

AMENDED IN ASSEMBLY AUGUST 1, 2016

AMENDED IN ASSEMBLY JUNE 21, 2016

AMENDED IN SENATE MAY 31, 2016

AMENDED IN SENATE APRIL 13, 2016

SENATE BILL

No. 1193

Introduced by Senator Hill

(Principal coauthor: Assembly Member Salas)

(Coauthor: Assembly Member Brough)

February 18, 2016

An act to amend Sections 4001, 4003, *4013*, 4081, 4107, 4110, 4119.1, 4127, 4127.3, 4127.7, 4127.8, 4127.9, 4128.6, 4161, 4180, 4201, *4301*, 4312, 4400, 4406, 4800, 4804.5, 4830, 4846.5, 4904, and 4905 of, to add Sections 4034, 4105.5, 4126.9, 4203.5, *4301.1*, 4303.1, 4316, 4826.5, 4848.1, and ~~4853.7~~, *4853.7* to, and to add Article 7.7 (commencing with Section 4129) to Chapter 9 of Division 2 of, the Business and Professions Code, 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.

LEGISLATIVE COUNSEL'S DIGEST

SB 1193, as amended, Hill. Healing arts.

(1) 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.

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 requires each application to conduct a pharmacy, wholesaler, 3rd-party logistics provider, or veterinary food-animal drug retailer to be made on a form furnished by the board and to state specified information. That law requires the executive officer to issue a license to conduct a pharmacy, wholesaler, 3rd-party logistics provider, or veterinary food-animal drug retailer, if specified conditions are met. That law authorizes the board to cancel a license if the licensed premises remains closed, as defined, other than by order of the board. That law requires a licensee whose license is canceled or who notifies the board of its intent to remain closed or to discontinue business to arrange for the transfer of all dangerous drugs and controlled substances or dangerous devices to another licensee within 10 days. That law authorizes the board to seek and obtain a specified court order authorizing the board to enter the premises, and inventory and store, transfer, sell, or arrange for the sale of, all dangerous drugs and controlled substances and dangerous devices found in the premises if the licensee does not comply with the requirement to do so.

This bill would require an outsourcing facility, as defined, to be licensed with the board before doing business within or into the state. The bill would require each application to conduct an outsourcing facility to be made on a form furnished by the board and to state specified information. The bill would require the executive officer to issue a license if specified conditions are met. The bill would prohibit an outsourcing facility from being concurrently licensed with the board as a sterile compounding pharmacy at the same location. The bill 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 (*FDA*) within 10 days of the action. The bill would prohibit the issuance or renewal of an outsourcing facility *license* until the board inspects the location of an outsourcing facility to ensure that the outsourcing facility is in compliance with all laws and regulations. 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 immediately cancel, revoke, or suspend by operation of law the license of any nonresident outsourcing facility whose registration is canceled, revoked, or suspended by the

FDA. The bill would authorize the board to cancel an outsourcing facility license if the outsourcing facility remains closed, as defined, other than by order of the board. The bill would require an outsourcing facility licensee whose license is canceled or who notifies the board of its intent to remain closed or to discontinue business to arrange for the transfer of all dangerous drugs and controlled substances or dangerous devices to another licensee within 10 days. The bill would authorize the board to seek and obtain a specified court order authorizing the board to enter the outsourcing facility, and inventory and store, transfer, sell, or arrange for the sale of, all dangerous drugs and controlled substances and dangerous devices found in the outsourcing facility if the licensee does not comply with the requirement to do so. 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 Pharmacy Law requires a facility licensed by the board to join the board's email notification list within 60 days of obtaining a license or at the time of license renewal and requires a facility to update its email address within 30 days of a change in the facility's email address.

This bill would require each pharmacist, intern pharmacist, pharmacy technician, designated representative, and designated representative of a 3rd-party logistics provider licensed in this state to join the board's email notification list within 60 days of obtaining a license or at the time of license renewal and to update the licensee's email address within 30 days of a change in the licensee's email address. The bill would prohibit the board from posting those email addresses on the board's license verification system. The bill would make these provisions operative on July 1, 2017.

The Pharmacy Law requires the board to take action against any licensee who is guilty of unprofessional conduct or whose license has been procured by fraud or misrepresentation or by mistake and includes, among others, gross immorality as unprofessional conduct. That law also includes the revocation, suspension, or other discipline by another state of a license to practice pharmacy, operate a pharmacy, or do any other act for which a license is required under the Pharmacy Law as grounds for unprofessional conduct.

This bill would delete gross immorality as unprofessional conduct and instead provide that procurement of a license by fraud or misrepresentation is unprofessional conduct. This bill would require that revocation, suspension, or other discipline by another state as the

basis for similar action under the pharmacy law be grounds for revocation, suspension, or other discipline under the Pharmacy Law and requires the board to take action coterminously with action taken by another state. The bill would authorize the board to exceed the term of discipline of another state consistent with the board's enforcement guidelines and provide that evidence of discipline by another state is conclusive proof of unprofessional conduct. The bill would also require the board, to ensure that its resources are maximized for the protection of the public health and safety, to prioritize its investigative and prosecutorial resources to ensure that pharmacists representing the greatest threat of actual patient harm are identified and disciplined expeditiously.

The Pharmacy 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 authorize the board to collect a fee of ~~\$4000~~ \$2,270 for the issuance ~~and renewal~~ of an outsourcing ~~license~~ facility license, which may be increased to up to \$3,180 by the board, a fee of \$1,325 for the renewal of that license, which may be increased to up to \$1,855 by the board, and a fee of \$715 for a temporary outsourcing facility license, as specified. ~~This~~ The bill would authorize the board to collect a fee of \$2,380 for the issuance of a nonresident outsourcing facility license, which may be increased to up to \$3,335 by the board, and a fee of \$2,270 for the renewal of that license, which may be increased to up to \$3,180 by the board, as specified. The bill would provide that the Pharmacy Board Contingent Fund is available for expenditure only upon an appropriation by the Legislature.

The Pharmacy Law requires all records of manufacture, and of sale, acquisition, receipt, shipment, or disposition of dangerous drugs or dangerous devices to be at all times, during business hours, open to inspection by authorized officers of the law, and to be preserved for at least 3 years from the date of making. That law requires specified entities and individuals to keep a current inventory of these records.

This bill would require *an* outsourcing facility to keep a current inventory of these records.

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.

This 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.

This bill would require a pharmacy that owns or provides dangerous drugs dispensed through an automated drug delivery system to register the system by providing the board in writing with the location of each automated drug delivery system within 30 days of installation and on an annual basis as part of the license renewal. The bill would also require the pharmacy to advise the board in writing within 30 days if the pharmacy discontinues operating an automated drug delivery system. The bill would exempt from these requirements an automated drug delivery system operated by a licensed hospital pharmacy for doses administered in a facility operated under a consolidated license. The bill would authorize a pharmacy to use an automated drug delivery system only if certain conditions are satisfied, including, among other conditions, that the pharmacy report to the board drug losses from the system. The bill would authorize the board to prohibit a pharmacy from using an automated drug delivery system if the board determines that those conditions are not satisfied. The bill would require the board to provide the pharmacy with written notice, as specified, if the board determines those conditions are not satisfied. The bill would authorize the pharmacy, within 30 days of receipt of the written notice, to request an office conference to appeal the board's decision. The bill would authorize the executive officer or designee to affirm or overturn the prohibition as a result of the office conference.

The Pharmacy 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. *Existing law authorizes the stocking of an automated drug delivery*

system to be done outside the facility if the automated drug delivery system utilizes removable pockets, cards, drawers, or similar technology and if certain conditions are met, including that the removable pockets, cards, or drawers are transported in a secured tamper-evident container.

This bill would make these provisions operative by repealing the provision that made them inoperative on January 1, 2012. *The bill would additionally authorize the stocking of an automated drug delivery system to be done outside the facility if the system utilizes unit of use or single dose containers, as specified.*

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.

This 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.

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. 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, as specified, 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.

This 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 Pharmacy 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. That 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 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.

(2) The Veterinary Medicine Practice Act provides for the licensure and registration of veterinarians and registered veterinary technicians and the regulation of the practice of veterinary medicine by the Veterinary Medical Board, which is within the Department of Consumer Affairs, and authorizes the board to appoint an executive officer, as specified.

Existing law repeals the provisions establishing the board and authorizing the board to appoint an executive officer as of January 1, 2017.

This bill would extend the operation of the board and the authorization of the board to appoint an executive officer until January 1, 2021. The bill would authorize a veterinarian or registered veterinary technician who is under the direct supervision of a licensed veterinarian to compound a drug for animal use pursuant to federal law and regulations promulgated by the board and would require those regulations to, at a minimum, address the storage of drugs, the level and type of supervision required for compounding drugs by a registered veterinary technician, and the equipment necessary for safe compounding of drugs.

The Veterinary Medicine Practice Act exempts certain persons from the requirements of the act, including a veterinarian employed by the University of California or the Western University of Health Sciences while engaged in the performance of specified duties. That act requires all premises where veterinary medicine, dentistry, and surgery is being practiced to register with the board.

~~The~~

This bill would instead require ~~veterinarians~~ a veterinarian engaged in the practice of veterinary medicine employed by the University of California or by the Western University of Health Sciences and engaged in the performance of specified duties to be licensed as a veterinarian in the state or be issued a university license, as specified. The bill would authorize an individual to apply for and be issued a university license if he or she meets certain requirements, including paying an application and license fee. The bill would require a university license, among other things, to automatically cease to be valid upon termination or cessation of employment by the University of California or the Western University of Health Sciences. The bill would also prohibit a premise registration that is not renewed within 5 years after its expiration from being renewed, restored, reissued, or reinstated; however, the bill would authorize a new premise registration to be issued to an applicant if no fact, circumstance, or condition exists that would justify the revocation or suspension of the registration if the registration was issued and if specified fees are paid.

The Veterinary Medicine Practice Act requires all fees collected on behalf of the board to be deposited into the Veterinary Medical Board Contingent Fund, which continuously appropriates fees deposited into the fund.

This bill would provide that the Veterinary Medical Board Contingent Fund is available for expenditure only upon an appropriation by the Legislature.

(3) The Pharmacy Law makes a violation of any of its provisions punishable as an infraction if no other penalty is provided. The Veterinary Medicine Practice Act makes a violation of any of its provisions punishable as a misdemeanor.

By placing new requirements on a pharmacy, this bill would expand an existing crime and would, therefore, impose a state-mandated local program. The bill would also expand the definition of an existing crime and, therefore, result in a state-mandated local program by requiring additional persons to be licensed under the act that were previously exempt.

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. 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

1 also include a pharmacist who is a member of a labor union that
2 represents pharmacists. For the purposes of this subdivision, a
3 “chain community pharmacy” means a chain of 75 or more stores
4 in California under the same ownership, and an “independent
5 community pharmacy” means a pharmacy owned by a person or
6 entity who owns no more than four pharmacies in California.

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

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

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

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

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

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

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

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

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

3 *SEC. 3. Section 4013 of the Business and Professions Code is*
4 *amended to read:*

5 4013. (a) Any facility licensed by the board shall join the
6 board's ~~e-mail~~ email notification list within 60 days of obtaining
7 a license or at the time of license renewal.

8 (b) Any facility licensed by the board shall update its ~~e-mail~~
9 email address with the board's ~~e-mail~~ email notification list within
10 30 days of a change in the facility's ~~e-mail~~ email address.

11 (c) An owner of two or more facilities licensed by the board
12 may comply with subdivisions (a) and (b) by subscribing a single
13 ~~e-mail~~ email address to the board's ~~e-mail~~ email notification list,
14 where the owner maintains an electronic notice system within all
15 of its licensed facilities that, upon receipt of an ~~e-mail~~ email
16 notification from the board, immediately transmits electronic notice
17 of the same notification to all of its licensed facilities. If an owner
18 chooses to comply with this section by using such an electronic
19 notice system, the owner shall register the electronic notice system
20 with the board by July 1, 2011, or within 60 days of initial
21 licensure, whichever is later, informing the board of the single
22 ~~e-mail~~ email address to be utilized by the owner, describing the
23 electronic notice system, and listing all facilities to which
24 immediate notice will be provided. The owner shall update its
25 ~~e-mail~~ email address with the board's ~~e-mail~~ email notification
26 list within 30 days of any change in the owner's ~~e-mail~~ email
27 address.

28 (d) (1) *Each pharmacist, intern pharmacist, pharmacy*
29 *technician, designated representative-3PL licensed in this state*
30 *shall join the board's email notification list within 60 days of*
31 *obtaining a license or at the time of license renewal.*

32 (2) *Each pharmacist, intern pharmacist, pharmacy technician,*
33 *designated representative, and designated representative-3PL*
34 *licensed in this state shall update his or her email address with*
35 *the board's email notification list within 30 days of a change in*
36 *the licensee's email address.*

37 (3) *The email address provided by a licensee shall not be posted*
38 *on the board's online license verification system.*

1 (4) The board shall, with each renewal application, remind
2 licensees of their obligation to report and keep current their email
3 address with the board's email notification list.

4 ~~(d)~~

5 (5) This ~~section~~ subdivision shall become operative on July 1,
6 ~~2010~~ 2017.

7 ~~SEC. 3.~~

8 SEC. 4. Section 4034 is added to the Business and Professions
9 Code, to read:

10 4034. "Outsourcing facility" means a facility that meets all of
11 the following:

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

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

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

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

21 ~~SEC. 4.~~

22 SEC. 5. Section 4081 of the Business and Professions Code is
23 amended to read:

24 4081. (a) All records of manufacture and of sale, acquisition,
25 receipt, shipment, or disposition of dangerous drugs or dangerous
26 devices shall be at all times during business hours open to
27 inspection by authorized officers of the law, and shall be preserved
28 for at least three years from the date of making. A current inventory
29 shall be kept by every manufacturer, wholesaler, third-party
30 logistics provider, pharmacy, veterinary food-animal drug retailer,
31 outsourcing facility, physician, dentist, podiatrist, veterinarian,
32 laboratory, clinic, hospital, institution, or establishment holding a
33 currently valid and unrevoked certificate, license, permit,
34 registration, or exemption under Division 2 (commencing with
35 Section 1200) of the Health and Safety Code or under Part 4
36 (commencing with Section 16000) of Division 9 of the Welfare
37 and Institutions Code who maintains a stock of dangerous drugs
38 or dangerous devices.

39 (b) The owner, officer, and partner of a pharmacy, wholesaler,
40 third-party logistics provider, or veterinary food-animal drug

1 retailer shall be jointly responsible, with the pharmacist-in-charge,
2 responsible manager, or designated representative-in-charge, for
3 maintaining the records and inventory described in this section.

4 (c) The pharmacist-in-charge, responsible manager, or
5 designated representative-in-charge shall not be criminally
6 responsible for acts of the owner, officer, partner, or employee
7 that violate this section and of which the pharmacist-in-charge,
8 responsible manager, or designated representative-in-charge had
9 no knowledge, or in which he or she did not knowingly participate.

10 ~~SEC. 5.~~

11 *SEC. 6.* Section 4105.5 is added to the Business and Professions
12 Code, to read:

13 4105.5. (a) For purposes of this section, an “automated drug
14 delivery system” has the same meaning as that term is defined in
15 paragraph (1) of subdivision (a) of Section 1261.6 of the Health
16 and Safety Code.

17 (b) Except as provided by subdivision (e), a pharmacy that owns
18 or provides dangerous drugs dispensed through an automated drug
19 delivery system shall register the automated drug delivery system
20 by providing the board in writing with the location of each device
21 within 30 days of installation of the device, and on an annual basis
22 as part of the license renewal pursuant to subdivision (a) of Section
23 4110. The pharmacy shall also advise the board in writing within
24 30 days if the pharmacy discontinues operating an automated drug
25 delivery system.

26 (c) A pharmacy may only use an automated drug delivery system
27 if all of the following conditions are satisfied:

28 (1) Use of the automated drug delivery system is consistent with
29 legal requirements.

30 (2) The pharmacy’s policies and procedures related to the
31 automated drug delivery system to include appropriate security
32 measures and monitoring of the inventory to prevent theft and
33 diversion.

34 (3) The pharmacy reports drug losses from the automated drug
35 delivery system to the board as required by law.

36 (4) The pharmacy license is unexpired and not subject to
37 disciplinary conditions.

38 (d) The board may prohibit a pharmacy from using an automated
39 drug delivery system if the board determines that the conditions
40 provided in subdivision (c) are not satisfied. If such a determination

1 is made, the board shall provide the pharmacy with written notice
2 including the basis for the determination. The pharmacy may
3 request an office conference to appeal the board’s decision within
4 30 days of receipt of the written notice. The executive officer or
5 designee may affirm or overturn the prohibition as a result of the
6 office conference.

7 (e) An automated drug delivery system operated by a licensed
8 hospital pharmacy as defined in Section 4029 for doses
9 administered in a facility operated under a consolidated license
10 under Section 1250.8 of the Health and Safety Code shall be
11 exempt from the requirements of subdivision (b).

12 ~~SEC. 6.~~

13 *SEC. 7.* Section 4107 of the Business and Professions Code is
14 amended to read:

15 4107. (a) The board shall not issue more than one site license
16 to a single premises except as follows:

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

19 (2) To issue a license to compound sterile drugs to a pharmacy
20 pursuant to Section 4127.1 or 4127.2.

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

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

26 ~~SEC. 7.~~

27 *SEC. 8.* 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 upon the conditions and for any periods of time as the board
39 determines to be in the public interest. A temporary permit fee
40 shall be required in an amount established by the board as specified

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

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

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

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

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

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

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

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

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

37 ~~SEC. 8.~~

38 *SEC. 9.* Section 4119.1 of the Business and Professions Code
39 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) This section shall not be construed to revise or limit the use
28 of automated drug delivery systems as permitted by the board in
29 any licensed health facility other than a facility defined in
30 subdivision (c) or (d), or both, of Section 1250 of the Health and
31 Safety Code.

32 ~~SEC. 9.~~

33 *SEC. 10.* Section 4126.9 is added to the Business and
34 Professions Code, to read:

35 4126.9. (a) A pharmacy that issues a recall notice regarding
36 a nonsterile compounded drug product shall, in addition to any
37 other duties, contact the recipient pharmacy, prescriber, or patient
38 of the recalled drug and the board within 12 hours of the recall
39 notice if both of the following apply:

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

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

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

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

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

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

16 (c) A pharmacy that has been advised that a patient has been
17 harmed by using a nonsterile compounded product potentially
18 attributable to the pharmacy shall report the event to MedWatch
19 within 72 hours of the pharmacy being advised.

20 ~~SEC. 10.~~

21 *SEC. 11.* Section 4127 of the Business and Professions Code
22 is amended to read:

23 4127. (a) A pharmacy that compounds sterile drug products
24 shall possess a sterile compounding pharmacy license as provided
25 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 ~~SEC. 11.~~

38 *SEC. 12.* 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 sterile drug products
4 poses an immediate threat to the public health or safety, the
5 executive officer of the board may issue an order to the pharmacy
6 to immediately cease and desist from compounding sterile drug
7 products. The cease and desist order shall remain in effect for no
8 more than 30 days or the date of a hearing seeking an interim
9 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. 12.~~

31 *SEC. 13.* Section 4127.7 of the Business and Professions Code
32 is amended to read:

33 4127.7. A pharmacy shall compound sterile products from one
34 or more nonsterile ingredients in one of the following
35 environments:

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

39 (b) An ISO class 5 cleanroom.

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

3 ~~SEC. 13.~~

4 *SEC. 14.* Section 4127.8 of the Business and Professions Code
5 is amended to read:

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

24 ~~SEC. 14.~~

25 *SEC. 15.* Section 4127.9 of the Business and Professions Code
26 is amended to read:

27 4127.9. (a) A pharmacy licensed pursuant to Section 4127.1
28 or 4127.2 that issues a recall notice regarding a sterile compounded
29 drug shall, in addition to any other duties, contact the recipient
30 pharmacy, prescriber, or patient of the recalled drug and the board
31 as soon as possible within 12 hours of the recall notice if both of
32 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. 15.~~

9 *SEC. 16.* Section 4128.6 of the Business and Professions Code
10 is amended to read:

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

17 ~~SEC. 16.~~

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

21
22 Article 7.7. Outsourcing Facilities

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

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

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

37 (d) The board shall review any formal requirements or guidance
38 documents developed by the FDA regarding outsourcing facilities
39 within 90 days after their release in order to determine whether

1 revisions are necessary for any regulations promulgated by the
2 board.

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

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

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

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

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

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

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

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

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

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

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

36 (3) A copy of any clinically related complaint it receives
37 involving an outsourcing facility's compounded products from or
38 involving any provider, pharmacy, or patient in California within
39 72 hours of receipt.

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

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

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

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

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

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

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

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

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

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

- 1 (1) A copy of any disciplinary or other action taken by another
- 2 state or the FDA within 10 days of the action.
- 3 (2) Notice within 24 hours of any recall notice issued by the
- 4 nonresident outsourcing facility.
- 5 (3) A copy of any complaint it receives involving an outsourcing
- 6 facility’s compounded products from or involving any provider,
- 7 pharmacy, or patient in California within 72 hours of receipt.
- 8 (4) Notice within 24 hours after learning of adverse effects
- 9 reported or potentially attributable to a nonresident outsourcing
- 10 facility’s products.
- 11 4129.3. (a) On or before January 1, 2018, the board shall
- 12 provide a report to the Legislature regarding the regulation of
- 13 nonresident outsourcing facilities. The report shall be submitted
- 14 to the Legislature in the manner required pursuant to Section 9795
- 15 of the Government Code. At a minimum, the report shall address
- 16 all of the following:
- 17 (1) A detailed description of board activities related to the
- 18 inspection and licensure of nonresident outsourcing facilities.
- 19 (2) Whether fee revenue collected pursuant to subdivision (x)
- 20 of Section 4400 and travel cost reimbursements collected pursuant
- 21 to subdivision (c) of Section 4129.2 provide revenue in an amount
- 22 sufficient to support the board’s activities related to the inspection
- 23 and licensure of nonresident outsourcing facilities.
- 24 (3) The status of proposed changes to federal law that are under
- 25 serious consideration and that would govern outsourcing facilities
- 26 and compounding pharmacies, including, but not limited to,
- 27 legislation pending before Congress, administrative rules,
- 28 regulations or orders under consideration by the FDA or other
- 29 appropriate federal agency, and cases pending before the courts.
- 30 (4) If applicable, recommended modifications to the board’s
- 31 statutory duties related to nonresident outsourcing facilities as a
- 32 result of changes to federal law or any additional modifications
- 33 necessary to protect the health and safety of the public.
- 34 (b) The requirement for submitting a report imposed under
- 35 subdivision (a) is inoperative on January 1, 2022, pursuant to
- 36 Section 10231.5 of the Government Code.
- 37 4129.4. (a) Whenever the board has a reasonable belief, based
- 38 on information obtained during an inspection or investigation by
- 39 the board, that an outsourcing facility compounding sterile drug
- 40 products or nonsterile drug products poses an immediate threat to

1 the public health or safety, the executive officer of the board may
2 issue an order to the outsourcing facility to immediately cease and
3 desist compounding sterile drug products or nonsterile drug
4 products. The cease and desist order shall remain in effect for no
5 more than 30 days or the date of a hearing seeking an interim
6 suspension order, whichever is earlier.

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

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

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

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

32 4129.8. The board, at its discretion, may issue a temporary
33 license to an outsourcing facility upon the conditions and for any
34 periods of time as the board determines to be in the public interest.
35 A temporary license fee shall be required as specified in
36 subdivision (w) of Section 4400. When needed to protect public
37 safety, a temporary license may be issued for a period not to exceed
38 180 days, and may be issued subject to terms and conditions the
39 board deems necessary. If the board determines a temporary license
40 was issued by mistake or denies the application for a permanent

1 license, the temporary license shall terminate upon the earlier of
2 personal service of the notice of termination upon the licenseholder
3 or service by certified mail with return receipt requested at the
4 licenseholder's address of record with the board. The temporary
5 licenseholder shall not be deemed to have a vested property right
6 or interest in the license for purposes of retaining a temporary
7 license or for purposes of any disciplinary or license denial
8 proceeding before the board.

9 4129.9. (a) An outsourcing facility licensed pursuant to Section
10 4129.1 or 4129.2 that issues a recall notice for a sterile drug or
11 nonsterile drug compounded by the outsourcing facility, in addition
12 to any other duties, shall contact the recipient pharmacy, prescriber,
13 or patient of the recalled drug and the board as soon as possible
14 within 24 hours of the recall notice if both of the following apply:

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

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

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

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

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

29 ~~SEC. 17.~~

30 *SEC. 18.* Section 4161 of the Business and Professions Code
31 is amended to read:

32 4161. (a) A person located outside this state that (1) ships,
33 sells, mails, warehouses, distributes, or delivers dangerous drugs
34 or dangerous devices into this state or (2) sells, brokers,
35 warehouses, or distributes dangerous drugs or devices within this
36 state shall be considered a nonresident wholesaler or a nonresident
37 third-party logistics provider.

38 (b) A nonresident wholesaler or nonresident third-party logistics
39 provider shall be licensed by the board prior to shipping, selling,
40 mailing, warehousing, distributing, or delivering dangerous drugs

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

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

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

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

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

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

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

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

39 (F) The third-party logistics provider is not a reverse third-party
40 logistics provider.

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

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

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

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

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

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

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

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

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

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

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

39 (2) The board shall not issue or renew a nonresident third-party
40 logistics provider license until the nonresident third-party logistics

1 provider identifies a responsible manager and notifies the board
2 in writing of the identity and license number of the designated
3 representative-3PL who will be the responsible manager.

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

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

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

36 ~~SEC. 18.~~

37 *SEC. 19.* Section 4180 of the Business and Professions Code
38 is amended to read:

39 4180. (a) (1) Notwithstanding any provision of this chapter,
40 any of the following clinics may purchase drugs at wholesale for

1 administration or dispensing, under the direction of a physician
2 and surgeon, to patients registered for care at the clinic:

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

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

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

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

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

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

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

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

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

33 ~~SEC. 19.~~

34 *SEC. 20.* Section 4201 of the Business and Professions Code
35 is amended to read:

36 4201. (a) Each application to conduct a pharmacy, wholesaler,
37 third-party logistics provider, veterinary food-animal drug retailer,
38 or outsourcing facility shall be made on a form furnished by the
39 board and shall state the name, address, usual occupation, and
40 professional qualifications, if any, of the applicant. If the applicant

1 is other than a natural person, the application shall state the
2 information as to each person beneficially interested therein.

3 (b) As used in this section, and subject to subdivision (c), the
4 term “person beneficially interested” means and includes:

5 (1) If the applicant is a partnership or other unincorporated
6 association, each partner or member.

7 (2) If the applicant is a corporation, each of its officers, directors,
8 and stockholders, provided that a natural person shall not be
9 deemed to be beneficially interested in a nonprofit corporation.

10 (3) If the applicant is a limited liability company, each officer,
11 manager, or member.

12 (c) If the applicant is a partnership or other unincorporated
13 association, a limited liability company, or a corporation, and the
14 number of partners, members, or stockholders, as the case may
15 be, exceeds five, the application shall so state, and shall further
16 state the information required by subdivision (a) as to each of the
17 five partners, members, or stockholders who own the five largest
18 interests in the applicant entity. Upon request by the executive
19 officer, the applicant shall furnish the board with the information
20 required by subdivision (a) as to partners, members, or stockholders
21 not named in the application, or shall refer the board to an
22 appropriate source of that information.

23 (d) The application shall contain a statement to the effect that
24 the applicant has not been convicted of a felony and has not
25 violated any of the provisions of this chapter. If the applicant
26 cannot make this statement, the application shall contain a
27 statement of the violation, if any, or reasons which will prevent
28 the applicant from being able to comply with the requirements
29 with respect to the statement.

30 (e) Upon the approval of the application by the board and
31 payment of the fee required by this chapter for each pharmacy,
32 wholesaler, third-party logistics provider, or veterinary food-animal
33 drug retailer, the executive officer of the board shall issue a license
34 to conduct a pharmacy, wholesaler, third-party logistics provider,
35 veterinary food-animal drug retailer, or outsourcing facility if all
36 of the provisions of this chapter have been complied with.

37 (f) Notwithstanding any other law, the pharmacy license shall
38 authorize the holder to conduct a pharmacy. The license shall be
39 renewed annually and shall not be transferable.

1 (g) Notwithstanding any other law, the wholesaler license shall
2 authorize the holder to wholesale dangerous drugs and dangerous
3 devices. The license shall be renewed annually and shall not be
4 transferable.

5 (h) Notwithstanding any other law, the third-party logistics
6 provider license shall authorize the holder to provide or coordinate
7 warehousing, distribution, or other similar services of dangerous
8 drugs and dangerous devices. The license shall be renewed annually
9 and shall not be transferable.

10 (i) Notwithstanding any other law, the veterinary food-animal
11 drug retailer license shall authorize the holder to conduct a
12 veterinary food-animal drug retailer and to sell and dispense
13 veterinary food-animal drugs as defined in Section 4042.

14 (j) For licenses referred to in subdivisions (f), (g), (h), and (i),
15 any change in the proposed beneficial ownership interest shall be
16 reported to the board within 30 days thereafter upon a form to be
17 furnished by the board.

18 ~~SEC. 20.~~

19 *SEC. 21.* Section 4203.5 is added to the Business and
20 Professions Code, to read:

21 4203.5. (a) Notwithstanding any other law, when a clinic
22 applicant submits either type of application described in subdivision
23 (b), the board shall issue a license or incorporate the reported
24 changes, as appropriate, within 30 days of receipt of a completed
25 application and payment of any prescribed fees.

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

- 27 (1) A new clinic license application filed under Section 4180.
- 28 (2) Applications to report changes to an existing site licensed
29 under Section 4180, including, but not limited to, changes in
30 professional director, clinic administrator, corporate officers,
31 change of location, or change of address.

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

36 *SEC. 22. Section 4301 of the Business and Professions Code*
37 *is amended to read:*

38 4301. The board shall take action against any holder of a license
39 who is guilty of unprofessional conduct or whose license has been
40 ~~procured by fraud or misrepresentation or~~ issued by mistake.

1 Unprofessional conduct shall include, but is not limited to, any of
2 the following:

3 ~~(a) Gross immorality.~~

4 (a) *Procurement of a license by fraud or misrepresentation.*

5 (b) Incompetence.

6 (c) Gross negligence.

7 (d) The clearly excessive furnishing of controlled substances
8 in violation of subdivision (a) of Section 11153 of the Health and
9 Safety Code.

10 (e) The clearly excessive furnishing of controlled substances in
11 violation of subdivision (a) of Section 11153.5 of the Health and
12 Safety Code. Factors to be considered in determining whether the
13 furnishing of controlled substances is clearly excessive shall
14 include, but not be limited to, the amount of controlled substances
15 furnished, the previous ordering pattern of the customer (including
16 size and frequency of orders), the type and size of the customer,
17 and where and to whom the customer distributes its product.

18 (f) The commission of any act involving moral turpitude,
19 dishonesty, fraud, deceit, or corruption, whether the act is
20 committed in the course of relations as a licensee or otherwise,
21 and whether the act is a felony or misdemeanor or not.

22 (g) Knowingly making or signing any certificate or other
23 document that falsely represents the existence or nonexistence of
24 a state of facts.

25 (h) The administering to oneself, of any controlled substance,
26 or the use of any dangerous drug or of alcoholic beverages to the
27 extent or in a manner as to be dangerous or injurious to oneself,
28 to a person holding a license under this chapter, or to any other
29 person or to the public, or to the extent that the use impairs the
30 ability of the person to conduct with safety to the public the practice
31 authorized by the license.

32 (i) Except as otherwise authorized by law, knowingly selling,
33 furnishing, giving away, or administering, or offering to sell,
34 furnish, give away, or administer, any controlled substance to an
35 addict.

36 (j) The violation of any of the statutes of this state, of any other
37 state, or of the United States regulating controlled substances and
38 dangerous drugs.

39 (k) The conviction of more than one misdemeanor or any felony
40 involving the use, consumption, or self-administration of any

1 dangerous drug or alcoholic beverage, or any combination of those
2 substances.

3 (l) The conviction of a crime substantially related to the
4 qualifications, functions, and duties of a licensee under this chapter.
5 The record of conviction of a violation of Chapter 13 (commencing
6 with Section 801) of Title 21 of the United States Code regulating
7 controlled substances or of a violation of the statutes of this state
8 regulating controlled substances or dangerous drugs shall be
9 conclusive evidence of unprofessional conduct. In all other cases,
10 the record of conviction shall be conclusive evidence only of the
11 fact that the conviction occurred. The board may inquire into the
12 circumstances surrounding the commission of the crime, in order
13 to fix the degree of discipline or, in the case of a conviction not
14 involving controlled substances or dangerous drugs, to determine
15 if the conviction is of an offense substantially related to the
16 qualifications, functions, and duties of a licensee under this chapter.
17 A plea or verdict of guilty or a conviction following a plea of nolo
18 contendere is deemed to be a conviction within the meaning of
19 this provision. The board may take action when the time for appeal
20 has elapsed, or the judgment of conviction has been affirmed on
21 appeal or when an order granting probation is made suspending
22 the imposition of sentence, irrespective of a subsequent order under
23 Section 1203.4 of the Penal Code allowing the person to withdraw
24 his or her plea of guilty and to enter a plea of not guilty, or setting
25 aside the verdict of guilty, or dismissing the accusation,
26 information, or indictment.

27 (m) The cash compromise of a charge of violation of Chapter
28 13 (commencing with Section 801) of Title 21 of the United States
29 Code regulating controlled substances or of Chapter 7
30 (commencing with Section 14000) of Part 3 of Division 9 of the
31 Welfare and Institutions Code relating to the Medi-Cal program.
32 ~~The record of the compromise is conclusive evidence of~~
33 ~~unprofessional conduct.~~

34 (n) The revocation, suspension, or other discipline by another
35 state of a license to practice pharmacy, operate a pharmacy, or do
36 any other act for which a license is required by this ~~chapter.~~ *chapter*
37 *that would be grounds for revocation, suspension, or other*
38 *discipline under this chapter. Any disciplinary action taken by the*
39 *board pursuant to this section shall be coterminous with action*
40 *taken by another state, except that the term of any discipline taken*

1 *by the board may exceed that of another state, consistent with the*
2 *board's enforcement guidelines. The evidence of discipline by*
3 *another state is conclusive proof of unprofessional conduct.*

4 (o) Violating or attempting to violate, directly or indirectly, or
5 assisting in or abetting the violation of or conspiring to violate any
6 provision or term of this chapter or of the applicable federal and
7 state laws and regulations governing pharmacy, including
8 regulations established by the board or by any other state or federal
9 regulatory agency.

10 (p) Actions or conduct that would have warranted denial of a
11 license.

12 (q) Engaging in any conduct that subverts or attempts to subvert
13 an investigation of the board.

14 (r) The selling, trading, transferring, or furnishing of drugs
15 obtained pursuant to Section 256b of Title 42 of the United States
16 Code to any person a licensee knows or reasonably should have
17 known, not to be a patient of a covered entity, as defined in
18 paragraph (4) of subsection (a) of Section 256b of Title 42 of the
19 United States Code.

20 (s) The clearly excessive furnishing of dangerous drugs by a
21 wholesaler to a pharmacy that primarily or solely dispenses
22 prescription drugs to patients of long-term care facilities. Factors
23 to be considered in determining whether the furnishing of
24 dangerous drugs is clearly excessive shall include, but not be
25 limited to, the amount of dangerous drugs furnished to a pharmacy
26 that primarily or solely dispenses prescription drugs to patients of
27 long-term care facilities, the previous ordering pattern of the
28 pharmacy, and the general patient population to whom the
29 pharmacy distributes the dangerous drugs. That a wholesaler has
30 established, and employs, a tracking system that complies with
31 the requirements of subdivision (b) of Section 4164 shall be
32 considered in determining whether there has been a violation of
33 this subdivision. This provision shall not be interpreted to require
34 a wholesaler to obtain personal medical information or be
35 authorized to permit a wholesaler to have access to personal
36 medical information except as otherwise authorized by Section 56
37 and following of the Civil Code. For purposes of this section,
38 "long-term care facility" shall have the same meaning given the
39 term in Section 1418 of the Health and Safety Code.

1 SEC. 23. Section 4301.1 is added to the Business and
2 Professions Code, to read:

3 4301.1. In order to ensure that the board’s resources are
4 maximized for the protection of the public health and safety, the
5 board shall prioritize its investigative and prosecutorial resources
6 to ensure that pharmacists representing the greatest threat of
7 actual patient harm are identified and disciplined expeditiously.

8 SEC. 24. Section 4303.1 is added to the Business and
9 Professions Code, to read:

10 4303.1. If the federal Food and Drug Administration (FDA)
11 cancels, revokes, or suspends an outsourcing facility’s registration
12 for any reason, any license issued pursuant to Section 4129.2 shall
13 be immediately canceled, revoked, or suspended by operation of
14 law.

15 ~~SEC. 21.~~

16 SEC. 25. Section 4312 of the Business and Professions Code
17 is amended to read:

18 4312. (a) The board may cancel the license of a wholesaler,
19 third-party logistics provider, pharmacy, veterinary food-animal
20 drug retailer, or outsourcing facility if the licensed premises remain
21 closed, as defined in subdivision (e), other than by order of the
22 board. For good cause shown, the board may cancel a license after
23 a shorter period of closure. To cancel a license pursuant to this
24 subdivision, the board shall make a diligent, good faith effort to
25 give notice by personal service on the licensee. If a written
26 objection is not received within 10 days after personal service is
27 made or a diligent, good faith effort to give notice by personal
28 service on the licensee has failed, the board may cancel the license
29 without the necessity of a hearing. If the licensee files a written
30 objection, the board shall file an accusation based on the licensee
31 remaining closed. Proceedings shall be conducted in accordance
32 with Chapter 5 (commencing with Section 11500) of Part 1 of
33 Division 3 of Title 2 of the Government Code, and the board shall
34 have all the powers granted in that chapter.

35 (b) If the license of a wholesaler, third-party logistics provider,
36 pharmacy, veterinary food-animal drug retailer, or outsourcing
37 facility is canceled pursuant to subdivision (a) or revoked pursuant
38 to Article 19 (commencing with Section 4300), or a wholesaler,
39 third-party logistics provider, pharmacy, veterinary food-animal
40 drug retailer, or outsourcing facility notifies the board of its intent

1 to remain closed or to discontinue business, the licensee shall,
2 within 10 days thereafter, arrange for the transfer of all dangerous
3 drugs and controlled substances or dangerous devices to another
4 licensee authorized to possess the dangerous drugs and controlled
5 substances or dangerous devices. The licensee transferring the
6 dangerous drugs and controlled substances or dangerous devices
7 shall immediately confirm in writing to the board that the transfer
8 has taken place.

9 (c) If a wholesaler, third-party logistics provider, pharmacy,
10 veterinary food-animal drug retailer, or outsourcing facility fails
11 to comply with subdivision (b), the board may seek and obtain an
12 order from the superior court in the county in which the wholesaler,
13 third-party logistics provider, pharmacy, veterinary food-animal
14 drug retailer, or outsourcing facility is located, authorizing the
15 board to enter the wholesaler, third-party logistics provider,
16 pharmacy, veterinary food-animal drug retailer, or outsourcing
17 facility and inventory and store, transfer, sell, or arrange for the
18 sale of, all dangerous drugs and controlled substances and
19 dangerous devices found in the wholesaler, third-party logistics
20 provider, pharmacy, veterinary food-animal drug retailer, or
21 outsourcing facility.

22 (d) If the board sells or arranges for the sale of any dangerous
23 drugs, controlled substances, or dangerous devices pursuant to
24 subdivision (c), the board may retain from the proceeds of the sale
25 an amount equal to the cost to the board of obtaining and enforcing
26 an order issued pursuant to subdivision (c), including the cost of
27 disposing of the dangerous drugs, controlled substances, or
28 dangerous devices. The remaining proceeds, if any, shall be
29 returned to the licensee from whose premises the dangerous drugs
30 or controlled substances or dangerous devices were removed.

31 (1) The licensee shall be notified of his or her right to the
32 remaining proceeds by personal service or by certified mail,
33 postage prepaid.

34 (2) If a statute or regulation requires the licensee to file with
35 the board his or her address, and any change of address, the notice
36 required by this subdivision may be sent by certified mail, postage
37 prepaid, to the latest address on file with the board and service of
38 notice in this manner shall be deemed completed on the 10th day
39 after the mailing.

1 (3) If the licensee is notified as provided in this subdivision,
2 and the licensee fails to contact the board for the remaining
3 proceeds within 30 calendar days after personal service has been
4 made or service by certified mail, postage prepaid, is deemed
5 completed, the remaining proceeds shall be deposited by the board
6 into the Pharmacy Board Contingent Fund. These deposits shall
7 be deemed to have been received pursuant to Chapter 7
8 (commencing with Section 1500) of Title 10 of Part 3 of the Code
9 of Civil Procedure and shall be subject to claim or other disposition
10 as provided in that chapter.

11 (e) For the purposes of this section, “closed” means not engaged
12 in the ordinary activity for which a license has been issued for at
13 least one day each calendar week during any 120-day period.

14 (f) Nothing in this section shall be construed as requiring a
15 pharmacy to be open seven days a week.

16 ~~SEC. 22. Section 4303.1 is added to the Business and~~
17 ~~Professions Code, to read:~~

18 ~~4303.1. If the federal Food and Drug Administration (FDA)~~
19 ~~cancels, revokes, or suspends an outsourcing facility’s registration~~
20 ~~for any reason, any license issued pursuant to Section 4129.2 shall~~
21 ~~be immediately canceled, revoked, or suspended by operation of~~
22 ~~law.~~

23 ~~SEC. 23.~~

24 ~~SEC. 26. Section 4316 is added to the Business and Professions~~
25 ~~Code, to read:~~

26 4316. (a) The board is authorized to issue a cease and desist
27 order for operating any facility under this chapter that requires
28 licensure or for practicing any activity under this chapter that
29 requires licensure.

30 (b) Whenever the board issues a cease and desist order pursuant
31 to subdivision (a), the board shall immediately issue the facility a
32 notice setting forth the acts or omissions with which it is charged,
33 specifying the pertinent code section or sections and any
34 regulations.

35 (c) The order shall provide that the facility, within 15 days of
36 receipt of the notice, may request a hearing before the president
37 of the board to contest the cease and desist order. Consideration
38 of the facility’s contest of the cease and desist order shall comply
39 with the requirements of Section 11425.10 of the Government
40 Code. The hearing shall be held no later than five days from the

1 date the request of the owner is received by the board. The
2 president shall render a written decision within five days of the
3 hearing. In the absence of the president of the board, the vice
4 president of the board may conduct the hearing permitted by this
5 subdivision. Review of the decision of the president of the board
6 may be sought by the owner or person in possession or control of
7 the pharmacy pursuant to Section 1094.5 of the Code of Civil
8 Procedure.

9 ~~SEC. 24.~~

10 *SEC. 27.* Section 4400 of the Business and Professions Code
11 is amended to read:

12 4400. The amount of fees and penalties prescribed by this
13 chapter, except as otherwise provided, is that fixed by the board
14 according to the following schedule:

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

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

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

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

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

34 (f) The fee for a nongovernmental wholesaler or third-party
35 logistics provider license and annual renewal shall be seven
36 hundred eighty dollars (\$780) and may be decreased to no less
37 than six hundred dollars (\$600). The application fee for any
38 additional location after licensure of the first 20 locations shall be
39 three hundred dollars (\$300) and may be decreased to no less than
40 two hundred twenty-five dollars (\$225). A temporary license fee

1 shall be seven hundred fifteen dollars (\$715) and may be decreased
2 to no less than five hundred fifty dollars (\$550).

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

6 (h) (1) The fee for application, investigation, and issuance of
7 a license as a designated representative pursuant to Section 4053,
8 or as a designated representative-3PL pursuant to Section 4053.1,
9 shall be three hundred thirty dollars (\$330) and may be decreased
10 to no less than two hundred fifty-five dollars (\$255).

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

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

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

24 (j) (1) The application fee for a nonresident wholesaler or
25 third-party logistics provider license issued pursuant to Section
26 4161 shall be seven hundred eighty dollars (\$780) and may be
27 decreased to no less than six hundred dollars (\$600).

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

38 (3) The annual renewal fee for a nonresident wholesaler license
39 or third-party logistics provider license issued pursuant to Section

1 4161 shall be seven hundred eighty dollars (\$780) and may be
2 decreased to no less than six hundred dollars (\$600).

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

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

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

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

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

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

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

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

37 (s) The fee for a veterinary food-animal drug retailer license
38 shall be four hundred five dollars (\$405) and may be increased to
39 four hundred twenty-five dollars (\$425). The annual renewal fee
40 for a veterinary food-animal drug retailer license shall be two

1 hundred fifty dollars (\$250) and may be increased to three hundred
2 twenty-five dollars (\$325).

3 (t) The fee for issuance of a retired license pursuant to Section
4 4200.5 shall be thirty-five dollars (\$35) and may be increased to
5 forty-five dollars (\$45).

6 (u) The fee for issuance or renewal of a nongovernmental sterile
7 compounding pharmacy license shall be six hundred dollars (\$600)
8 and may be increased to seven hundred eighty dollars (\$780). The
9 fee for a temporary license shall be five hundred fifty dollars (\$550)
10 and may be increased to seven hundred fifteen dollars (\$715).

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

26 (w) The fee for the issuance ~~or renewal~~ of an outsourcing facility
27 license shall be ~~four thousand dollars (\$4000)~~. *two thousand two*
28 *hundred seventy dollars (\$2,270) and may be increased to up to*
29 *three thousand one hundred eighty dollars (\$3,180) by the board.*
30 *The fee for the renewal of an outsourcing facility license shall be*
31 *one thousand three hundred twenty-five dollars (\$1,325) and may*
32 *be increased to up to one thousand eight hundred fifty-five dollars*
33 *(\$1,855) by the board.* The fee for a temporary outsourcing facility
34 license shall be seven hundred fifteen dollars (\$715).

35 (x) The fee for the issuance ~~or renewal~~ of a nonresident
36 outsourcing facility license shall be ~~four thousand dollars (\$4000)~~.
37 *two thousand three hundred eighty dollars (\$2,380) and may be*
38 *increased to up to three thousand three hundred thirty-five dollars*
39 *(\$3,335) by the board.* *The fee for the renewal of a nonresident*
40 *outsourcing facility license shall be two thousand two hundred*

1 *seventy dollars (\$2,270) and may be increased to up to three*
2 *thousand one hundred eighty dollars (\$3,180) by the board. In*
3 *addition to paying that application fee, the nonresident outsourcing*
4 *facility shall deposit, when submitting the application, a reasonable*
5 *amount, as determined by the board, necessary to cover the board's*
6 *estimated cost of performing the inspection required by Section*
7 *4129.2. If the required deposit is not submitted with the application,*
8 *the application shall be deemed to be incomplete. If the actual cost*
9 *of the inspection exceeds the amount deposited, the board shall*
10 *provide to the applicant a written invoice for the remaining amount*
11 *and shall not take action on the application until the full amount*
12 *has been paid to the board. If the amount deposited exceeds the*
13 *amount of actual and necessary costs incurred, the board shall*
14 *remit the difference to the applicant.*

15 ~~SEC. 25.~~

16 *SEC. 28.* Section 4406 of the Business and Professions Code
17 is amended to read:

18 4406. All fees collected on behalf of the board and all receipts
19 of every kind and nature shall be reported each month for the month
20 preceding to the Controller and at the same time the entire amount
21 shall be paid into the State Treasury and shall be credited to the
22 Pharmacy Board Contingent Fund which is hereby created. This
23 contingent fund shall be available, upon appropriation of the
24 Legislature, for the use of the board.

25 ~~SEC. 26.~~

26 *SEC. 29.* Section 4800 of the Business and Professions Code
27 is amended to read:

28 4800. (a) There is in the Department of Consumer Affairs a
29 Veterinary Medical Board in which the administration of this
30 chapter is vested. The board consists of the following members:

- 31 (1) Four licensed veterinarians.
- 32 (2) One registered veterinary technician.
- 33 (3) Three public members.

34 (b) This section shall remain in effect only until January 1, ~~2018,~~
35 *2021*, and as of that date is repealed.

36 (c) Notwithstanding any other law, the repeal of this section
37 renders the board subject to review by the appropriate policy
38 committees of the Legislature. However, the review of the board
39 shall be limited to those issues identified by the appropriate policy
40 committees of the Legislature and shall not involve the preparation

1 or submission of a sunset review document or evaluative
2 questionnaire.

3 ~~SEC. 27.~~

4 *SEC. 30.* Section 4804.5 of the Business and Professions Code
5 is amended to read:

6 4804.5. The board may appoint a person exempt from civil
7 service who shall be designated as an executive officer and who
8 shall exercise the powers and perform the duties delegated by the
9 board and vested in him or her by this chapter.

10 This section shall remain in effect only until January 1, 2021,
11 and as of that date is repealed.

12 ~~SEC. 28.~~

13 *SEC. 31.* Section 4826.5 is added to the Business and
14 Professions Code, to read:

15 4826.5. Notwithstanding any other law, a licensed veterinarian
16 or a registered veterinary technician under the supervision of a
17 licensed veterinarian may compound drugs for animal use pursuant
18 to Section 530 of Title 21 of the Code of Federal Regulations and
19 in accordance with regulations promulgated by the board. The
20 regulations promulgated by the board shall, at a minimum, address
21 the storage of drugs, the level and type of supervision required for
22 compounding drugs by a registered veterinary technician, and the
23 equipment necessary for the safe compounding of drugs. Any
24 violation of the regulations adopted by the board pursuant to this
25 section shall constitute grounds for an enforcement or disciplinary
26 action.

27 ~~SEC. 29.~~

28 *SEC. 32.* Section 4830 of the Business and Professions Code
29 is amended to read:

30 4830. (a) This chapter does not apply to:

31 (1) Veterinarians while serving in any armed branch of the
32 military service of the United States or the United States
33 Department of Agriculture while actually engaged and employed
34 in their official capacity.

35 (2) Regularly licensed veterinarians in actual consultation from
36 other states.

37 (3) Regularly licensed veterinarians actually called from other
38 states to attend cases in this state, but who do not open an office
39 or appoint a place to do business within this state.

1 (4) Students in the School of Veterinary Medicine of the
2 University of California or the College of Veterinary Medicine of
3 the Western University of Health Sciences who participate in
4 diagnosis and treatment as part of their educational experience,
5 including those in off-campus educational programs under the
6 direct supervision of a licensed veterinarian in good standing, as
7 defined in paragraph (1) of subdivision (b) of Section 4848,
8 appointed by the University of California, Davis, or the Western
9 University of Health Sciences.

10 (5) A veterinarian who is employed by the Meat and Poultry
11 Inspection Branch of the California Department of Food and
12 Agriculture while actually engaged and employed in his or her
13 official capacity. A person exempt under this paragraph shall not
14 otherwise engage in the practice of veterinary medicine unless he
15 or she is issued a license by the board.

16 (6) Unlicensed personnel employed by the Department of Food
17 and Agriculture or the United States Department of Agriculture
18 when in the course of their duties they are directed by a veterinarian
19 supervisor to conduct an examination, obtain biological specimens,
20 apply biological tests, or administer medications or biological
21 products as part of government disease or condition monitoring,
22 investigation, control, or eradication activities.

23 (b) (1) For purposes of paragraph (3) of subdivision (a), a
24 regularly licensed veterinarian in good standing who is called from
25 another state by a law enforcement agency or animal control
26 agency, as defined in Section 31606 of the Food and Agricultural
27 Code, to attend to cases that are a part of an investigation of an
28 alleged violation of federal or state animal fighting or animal
29 cruelty laws within a single geographic location shall be exempt
30 from the licensing requirements of this chapter if the law
31 enforcement agency or animal control agency determines that it
32 is necessary to call the veterinarian in order for the agency or
33 officer to conduct the investigation in a timely, efficient, and
34 effective manner. In determining whether it is necessary to call a
35 veterinarian from another state, consideration shall be given to the
36 availability of veterinarians in this state to attend to these cases.
37 An agency, department, or officer that calls a veterinarian pursuant
38 to this subdivision shall notify the board of the investigation.

39 (2) Notwithstanding any other provision of this chapter, a
40 regularly licensed veterinarian in good standing who is called from

1 another state to attend to cases that are a part of an investigation
2 described in paragraph (1) may provide veterinary medical care
3 for animals that are affected by the investigation with a temporary
4 shelter facility, and the temporary shelter facility shall be exempt
5 from the registration requirement of Section 4853 if all of the
6 following conditions are met:

7 (A) The temporary shelter facility is established only for the
8 purpose of the investigation.

9 (B) The temporary shelter facility provides veterinary medical
10 care, shelter, food, and water only to animals that are affected by
11 the investigation.

12 (C) The temporary shelter facility complies with Section 4854.

13 (D) The temporary shelter facility exists for not more than 60
14 days, unless the law enforcement agency or animal control agency
15 determines that a longer period of time is necessary to complete
16 the investigation.

17 (E) Within 30 calendar days upon completion of the provision
18 of veterinary health care services at a temporary shelter facility
19 established pursuant to this section, the veterinarian called from
20 another state by a law enforcement agency or animal control agency
21 to attend to a case shall file a report with the board. The report
22 shall contain the date, place, type, and general description of the
23 care provided, along with a listing of the veterinary health care
24 practitioners who participated in providing that care.

25 (c) For purposes of paragraph (3) of subdivision (a), the board
26 may inspect temporary facilities established pursuant to this
27 section.

28 ~~SEC. 30.~~

29 *SEC. 33.* Section 4846.5 of the Business and Professions Code
30 is amended to read:

31 4846.5. (a) Except as provided in this section, the board shall
32 issue renewal licenses only to those applicants that have completed
33 a minimum of 36 hours of continuing education in the preceding
34 two years.

35 (b) (1) Notwithstanding any other law, continuing education
36 hours shall be earned by attending courses relevant to veterinary
37 medicine and sponsored or cosponsored by any of the following:

38 (A) American Veterinary Medical Association (AVMA)
39 accredited veterinary medical colleges.

1 (B) Accredited colleges or universities offering programs
2 relevant to veterinary medicine.

3 (C) The American Veterinary Medical Association.

4 (D) American Veterinary Medical Association recognized
5 specialty or affiliated allied groups.

6 (E) American Veterinary Medical Association's affiliated state
7 veterinary medical associations.

8 (F) Nonprofit annual conferences established in conjunction
9 with state veterinary medical associations.

10 (G) Educational organizations affiliated with the American
11 Veterinary Medical Association or its state affiliated veterinary
12 medical associations.

13 (H) Local veterinary medical associations affiliated with the
14 California Veterinary Medical Association.

15 (I) Federal, state, or local government agencies.

16 (J) Providers accredited by the Accreditation Council for
17 Continuing Medical Education (ACCME) or approved by the
18 American Medical Association (AMA), providers recognized by
19 the American Dental Association Continuing Education
20 Recognition Program (ADA CERP), and AMA or ADA affiliated
21 state, local, and specialty organizations.

22 (2) Continuing education credits shall be granted to those
23 veterinarians taking self-study courses, which may include, but
24 are not limited to, reading journals, viewing video recordings, or
25 listening to audio recordings. The taking of these courses shall be
26 limited to no more than six hours biennially.

27 (3) The board may approve other continuing veterinary medical
28 education providers not specified in paragraph (1).

29 (A) The board has the authority to recognize national continuing
30 education approval bodies for the purpose of approving continuing
31 education providers not specified in paragraph (1).

32 (B) Applicants seeking continuing education provider approval
33 shall have the option of applying to the board or to a
34 board-recognized national approval body.

35 (4) For good cause, the board may adopt an order specifying,
36 on a prospective basis, that a provider of continuing veterinary
37 medical education authorized pursuant to paragraph (1) or (3) is
38 no longer an acceptable provider.

39 (5) Continuing education hours earned by attending courses
40 sponsored or cosponsored by those entities listed in paragraph (1)

1 between January 1, 2000, and January 1, 2001, shall be credited
2 toward a veterinarian's continuing education requirement under
3 this section.

4 (c) Every person renewing his or her license issued pursuant to
5 Section 4846.4, or any person applying for relicensure or for
6 reinstatement of his or her license to active status, shall submit
7 proof of compliance with this section to the board certifying that
8 he or she is in compliance with this section. Any false statement
9 submitted pursuant to this section shall be a violation subject to
10 Section 4831.

11 (d) This section shall not apply to a veterinarian's first license
12 renewal. This section shall apply only to second and subsequent
13 license renewals granted on or after January 1, 2002.

14 (e) The board shall have the right to audit the records of all
15 applicants to verify the completion of the continuing education
16 requirement. Applicants shall maintain records of completion of
17 required continuing education coursework for a period of four
18 years and shall make these records available to the board for
19 auditing purposes upon request. If the board, during this audit,
20 questions whether any course reported by the veterinarian satisfies
21 the continuing education requirement, the veterinarian shall provide
22 information to the board concerning the content of the course; the
23 name of its sponsor and cosponsor, if any; and specify the specific
24 curricula that was of benefit to the veterinarian.

25 (f) A veterinarian desiring an inactive license or to restore an
26 inactive license under Section 701 shall submit an application on
27 a form provided by the board. In order to restore an inactive license
28 to active status, the veterinarian shall have completed a minimum
29 of 36 hours of continuing education within the last two years
30 preceding application. The inactive license status of a veterinarian
31 shall not deprive the board of its authority to institute or continue
32 a disciplinary action against a licensee.

33 (g) Knowing misrepresentation of compliance with this article
34 by a veterinarian constitutes unprofessional conduct and grounds
35 for disciplinary action or for the issuance of a citation and the
36 imposition of a civil penalty pursuant to Section 4883.

37 (h) The board, in its discretion, may exempt from the continuing
38 education requirement any veterinarian who for reasons of health,
39 military service, or undue hardship cannot meet those requirements.

1 Applications for waivers shall be submitted on a form provided
2 by the board.

3 (i) The administration of this section may be funded through
4 professional license and continuing education provider fees. The
5 fees related to the administration of this section shall not exceed
6 the costs of administering the corresponding provisions of this
7 section.

8 (j) For those continuing education providers not listed in
9 paragraph (1) of subdivision (b), the board or its recognized
10 national approval agent shall establish criteria by which a provider
11 of continuing education shall be approved. The board shall initially
12 review and approve these criteria and may review the criteria as
13 needed. The board or its recognized agent shall monitor, maintain,
14 and manage related records and data. The board may impose an
15 application fee, not to exceed two hundred dollars (\$200)
16 biennially, for continuing education providers not listed in
17 paragraph (1) of subdivision (b).

18 (k) (1) Beginning January 1, 2018, a licensed veterinarian who
19 renews his or her license shall complete a minimum of one credit
20 hour of continuing education on the judicious use of medically
21 important antimicrobial drugs every four years as part of his or
22 her continuing education requirements.

23 (2) For purposes of this subdivision, “medically important
24 antimicrobial drug” means an antimicrobial drug listed in Appendix
25 A of the federal Food and Drug Administration’s Guidance for
26 Industry #152, including critically important, highly important,
27 and important antimicrobial drugs, as that appendix may be
28 amended.

29 ~~SEC. 31.~~

30 *SEC. 34.* Section 4848.1 is added to the Business and
31 Professions Code, to read:

32 4848.1. (a) A veterinarian engaged in the practice of veterinary
33 medicine, as defined in Section 4826, employed by the University
34 of California and engaged in the performance of duties in
35 connection with the School of Veterinary Medicine or employed
36 by the Western University of Health Sciences and engaged in the
37 performance of duties in connection with the College of Veterinary
38 Medicine shall be issued a university license pursuant to this
39 section or hold a license to practice veterinary medicine in this
40 state.

1 (b) An individual may apply for and be issued a university
2 license if all of the following are satisfied:

3 (1) He or she is currently employed by the University of
4 California or Western University of Health Sciences, as defined
5 in subdivision (a).

6 (2) He or she passes an examination concerning the statutes and
7 regulations of the Veterinary Medicine Practice Act, administered
8 by the board, pursuant to subparagraph (C) of paragraph (2) of
9 subdivision (a) of Section 4848.

10 (3) He or she successfully completes the approved educational
11 curriculum described in paragraph (5) of subdivision (b) of Section
12 4848 on regionally specific and important diseases and conditions.

13 (4) He or she completes and submits the application specified
14 by the board and pays the application fee, pursuant to subdivision
15 (g) of Section 4905, and the initial license fee, pursuant to
16 subdivision (h) of Section 4905.

17 (c) A university license:

18 (1) Shall be numbered as described in Section 4847.

19 (2) Shall automatically cease to be valid upon termination or
20 cessation of employment by the University of California or by the
21 Western University of Health Sciences.

22 (3) Shall be subject to the license renewal provisions in Section
23 4846.4 and the payment of the renewal fee pursuant to subdivision
24 (i) of Section 4905.

25 (4) Shall be subject to denial, revocation, or suspension pursuant
26 to Sections 480, 4875, and 4883.

27 (5) Authorizes the holder to practice veterinary medicine only
28 at ~~the~~ *an* educational institution described in subdivision (a) and
29 any locations formally affiliated with those institutions.

30 (d) An individual who holds a university license is exempt from
31 satisfying the license renewal requirements of Section 4846.5.

32 ~~SEC. 32.~~

33 *SEC. 35.* Section 4853.7 is added to the Business and
34 Professions Code, to read:

35 4853.7. A premise registration that is not renewed within five
36 years after its expiration may not be renewed and shall not be
37 restored, reissued, or reinstated thereafter. However, an application
38 for a new premise registration may be submitted and obtained if
39 both of the following conditions are met:

1 (a) No fact, circumstance, or condition exists that, if the premise
2 registration was issued, would justify its revocation or suspension.

3 (b) All of the fees that would be required for the initial premise
4 registration are paid at the time of application.

5 ~~SEC. 33.~~

6 *SEC. 36.* Section 4904 of the Business and Professions Code
7 is amended to read:

8 4904. All fees collected on behalf of the board and all receipts
9 of every kind and nature shall be reported each month for the month
10 preceding to the State Controller and at the same time the entire
11 amount shall be paid into the State Treasury and shall be credited
12 to the Veterinary Medical Board Contingent Fund. This contingent
13 fund shall be available, upon appropriation by the Legislature, for
14 the use of the Veterinary Medical Board.

15 ~~SEC. 34.~~

16 *SEC. 37.* Section 4905 of the Business and Professions Code
17 is amended to read:

18 4905. The following fees shall be collected by the board and
19 shall be credited to the Veterinary Medical Board Contingent Fund:

20 (a) The fee for filing an application for examination shall be set
21 by the board in an amount it determines is reasonably necessary
22 to provide sufficient funds to carry out the purpose of this chapter,
23 not to exceed three hundred fifty dollars (\$350).

24 (b) The fee for the California state board examination shall be
25 set by the board in an amount it determines is reasonably necessary
26 to provide sufficient funds to carry out the purpose of this chapter,
27 not to exceed three hundred fifty dollars (\$350).

28 (c) The fee for the Veterinary Medicine Practice Act
29 examination shall be set by the board in an amount it determines
30 reasonably necessary to provide sufficient funds to carry out the
31 purpose of this chapter, not to exceed one hundred dollars (\$100).

32 (d) The initial license fee shall be set by the board not to exceed
33 five hundred dollars (\$500) except that, if the license is issued less
34 than one year before the date on which it will expire, then the fee
35 shall be set by the board not to exceed two hundred fifty dollars
36 (\$250). The board may, by appropriate regulation, provide for the
37 waiver or refund of the initial license fee where the license is issued
38 less than 45 days before the date on which it will expire.

39 (e) The renewal fee shall be set by the board for each biennial
40 renewal period in an amount it determines is reasonably necessary

1 to provide sufficient funds to carry out the purpose of this chapter,
2 not to exceed five hundred dollars (\$500).

3 (f) The temporary license fee shall be set by the board in an
4 amount it determines is reasonably necessary to provide sufficient
5 funds to carry out the purpose of this chapter, not to exceed two
6 hundred fifty dollars (\$250).

7 (g) The fee for filing an application for a university license shall
8 be one hundred twenty-five dollars (\$125), which may be revised
9 by the board in regulation but shall not exceed three hundred fifty
10 dollars (\$350).

11 (h) The initial license fee for a university license shall be two
12 hundred ninety dollars (\$290), which may be revised by the board
13 in regulation but shall not exceed five hundred dollars (\$500).

14 (i) The biennial renewal fee for a university license shall be two
15 hundred ninety dollars (\$290), which may be revised by the board
16 in regulation but shall not exceed five hundred dollars (\$500).

17 (j) The delinquency fee shall be set by the board, not to exceed
18 fifty dollars (\$50).

19 (k) The fee for issuance of a duplicate license is twenty-five
20 dollars (\$25).

21 (l) Any charge made for duplication or other services shall be
22 set at the cost of rendering the service, except as specified in
23 subdivision (k).

24 (m) The fee for failure to report a change in the mailing address
25 is twenty-five dollars (\$25).

26 (n) The initial and annual renewal fees for registration of
27 veterinary premises shall be set by the board in an amount not to
28 exceed four hundred dollars (\$400) annually.

29 (o) If the money transferred from the Veterinary Medical Board
30 Contingent Fund to the General Fund pursuant to the Budget Act
31 of 1991 is redeposited into the Veterinary Medical Board
32 Contingent Fund, the fees assessed by the board shall be reduced
33 correspondingly. However, the reduction shall not be so great as
34 to cause the Veterinary Medical Board Contingent Fund to have
35 a reserve of less than three months of annual authorized board
36 expenditures. The fees set by the board shall not result in a
37 Veterinary Medical Board Contingent Fund reserve of more than
38 10 months of annual authorized board expenditures.

1 ~~SEC. 35.~~

2 *SEC. 38.* Section 13401.5 of the Corporations Code is amended
3 to read:

4 13401.5. Notwithstanding subdivision (d) of Section 13401
5 and any other provision of law, the following licensed persons
6 may be shareholders, officers, directors, or professional employees
7 of the professional corporations designated in this section so long
8 as the sum of all shares owned by those licensed persons does not
9 exceed 49 percent of the total number of shares of the professional
10 corporation so designated herein, and so long as the number of
11 those licensed persons owning shares in the professional
12 corporation so designated herein does not exceed the number of
13 persons licensed by the governmental agency regulating the
14 designated professional corporation. This section does not limit
15 employment by a professional corporation designated in this section
16 to only those licensed professionals listed under each subdivision.
17 Any person duly licensed under Division 2 (commencing with
18 Section 500) of the Business and Professions Code, the
19 Chiropractic Act, or the Osteopathic Act may be employed to
20 render professional services by a professional corporation
21 designated in this section.

- 22 (a) Medical corporation.
- 23 (1) Licensed doctors of podiatric medicine.
 - 24 (2) Licensed psychologists.
 - 25 (3) Registered nurses.
 - 26 (4) Licensed optometrists.
 - 27 (5) Licensed marriage and family therapists.
 - 28 (6) Licensed clinical social workers.
 - 29 (7) Licensed physician assistants.
 - 30 (8) Licensed chiropractors.
 - 31 (9) Licensed acupuncturists.
 - 32 (10) Naturopathic doctors.
 - 33 (11) Licensed professional clinical counselors.
 - 34 (12) Licensed physical therapists.
 - 35 (13) Licensed pharmacists.
- 36 (b) Podiatric medical corporation.
- 37 (1) Licensed physicians and surgeons.
 - 38 (2) Licensed psychologists.
 - 39 (3) Registered nurses.
 - 40 (4) Licensed optometrists.

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

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

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

- 1 (5) Licensed occupational therapists.
- 2 (6) Licensed speech-language therapists.
- 3 (7) Licensed audiologists.
- 4 (8) Registered nurses.
- 5 (9) Licensed psychologists.
- 6 (10) Licensed physician assistants.
- 7 (q) Registered dental hygienist in alternative practice
- 8 corporation.
- 9 (1) Registered dental assistants.
- 10 (2) Licensed dentists.
- 11 (3) Registered dental hygienists.
- 12 (4) Registered dental hygienists in extended functions.

13 ~~SEC. 36.~~

14 *SEC. 39.* Section 1261.6 of the Health and Safety Code is
15 amended to read:

16 1261.6. (a) (1) For purposes of this section and Section 1261.5,
17 an “automated drug delivery system” means a mechanical system
18 that performs operations or activities, other than compounding or
19 administration, relative to the storage, dispensing, or distribution
20 of drugs. An automated drug delivery system shall collect, control,
21 and maintain all transaction information to accurately track the
22 movement of drugs into and out of the system for security,
23 accuracy, and accountability.

24 (2) For purposes of this section, “facility” means a health facility
25 licensed pursuant to subdivision (c), (d), or (k), of Section 1250
26 that has an automated drug delivery system provided by a
27 pharmacy.

28 (3) For purposes of this section, “pharmacy services” means
29 the provision of both routine and emergency drugs and biologicals
30 to meet the needs of the patient, as prescribed by a physician.

31 (b) Transaction information shall be made readily available in
32 a written format for review and inspection by individuals
33 authorized by law. These records shall be maintained in the facility
34 for a minimum of three years.

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

38 (d) (1) The facility and the pharmacy shall develop and
39 implement written policies and procedures to ensure safety,
40 accuracy, accountability, security, patient confidentiality, and

1 maintenance of the quality, potency, and purity of stored drugs.
2 Policies and procedures shall define access to the automated drug
3 delivery system and limits to access to equipment and drugs.

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

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

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

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

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

26 (f) When used to provide pharmacy services pursuant to Section
27 4119.1 of the Business and Professions Code, the automated drug
28 delivery system shall be subject to all of the following
29 requirements:

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

33 (2) A pharmacist shall review and approve all orders prior to a
34 drug being removed from the automated drug delivery system for
35 administration to a patient. The pharmacist shall review the
36 prescriber's order and the patient's profile for potential
37 contraindications and adverse drug reactions.

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

1 (4) Access to the automated drug delivery system shall be
2 controlled and tracked using an identification or password system
3 or biosensor.

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

8 (6) After the pharmacist reviews the prescriber's order, access
9 by licensed personnel to the automated drug delivery system shall
10 be limited only to drugs ordered by the prescriber and reviewed
11 by the pharmacist and that are specific to the patient. When the
12 prescriber's order requires a dosage variation of the same drug,
13 licensed personnel shall have access to the drug ordered for that
14 scheduled time of administration.

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

27 (B) As part of its routine oversight of these facilities, the
28 department shall review a facility's medication training, storage,
29 and security, and its administration procedures related to its use
30 of an automated drug delivery system to ensure that adequate staff
31 training and safeguards are in place to make sure that the drugs
32 delivered are appropriate for the patient. If the department
33 determines that a facility is not in compliance with this section,
34 the department may revoke its authorization to use automated drug
35 delivery systems granted under subparagraph (A).

36 (g) The stocking of an automated drug delivery system shall be
37 performed by a pharmacist. If the automated drug delivery system
38 utilizes removable pockets, cards, drawers, ~~or~~ similar technology,
39 *or unit of use or single dose containers as defined by the United*
40 *States Pharmacopoeia*, the stocking system may be done outside

1 of the facility and be delivered to the facility if all of the following
2 conditions are met:

3 (1) The task of placing drugs into the removable pockets, cards,
4 ~~or drawers drawers, or unit of use or single dose containers~~ is
5 performed by a ~~pharmacist~~ *pharmacist*, or by an intern pharmacist
6 or a pharmacy technician working under the direct supervision of
7 a pharmacist.

8 (2) The removable pockets, cards, ~~or drawers drawers, or unit~~
9 ~~of use or single dose containers~~ are transported between the
10 pharmacy and the facility in a secure tamper-evident container.

11 (3) The facility, in conjunction with the pharmacy, has
12 developed policies and procedures to ensure that the *removable*
13 ~~pockets, cards, or drawers drawers, or unit of use or single dose~~
14 ~~containers~~ are properly placed into the automated drug delivery
15 system.

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

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

35 ~~SEC. 37.~~

36 *SEC. 40.* Section 11164.5 of the Health and Safety Code is
37 amended to read:

38 11164.5. (a) Notwithstanding Section 11164, if only recorded
39 and stored electronically, on magnetic media, or in any other
40 computerized form, the pharmacy's or hospital's computer system

1 shall not permit the received information or the controlled
2 substance dispensing information required by this section to be
3 changed, obliterated, destroyed, or disposed of, for the record
4 maintenance period required by law, once the information has been
5 received by the pharmacy or the hospital and once the controlled
6 substance has been dispensed, respectively. Once the controlled
7 substance has been dispensed, if the previously created record is
8 determined to be incorrect, a correcting addition may be made
9 only by or with the approval of a pharmacist. After a pharmacist
10 enters the change or enters his or her approval of the change into
11 the computer, the resulting record shall include the correcting
12 addition and the date it was made to the record, the identity of the
13 person or pharmacist making the correction, and the identity of
14 the pharmacist approving the correction.

15 (b) Nothing in this section shall be construed to exempt any
16 pharmacy or hospital dispensing Schedule II controlled substances
17 pursuant to electronic transmission prescriptions from existing
18 reporting requirements.

19 ~~SEC. 38.~~

20 *SEC. 41.* No reimbursement is required by this act pursuant to
21 Section 6 of Article XIII B of the California Constitution because
22 the only costs that may be incurred by a local agency or school
23 district will be incurred because this act creates a new crime or
24 infraction, eliminates a crime or infraction, or changes the penalty
25 for a crime or infraction, within the meaning of Section 17556 of
26 the Government Code, or changes the definition of a crime within
27 the meaning of Section 6 of Article XIII B of the California
28 Constitution.