as follows:

39         (1) If the recalled drug was dispensed directly to the patient,  
40 the notice shall be made to the patient.

1 (2) If the recalled drug was dispensed directly to the prescriber,  
2 the notice shall be made to the prescriber, who shall ensure the  
3 patient is notified.

4 (3) If the recalled drug was dispensed directly to a pharmacy,  
5 the notice shall be made to the pharmacy, who shall notify the  
6 prescriber or patient, as appropriate. If the pharmacy notifies the  
7 prescriber, the prescriber shall ensure the patient is notified.

8 *SEC. 13. Section 4128.6 of the Business and Professions Code*  
9 *is amended to read:*

10 4128.6. All compounding and packaging functions specified  
11 in Section 4128 shall be performed only in the licensed centralized  
12 hospital packaging pharmacy and that pharmacy shall comply with  
13 all applicable federal and state statutes and regulations, including,  
14 but not limited to, regulations regarding compounding and, when  
15 appropriate, sterile-injectable compounding.

16 ~~SEC. 5.~~

17 *SEC. 14.* Article 7.7 (commencing with Section 4129) is added  
18 to Chapter 9 of Division 2 of the Business and Professions Code,  
19 to read:

20  
21 Article 7.7. Outsourcing Facilities

22  
23 4129. (a) A facility licensed as an outsourcing facility with  
24 the federal Food and Drug Administration (FDA) shall be  
25 concurrently licensed with the board as an outsourcing facility if  
26 it compounds sterile medication or nonsterile medication for  
27 nonpatient-specific distribution within or into California.

28 (b) A facility premises licensed with the board as a sterile  
29 compounding pharmacy shall not be concurrently licensed with  
30 the board as an outsourcing facility at the same location.

31 (c) The board may adopt regulations in accordance with the  
32 Administrative Procedure Act (Chapter 3.5 (commencing with  
33 Section 11340) of Part 1 of Division 3 of Title 2 of the Government  
34 Code) to establish policies, guidelines, and procedures to  
35 implement this article.

36 (d) The board shall review any formal requirements or guidance  
37 documents developed by the FDA regarding outsourcing facilities  
38 within 90 days after their release in order to determine whether  
39 revisions are necessary for any regulations promulgated by the  
40 board.

1 (e) An outsourcing facility licensed by the board shall not  
2 perform the duties of a pharmacy, such as filling individual  
3 prescriptions for individual patients.

4 4129.1. (a) An outsourcing facility that is licensed with the  
5 federal Food and Drug Administration (FDA) and with an address  
6 in this state shall also be licensed by the board as an outsourcing  
7 facility before doing business within this state. The license shall  
8 be renewed annually and is not transferable.

9 (b) An outsourcing facility shall compound all sterile products  
10 and nonsterile products in compliance with regulations issued by  
11 the board and with federal current good manufacturing practices  
12 applicable to outsourcing facilities.

13 (c) An outsourcing facility license shall not be issued or renewed  
14 until the location is inspected by the board and found in compliance  
15 with this article and regulations adopted by the board.

16 (d) An outsourcing facility license shall not be issued or renewed  
17 until the board does all of the following:

18 (1) Prior to inspection, reviews a current copy of the outsourcing  
19 facility's policies and procedures for sterile compounding and  
20 nonsterile compounding.

21 (2) Is provided with copies of all federal and state regulatory  
22 agency inspection reports, as well as accreditation reports, and  
23 certification reports of facilities or equipment of the outsourcing  
24 facility's premises conducted in the prior 12 months.

25 (3) Prior to inspection, receives a list of all sterile drugs and  
26 nonsterile drugs compounded by the outsourcing facility as reported  
27 to the FDA in the last 12 months.

28 (e) An outsourcing facility licensed pursuant to this section shall  
29 provide the board with all of the following:

30 (1) A copy of any disciplinary or other action taken by another  
31 state or the FDA within 10 days of the action.

32 (2) Notice within 24 hours of any recall notice issued by the  
33 outsourcing facility.

34 (3) A copy of any clinically related complaint it receives  
35 involving an outsourcing facility's compounded products from or  
36 involving any provider, pharmacy, or patient in California within  
37 72 hours of receipt.

38 (4) Notice within 24 hours after learning of adverse effects  
39 reported or potentially attributable to the outsourcing facility's  
40 products.

1 4129.2. (a) An outsourcing facility that is licensed with the  
2 federal Food and Drug Administration (FDA) as an outsourcing  
3 facility and has an address outside of this state but in the United  
4 States of America is a nonresident outsourcing facility. A  
5 nonresident outsourcing facility shall not compound sterile drug  
6 products or nonsterile drug products for distribution or use into  
7 this state without an outsourcing license issued by the board  
8 pursuant to this section. The license shall be renewed annually and  
9 shall not be transferable.

10 (b) A nonresident outsourcing facility shall compound all sterile  
11 products and nonsterile products to be distributed or used in this  
12 state in compliance with regulations of the board and with federal  
13 current good manufacturing practices applicable to outsourcing  
14 facilities.

15 (c) A license for a nonresident outsourcing facility shall not be  
16 issued or renewed until the location is inspected by the board and  
17 found in compliance with this article and any regulations adopted  
18 by the board. The nonresident outsourcing facility shall reimburse  
19 the board for all actual and necessary costs incurred by the board  
20 in conducting an inspection of the nonresident outsourcing facility  
21 at least once annually pursuant to subdivision (x) of Section 4400.

22 (d) A license for a nonresident outsourcing facility shall not be  
23 issued or renewed until the board:

24 (1) Prior to inspection, reviews a current copy of the nonresident  
25 outsourcing facility's policies and procedures for sterile  
26 compounding and nonsterile compounding.

27 (2) (A) Is provided with copies of all federal and state regulatory  
28 agency inspection reports, as well as accreditation reports, and  
29 certification reports of facilities or equipment of the nonresident  
30 outsourcing facility's premises conducted in the prior 12 months.

31 (B) *For purposes of this paragraph, "state" refers to the state*  
32 *in which the nonresident outsourcing facility resides.*

33 (3) Prior to inspection, receives a list of all sterile drug products  
34 and nonsterile drug products compounded by the pharmacy as  
35 reported to the FDA within the prior 12 months.

36 (e) A nonresident outsourcing facility licensed pursuant to this  
37 section shall provide the board with all of the following:

38 (1) A copy of any disciplinary or other action taken by another  
39 state or the FDA within 10 days of the action.

1 (2) Notice within 24 hours of any recall notice issued by the  
2 nonresident outsourcing facility.

3 (3) A copy of any complaint it receives involving an outsourcing  
4 facility's compounded products from or involving any provider,  
5 pharmacy, or patient in California within 72 hours of receipt.

6 (4) Notice within 24 hours after learning of adverse effects  
7 reported or potentially attributable to a nonresident outsourcing  
8 facility's products.

9 4129.3. (a) On or before January 1, 2018, the board shall  
10 provide a report to the Legislature regarding the regulation of  
11 nonresident outsourcing facilities. The report shall be submitted  
12 to the Legislature in the manner required pursuant to Section 9795  
13 of the Government Code. At a minimum, the report shall address  
14 all of the following:

15 (1) A detailed description of board activities related to the  
16 inspection and licensure of nonresident outsourcing facilities.

17 (2) Whether fee revenue collected pursuant to subdivision (x)  
18 of Section 4400 and travel cost reimbursements collected pursuant  
19 to subdivision (c) of Section 4129.2 provide revenue in an amount  
20 sufficient to support the board's activities related to the inspection  
21 and licensure of nonresident outsourcing facilities.

22 (3) The status of proposed changes to federal law that are under  
23 serious consideration and that would govern outsourcing facilities  
24 and compounding pharmacies, including, but not limited to,  
25 legislation pending before Congress, administrative rules,  
26 regulations or orders under consideration by the FDA or other  
27 appropriate federal agency, and cases pending before the courts.

28 (4) If applicable, recommended modifications to the board's  
29 statutory duties related to nonresident outsourcing facilities as a  
30 result of changes to federal law or any additional modifications  
31 necessary to protect the health and safety of the public.

32 (b) The requirement for submitting a report imposed under  
33 subdivision (a) is inoperative on January 1, 2022, pursuant to  
34 Section 10231.5 of the Government Code.

35 4129.4. (a) Whenever the board has a reasonable belief, based  
36 on information obtained during an inspection or investigation by  
37 the board, that an outsourcing facility compounding sterile drug  
38 products or nonsterile drug products poses an immediate threat to  
39 the public health or safety, the executive officer of the board may  
40 issue an order to the outsourcing facility to immediately cease and

1 desist compounding sterile drug products or nonsterile drug  
2 products. The cease and desist order shall remain in effect for no  
3 more than 30 days or the date of a hearing seeking an interim  
4 suspension order, whichever is earlier.

5 (b) Whenever the board issues a cease and desist order pursuant  
6 to subdivision (a), the board shall immediately issue a notice to  
7 the owner setting forth the acts or omissions with which the owner  
8 is charged, specifying the pertinent code section or sections and  
9 any regulations.

10 (c) The cease and desist order shall state that the owner, within  
11 15 days of receipt of the notice, may request a hearing before the  
12 president of the board to contest the cease and desist order.  
13 Consideration of the owner's contest of the cease and desist order  
14 shall comply with the requirements of Section 11425.10 of the  
15 Government Code. The hearing shall be held no later than five  
16 days after the date the request of the owner is received by the  
17 board. The president shall render a written decision within five  
18 days after the hearing. In the absence of the president of the board,  
19 the vice president of the board may conduct the hearing permitted  
20 by this subdivision. Review of the decision may be sought by the  
21 owner or person in possession or control of the outsourcing facility  
22 pursuant to Section 1094.5 of the Code of Civil Procedure.

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

25 4129.5. Notwithstanding any other law, a violation of this  
26 article, or regulation adopted pursuant thereto, may subject the  
27 person or entity that committed the violation to a fine of up to five  
28 thousand dollars (\$5,000) per occurrence pursuant to a citation  
29 issued by the board.

30 4129.6. For purposes of this article, "sterile compounded  
31 products" means compounded preparations for injection,  
32 administration into the eye, or inhalation.

33 4129.8. The board, at its discretion, may issue a temporary  
34 license to an outsourcing facility when the ownership of the  
35 outsourcing facility is transferred from one person to another, upon  
36 the conditions and for any periods of time as the board determines  
37 to be in the public interest. A temporary license fee shall be  
38 required as specified in subdivision (w) of Section 4400. When  
39 needed to protect public safety, a temporary license may be issued  
40 for a period not to exceed 180 days, and may be issued subject to

1 terms and conditions the board deems necessary. If the board  
2 determines a temporary license was issued by mistake or denies  
3 the application for a permanent license, the temporary license shall  
4 terminate upon the earlier of personal service of the notice of  
5 termination upon the licenseholder or service by certified mail  
6 with return receipt requested at the licenseholder's address of  
7 record with the board. The temporary licenseholder shall not be  
8 deemed to have a vested property right or interest in the license  
9 for purposes of retaining a temporary license or for purposes of  
10 any disciplinary or license denial proceeding before the board.

11 4129.9. (a) An outsourcing facility licensed pursuant to Section  
12 4129.1 or 4129.2 that issues a recall notice for a sterile drug or  
13 nonsterile drug compounded by the outsourcing facility, in addition  
14 to any other duties, shall contact the recipient pharmacy, prescriber,  
15 or patient of the recalled drug and the board as soon as possible  
16 within 24 hours of the recall notice if both of the following apply:

17 (1) Use of or exposure to the recalled drug may cause serious  
18 adverse health consequences or death.

19 (2) The recalled drug was dispensed, or is intended for use, in  
20 this state.

21 (b) A recall notice issued pursuant to subdivision (a) shall be  
22 made as follows:

23 (1) If the recalled drug was dispensed directly to the prescriber,  
24 the notice shall be made to the prescriber and the prescriber shall  
25 ensure the patient is notified.

26 (2) If the recalled drug was dispensed directly to a pharmacy,  
27 the notice shall be made to the pharmacy and that pharmacy shall  
28 notify the prescriber or patient, as appropriate. If the pharmacy  
29 notifies the prescriber, the prescriber shall ensure the patient is  
30 notified.

31 *SEC. 15. Section 4161 of the Business and Professions Code*  
32 *is amended to read:*

33 4161. (a) A person located outside this state that (1) ships,  
34 sells, mails, warehouses, distributes, or delivers dangerous drugs  
35 or dangerous devices into this state or (2) sells, brokers,  
36 warehouses, or distributes dangerous drugs or devices within this  
37 state shall be considered a nonresident wholesaler or a nonresident  
38 third-party logistics provider.

39 (b) A nonresident wholesaler or nonresident third-party logistics  
40 provider shall be licensed by the board prior to shipping, selling,

1 mailing, warehousing, distributing, or delivering dangerous drugs  
2 or dangerous devices to a site located in this state or selling,  
3 brokering, warehousing, or distributing dangerous drugs or devices  
4 within this state.

5 (c) (1) A separate license shall be required for each place of  
6 business owned or operated by a nonresident wholesaler or  
7 nonresident third-party logistics provider from or through which  
8 dangerous drugs or dangerous devices are shipped, sold, mailed,  
9 warehoused, distributed, or delivered to a site located in this state  
10 or sold, brokered, warehoused, or distributed within this state.  
11 Each place of business may only be issued a single license by the  
12 board, except as provided in paragraph (2). A license shall be  
13 renewed annually and shall not be transferable.

14 (2) A nonresident wholesaler and a nonresident third-party  
15 logistics provider under common ownership may be licensed at  
16 the same place of business provided that all of the following  
17 requirements are satisfied:

18 (A) The wholesaler and the third-party logistics provider each  
19 separately maintain the records required under Section 4081.

20 (B) Dangerous drugs and dangerous devices owned by the  
21 wholesaler are not commingled with the dangerous drugs and  
22 dangerous devices handled by the third-party logistics provider.

23 (C) Any individual acting as a designated representative for the  
24 wholesaler is not concurrently acting as a designated  
25 representative-3PL on behalf of the third-party logistics provider.  
26 Nothing in this subparagraph shall be construed to prohibit an  
27 individual from concurrently holding a license to act as a  
28 designated representative and to act as a designated  
29 representative-3PL.

30 (D) The wholesaler has its own designated  
31 representative-in-charge responsible for the operations of the  
32 wholesaler and the third-party logistics provider has its own  
33 responsible manager responsible for the operations of the  
34 third-party logistics provider. The same individual shall not  
35 concurrently serve as the responsible manager and the designated  
36 representative-in-charge for a wholesaler and a third-party logistics  
37 provider licensed at the same place of business.

38 (E) The third-party logistics provider does not handle the  
39 prescription drugs or prescription devices owned by a prescriber.

1 (F) The third-party logistics provider is not a reverse third-party  
2 logistics provider.

3 (G) The wholesaler is not acting as a reverse distributor.

4 (d) The following information shall be reported, in writing, to  
5 the board at the time of initial application for licensure by a  
6 nonresident wholesaler or a nonresident third-party logistics  
7 provider, on renewal of a nonresident wholesaler or nonresident  
8 third-party logistics provider license, or within 30 days of a change  
9 in that information:

10 (1) Its agent for service of process in this state.

11 (2) Its principal corporate officers, as specified by the board, if  
12 any.

13 (3) Its general partners, as specified by the board, if any.

14 (4) Its owners if the applicant is not a corporation or partnership.

15 (e) A report containing the information in subdivision (d) shall  
16 be made within 30 days of any change of ownership, office,  
17 corporate officer, or partner.

18 (f) A nonresident wholesaler or nonresident third-party logistics  
19 provider shall comply with all directions and requests for  
20 information from the regulatory or licensing agency of the state  
21 in which it is licensed, as well as with all requests for information  
22 made by the board.

23 (g) A nonresident wholesaler or nonresident third-party logistics  
24 provider shall maintain records of dangerous drugs and dangerous  
25 devices sold, traded, transferred, warehoused, or distributed to  
26 persons in this state or within this state, so that the records are in  
27 a readily retrievable form.

28 (h) A nonresident wholesaler or nonresident third-party logistics  
29 provider shall at all times maintain a valid, unexpired license,  
30 permit, or registration to conduct the business of the wholesaler  
31 or nonresident third-party logistics provider in compliance with  
32 the laws of the state in which it is a resident. An application for a  
33 nonresident wholesaler or nonresident third-party logistics provider  
34 license in this state shall include a license verification from the  
35 licensing authority in the applicant's state of residence.

36 (i) (1) The board shall not issue or renew a nonresident  
37 wholesaler license until the nonresident wholesaler identifies a  
38 designated representative-in-charge and notifies the board in  
39 writing of the identity and license number of the designated  
40 representative-in-charge.

1 (2) The board shall not issue or renew a nonresident third-party  
2 logistics provider license until the nonresident third-party logistics  
3 provider identifies a responsible manager and notifies the board  
4 in writing of the identity and license number of the designated  
5 representative-3PL who will be the responsible manager.

6 (j) The designated representative-in-charge shall be responsible  
7 for the compliance of the nonresident wholesaler with state and  
8 federal laws governing wholesalers. The responsible manager shall  
9 be responsible for the compliance of the nonresident third-party  
10 logistics provider's place of business with state and federal laws  
11 governing third-party logistics providers. A nonresident wholesaler  
12 or nonresident third-party logistics provider shall identify and  
13 notify the board of a new designated representative-in-charge or  
14 responsible manager within 30 days of the date that the prior  
15 designated representative-in-charge or responsible manager ceases  
16 to be the designated representative-in-charge or responsible  
17 manager.

18 (k) The board may issue a temporary license, upon conditions  
19 and for periods of time as the board determines to be in the public  
20 interest. A temporary license fee shall be five hundred fifty dollars  
21 (\$550) or another amount established by the board not to exceed  
22 the annual fee for renewal of a license to compound-injectable  
23 sterile drug products. When needed to protect public safety, a  
24 temporary license may be issued for a period not to exceed 180  
25 days, subject to terms and conditions that the board deems  
26 necessary. If the board determines that a temporary license was  
27 issued by mistake or denies the application for a permanent license,  
28 the temporary license shall terminate upon either personal service  
29 of the notice of termination upon the licenseholder or service by  
30 certified mail, return receipt requested, at the licenseholder's  
31 address of record with the board, whichever occurs first. Neither  
32 for purposes of retaining a temporary license, nor for purposes of  
33 any disciplinary or license denial proceeding before the board,  
34 shall the temporary licenseholder be deemed to have a vested  
35 property right or interest in the license.

36 (l) The registration fee shall be the fee specified in subdivision  
37 (f) of Section 4400.

38 *SEC. 16. Section 4180 of the Business and Professions Code*  
39 *is amended to read:*

1 4180. (a) (1) Notwithstanding any provision of this chapter,  
2 any of the following clinics may purchase drugs at wholesale for  
3 administration or dispensing, under the direction of a physician  
4 and surgeon, to patients registered for care at the clinic:

5 (A) A licensed nonprofit community clinic or free clinic as  
6 defined in paragraph (1) of subdivision (a) of Section 1204 of the  
7 Health and Safety Code.

8 (B) A primary care clinic owned or operated by a county as  
9 referred to in subdivision (b) of Section 1206 of the Health and  
10 Safety Code.

11 (C) A clinic operated by a federally recognized Indian tribe or  
12 tribal organization as referred to in subdivision (c) of Section 1206  
13 of the Health and Safety Code.

14 (D) A clinic operated by a primary care community or free  
15 clinic, operated on separate premises from a licensed clinic, and  
16 that is open no more than 20 hours per week as referred to in  
17 subdivision (h) of Section 1206 of the Health and Safety Code.

18 (E) A student health center clinic operated by a public institution  
19 of higher education as referred to in subdivision (j) of Section 1206  
20 of the Health and Safety Code.

21 (F) A nonprofit multispecialty clinic as referred to in subdivision  
22 (l) of Section 1206 of the Health and Safety Code.

23 (2) The clinic shall keep records of the kind and amounts of  
24 drugs purchased, administered, and dispensed, and the records  
25 shall be available and maintained for a minimum of three years  
26 for inspection by all properly authorized personnel.

27 (b) No clinic shall be entitled to the benefits of this section until  
28 it has obtained a license from the board. A separate license shall  
29 be required for each clinic location. A clinic shall notify the board  
30 of any change in the clinic's address on a form furnished by the  
31 board.

32 (c) *The board shall synchronize license renewal dates and*  
33 *aggregate fees for multiple clinics under common nonprofit*  
34 *ownership at the request of the parent organization.*

35 ~~SEC. 6.~~

36 *SEC. 17.* Section 4203.5 is added to the Business and  
37 Professions Code, to read:

38 4203.5. (a) Notwithstanding any other law, when a clinic  
39 applicant submits either type of application described in subdivision  
40 (b), the board shall issue a license or incorporate the reported

1 changes, as appropriate, within 30 days of receipt of a completed  
2 application and payment of any prescribed fees.

3 (b) This section applies to the following types of applications:

4 (1) A new clinic license application filed under Section 4180.

5 (2) Applications to report changes to an existing site licensed  
6 under Section 4180, including, but not limited to, changes in  
7 professional director, clinic administrator, corporate officers,  
8 change of location, or change of address.

9 (c) This section shall not be construed to limit the board's  
10 authority to conduct an investigation to determine whether  
11 applicants and the premises for which an application is made  
12 qualify for a license.

13 ~~SEC. 7.~~

14 *SEC. 18.* Section 4316 is added to the Business and Professions  
15 Code, to read:

16 4316. (a) The board is authorized to issue a cease and desist  
17 order for operating any facility under this chapter that requires  
18 licensure or for practicing any activity under this chapter that  
19 requires licensure.

20 (b) Whenever the board issues a cease and desist order pursuant  
21 to subdivision (a), the board shall immediately issue the facility a  
22 notice setting forth the acts or omissions with which it is charged,  
23 specifying the pertinent code section or sections and any  
24 regulations.

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

1     ~~SEC. 8.~~

2     *SEC. 19.* Section 4400 of the Business and Professions Code  
3 is amended to read:

4     4400. The amount of fees and penalties prescribed by this  
5 chapter, except as otherwise provided, is that fixed by the board  
6 according to the following schedule:

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

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

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

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

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

26     (f) The fee for a nongovernmental wholesaler or third-party  
27 logistics provider license and annual renewal shall be seven  
28 hundred eighty dollars (\$780) and may be decreased to no less  
29 than six hundred dollars (\$600). The application fee for any  
30 additional location after licensure of the first 20 locations shall be  
31 three hundred dollars (\$300) and may be decreased to no less than  
32 two hundred twenty-five dollars (\$225). A temporary license fee  
33 shall be seven hundred fifteen dollars (\$715) and may be decreased  
34 to no less than five hundred fifty dollars (\$550).

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

38     (h) (1) The fee for application, investigation, and issuance of  
39 a license as a designated representative pursuant to Section 4053,  
40 or as a designated representative-3PL pursuant to Section 4053.1,

1 shall be three hundred thirty dollars (\$330) and may be decreased  
2 to no less than two hundred fifty-five dollars (\$255).

3 (2) The fee for the annual renewal of a license as a designated  
4 representative or designated representative-3PL shall be one  
5 hundred ninety-five dollars (\$195) and may be decreased to no  
6 less than one hundred fifty dollars (\$150).

7 (i) (1) The fee for the application, investigation, and issuance  
8 of a license as a designated representative for a veterinary  
9 food-animal drug retailer pursuant to Section 4053 shall be three  
10 hundred thirty dollars (\$330) and may be decreased to no less than  
11 two hundred fifty-five dollars (\$255).

12 (2) The fee for the annual renewal of a license as a designated  
13 representative for a veterinary food-animal drug retailer shall be  
14 one hundred ninety-five dollars (\$195) and may be decreased to  
15 no less than one hundred fifty dollars (\$150).

16 (j) (1) The application fee for a nonresident wholesaler or  
17 third-party logistics provider license issued pursuant to Section  
18 4161 shall be seven hundred eighty dollars (\$780) and may be  
19 decreased to no less than six hundred dollars (\$600).

20 (2) For nonresident wholesalers or third-party logistics providers  
21 that have 21 or more facilities operating nationwide the application  
22 fees for the first 20 locations shall be seven hundred eighty dollars  
23 (\$780) and may be decreased to no less than six hundred dollars  
24 (\$600). The application fee for any additional location after  
25 licensure of the first 20 locations shall be three hundred dollars  
26 (\$300) and may be decreased to no less than two hundred  
27 twenty-five dollars (\$225). A temporary license fee shall be seven  
28 hundred fifteen dollars (\$715) and may be decreased to no less  
29 than five hundred fifty dollars (\$550).

30 (3) The annual renewal fee for a nonresident wholesaler license  
31 or third-party logistics provider license issued pursuant to Section  
32 4161 shall be seven hundred eighty dollars (\$780) and may be  
33 decreased to no less than six hundred dollars (\$600).

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

37 (l) The fee for an intern pharmacist license shall be ninety dollars  
38 (\$90) and may be increased to one hundred fifteen dollars (\$115).  
39 The fee for transfer of intern hours or verification of licensure to

1 another state shall be twenty-five dollars (\$25) and may be  
2 increased to thirty dollars (\$30).

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

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

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

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

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

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

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

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

38 (u) The fee for issuance or renewal of a nongovernmental sterile  
39 compounding pharmacy license shall be six hundred dollars (\$600)  
40 and may be increased to seven hundred eighty dollars (\$780). The

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

3 (v) The fee for the issuance or renewal of a nonresident sterile  
4 compounding pharmacy license shall be seven hundred eighty  
5 dollars (\$780). In addition to paying that application fee, the  
6 nonresident sterile compounding pharmacy shall deposit, when  
7 submitting the application, a reasonable amount, as determined by  
8 the board, necessary to cover the board's estimated cost of  
9 performing the inspection required by Section 4127.2. If the  
10 required deposit is not submitted with the application, the  
11 application shall be deemed to be incomplete. If the actual cost of  
12 the inspection exceeds the amount deposited, the board shall  
13 provide to the applicant a written invoice for the remaining amount  
14 and shall not take action on the application until the full amount  
15 has been paid to the board. If the amount deposited exceeds the  
16 amount of actual and necessary costs incurred, the board shall  
17 remit the difference to the applicant.

18 (w) The fee for the issuance or renewal of an outsourcing facility  
19 license shall be seven hundred eighty dollars (\$780). The fee for  
20 a temporary outsourcing facility license shall be seven hundred  
21 fifteen dollars (\$715).

22 (x) The fee for the issuance or renewal of a nonresident  
23 outsourcing facility license shall be seven hundred eighty dollars  
24 (\$780). In addition to paying that application fee, the nonresident  
25 outsourcing facility shall deposit, when submitting the application,  
26 a reasonable amount, as determined by the board, necessary to  
27 cover the board's estimated cost of performing the inspection  
28 required by Section 4129.2. If the required deposit is not submitted  
29 with the application, the application shall be deemed to be  
30 incomplete. If the actual cost of the inspection exceeds the amount  
31 deposited, the board shall provide to the applicant a written invoice  
32 for the remaining amount and shall not take action on the  
33 application until the full amount has been paid to the board. If the  
34 amount deposited exceeds the amount of actual and necessary  
35 costs incurred, the board shall remit the difference to the applicant.

36 *SEC. 20. Section 4406 of the Business and Professions Code*  
37 *is amended to read:*

38 4406. All fees collected on behalf of the board and all receipts  
39 of every kind and nature shall be reported each month for the month  
40 preceding to the State Controller and at the same time the entire

1 amount shall be paid into the State Treasury and shall be credited  
2 to the Pharmacy Board Contingent Fund which is hereby created.  
3 This contingent fund shall be *available, upon appropriation of the*  
4 *Legislature*, for the use of the board and out of it and not otherwise  
5 shall be paid all expenses of the board.

6 ~~SEC. 9.~~

7 *SEC. 21.* Section 13401.5 of the Corporations Code is amended  
8 to read:

9 13401.5. Notwithstanding subdivision (d) of Section 13401  
10 and any other provision of law, the following licensed persons  
11 may be shareholders, officers, directors, or professional employees  
12 of the professional corporations designated in this section so long  
13 as the sum of all shares owned by those licensed persons does not  
14 exceed 49 percent of the total number of shares of the professional  
15 corporation so designated herein, and so long as the number of  
16 those licensed persons owning shares in the professional  
17 corporation so designated herein does not exceed the number of  
18 persons licensed by the governmental agency regulating the  
19 designated professional corporation. This section does not limit  
20 employment by a professional corporation designated in this section  
21 to only those licensed professionals listed under each subdivision.  
22 Any person duly licensed under Division 2 (commencing with  
23 Section 500) of the Business and Professions Code, the  
24 Chiropractic Act, or the Osteopathic Act may be employed to  
25 render professional services by a professional corporation  
26 designated in this section.

27 (a) Medical corporation.

- 28 (1) Licensed doctors of podiatric medicine.
- 29 (2) Licensed psychologists.
- 30 (3) Registered nurses.
- 31 (4) Licensed optometrists.
- 32 (5) Licensed marriage and family therapists.
- 33 (6) Licensed clinical social workers.
- 34 (7) Licensed physician assistants.
- 35 (8) Licensed chiropractors.
- 36 (9) Licensed acupuncturists.
- 37 (10) Naturopathic doctors.
- 38 (11) Licensed professional clinical counselors.
- 39 (12) Licensed physical therapists.
- 40 (13) Licensed pharmacists.

- 1 (b) Podiatric medical corporation.
- 2 (1) Licensed physicians and surgeons.
- 3 (2) Licensed psychologists.
- 4 (3) Registered nurses.
- 5 (4) Licensed optometrists.
- 6 (5) Licensed chiropractors.
- 7 (6) Licensed acupuncturists.
- 8 (7) Naturopathic doctors.
- 9 (8) Licensed physical therapists.
- 10 (c) Psychological corporation.
- 11 (1) Licensed physicians and surgeons.
- 12 (2) Licensed doctors of podiatric medicine.
- 13 (3) Registered nurses.
- 14 (4) Licensed optometrists.
- 15 (5) Licensed marriage and family therapists.
- 16 (6) Licensed clinical social workers.
- 17 (7) Licensed chiropractors.
- 18 (8) Licensed acupuncturists.
- 19 (9) Naturopathic doctors.
- 20 (10) Licensed professional clinical counselors.
- 21 (d) Speech-language pathology corporation.
- 22 (1) Licensed audiologists.
- 23 (e) Audiology corporation.
- 24 (1) Licensed speech-language pathologists.
- 25 (f) Nursing corporation.
- 26 (1) Licensed physicians and surgeons.
- 27 (2) Licensed doctors of podiatric medicine.
- 28 (3) Licensed psychologists.
- 29 (4) Licensed optometrists.
- 30 (5) Licensed marriage and family therapists.
- 31 (6) Licensed clinical social workers.
- 32 (7) Licensed physician assistants.
- 33 (8) Licensed chiropractors.
- 34 (9) Licensed acupuncturists.
- 35 (10) Naturopathic doctors.
- 36 (11) Licensed professional clinical counselors.
- 37 (g) Marriage and family therapist corporation.
- 38 (1) Licensed physicians and surgeons.
- 39 (2) Licensed psychologists.
- 40 (3) Licensed clinical social workers.

- 1 (4) Registered nurses.
- 2 (5) Licensed chiropractors.
- 3 (6) Licensed acupuncturists.
- 4 (7) Naturopathic doctors.
- 5 (8) Licensed professional clinical counselors.
- 6 (h) Licensed clinical social worker corporation.
- 7 (1) Licensed physicians and surgeons.
- 8 (2) Licensed psychologists.
- 9 (3) Licensed marriage and family therapists.
- 10 (4) Registered nurses.
- 11 (5) Licensed chiropractors.
- 12 (6) Licensed acupuncturists.
- 13 (7) Naturopathic doctors.
- 14 (8) Licensed professional clinical counselors.
- 15 (i) Physician assistants corporation.
- 16 (1) Licensed physicians and surgeons.
- 17 (2) Registered nurses.
- 18 (3) Licensed acupuncturists.
- 19 (4) Naturopathic doctors.
- 20 (j) Optometric corporation.
- 21 (1) Licensed physicians and surgeons.
- 22 (2) Licensed doctors of podiatric medicine.
- 23 (3) Licensed psychologists.
- 24 (4) Registered nurses.
- 25 (5) Licensed chiropractors.
- 26 (6) Licensed acupuncturists.
- 27 (7) Naturopathic doctors.
- 28 (k) Chiropractic corporation.
- 29 (1) Licensed physicians and surgeons.
- 30 (2) Licensed doctors of podiatric medicine.
- 31 (3) Licensed psychologists.
- 32 (4) Registered nurses.
- 33 (5) Licensed optometrists.
- 34 (6) Licensed marriage and family therapists.
- 35 (7) Licensed clinical social workers.
- 36 (8) Licensed acupuncturists.
- 37 (9) Naturopathic doctors.
- 38 (10) Licensed professional clinical counselors.
- 39 (l) Acupuncture corporation.
- 40 (1) Licensed physicians and surgeons.

- 1 (2) Licensed doctors of podiatric medicine.
- 2 (3) Licensed psychologists.
- 3 (4) Registered nurses.
- 4 (5) Licensed optometrists.
- 5 (6) Licensed marriage and family therapists.
- 6 (7) Licensed clinical social workers.
- 7 (8) Licensed physician assistants.
- 8 (9) Licensed chiropractors.
- 9 (10) Naturopathic doctors.
- 10 (11) Licensed professional clinical counselors.
- 11 (m) Naturopathic doctor corporation.
- 12 (1) Licensed physicians and surgeons.
- 13 (2) Licensed psychologists.
- 14 (3) Registered nurses.
- 15 (4) Licensed physician assistants.
- 16 (5) Licensed chiropractors.
- 17 (6) Licensed acupuncturists.
- 18 (7) Licensed physical therapists.
- 19 (8) Licensed doctors of podiatric medicine.
- 20 (9) Licensed marriage and family therapists.
- 21 (10) Licensed clinical social workers.
- 22 (11) Licensed optometrists.
- 23 (12) Licensed professional clinical counselors.
- 24 (n) Dental corporation.
- 25 (1) Licensed physicians and surgeons.
- 26 (2) Dental assistants.
- 27 (3) Registered dental assistants.
- 28 (4) Registered dental assistants in extended functions.
- 29 (5) Registered dental hygienists.
- 30 (6) Registered dental hygienists in extended functions.
- 31 (7) Registered dental hygienists in alternative practice.
- 32 (o) Professional clinical counselor corporation.
- 33 (1) Licensed physicians and surgeons.
- 34 (2) Licensed psychologists.
- 35 (3) Licensed clinical social workers.
- 36 (4) Licensed marriage and family therapists.
- 37 (5) Registered nurses.
- 38 (6) Licensed chiropractors.
- 39 (7) Licensed acupuncturists.
- 40 (8) Naturopathic doctors.

- 1 (p) Physical therapy corporation.
- 2 (1) Licensed physicians and surgeons.
- 3 (2) Licensed doctors of podiatric medicine.
- 4 (3) Licensed acupuncturists.
- 5 (4) Naturopathic doctors.
- 6 (5) Licensed occupational therapists.
- 7 (6) Licensed speech-language therapists.
- 8 (7) Licensed audiologists.
- 9 (8) Registered nurses.
- 10 (9) Licensed psychologists.
- 11 (10) Licensed physician assistants.
- 12 (q) Registered dental hygienist in alternative practice
- 13 corporation.
- 14 (1) Registered dental assistants.
- 15 (2) Licensed dentists.
- 16 (3) Registered dental hygienists.
- 17 (4) Registered dental hygienists in extended functions.
- 18 *SEC. 22. Section 1261.6 of the Health and Safety Code is*
- 19 *amended to read:*
- 20 1261.6. (a) (1) For purposes of this section and Section 1261.5,
- 21 an “automated drug delivery system” means a mechanical system
- 22 that performs operations or activities, other than compounding or
- 23 administration, relative to the storage, dispensing, or distribution
- 24 of drugs. An automated drug delivery system shall collect, control,
- 25 and maintain all transaction information to accurately track the
- 26 movement of drugs into and out of the system for security,
- 27 accuracy, and accountability.
- 28 (2) For purposes of this section, “facility” means a health facility
- 29 licensed pursuant to subdivision (c), (d), or (k), of Section 1250
- 30 that has an automated drug delivery system provided by a
- 31 pharmacy.
- 32 (3) For purposes of this section, “pharmacy services” means
- 33 the provision of both routine and emergency drugs and biologicals
- 34 to meet the needs of the patient, as prescribed by a physician.
- 35 (b) Transaction information shall be made readily available in
- 36 a written format for review and inspection by individuals
- 37 authorized by law. These records shall be maintained in the facility
- 38 for a minimum of three years.

1 (c) Individualized and specific access to automated drug delivery  
2 systems shall be limited to facility and contract personnel  
3 authorized by law to administer drugs.

4 (d) (1) The facility and the pharmacy shall develop and  
5 implement written policies and procedures to ensure safety,  
6 accuracy, accountability, security, patient confidentiality, and  
7 maintenance of the quality, potency, and purity of stored drugs.  
8 Policies and procedures shall define access to the automated drug  
9 delivery system and limits to access to equipment and drugs.

10 (2) All policies and procedures shall be maintained at the  
11 pharmacy operating the automated drug delivery system and the  
12 location where the automated drug delivery system is being used.

13 (e) When used as an emergency pharmaceutical supplies  
14 container, drugs removed from the automated drug delivery system  
15 shall be limited to the following:

16 (1) A new drug order given by a prescriber for a patient of the  
17 facility for administration prior to the next scheduled delivery from  
18 the pharmacy, or 72 hours, whichever is less. The drugs shall be  
19 retrieved only upon authorization by a pharmacist and after the  
20 pharmacist has reviewed the prescriber's order and the patient's  
21 profile for potential contraindications and adverse drug reactions.

22 (2) Drugs that a prescriber has ordered for a patient on an  
23 as-needed basis, if the utilization and retrieval of those drugs are  
24 subject to ongoing review by a pharmacist.

25 (3) Drugs designed by the patient care policy committee or  
26 pharmaceutical service committee of the facility as emergency  
27 drugs or acute onset drugs. These drugs may be retrieved from an  
28 automated drug delivery system pursuant to the order of a  
29 prescriber for emergency or immediate administration to a patient  
30 of the facility. Within 48 hours after retrieval under this paragraph,  
31 the case shall be reviewed by a pharmacist.

32 (f) When used to provide pharmacy services pursuant to Section  
33 4119.1 of the Business and Professions Code, the automated drug  
34 delivery system shall be subject to all of the following  
35 requirements:

36 (1) Drugs removed from the automated drug delivery system  
37 for administration to a patient shall be in properly labeled units of  
38 administration containers or packages.

39 (2) A pharmacist shall review and approve all orders prior to a  
40 drug being removed from the automated drug delivery system for

1 administration to a patient. The pharmacist shall review the  
2 prescriber's order and the patient's profile for potential  
3 contraindications and adverse drug reactions.

4 (3) The pharmacy providing services to the facility pursuant to  
5 Section 4119.1 of the Business and Professions Code shall control  
6 access to the drugs stored in the automated drug delivery system.

7 (4) Access to the automated drug delivery system shall be  
8 controlled and tracked using an identification or password system  
9 or biosensor.

10 (5) The automated drug delivery system shall make a complete  
11 and accurate record of all transactions that will include all users  
12 accessing the system and all drugs added to, or removed from, the  
13 system.

14 (6) After the pharmacist reviews the prescriber's order, access  
15 by licensed personnel to the automated drug delivery system shall  
16 be limited only to drugs ordered by the prescriber and reviewed  
17 by the pharmacist and that are specific to the patient. When the  
18 prescriber's order requires a dosage variation of the same drug,  
19 licensed personnel shall have access to the drug ordered for that  
20 scheduled time of administration.

21 (7) (A) Systems that allow licensed personnel to have access  
22 to multiple drugs and are not patient specific in their design, shall  
23 be allowed under this subdivision if those systems have electronic  
24 and mechanical safeguards in place to ensure that the drugs  
25 delivered to the patient are specific to that patient. Each facility  
26 using such an automated drug system shall notify the department  
27 in writing prior to the utilization of the system. The notification  
28 submitted to the department pursuant to this paragraph shall  
29 include, but is not limited to, information regarding system design,  
30 personnel with system access, and policies and procedures covering  
31 staff training, storage, and security, and the facility's administration  
32 of these types of systems.

33 (B) As part of its routine oversight of these facilities, the  
34 department shall review a facility's medication training, storage,  
35 and security, and its administration procedures related to its use  
36 of an automated drug delivery system to ensure that adequate staff  
37 training and safeguards are in place to make sure that the drugs  
38 delivered are appropriate for the patient. If the department  
39 determines that a facility is not in compliance with this section,

1 the department may revoke its authorization to use automated drug  
2 delivery systems granted under subparagraph (A).

3 ~~(C) This paragraph shall remain in effect only until January 1,~~  
4 ~~2012, unless a later enacted statute is enacted on or before January~~  
5 ~~1, 2012, deletes or extends that date.~~

6 (g) The stocking of an automated drug delivery system shall be  
7 performed by a pharmacist. If the automated drug delivery system  
8 utilizes removable pockets, cards, drawers, or similar technology,  
9 the stocking system may be done outside of the facility and be  
10 delivered to the facility if all of the following conditions are met:

11 (1) The task of placing drugs into the removable pockets, cards,  
12 or drawers is performed by a pharmacist or by an intern pharmacist  
13 or a pharmacy technician working under the direct supervision of  
14 a pharmacist.

15 (2) The removable pockets, cards, or drawers are transported  
16 between the pharmacy and the facility in a secure tamper-evident  
17 container.

18 (3) The facility, in conjunction with the pharmacy, has  
19 developed policies and procedures to ensure that the pockets, cards,  
20 or drawers are properly placed into the automated drug delivery  
21 system.

22 (h) Review of the drugs contained within, and the operation and  
23 maintenance of, the automated drug delivery system shall be done  
24 in accordance with law and shall be the responsibility of the  
25 pharmacy. The review shall be conducted on a monthly basis by  
26 a pharmacist and shall include a physical inspection of the drugs  
27 in the automated drug delivery system, an inspection of the  
28 automated drug delivery system machine for cleanliness, and a  
29 review of all transaction records in order to verify the security and  
30 accountability of the system.

31 (i) Drugs dispensed from an automated drug delivery system  
32 that meets the requirements of this section shall not be subject to  
33 the labeling requirements of Section 4076 of the Business and  
34 Professions Code or Section 111480 of this code if the drugs to  
35 be placed into the automated drug delivery system are in unit dose  
36 packaging or unit of use and if the information required by Section  
37 4076 of the Business and Professions Code and Section 111480  
38 of this code is readily available at the time of drug administration.  
39 For purposes of this section, unit dose packaging includes blister  
40 pack cards.

1     *SEC. 23. Section 11164.5 of the Health and Safety Code is*  
2 *amended to read:*

3     ~~11164.5. (a) Notwithstanding Section 11164, with the approval~~  
4 ~~of the California State Board of Pharmacy and the Department of~~  
5 ~~Justice, a pharmacy or hospital may receive electronic data~~  
6 ~~transmission prescriptions or computer entry prescriptions or orders~~  
7 ~~as specified in Section 4071.1 of the Business and Professions~~  
8 ~~Code, for controlled substances in Schedule II, III, IV, or V if~~  
9 ~~authorized by federal law and in accordance with regulations~~  
10 ~~promulgated by the Drug Enforcement Administration. The~~  
11 ~~California State Board of Pharmacy shall maintain a list of all~~  
12 ~~requests and approvals granted pursuant to this subdivision.~~

13     ~~(b) Notwithstanding Section 11164, if approved pursuant to~~  
14 ~~subdivision (a), a pharmacy or hospital receiving an electronic~~  
15 ~~transmission prescription or a computer entry prescription or order~~  
16 ~~for a controlled substance classified in Schedule II, III, IV, or V~~  
17 ~~shall not be required to reduce that prescription or order to writing~~  
18 ~~or to hard copy form, if for three years from the last day of~~  
19 ~~dispensing that prescription, the pharmacy or hospital is able, upon~~  
20 ~~request of the board or the Department of Justice, to immediately~~  
21 ~~produce a hard copy report that includes for each date of dispensing~~  
22 ~~of a controlled substance in Schedules II, III, IV, and V pursuant~~  
23 ~~to the prescription all of the information described in subparagraphs~~  
24 ~~(A) to (E), inclusive, of paragraph (1) of subdivision (a) of Section~~  
25 ~~4040 of the Business and Professions Code and the name or~~  
26 ~~identifier of the pharmacist who dispensed the controlled substance.~~

27     ~~(c)~~

28     ~~11164.5. (a) Notwithstanding Section 11164, if only recorded~~  
29 ~~and stored electronically, on magnetic media, or in any other~~  
30 ~~computerized form, the pharmacy's or hospital's computer system~~  
31 ~~shall not permit the received information or the controlled~~  
32 ~~substance dispensing information required by this section to be~~  
33 ~~changed, obliterated, destroyed, or disposed of, for the record~~  
34 ~~maintenance period required by law, once the information has been~~  
35 ~~received by the pharmacy or the hospital and once the controlled~~  
36 ~~substance has been dispensed, respectively. Once the controlled~~  
37 ~~substance has been dispensed, if the previously created record is~~  
38 ~~determined to be incorrect, a correcting addition may be made~~  
39 ~~only by or with the approval of a pharmacist. After a pharmacist~~  
40 ~~enters the change or enters his or her approval of the change into~~

1 the computer, the resulting record shall include the correcting  
2 addition and the date it was made to the record, the identity of the  
3 person or pharmacist making the correction, and the identity of  
4 the pharmacist approving the correction.

5 ~~(d)~~

6 (b) Nothing in this section shall be construed to exempt any  
7 pharmacy or hospital dispensing Schedule II controlled substances  
8 pursuant to electronic transmission prescriptions from existing  
9 reporting requirements.

10 ~~SEC. 10.~~

11 *SEC. 24.* No reimbursement is required by this act pursuant to  
12 Section 6 of Article XIII B of the California Constitution because  
13 the only costs that may be incurred by a local agency or school  
14 district will be incurred because this act creates a new crime or  
15 infraction, eliminates a crime or infraction, or changes the penalty  
16 for a crime or infraction, within the meaning of Section 17556 of  
17 the Government Code, or changes the definition of a crime within  
18 the meaning of Section 6 of Article XIII B of the California  
19 Constitution.