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, *4081,* 4107, 4110, 4119.1, 4127, 4127.3, 4127.7, 4127.8, 4127.9, 4128.6, 4161, 4180, *4201, 4312,* 4400, ~~and 4406~~ *4406, 4800, 4804.5, 4830, 4846.5, 4904, and 4905* of, to add Sections 4034, *4105.5,* 4126.9, 4203.5, ~~and 4316~~ *4303.1, 4316, 4826.5, 4848.1, and 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, and making an appropriation therefor.~~ *arts.*

LEGISLATIVE COUNSEL'S DIGEST

SB 1193, as amended, Hill. ~~Pharmacy: Law.~~ *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 within 10 days of the action. The bill would prohibit the issuance or renewal of an outsourcing facility 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 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 for the issuance and renewal of an outsourcing license and a fee of $715 for a temporary license, as specified. This 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 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.

~~The~~

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~~ *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 ~~to register use of an automated drug delivery system with the board, including the address and location of use.~~ *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.*

~~Existing law,~~

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.

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

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

This bill would 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~~ *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.

~~The~~

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.

~~This bill would require the board to license an outsourcing facility, as defined, and would prohibit an outsourcing facility to be concurrently licensed with the board as a sterile compounding pharmacy at the same location. The bill would require an outsourcing facility to be licensed~~

~~with the board before doing business within or into the state and would require an outsourcing facility to, among other things, notify the board of any disciplinary or other action taken by another state or the federal Food and Drug Administration within 10 days of the action. The bill would require the board to, among other things, inspect the location of an outsourcing facility to ensure that the outsourcing facility is in compliance with all laws and regulations before issuing or renewing an outsourcing facility's license. The bill would make a violation of any of these provisions or regulations adopted thereto punishable by a fine of up to $5,000 per occurrence. The bill would, on or after January 1, 2018, require the board to provide a report, as specified, to the Legislature regarding the regulation of nonresident outsourcing facilities.~~

~~Existing law~~

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. ~~Existing~~ *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 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 $780 for the issuance and renewal of an outsourcing license and a fee of $715 for a temporary license, as specified. This bill would provide that the Pharmacy Board Contingent Fund is available for expenditure only upon an appropriation by the Legislature.~~

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

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

Existing law authorizes, with the approval of the board and the Department of Justice, a pharmacy or hospital to receive electronic data transmission prescriptions and computer entry prescriptions or orders for controlled substances in Schedule II, III, IV, or V, if authorized by

federal law and in accordance with regulations promulgated by the federal Drug Enforcement Administration. Existing law requires the board to maintain a list of all requests and approvals granted. Existing law prohibits an approved pharmacy or hospital receiving an electronic transmission prescription or a computer entry prescription or order for a controlled substance in Schedule II, III, IV, or V from being required to reduce that prescription or order to writing or to hard copy form as long as the pharmacy or hospital is able to immediately produce a specified hard copy upon request.

This bill would remove these provisions.

(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 bill would instead require veterinarians 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:

SECTION 1. Section 4001 of the Business and Professions Code is amended to read:

4001. (a) There is in the Department of Consumer Affairs a California State Board of Pharmacy in which the administration and enforcement of this chapter is vested. The board consists of 13 members.

(b) The Governor shall appoint seven competent pharmacists who reside in different parts of the state to serve as members of the board. The Governor shall appoint four public members, and the Senate Committee on Rules and the Speaker of the Assembly shall each appoint a public member who shall not be a licensee of the board, any other board under this division, or any board referred to in Section 1000 or 3600.

(c) At least five of the seven pharmacist appointees to the board shall be pharmacists who are actively engaged in the practice of pharmacy. Additionally, the membership of the board shall include at least one pharmacist representative from each of the following practice settings: an acute care hospital, an independent community pharmacy, a chain community pharmacy, and a long-term health care or skilled nursing facility. The pharmacist appointees shall also include a pharmacist who is a member of a labor union that represents pharmacists. For the purposes of this subdivision, a "chain community pharmacy" means a chain of 75 or more stores in California under the same ownership, and an "independent community pharmacy" means a pharmacy owned by a person or entity who owns no more than four pharmacies in California.

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

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

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

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

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

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

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

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

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

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

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

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

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

(c) Is doing business within or into California.

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

SEC. 4. Section 4081 of the Business and Professions Code is amended to read:

4081. (a) All records of manufacture and of sale, acquisition, receipt, shipment, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory

shall be kept by every manufacturer, wholesaler, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, *outsourcing facility,* physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices.

(b) The owner, officer, and partner of a pharmacy, wholesaler, third-party logistics provider, or veterinary food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge, responsible manager, or designated representative-in-charge, for maintaining the records and inventory described in this section.

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

SEC. 5. Section 4105.5 is added to the Business and Professions Code, to read:

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

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

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

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

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

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

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

(d) The board may prohibit a pharmacy from using an automated drug delivery system if the board determines that the conditions provided in subdivision (c) are not satisfied. If such a determination is made, the board shall provide the pharmacy with written notice including the basis for the determination. The pharmacy may request an office conference to appeal the board's decision within 30 days of receipt of the written notice. The executive officer or designee may affirm or overturn the prohibition as a result of the office conference.

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

~~SEC. 4.~~

SEC. 6. Section 4107 of the Business and Professions Code is amended to read:

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

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

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

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

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

~~SEC. 5.~~

SEC. 7. Section 4110 of the Business and Professions Code is amended to read:

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

(b) The board may, at its discretion, issue a temporary permit upon the conditions and for any periods of time as the board determines to be in the public interest. A temporary permit fee shall be required in an amount established by the board as specified in subdivision (a) of Section 4400. When needed to protect public safety, a temporary permit may be issued for a period not to exceed 180 days, and may be issued subject to terms and conditions the board deems necessary. If the board determines a temporary permit was issued by mistake or denies the application for a permanent license or registration, the temporary license or registration shall terminate upon either personal service of the notice of termination upon the permitholder or service by certified mail, return receipt requested, at the permitholder's address of record with the board, whichever comes first. Neither for purposes of retaining a temporary permit nor for purposes of any disciplinary or license denial proceeding before the board shall the temporary permitholder be deemed to have a vested property right or interest in the permit.

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

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

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

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

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

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

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

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

~~SEC. 6.~~

SEC. 8. Section 4119.1 of the Business and Professions Code is amended to read:

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

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

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

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

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

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

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

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

~~(f)~~

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

~~SEC. 7.~~

SEC. 9. Section 4126.9 is added to the Business and Professions Code, to read:

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

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

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

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

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

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

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

(c) ~~In cases where patient harm has occurred resulting from use of the compounded product, the event shall be reported~~ *A pharmacy that has been advised that a patient has been harmed by using a nonsterile compounded product potentially attributable to the pharmacy shall report the event* to MedWatch within 72 hours of the pharmacy being advised.

~~SEC. 8.~~

SEC. 10. Section 4127 of the Business and Professions Code is amended to read:

4127. (a) A pharmacy that compounds sterile drug products shall possess a sterile compounding pharmacy license as provided in this article.

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

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

~~SEC. 9.~~

SEC. 11. Section 4127.3 of the Business and Professions Code is amended to read:

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

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

(c) The order shall provide that the owner, within 15 days of receipt of the notice, may request a hearing before the president of the board to contest the cease and desist order. Consideration of the owner's contest of the cease and desist order shall comply with the requirements of Section 11425.10 of the Government Code. The hearing shall be held no later than five days from the date the request of the owner is received by the board. The president shall render a written decision within five days of the hearing. In the absence of the president of the board, the vice president of the board may conduct the hearing permitted by this

subdivision. Review of the decision of the president of the board may be sought by the owner or person in possession or control of the pharmacy pursuant to Section 1094.5 of the Code of Civil Procedure.

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

~~SEC. 10.~~

SEC. 12. Section 4127.7 of the Business and Professions Code is amended to read:

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

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

(b) An ISO class 5 cleanroom.

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

~~SEC. 11.~~

SEC. 13. Section 4127.8 of the Business and Professions Code is amended to read:

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

~~SEC. 12.~~

SEC. 14. Section 4127.9 of the Business and Professions Code is amended to read:

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

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

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

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

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

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

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

~~SEC. 13.~~

SEC. 15. Section 4128.6 of the Business and Professions Code is amended to read:

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

~~SEC. 14.~~

SEC. 16. Article 7.7 (commencing with Section 4129) is added to Chapter 9 of Division 2 of the Business and Professions Code, to read:

Article 7.7. Outsourcing Facilities

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(c) A license for a nonresident outsourcing facility shall not be issued or renewed until the location is inspected by the board and found in compliance with this article and any regulations adopted by the board. The nonresident outsourcing facility shall reimburse the board for all actual and necessary costs incurred by the board

in conducting an inspection of the nonresident outsourcing facility at least once annually pursuant to subdivision (x) of Section 4400.

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

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

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

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

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

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

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

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

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

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

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

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

(2) Whether fee revenue collected pursuant to subdivision (x) of Section 4400 and travel cost reimbursements collected pursuant to subdivision (c) of Section 4129.2 provide revenue in an amount

sufficient to support the board's activities related to the inspection and licensure of nonresident outsourcing facilities.

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

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

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

4129.4. (a) Whenever the board has a reasonable belief, based on information obtained during an inspection or investigation by the board, that an outsourcing facility compounding sterile drug products or nonsterile drug products poses an immediate threat to the public health or safety, the executive officer of the board may issue an order to the outsourcing facility to immediately cease and desist compounding sterile drug products or nonsterile drug products. The cease and desist order shall remain in effect for no more than 30 days or the date of a hearing seeking an interim suspension order, whichever is earlier.

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

(c) The cease and desist order shall state that the owner, within 15 days of receipt of the notice, may request a hearing before the president of the board to contest the cease and desist order. Consideration of the owner's contest of the cease and desist order shall comply with the requirements of Section 11425.10 of the Government Code. The hearing shall be held no later than five days after the date the request of the owner is received by the board. The president shall render a written decision within five days after the hearing. In the absence of the president of the board, the vice president of the board may conduct the hearing permitted

by this subdivision. Review of the decision may be sought by the owner or person in possession or control of the outsourcing facility pursuant to Section 1094.5 of the Code of Civil Procedure.

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

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

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

4129.8. The board, at its discretion, may issue a temporary license to an outsourcing facility ~~when the ownership of the outsourcing facility is transferred from one person to another,~~ upon the conditions and for any periods of time as the board determines to be in the public interest. A temporary license fee shall be required as specified in subdivision (w) of Section 4400. When needed to protect public safety, a temporary license may be issued for a period not to exceed 180 days, and may be issued subject to terms and conditions the board deems necessary. If the board determines a temporary license was issued by mistake or denies the application for a permanent license, the temporary license shall terminate upon the earlier of personal service of the notice of termination upon the licenseholder or service by certified mail with return receipt requested at the licenseholder's address of record with the board. The temporary licenseholder shall not be deemed to have a vested property right or interest in the license for purposes of retaining a temporary license or for purposes of any disciplinary or license denial proceeding before the board.

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

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

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

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

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

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

~~SEC. 15.~~

SEC. 17. Section 4161 of the Business and Professions Code is amended to read:

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

(b) A nonresident wholesaler or nonresident third-party logistics provider shall be licensed by the board prior to shipping, selling, mailing, warehousing, distributing, or delivering dangerous drugs or dangerous devices to a site located in this state or selling, brokering, warehousing, or distributing dangerous drugs or devices within this state.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

~~SEC. 16.~~

SEC. 18. Section 4180 of the Business and Professions Code is amended to read:

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

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

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

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

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

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

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

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

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

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

SEC. 19. Section 4201 of the Business and Professions Code is amended to read:

4201. (a) Each application to conduct a pharmacy, wholesaler, third-party logistics provider,~~or~~ veterinary food-animal drug ~~retailer~~ *retailer, or outsourcing facility* shall be made on a form furnished by the board and shall state the name, address, usual occupation, and professional qualifications, if any, of the applicant. If the applicant is other than a natural person, the application shall state the information as to each person beneficially interested therein.

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

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

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

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

(c) If the applicant is a partnership or other unincorporated association, a limited liability company, or a corporation, and the number of partners, members, or stockholders, as the case may be, exceeds five, the application shall so state, and shall further

state the information required by subdivision (a) as to each of the five partners, members, or stockholders who own the five largest interests in the applicant entity. Upon request by the executive officer, the applicant shall furnish the board with the information required by subdivision (a) as to partners, members, or stockholders not named in the application, or shall refer the board to an appropriate source of that information.

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

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

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

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

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

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

(j) For licenses referred to in subdivisions (f), (g), (h), and (i), any change in the proposed beneficial ownership interest shall be

reported to the board within 30 days thereafter upon a form to be furnished by the board.

~~SEC. 17.~~

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

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

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

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

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

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

SEC. 21. Section 4312 of the Business and Professions Code is amended to read:

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

(b) If the license of a wholesaler, third-party logistics provider, pharmacy, ~~or~~ veterinary food-animal drug ~~retailer~~ *retailer, or outsourcing facility* is canceled pursuant to subdivision (a) or revoked pursuant to Article 19 (commencing with Section 4300), or a wholesaler, third-party logistics provider, pharmacy, ~~or~~ veterinary food-animal drug ~~retailer~~ *retailer, or outsourcing facility* notifies the board of its intent to remain closed or to discontinue business, the licensee shall, within 10 days thereafter, arrange for the transfer of all dangerous drugs and controlled substances or dangerous devices to another licensee authorized to possess the dangerous drugs and controlled substances or dangerous devices. The licensee transferring the dangerous drugs and controlled substances or dangerous devices shall immediately confirm in writing to the board that the transfer has taken place.

(c) If a wholesaler, third-party logistics provider, pharmacy, ~~or~~ veterinary food-animal drug ~~retailer~~ *retailer, or outsourcing facility* fails to comply with subdivision (b), the board may seek and obtain an order from the superior court in the county in which the wholesaler, third-party logistics provider, pharmacy, ~~or~~ veterinary food-animal drug ~~retailer~~ *retailer, or outsourcing facility* is located, authorizing the board to enter the wholesaler, third-party logistics provider, pharmacy, ~~or~~ veterinary food-animal drug ~~retailer~~ *retailer, or 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 wholesaler, third-party logistics provider, pharmacy, ~~or~~ veterinary food-animal drug ~~retailer.~~ *retailer, or outsourcing facility.*

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

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

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

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

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

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

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

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

~~SEC. 18.~~

SEC. 23. Section 4316 is added to the Business and Professions Code, to read:

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

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

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

~~SEC. 19.~~

SEC. 24. Section 4400 of the Business and Professions Code is amended to read:

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

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

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

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

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

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

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

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

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

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

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

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

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

(2) For nonresident wholesalers or third-party logistics providers that have 21 or more facilities operating nationwide the application fees for the first 20 locations shall be seven hundred eighty dollars ($780) and may be decreased to no less than six hundred dollars ($600). The application fee for any additional location after licensure of the first 20 locations shall be three hundred dollars

($300) and may be decreased to no less than two hundred twenty-five dollars ($225). A temporary license fee shall be seven hundred fifteen dollars ($715) and may be decreased to no less than five hundred fifty dollars ($550).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(w) The fee for the issuance or renewal of an outsourcing facility license shall be ~~seven hundred eighty dollars ($780).~~ *four thousand dollars ($4000).* The fee for a temporary outsourcing facility license shall be seven hundred fifteen dollars ($715).

(x) The fee for the issuance or renewal of a nonresident outsourcing facility license shall be ~~seven hundred eighty dollars ($780).~~ *four thousand dollars ($4000).* In addition to paying that application fee, the nonresident outsourcing facility shall deposit, when submitting the application, a reasonable amount, as

determined by the board, necessary to cover the board's estimated cost of performing the inspection required by Section 4129.2. If the required deposit is not submitted with the application, the application shall be deemed to be incomplete. If the actual cost of the inspection exceeds the amount deposited, the board shall provide to the applicant a written invoice for the remaining amount and shall not take action on the application until the full amount has been paid to the board. If the amount deposited exceeds the amount of actual and necessary costs incurred, the board shall remit the difference to the applicant.

~~SEC. 20.~~

SEC. 25. Section 4406 of the Business and Professions Code is amended to read:

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

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

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

(1) Four licensed veterinarians.

(2) One registered veterinary technician.

(3) Three public members.

(b) This section shall remain in effect only until January 1, ~~2017,~~ *2018,* and as of that date is ~~repealed, unless a later enacted statute, that is enacted before January 1, 2017, deletes or extends that date.~~ *repealed.*

(c) Notwithstanding any other law, the repeal of this section renders the board subject to review by the appropriate policy committees of the Legislature. However, the review of the board shall be limited to those issues identified by the appropriate policy committees of the Legislature and shall not involve the preparation or submission of a sunset review document or evaluative questionnaire.

SEC. 27. Section 4804.5 of the Business and Professions Code is amended to read:

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

This section shall remain in effect only until January 1, ~~2017,~~ *2021,* and as of that date is ~~repealed, unless a later enacted statute, that is enacted before January 1, 2017, deletes or extends that date.~~ *repealed.*

SEC. 28. Section 4826.5 is added to the Business and Professions Code, to read:

4826.5. Notwithstanding any other law, a licensed veterinarian or a registered veterinary technician under the supervision of a licensed veterinarian may compound drugs for animal use pursuant to Section 530 of Title 21 of the Code of Federal Regulations and in accordance with regulations promulgated by the board. The regulations promulgated by the board shall, 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 the safe compounding of drugs. Any violation of the regulations adopted by the board pursuant to this section shall constitute grounds for an enforcement or disciplinary action.

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

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

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

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

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

~~(4) Veterinarians employed by the University of California while engaged in the performance of duties in connection with the College of Agriculture, the Agricultural Experiment Station, the School of Veterinary Medicine, or the agricultural extension work~~

~~of the university or employed by the Western University of Health Sciences while engaged in the performance of duties in connection with the College of Veterinary Medicine or the agricultural extension work of the university.~~

~~(5)~~

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

~~(6)~~

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

~~(7)~~

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

(b) (1) For purposes of paragraph (3) of subdivision (a), a regularly licensed veterinarian in good standing who is called from another state by a law enforcement agency or animal control agency, as defined in Section 31606 of the Food and Agricultural Code, to attend to cases that are a part of an investigation of an alleged violation of federal or state animal fighting or animal cruelty laws within a single geographic location shall be exempt from the licensing requirements of this chapter if the law enforcement agency or animal control agency determines that it is necessary to call the veterinarian in order for the agency or officer to conduct the investigation in a timely, efficient, and

effective manner. In determining whether it is necessary to call a veterinarian from another state, consideration shall be given to the availability of veterinarians in this state to attend to these cases. An agency, department, or officer that calls a veterinarian pursuant to this subdivision shall notify the board of the investigation.

(2) Notwithstanding any other provision of this chapter, a regularly licensed veterinarian in good standing who is called from another state to attend to cases that are a part of an investigation described in paragraph (1) may provide veterinary medical care for animals that are affected by the investigation with a temporary shelter facility, and the temporary shelter facility shall be exempt from the registration requirement of Section 4853 if all of the following conditions are met:

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

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

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

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

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

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

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

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

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

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

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

(C) The American Veterinary Medical Association.

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

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

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

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

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

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

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

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

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

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

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

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

(5) Continuing education hours earned by attending courses sponsored or cosponsored by those entities listed in paragraph (1) between January 1, 2000, and January 1, 2001, shall be credited toward a veterinarian's continuing education requirement under this section.

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

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

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

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

(g) Knowing misrepresentation of compliance with this article by a veterinarian constitutes unprofessional conduct and grounds

for disciplinary action or for the issuance of a citation and the imposition of a civil penalty pursuant to Section 4883.

(h) The board, in its discretion, may exempt from the continuing education requirement any veterinarian who for reasons of health, military service, or undue hardship cannot meet those requirements. Applications for waivers shall be submitted on a form provided by the board.

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

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

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

(2) For purposes of this subdivision, "medically important antimicrobial drug" means an antimicrobial drug listed in Appendix A of the federal Food and Drug Administration's Guidance for Industry #152, including critically important, highly important, and important antimicrobial drugs, as that appendix may be amended.

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

4848.1. (a) A veterinarian engaged in the practice of veterinary medicine, as defined in Section 4826, employed by the University of California and engaged in the performance of duties in connection with the School of Veterinary Medicine or employed by the Western University of Health Sciences and engaged in the

performance of duties in connection with the College of Veterinary Medicine shall be issued a university license pursuant to this section or hold a license to practice veterinary medicine in this state.

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

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

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

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

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

(c) A university license:

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

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

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

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

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

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

SEC. 32. Section 4853.7 is added to the Business and Professions Code, to read:

4853.7. A premise registration that is not renewed within five years after its expiration may not be renewed and shall not be restored, reissued, or reinstated thereafter. However, an

application for a new premise registration may be submitted and obtained if both of the following conditions are met:

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

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

SEC. 33. Section 4904 of the Business and Professions Code is amended to read:

4904. All fees collected on behalf of the board and all receipts of every kind and nature shall be reported each month for the month preceding to the State Controller and at the same time the entire amount shall be paid into the State Treasury and shall be credited to the Veterinary Medical Board Contingent Fund. This contingent fund shall be *available, upon appropriation by the Legislature,* for the use of the Veterinary Medical ~~Board and out of it and not otherwise shall be paid all expenses of the board.~~ *Board.*

SEC. 34. Section 4905 of the Business and Professions Code is amended to read:

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

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

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

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

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

(e) The renewal fee shall be set by the board for each biennial renewal period in an amount it determines is reasonably necessary to provide sufficient funds to carry out the purpose of this chapter, not to exceed five hundred dollars ($500).

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

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

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

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

~~(g)~~

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

~~(h)~~

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

~~(i)~~

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

~~(j)~~

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

~~(k)~~

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

~~(l)~~

(o) If the money transferred from the Veterinary Medical Board Contingent Fund to the General Fund pursuant to the Budget Act of 1991 is redeposited into the Veterinary Medical Board Contingent Fund, the fees assessed by the board shall be reduced

correspondingly. However, the reduction shall not be so great as to cause the Veterinary Medical Board Contingent Fund to have a reserve of less than three months of annual authorized board expenditures. The fees set by the board shall not result in a Veterinary Medical Board Contingent Fund reserve of more than 10 months of annual authorized board expenditures.

~~SEC. 21.~~

SEC. 35. Section 13401.5 of the Corporations Code is amended to read:

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

(a) Medical corporation.

(1) Licensed doctors of podiatric medicine.

(2) Licensed psychologists.

(3) Registered nurses.

(4) Licensed optometrists.

(5) Licensed marriage and family therapists.

(6) Licensed clinical social workers.

(7) Licensed physician assistants.

(8) Licensed chiropractors.

(9) Licensed acupuncturists.

(10) Naturopathic doctors.

(11) Licensed professional clinical counselors.

(12) Licensed physical therapists.

(13) Licensed pharmacists.
(b) Podiatric medical corporation.
(1) Licensed physicians and surgeons.
(2) Licensed psychologists.
(3) Registered nurses.
(4) Licensed optometrists.
(5) Licensed chiropractors.
(6) Licensed acupuncturists.
(7) Naturopathic doctors.
(8) Licensed physical therapists.
(c) Psychological corporation.
(1) Licensed physicians and surgeons.
(2) Licensed doctors of podiatric medicine.
(3) Registered nurses.
(4) Licensed optometrists.
(5) Licensed marriage and family therapists.
(6) Licensed clinical social workers.
(7) Licensed chiropractors.
(8) Licensed acupuncturists.
(9) Naturopathic doctors.
(10) Licensed professional clinical counselors.
(d) Speech-language pathology corporation.
(1) Licensed audiologists.
(e) Audiology corporation.
(1) Licensed speech-language pathologists.
(f) Nursing corporation.
(1) Licensed physicians and surgeons.
(2) Licensed doctors of podiatric medicine.
(3) Licensed psychologists.
(4) Licensed optometrists.
(5) Licensed marriage and family therapists.
(6) Licensed clinical social workers.
(7) Licensed physician assistants.
(8) Licensed chiropractors.
(9) Licensed acupuncturists.
(10) Naturopathic doctors.
(11) Licensed professional clinical counselors.
(g) Marriage and family therapist corporation.
(1) Licensed physicians and surgeons.
(2) Licensed psychologists.

(3) Licensed clinical social workers.
(4) Registered nurses.
(5) Licensed chiropractors.
(6) Licensed acupuncturists.
(7) Naturopathic doctors.
(8) Licensed professional clinical counselors.
(h) Licensed clinical social worker corporation.
(1) Licensed physicians and surgeons.
(2) Licensed psychologists.
(3) Licensed marriage and family therapists.
(4) Registered nurses.
(5) Licensed chiropractors.
(6) Licensed acupuncturists.
(7) Naturopathic doctors.
(8) Licensed professional clinical counselors.
(i) Physician assistants corporation.
(1) Licensed physicians and surgeons.
(2) Registered nurses.
(3) Licensed acupuncturists.
(4) Naturopathic doctors.
(j) Optometric corporation.
(1) Licensed physicians and surgeons.
(2) Licensed doctors of podiatric medicine.
(3) Licensed psychologists.
(4) Registered nurses.
(5) Licensed chiropractors.
(6) Licensed acupuncturists.
(7) Naturopathic doctors.
(k) Chiropractic corporation.
(1) Licensed physicians and surgeons.
(2) Licensed doctors of podiatric medicine.
(3) Licensed psychologists.
(4) Registered nurses.
(5) Licensed optometrists.
(6) Licensed marriage and family therapists.
(7) Licensed clinical social workers.
(8) Licensed acupuncturists.
(9) Naturopathic doctors.
(10) Licensed professional clinical counselors.
(*l*) Acupuncture corporation.

(1) Licensed physicians and surgeons.
(2) Licensed doctors of podiatric medicine.
(3) Licensed psychologists.
(4) Registered nurses.
(5) Licensed optometrists.
(6) Licensed marriage and family therapists.
(7) Licensed clinical social workers.
(8) Licensed physician assistants.
(9) Licensed chiropractors.
(10) Naturopathic doctors.
(11) Licensed professional clinical counselors.
(m) Naturopathic doctor corporation.
(1) Licensed physicians and surgeons.
(2) Licensed psychologists.
(3) Registered nurses.
(4) Licensed physician assistants.
(5) Licensed chiropractors.
(6) Licensed acupuncturists.
(7) Licensed physical therapists.
(8) Licensed doctors of podiatric medicine.
(9) Licensed marriage and family therapists.
(10) Licensed clinical social workers.
(11) Licensed optometrists.
(12) Licensed professional clinical counselors.
(n) Dental corporation.
(1) Licensed physicians and surgeons.
(2) Dental assistants.
(3) Registered dental assistants.
(4) Registered dental assistants in extended functions.
(5) Registered dental hygienists.
(6) Registered dental hygienists in extended functions.
(7) Registered dental hygienists in alternative practice.
(o) Professional clinical counselor corporation.
(1) Licensed physicians and surgeons.
(2) Licensed psychologists.
(3) Licensed clinical social workers.
(4) Licensed marriage and family therapists.
(5) Registered nurses.
(6) Licensed chiropractors.
(7) Licensed acupuncturists.

(8) Naturopathic doctors.

(p) Physical therapy corporation.

(1) Licensed physicians and surgeons.

(2) Licensed doctors of podiatric medicine.

(3) Licensed acupuncturists.

(4) Naturopathic doctors.

(5) Licensed occupational therapists.

(6) Licensed speech-language therapists.

(7) Licensed audiologists.

(8) Registered nurses.

(9) Licensed psychologists.

(10) Licensed physician assistants.

(q) Registered dental hygienist in alternative practice corporation.

(1) Registered dental assistants.

(2) Licensed dentists.

(3) Registered dental hygienists.

(4) Registered dental hygienists in extended functions.

~~SEC. 22.~~

SEC. 36. Section 1261.6 of the Health and Safety Code is amended to read:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

~~SEC. 23.~~

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

11164.5. (a) Notwithstanding Section 11164, if only recorded and stored electronically, on magnetic media, or in any other computerized form, the pharmacy's or hospital's computer system shall not permit the received information or the controlled substance dispensing information required by this section to be changed, obliterated, destroyed, or disposed of, for the record maintenance period required by law, once the information has been received by the pharmacy or the hospital and once the controlled substance has been dispensed, respectively. Once the controlled substance has been dispensed, if the previously created record is determined to be incorrect, a correcting addition may be made only by or with the approval of a pharmacist. After a pharmacist enters the change or enters his or her approval of the change into the computer, the resulting record shall include the correcting addition and the date it was made to the record, the identity of the person or pharmacist making the correction, and the identity of the pharmacist approving the correction.

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

~~SEC. 24.~~

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

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