



California State Board of Pharmacy

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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

LEGISLATION AND REGULATION COMMITTEE

Greg Lippe, CPA, Chairperson, Public Member
Ramon Castellblanch, Ph.D, Public Member
Deborah Veale, RPh, Professional Member
Albert Wong, PharmD, Professional Member
LaVanza Butler, RPH, Professional Member

Part 1: LEGISLATION REPORT

a. Board Sunset Legislation

Copies of each bill and related documents are provided as Attachments.

1. SB 1193 (Hill) California State Board of Pharmacy

Version: June 21, 2016 Amended

Location: Assembly Appropriations (6/28)

This measure would extend the operations of the California Board of Pharmacy and the board's authority to appoint an executive officer until January 1, 2021; would establish the framework for the licensure of outsourcing facilities; would authorize the board to synchronize license renewal dates and aggregate fees for clinics, as specified; would authorize the board to issue a temporary permit for specified licenses; would repeal obsolete provisions related electronic data transmission prescriptions in the Health and Safety Code, and makes other technical changes. Staff attended the June 28th hearing and was available for questions. The bill passed out of Assembly Business and Professions 13-0 and was re-referred to Appropriations. Staff recommends the board maintain its Support position.

2. SB 1039 (Hill) Professions and Vocations

Version: June 21, 2016 Amended

Location: Assembly Appropriations (6/28)

Senate Bill 1039 would set forth a new fee schedule, which is needed to sustain board operations. The bill amends numerous provisions related to various professions and vocations, to include the Board of Podiatric Medicine, Dental Hygiene Committee, and others. Staff recommends the committee recommend support of Senate Bill 1039.

b. Legislation Impacting the Practice of Pharmacy or the Board's Jurisdiction

Copies of each bill and related documents are provided as Attachments.

1. AB 45 (Mullin) Household Hazardous Waste

Version: January 21, 2016 Amended

Location: Senate Environmental Quality Committee

Position: Oppose Unless Amended

The bill adds Article 3.4 "Household Hazardous Waste Collection and Reduction" to the Public Resources Code. The bill would require the Department of Resources Recycling and Recovery (CalRecycle) to adopt one or more model ordinances for a comprehensive program for the collection of household hazardous waste, and then post the ordinance(s) on CalRecycle's web site. Thereafter, a local jurisdiction that provides for the residential collection and disposal of solid waste that proposes to enact an ordinance governing the collection and diversion of household hazardous waste may adopt one of the model ordinances posted by CalRecycle.

The bill establishes various definitions, including but not limited to "comprehensive program for the collection of household hazardous waste," "household hazardous waste," and "home-generated pharmaceutical waste."

Further, the bill requires CalRecycle to determine whether a nonprofit organization has been created and funded to make grants to local jurisdictions for specified purposes related to household hazardous waste disposal. This bill would specify if CalRecycle makes no such determination by December 31, 2018, then the provisions of the bill are repealed on January 1, 2019.

The board has requested amendments that would require mail back of dangerous drugs; the amendments were not accepted.

2. AB 1069 (Gordon) Prescription Drugs: Collection and Distribution Program

Version: July 1, 2015 Amended

Location: Senate Appropriations Committee (7/7/2015)

Position: Oppose Unless Amended

AB 1069 would expand the provisions under which a county-established repository and distribution program allows the transfer of drugs to other counties (not just adjacent counties) and would allow for the advance repackaging of donated medications in advance of a prescription.

Board staff has worked with the author's office to secure amendments to address many of the legal conflicts the measure initially contained, but there are still some concerns with the bill in its current form. Currently, the bill would remove a pharmacist from several aspects of the redistribution program of prescription drugs; would allow a

“participating entity” to transfer drugs like a distributor without appropriate licensure and control; and would permit what is currently unlawful repackaging and co-mingling of previously dispensed medications, including donated medications from various sources, all to the detriment of patient safety. Staff continues to reach out to the author’s office and will provide updates – if any are available – at the committee meeting.

3. AB 1386 (Low) Emergency Medical Care: Epinephrine Auto-Injectors

Version: June 28, 2016 Amended

Location: Hearing in Senate Appropriations Scheduled for August 1, 2016

This measure would amend Pharmacy Law and other provisions of the Civil Code and Health and Safety Code to authorize a health care provider to issue a prescription, and a pharmacy to furnish, epinephrine auto-injectors to an authorized *entity*, as defined. The bill calls for specific labeling on any epinephrine auto-injectors dispensed pursuant to the bill’s provisions. Authorized entities include any for-profit, nonprofit, or government entity or organization that employs at least one person or utilizes at least one volunteer or agent that has voluntarily completed a training course, as defined. As is with current law, authorized training providers shall be approved, and the minimum standards for training and the use and administration of epinephrine auto-injectors shall be established and approved by the California Emergency Medical Services Authority.

Staff recommends the board support the June 28th version of the bill.

4. AB 1748 (Mayes) Emergency medical care: Naloxone Hydrochloride or other Opioid Antagonist

Version: June 20, 2016 Amendment

Location: Senate Appropriations – Hearing set for August 1, 2016

Position: None

This bill would authorize specified educational agencies to provide an emergency opioid antagonist to school nurses or trained personnel and would authorize a school nurse or trained individual (volunteer) to administer an opioid antagonist to a person who is believed to be suffering from an opioid overdose, as specified. The bill contains provisions that authorize the writing of a prescription by a physician and surgeon, and a pharmacist’s authority to dispense naloxone hydrochloride or other opioid antagonist pursuant to that prescription.

The author’s office indicated this measure is modeled after provisions that allow a pharmacist to dispense emergency epinephrine auto-injectors to authorized entities for the purpose of providing emergency medical assistance. The board has not considered this measure previously.

5. AB 2144 (Rodriguez) Pharmacy: Prescriptions

Version: March 18, 2016 Amended
Status: Dead

As amended this measure would amend Section 4074 of the Business and Professions Code to specify that a health facility shall require each patient to acknowledge in writing that a patient has received specified drug warning, storage and other specified information at the time of discharge. This bill is now considered to be dead, so a staff analysis was not prepared.

7. SB 482 (Lara) Controlled Substances: CURES database

Version: June 21, 2016
Location: Assembly Rules
Position: Support

This measure would require a prescriber to access the CURES system under specified conditions, to include checking the system before prescribing a Schedule II, III or IV medication for the first time and at least every four months. The bill also limits the dispensing of a controlled substance in specified settings to either a 5- or 7-day supply.

Staff recommends that the board support the June 21st version of the bill.

8. SB 999 (Pavley) Health Insurance: Contraceptives: Annual Supply

Version: June 20, 2016, Amended
Location: Assembly Appropriations
Position: None

This bill would authorize a pharmacist to dispense prescribed, FDA-approved, self-administered hormonal contraceptives either as prescribed or, at the patient's request, in a 12-month supply, unless the prescriber specifically indicates no change to quantity. The measure would also require a health care service plan or health insurance policy, on or after January 1, 2017, to cover a 12-month supply of a self-administered hormonal contraception dispensed at one time by a prescriber or dispenser. As recently amended, the bill incorporates reference to Section 733 of the Business and Professions Code (conscious clause). The board does not have a position on Senate Bill 999.

10. SB 1229 (Jackson) Pharmacies: Secure Drug Take-Back Bins

Version: June 27, 2016 as Amended
Location: Assembly Floor
Position: Support

Senate Bill 1229, as amended, states the Legislature's intent to encourage good faith participation of federally authorized entities to maintain secure drug take-back bins for

the convenience and public health and safety of prescription drug consumers, and for the proper disposal in the waste stream of pharmaceutical waste contained in the bins.

The bill incorporates the Secure and Responsible Drug Disposal Act of 2010 (Public Law 111-273) and states that the provisions of the bill shall be construed in a manner that is consistent with the requirements imposed by the DEA's final rule and any regulations promulgated by the state. Staff recommends that the board maintain its support of the bill.

c. Legislation Impacting Board Operations

Copies of each bill and related documents are provided as Attachments

1. AB 12 (Cooley) State Government: Administrative Regulations: Review

Version: August 19, 2015

Location: Last location was Senate Appropriations / Held under submission

Position: Oppose (4/22/15 text version)

AB 12 would require state agencies to review, adopt, amend or repeal any regulations that are duplicative, overlapping, and inconsistent or out-of-date by January 1, 2018, and establish reporting requirements. The bill was amended on August 19, 2015, but there are no substantive differences from the prior version.

The bill has not moved since August 2015. If there are any recent developments, staff will provide an update at the meeting.

2. SB 1155 (Morrell) Professions and Vocations: Licenses: Military Service

Version: June 23, 2016 - Amended

Location: Assembly Appropriations

Position: None

This measure would allow a veteran who is honorably discharged who served as an active duty member of the California National Guard or the United States Armed Forces to have one fee waiver for the application for an issuance of one license by one of the boards within the Department of Consumer Affairs. The provisions would go into effect on January 1, 2018. The most recent amendment specifies information that would constitute "satisfactory evidence" of being honorably discharged.

Part 2: Regulation Report

a. Board Approved – Submitted for Administrative Review to the Department of Consumer Affairs or the Office of Administrative Law

1. Proposed Regulations to Add Title 16 California Code of Regulations (CCR) sections 1730, 1730.1 and Amend section 1749 related to Advanced Practice Pharmacists

In July 2015, staff initiated a formal rulemaking to add Title 16 CCR sections 1730, 1730.1, and amend section 1749 related to the licensing requirements for advanced practice pharmacist. At the February 2016 board meeting, the board adopted the final regulation text. The final rulemaking file was submitted to the Office of Administrative Law for final review on June 3, 2016. A copy of the adopted regulation language is provided in Attachment 1.

2. Proposed Regulations to Add Title 16 CCR section 1730.2 Related to Advanced Practice Pharmacists – Certification Programs

At the November 2015 Board Meeting, the board approved proposed text to add Title 16 CCR section 1730.2, establishing the certification program criteria for advanced practice pharmacist. At the February 2016 board meeting, the board adopted the final regulation text. The final rulemaking file was submitted to the Office of Administrative Law for final review on June 29, 2016. A copy of the adopted regulation language is provided in Attachment 1.

3. Proposed Regulations to Amend Title 16 CCR sections 1735 and 1751 et seq. related to Compounding

On May 8, 2015, the board initiated a formal rulemaking related to compounded drug preparations. On January 19, 2016, following the completion of a 45-day comment period and two 15-day comment periods, the board adopted the final regulation text. The final rulemaking file was submitted to the Department of Consumer Affairs for final review on March 10, 2016. A copy of the adopted regulation language is provided in Attachment 1.

4. Proposed Regulations to Add Title 16 CCR section 1746.5 related to Travel Medications

At the June 2015 Board Meeting, the board approved proposed text to add Title 16 CCR section 1746.5, related to the furnishing of travel medications. At the April 2016 board meeting, the board adopted the final regulation text. The final rulemaking file was submitted to the Department of Consumer Affairs for final review on May 9, 2016. A copy of the adopted regulation language is provided in Attachment 1.

b. Board Approved – Rulemaking File Being Prepared by Staff for Submission to the Department of Consumer Affairs or the Office of Administrative Law

1. Proposed Regulations to Amend Title 16 CCR section 1760 Related to the Board’s Disciplinary Guidelines

In September 2015, the board initiated a formal rulemaking to amend Title 16 CCR section 1760 related to the board’s disciplinary guidelines. Following the initial comment periods, the board, at the April 2016 board meeting, adopted the final regulation text. Board staff is currently compiling the final rulemaking package to submit for administrative review by the Department of Consumer Affairs and the Office of Administrative Law. A copy of the adopted regulation language is provided in Attachment 2.

2. Proposed Regulations to Add Title 16 CCR section 1746.4 related to Immunizations (Vaccinations)

In July 2015, the board initiated a formal rulemaking to add Title 16 CCR section 1746.4 to specify the requirements for a pharmacist to administer vaccinations. On January 19, 2016, following the completion of a 45-day comment period and two 15-day comment periods, the board adopted the final regulation text. In June 2016, the board clarified that the protocol should apply to all pharmacist-provided immunizations. The board voted to amend the protocol language for clarity and released the amended text for a 15-day comment period. The 15-day comment period ended on June 25, 2016 and the board adopted the final regulation text at the July 1, 2016 Board Meeting. A copy of the adopted regulation language is provided in Attachment 2.

c. Board Action to Initiate Rulemaking – Comment Period Closed; Awaiting Action by Board / Licensing Committee

1. Proposed Regulation to Amend Title 16 CCR section 1703 related to Delegation of Certain Functions

At the October 2013 Board Meeting, the board approved proposed text to amend Title 16 CCR section 1703 related to “Section 100” regulation changes and to delegate to the Executive Officer the authority to initiate a rulemaking to adopt “changes without regulatory effect.” Additionally, at the February 2016 Board Meeting, the board approved proposed text to delegate to the Executive Officer the authority to “approve waivers pursuant to Section 4076.5(e)” regarding patient-centered labels. The 45-day comment period closed on June 6, 2016. The comments are pending review by the full board in July. A copy of the language released for the 45-day comment period is provided in Attachment 3.

2. Proposed Regulations to Amend Title 16 CCR section 1744 related to Drug Warnings

At the April 2015 Board Meeting, the board approved proposed text to amend Title 16 CCR section 1744 related to the drug warning label requirements. At the April 2016 Board Meeting, the board approved a modified text and initiated a 15-day comment period. The 15-day comment period closed on May 26, 2016. The comments are pending review by the full board in July. A copy of the language released for the 15-day comment period is provided in Attachment 3.

3. Proposed Regulations to Amend Title 16 CCR section 1707.5 related to Patient-Centered Labels

At the January 2015 Board Meeting, the board approved proposed text to amend Title 16 CCR section 1707.5(a)(1)(B) to add "Generic for _____" and translation services. At the April 28, 2016 Board meeting, the board approved a modified text and initiated a 15-day comment period. The 15-day comment period closed on May 26, 2016. The comments are pending review by the full board in July. A copy of the language released for the 15-day comment period is provided in Attachment 3.

4. Proposed Regulations to Add Title 16 CCR sections 1776-1776.6 related to Prescription Drug Take-Back Programs

At the January 2016 Board Meeting, the board approved proposed text to add Title 16 CCR sections 1776-1776.6 et seq., related to prescription drug take-back programs. This rulemaking was initiated in February 2016 and on April 13, 2016, two regulation hearings were held. The board reviewed the 45-day comments at the April 28, 2016 Board meeting and at that time approved a modified text. The modified language was released for a 15-day comment period, which concluded on May 18, 2016. The board reviewed the 15-day comments at its June 2016 Board Meeting. The Board made policy decisions based on the 15-day comments, and instructed board staff to make the recommended changes to the language and present the modified language at the July 2016 Board Meeting for discussion. A copy of the language released for the 15-day comment period is provided in Attachment 3.

5. Proposed Regulations to Add Title 16 CCR section 1715.65 related to Reconciliation and Inventory of Controlled Substances

At the July 2015 Board Meeting, the board approved proposed text to add Title 16 CCR section 1715.65 related to reconciliation and inventory of controlled substances. At the April 2016 board meeting, the board voted to return the language to the enforcement committee to review the inventory requirements for hospitals and automated drug devices. The enforcement committee reviewed the inventory requirements at its June 2016 meeting. Modified language, as recommended by the enforcement committee, will be presented at the July Board meeting for discussion.

A copy of the language released for the 45-day comment period is provided in Attachment 3.

6. Proposed Regulations to Amend Title 16 CCR section 1732.05, 1732.2 and 1732.5 related to Continuing Education

In 2013, the board approved a proposal to initial a formal rulemaking to amend the text of 16 CCR Sections 1732.05, 1732.2, and 1732.5 relative to continuing education. At the October 2014 board meeting, the board discussed and thereafter voted to add “compounding education” as a sixth area of subject-specific continuing education in Section 1732.5. At the April 2015 board meeting, the board discussed and thereafter voted to add “Including Indicated of Red Flags and a Pharmacist’s Corresponding Responsibility” to area five “Substance Abuse.” The 45-day comment period ended on December 28, 2015. At the February 2016 board meeting, the board voted to return the language to the licensing committee to review the six subject-specific areas for possible consolidation. At the June 2016 committee meeting, the committee voted to withdraw the proposed changes. A copy of the language released for the 45-day comment period is provided in Attachment 3.

d. Board Action to Initiate Rulemaking – Awaiting Notice

1. Proposed Regulations to Amend and/or Add Title 16 CCR section 1702, 1702.1, 1702.2, and 1702.5, related to Renewal Requirements

At the July 2013 Board Meeting, the board approved proposed text to amend and/or add Title 16 CCR sections 1702, 1702.1, 1702.2, and 1702.5 related to standardized reporting of convictions and discipline at the time of renewal for pharmacists, pharmacy technicians and designated representatives, as well as require nonresident wholesalers and nonresident pharmacies to report disciplinary actions by other entities at the time of renewal. Board staff is preparing the required notice documents and anticipates initiating the rulemaking process in July 2016. A copy of the board-approved language (not yet noticed) is provided in Attachment 4.

2. Proposed Regulations to Amend Title 16 CCR sections 1780 – 1785, et seq., related to Third Party Logistics Providers

At the July 2015 Board Meeting, the board approved proposed text to amend Title 16 CCR sections 1780 et seq. to establish regulatory requirements for Third-Party Logistics Providers. Board staff prepared the required notice documents; however, the language will be reviewed at the July Board Meeting prior to initiation of the 45-day comment period. A copy of the board-approved language (not yet noticed) is provided in Attachment 4.



Bill Number:	SB 1193
Current Version:	As Amended June 21, 2016
Author:	Hill
Topic:	California State Board of Pharmacy; Outsourcing Facilities
Board Position:	Support (ver. 4/13/16)

Affected Sections: Section 4001 and 4003 of the Business and Professions Code

Status: Do pass from Assembly Business and Professions (6/28/16) 13-0

Location: Assembly Appropriations

SUMMARY:

The introduced version of the bill extended the operations of the California Board of Pharmacy and the board's authority to appoint an executive officer until January 1, 2021.

Since it was introduced, the bill has been amended to incorporate board sponsored "outsourcing" provisions. Additional amendments would authorize the board to issue a cease and desist order, and provides for related notice, hearing, appeal, and decision related to such an order; specify conditions and a time frame when a pharmacy issues a recall for a nonsterile drug product; make technical changes to remove "injectable" from various pharmacy law provisions; and clarify the board's authority to issue a temporary permit upon conditions and for any periods of time as the board determines to be in the public interest; add "licensed pharmacists" to the list of individuals that may be shareholders, officers, directors, or professional employees of a professional Medical Corporation; and provide for the registration of automated drug delivery systems with the board (hospitals exempt).

EXISTING LAW:

Existing law establishes the California State Board of Pharmacy which is responsible for administration and enforcement of pharmacy law. Existing law includes a sunset provision after which the board would no longer exist, unless the date is extended. Further, existing law provides that the board may appoint an executive officer.

Emergency Pharmaceutical Supplies Container

Existing law permits a pharmacy in a health facility to utilize a ¹secured emergency pharmaceutical supplies container maintained within a health care facility for the purpose of replenishing drugs in an ambulance or other emergency medical services provider.

¹ Business and Professions Code section 4119

Clinic Licensure

Article 14 of Division 2 of Chapter 9 (starting with section 4190) specifies licensure requirements related to drug distribution in clinics.

Further, Title 16 CCR Section 1709 requires that notifications be made to the board related to changes in beneficial interest in any business entity licensed by the board.

Professional Corporations

Section 4306 specifies that any individual licensed under Pharmacy Law that violates, attempts to violates, any provision or term of Pharmacy Law, the Moscone-Knox Professional Corporation Act, or any regulations duly adopted under these laws shall constitute unprofessional conduct.

Pharmacy Corporations are defined in Article 10 of Division 2 of Chapter 9 (commencing with Section 4150), and specifies that persons defined in Section 13401 of the Corporations Code shall not in any manner accrue to the benefit of the shareholder or his or her shares in the pharmacy corporation.

THIS BILL WOULD:Sunset Provisions

Amend Section 4001(f) to extend the board's sunset date to January 1, 2021.

Amend Section 4003 to extend the provisions of the executive officer to January 1, 2021.

Emergency Pharmaceutical Supplies Container

Add section 4119.1 to require that a health facility that utilizes a secured emergency pharmaceutical supplies container, as defined, register the use of the automated drug delivery system with the board, to include the address and location of use.

Clinic Applications

Add Section 4203.5 to mandate that the board issue a clinic license or incorporate reported changes, within 30 days of the receipt of a completed application and fees, as specified.

Cease and Desist / Facilities

Add section 4316 to authorize the board to issue a cease and desist order for unlicensed activity within a facility, as specified, and to set forth notice and appeal hearings for the same.

Professional Medical Corporations

Amend Corporations Code Section 13401.5 to add "licensed pharmacists" to the list of individuals that may be shareholders, officers, directors, or professional employees of a professional Medical Corporation.

Outsourcing Facility Provisions

Add Section 4034 to define "outsourcing facility."

Amend Section 4400 to specify licensing and renewal fees for outsourcing facility licenses, as well as nonresident outsourcing facility licenses.

Add Article 7.7. entitled “Outsourcing Facilities” and add Sections 4129, 4129.1, 4129.2, 4129.3, 4129.4, 4129.5, 4129.6, 4129.8, 4129.9 to establish the regulatory framework for board licensure of resident and nonresident outsourcing facilities that compound non-specific medications and ship those medications into California for administration to California patients. The previous were contained in SB 619 (Morrell, 2015), but the bill was held on suspense and died in Senate Appropriations in 2015.

STAFF COMMENTS:

The board president and executive staff provided testimony during a joint hearing of the Senate and Assembly oversight committee on March 14, 2016. A second hearing of the joint oversight committee occurred on April 18, 2016.

As part of the Sunset review process, the board has had the opportunity to also provide written responses to all of the issues identified by the joint oversight committee. Recently, staff attended the Assembly Business and Professions Committee hearing and was available to provide information. The bill passed out of committee 13-0 and was re-referred to Assembly Appropriations.

STAFF RECOMMENDATION:

Support the June 21, 2016 version of the bill.

FISCAL IMPACT:

Staff is working to provide Assembly Appropriations with fiscal information the first week of July.

HISTORY:

Last 5 History Actions	
Date	Action
06/28/16	From committee: Do pass and re-refer to Com. on APPR. (Ayes 13. Noes 0.) (June 28). Re-referred to Com. on APPR.
06/21/16	From committee with author's amendments. Read second time and amended. Re-referred to Com. on B. & P.
06/13/16	Referred to Com. on B. & P.
06/02/16	In Assembly. Read first time. Held at Desk.
06/01/16	Read third time. Passed. (Ayes 39. Noes 0. Page 4106.) Ordered to the Assembly.



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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

June 2, 2016

The Honorable Jerry Hill
Member, California State Senate
Chair, Senate Committee on Business,
Professions and Economic Development
State Capitol, Room 2053
Sacramento, CA 95816

RE: SB 1193 – Support

Dear Senator Hill:

I am pleased to advise you that at its April 27th meeting, the Board of unanimously voted to support Senate Bill 1193. The board very much appreciates your authorship of this legislation, as well as the opportunities you have provided for the board to address various issues through the sunset process.

The board remains committed to the sunset review process and to securing changes that will strengthen the board's mandate to protect the public as it exercises its licensing, regulatory and enforcement functions. Thank you for your role in advocating for these provisions.

Please do not hesitate to contact me at (916) 574-7911 if you have any questions.

Sincerely,

A handwritten signature in black ink that reads "Virginia Herold". The signature is fluid and cursive.

VIRGINIA HEROLD
Executive Officer

cc: Department of Consumer Affairs



California
LEGISLATIVE INFORMATION

SB 1193 (Hill)
As Amended 6/21/16

SB-1193 Healing arts. (2015-2016)

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, ~~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.* Notwithstanding any other ~~provision of~~ 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, ~~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. 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 ~~may~~ *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 ~~injectable-~~ drugs to a pharmacy pursuant to Section ~~4127.1.~~ *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, when the ownership of a pharmacy is transferred from one person to another,~~ *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.~~

(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) ~~Nothing in this-~~ *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. 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) 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 ~~for injection, administration into the eye, or inhalation~~ 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).

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

~~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 ~~injectable~~ 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 ~~injectable~~ 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. ~~On and after July 1, 2005, a~~ **A** pharmacy shall compound sterile ~~injectable~~ 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, when the ownership of a pharmacy that is licensed to compound injectable sterile drug products is transferred~~

~~from one person to another,~~ *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, including a pharmacy that is exempt from licensure pursuant to subdivision (d) of Section 4127.1 and subdivision (c) of Section 4127.2, that~~ *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 ~~injectable~~ compounding.

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.*

4129.8. *The board, at its discretion, may issue a temporary license to an outsourcing facility 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 ~~injectable~~ 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. 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. 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) ~~This section shall become operative on July 1, 2014.~~ *The fee for the issuance or renewal of an outsourcing facility license shall be 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 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 ~~for the use of the board and out of it and not otherwise shall be paid all expenses of the~~ 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).

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

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

~~(l)~~ *(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)*.

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

~~(n)~~ *(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.

~~(o)~~ *(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).

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

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

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

~~(c)~~ (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.

~~(d)~~ (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. 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.*



Bill Number: SB 1039
Current Version: As Amended June 30, 2016
Authors: Senator Hill
Topic: Professions and Vocations
Board Position:

Affected Section(s) (*Pharmacy provisions only*):

Amend 4128.2 and 4400 of the Business and Professions Code

Status: Passed from Assembly Business and Professions (6/28) (11-5) and Re-referred to Assembly Appropriations

SUMMARY

Senate Bill 1039 amends numerous provisions related to various professions and vocations, to include the Board of Podiatric Medicine, Dental Hygiene Committee, and others.

Specific to the Board of Pharmacy, this bill would set forth a new fee schedule, which is needed to sustain board operations.

EXISTING LAW:

Authorizes the board to issue a centralized hospital packaging license and sets the related fee.

Establishes the board's fee schedule.

THIS BILL WOULD (Pharmacy provisions only):

Sections 26 and 27 of SB 1039 apply to the Board of Pharmacy.

Centralized Hospital Packaging.

The bill would amend Section 4128.2 to extend the current fee to July 1, 2017.

Fee Schedule

The bill would amend Section 4400 to make the board's current fee schedule inoperative on July 1, 2017, and to set a new fee schedule that will become operative on July 1, 2017 (and also incorporate the fee for centralized hospital packaging).

STAFF RECOMMENDATION:

Recommend that the board Support Senate Bill 1039.

HISTORY:

Last 5 History Actions	
Date	Action
06/30/16	Read second time and amended. Re-referred to Com. on APPR.
06/29/16	From committee: Do pass as amended and re-refer to Com. on APPR. (Ayes 11. Noes 5.) (June 28).
06/22/16	From committee with author's amendments. Read second time and amended. Re-referred to Com. on B. & P.
06/09/16	Referred to Com. on B. & P.
06/02/16	In Assembly. Read first time. Held at Desk.



SB-1039 Professions and vocations. (2015-2016)

SECTION 1. *It is the intent of the Legislature to enact future legislation that would establish a Dental Corps Scholarship Program within the Health Professions Education Foundation to increase the supply of dentists serving in medically underserved areas.*

SEC. 15. **SEC. 2.** Section 1944 of the Business and Professions Code is amended to read:

1944. (a) The committee shall establish by resolution the amount of the fees that relate to the licensing of a registered dental hygienist, a registered dental hygienist in alternative practice, and a registered dental hygienist in extended functions. The fees established by board resolution in effect on June 30, 2009, as they relate to the licensure of registered dental hygienists, registered dental hygienists in alternative practice, and registered dental hygienists in extended functions, shall remain in effect until modified by the committee. The fees are subject to the following limitations:

(1) The application fee for an original license and the fee for issuance of an original license shall not exceed two hundred fifty dollars (\$250).

(2) The fee for examination for licensure as a registered dental hygienist shall not exceed the actual cost of the examination.

(3) The fee for examination for licensure as a registered dental hygienist in extended functions shall not exceed the actual cost of the examination.

(4) The fee for examination for licensure as a registered dental hygienist in alternative practice shall not exceed the actual cost of administering the examination.

(5) The biennial renewal fee shall not exceed ~~one~~ **five** hundred ~~sixty~~ dollars ~~(\$160)~~ **(\$500)**.

(6) The delinquency fee shall not exceed one-half of the renewal fee. Any delinquent license may be restored only upon payment of all fees, including the delinquency fee, and compliance with all other applicable requirements of this article.

(7) The fee for issuance of a duplicate license to replace one that is lost or destroyed, or in the event of a name change, shall not exceed twenty-five dollars (\$25) or one-half of the renewal fee, whichever is greater.

(8) The fee for certification of licensure shall not exceed one-half of the renewal fee.

(9) The fee for each curriculum review, feasibility study review, and site evaluation for educational programs for dental hygienists who are not accredited by a committee-approved agency shall not exceed two thousand one hundred dollars (\$2,100).

(10) The fee for each review or approval of course requirements for licensure or procedures that require additional training shall not exceed seven hundred fifty dollars (\$750).

(11) The initial application and biennial fee for a provider of continuing education shall not exceed five hundred dollars (\$500).

(12) The amount of fees payable in connection with permits issued under Section 1962 is as follows:

(A) The initial permit fee is an amount equal to the renewal fee for the applicant's license to practice dental hygiene in effect on the last regular renewal date before the date on which the permit is issued.

(B) If the permit will expire less than one year after its issuance, then the initial permit fee is an amount equal to 50 percent of the renewal fee in effect on the last regular renewal date before the date on which the permit is issued.

(b) The renewal and delinquency fees shall be fixed by the committee by resolution at not more than the current amount of the renewal fee for a license to practice under this article nor less than five dollars (\$5).

(c) Fees fixed by the committee by resolution pursuant to this section shall not be subject to the approval of the Office of Administrative Law.

(d) Fees collected pursuant to this section shall be collected by the committee and deposited into the State Dental Hygiene Fund, which is hereby created. All money in this fund shall, upon appropriation by the Legislature in the annual Budget Act, be used to implement this article.

(e) No fees or charges other than those listed in this section shall be levied by the committee in connection with the licensure of registered dental hygienists, registered dental hygienists in alternative practice, or registered dental hygienists in extended functions.

(f) The fee for registration of an extramural dental facility shall not exceed two hundred fifty dollars (\$250).

(g) The fee for registration of a mobile dental hygiene unit shall not exceed one hundred fifty dollars (\$150).

(h) The biennial renewal fee for a mobile dental hygiene unit shall not exceed two hundred fifty dollars (\$250).

(i) The fee for an additional office permit shall not exceed two hundred fifty dollars (\$250).

(j) The biennial renewal fee for an additional office as described in Section 1926.4 shall not exceed two hundred fifty dollars (\$250).

(k) The initial application and biennial special permit fee is an amount equal to the biennial renewal fee specified in paragraph (6) of subdivision (a).

(l) The fees in this section shall not exceed an amount sufficient to cover the reasonable regulatory cost of carrying out this article.

SEC. 3. Section 2472 of the Business and Professions Code is amended to read:

2472. (a) The certificate to practice podiatric medicine authorizes the holder to practice podiatric medicine.

(b) As used in this chapter, "podiatric medicine" means the diagnosis, medical, surgical, mechanical, manipulative, and electrical treatment of the human foot, including the ankle and tendons that insert into the foot and the nonsurgical treatment of the muscles and tendons of the leg governing the functions of the foot.

(c) A doctor of podiatric medicine ~~may~~ *shall* not administer an anesthetic other than local. If an anesthetic other than local is required for any procedure, the anesthetic shall be administered by another licensed health care practitioner who is authorized to administer the required anesthetic within the scope of his or her practice.

(d) (1) A doctor of podiatric medicine ~~who is ankle certified by the board on and after January 1, 1984,~~ may do the following:

(A) Perform surgical treatment of the ankle and tendons at the level of the ankle pursuant to subdivision (e).

(B) Perform services under the direct supervision of a physician and surgeon, as an assistant at surgery, in surgical procedures that are otherwise beyond the scope of practice of a doctor of podiatric medicine.

(C) Perform a partial amputation of the foot no further proximal than the Chopart's joint.

(2) Nothing in this subdivision shall be construed to permit a doctor of podiatric medicine to function as a primary surgeon for any procedure beyond his or her scope of practice.

(e) A doctor of podiatric medicine may perform surgical treatment of the ankle and tendons at the level of the ankle only in the following locations:

(1) A licensed general acute care hospital, as defined in Section 1250 of the Health and Safety Code.

(2) A licensed surgical clinic, as defined in Section 1204 of the Health and Safety Code, if the doctor of podiatric medicine has surgical privileges, including the privilege to perform surgery on the ankle, in a general acute care hospital described in paragraph (1) and meets all the protocols of the surgical clinic.

(3) An ambulatory surgical center that is certified to participate in the Medicare program under Title XVIII (42 U.S.C. Sec. 1395 et seq.) of the federal Social Security Act, if the doctor of podiatric medicine has surgical

privileges, including the privilege to perform surgery on the ankle, in a general acute care hospital described in paragraph (1) and meets all the protocols of the surgical center.

(4) A freestanding physical plant housing outpatient services of a licensed general acute care hospital, as defined in Section 1250 of the Health and Safety Code, if the doctor of podiatric medicine has surgical privileges, including the privilege to perform surgery on the ankle, in a general acute care hospital described in paragraph (1). For purposes of this section, a "freestanding physical plant" means any building that is not physically attached to a building where inpatient services are provided.

(5) An outpatient setting accredited pursuant to subdivision (g) of Section 1248.1 of the Health and Safety Code.

SEC. 4. Section 2499.5 of the Business and Professions Code is amended to read:

2499.5. The following fees apply to certificates to practice podiatric medicine. The amount of fees prescribed for doctors of podiatric medicine shall be those set forth in this section unless a lower fee is established by the board in accordance with Section 2499.6. Fees collected pursuant to this section shall be fixed by the board in amounts not to exceed the actual costs of providing the service for which the fee is collected.

(a) Each applicant for a certificate to practice podiatric medicine shall pay an application fee of ~~twenty one hundred~~ dollars ~~(~~\$20~~)~~ ~~(~~\$100~~)~~ at the time the application is filed. If the applicant qualifies for a certificate, he or she shall pay a fee which shall be fixed by the board at an amount not to exceed one hundred dollars (\$100) nor less than five dollars (\$5) for the issuance of the certificate.

(b) The oral examination fee shall be seven hundred dollars (\$700), or the actual cost, whichever is lower, and shall be paid by each applicant. If the applicant's credentials are insufficient or if the applicant does not desire to take the examination, and has so notified the board 30 days prior to the examination date, only the examination fee is returnable to the applicant. The board may charge an examination fee for any subsequent reexamination of the applicant.

(c) Each applicant who qualifies for a certificate, as a condition precedent to its issuance, in addition to other fees required by this section, shall pay an initial license fee. The initial license fee shall be eight hundred dollars (\$800). The initial license shall expire the second year after its issuance on the last day of the month of birth of the licensee. The board may reduce the initial license fee by up to 50 percent of the amount of the fee for any applicant who is enrolled in a postgraduate training program approved by the board or who has completed a postgraduate training program approved by the board within six months prior to the payment of the initial license fee.

(d) The biennial renewal fee shall be nine hundred dollars (\$900). Any licensee enrolled in an approved residency program shall be required to pay only 50 percent of the biennial renewal fee at the time of his or her first renewal.

(e) The delinquency fee is one hundred fifty dollars (\$150).

(f) The duplicate wall certificate fee is ~~forty one hundred~~ dollars ~~(~~\$40~~)~~ ~~(~~\$100~~)~~.

(g) The duplicate renewal receipt fee is ~~forty fifty~~ dollars ~~(~~\$40~~)~~ ~~(~~\$50~~)~~.

(h) The endorsement fee is thirty dollars (\$30).

(i) The letter of good standing fee or for loan deferment is ~~thirty one hundred~~ dollars ~~(~~\$30~~)~~ ~~(~~\$100~~)~~.

(j) There shall be a fee of ~~sixty one hundred~~ dollars ~~(~~\$60~~)~~ ~~(~~\$100~~)~~ for the issuance of a resident's license under Section 2475.

~~(k) The application fee for ankle certification under Section 2472 for persons licensed prior to January 1, 1984, shall be fifty dollars (\$50). The examination and reexamination fee for this certification shall be seven hundred dollars (\$700).~~

~~(k)~~

†

‡ The filing fee to appeal the failure of an oral examination shall be ~~twenty five one hundred~~ dollars ~~(~~\$25~~)~~ ~~(~~\$100~~)~~.

~~(m)~~ (l) The fee for approval of a continuing education course or program shall be ~~one two~~ hundred ~~fifty~~ dollars ~~(~~\$100~~)~~ ~~(~~\$250~~)~~.

~~SEC. 19.~~**SEC. 5.** Section 2546.9 of the Business and Professions Code is repealed.

~~2546.9.~~ The amount of fees prescribed in connection with the registration of nonresident contact lens sellers is that established by the following schedule:

- ~~(a) The initial registration fee shall be one hundred dollars (\$100).~~
- ~~(b) The renewal fee shall be one hundred dollars (\$100).~~
- ~~(c) The delinquency fee shall be twenty-five dollars (\$25).~~
- ~~(d) The fee for replacement of a lost, stolen, or destroyed registration shall be twenty-five dollars (\$25).~~
- ~~(e) The fees collected pursuant to this chapter shall be deposited in the Dispensing Opticians Fund, and shall be available, upon appropriation, to the State Board of Optometry for the purposes of this chapter.~~

SEC. 6. Section 2546.9 is added to the Business and Professions Code, to read:

2546.9. The amount of fees prescribed in connection with the registration of nonresident contact lens sellers is that established by the following schedule:

- (a) The application fee for a nonresident contact lens seller shall be a minimum of one hundred fifty dollars (\$150) and shall not exceed two hundred dollars (\$200).
- (b) The initial registration fee shall be a minimum of two hundred dollars (\$200) and shall not exceed three hundred dollars (\$300).
- (c) The renewal fee shall be a minimum of two hundred dollars (\$200) and shall not exceed three hundred dollars (\$300).
- (d) The delinquency fee shall be a minimum of fifty dollars (\$50) and shall not exceed seventy-five dollars (\$75).
- (e) The fee for replacement of a lost, stolen, or destroyed registration shall be twenty-five dollars (\$25).
- (f) The State Board of Optometry may periodically revise and fix by regulation the fees specified in subdivisions (a), (b), (c), and (d), and these revised fees shall not exceed the reasonable regulatory cost.
- (g) The fees collected pursuant to this chapter shall be deposited in the Dispensing Opticians Fund, and shall be available, upon appropriation, to the State Board of Optometry for the purposes of this chapter.

~~SEC. 21.~~**SEC. 7.** Section 2565 of the Business and Professions Code is repealed.

~~2565.~~ The amount of fees prescribed in connection with the registration of dispensing opticians shall be as set forth in this section unless a lower fee is fixed by the division:

- ~~(a) The initial registration fee is one hundred dollars (\$100).~~
- ~~(b) The renewal fee is one hundred dollars (\$100).~~
- ~~(c) The delinquency fee is twenty-five dollars (\$25).~~
- ~~(d) The fee for replacement of a lost, stolen, or destroyed certificate is twenty-five dollars (\$25).~~

~~This section shall become operative on January 1, 1988.~~

SEC. 8. Section 2565 is added to the Business and Professions Code, to read:

2565. The amount of fees prescribed in connection with the registration of dispensing opticians shall be as set forth in this section.

- (a) The application fee for registration shall be a minimum of one hundred fifty dollars (\$150) and shall not exceed two hundred dollars (\$200).
- (b) The initial registration fee shall be a minimum of two hundred dollars (\$200) and shall not exceed three hundred dollars (\$300).

(c) *The renewal fee shall be a minimum of two hundred dollars (\$200) and shall not exceed three hundred dollars (\$300).*

(d) *The delinquency fee shall be a minimum of fifty dollars (\$50) and shall not exceed seventy-five dollars (\$75).*

(e) *The fee for replacement of a lost, stolen, or destroyed certificate shall be twenty-five dollars (\$25).*

(f) *The State Board of Optometry may periodically revise and fix by regulation the fees specified in subdivisions (a), (b), (c), and (d), and these revised fees shall not exceed the reasonable regulatory cost.*

SEC. 23. **SEC. 9.** Section 2566 of the Business and Professions Code is repealed.

~~2566. The amount of fees prescribed in connection with certificates for contact lens dispensers, unless a lower fee is fixed by the division, is as follows:~~

~~(a) The application fee for a registered contact lens dispenser shall be one hundred dollars (\$100).~~

~~(b) The biennial fee for the renewal of certificates shall be fixed by the division in an amount not to exceed one hundred dollars (\$100).~~

~~(c) The delinquency fee is twenty five dollars (\$25).~~

~~(d) The division may by regulation provide for a refund of a portion of the application fee to applicants who do not meet the requirements for registration.~~

~~(e) The fee for replacement of a lost, stolen, or destroyed certificate is twenty five dollars (\$25).~~

~~This section shall become operative on January 1, 1988.~~

SEC. 10. Section 2566 is added to the Business and Professions Code, to read:

2566. *The amount of fees prescribed in connection with certificates for contact lens dispensers is as follows:*

(a) *The application fee for a registered contact lens dispenser shall be a minimum of one hundred fifty dollars (\$150) and shall not exceed two hundred dollars (\$200).*

(b) *The initial registration fee shall be a minimum of two hundred dollars (\$200) and shall not exceed three hundred dollars (\$300).*

(c) *The biennial fee for the renewal of certificates shall be a minimum of two hundred dollars (\$200) and shall not exceed three hundred dollars (\$300).*

(d) *The delinquency fee shall be a minimum of fifty dollars (\$50) and shall not exceed seventy-five dollars (\$75).*

(e) *The division may by regulation provide for a refund of a portion of the application fee to applicants who do not meet the requirements for registration.*

(f) *The State Board of Optometry may periodically revise and fix by regulation the fees specified in subdivisions (a), (b), (c), and (d), and these revised fees shall not exceed the reasonable regulatory cost.*

(g) *The fee for replacement of a lost, stolen, or destroyed certificate is twenty-five dollars (\$25).*

SEC. 25. **SEC. 11.** Section 2566.1 of the Business and Professions Code is repealed.

~~2566.1. The amount of fees prescribed in connection with certificates for spectacle lens dispensers shall be as set forth in this section unless a lower fee is fixed by the division:~~

~~(a) The initial registration fee is one hundred dollars (\$100).~~

~~(b) The renewal fee shall be one hundred dollars (\$100).~~

~~(c) The delinquency fee is twenty five dollars (\$25).~~

~~(d) The fee for replacement of a lost, stolen or destroyed certificate is twenty five dollars (\$25).~~

SEC. 12. Section 2566.1 is added to the Business and Professions Code, to read:

2566.1. *The amount of fees prescribed in connection with certificates for spectacle lens dispensers shall be as set forth in this section:*

(a) The application for registration fee shall be a minimum of one hundred fifty dollars (\$150) and shall not exceed two hundred dollars (\$200).

(b) The initial registration fee shall be a minimum of two hundred dollars (\$200) and shall not exceed three hundred dollars (\$300).

(c) The renewal fee shall be a minimum of two hundred dollars (\$200) and shall not exceed three hundred dollars (\$300).

(d) The delinquency fee shall be a minimum of fifty dollars (\$50) and shall not exceed seventy-five dollars (\$75).

(e) The fee for replacement of a lost, stolen or destroyed certificate is twenty-five dollars (\$25).

(f) The State Board of Optometry may periodically revise and fix by regulation the fees specified in subdivisions (a), (b), (c), and (d), and these revised fees shall not exceed the reasonable regulatory cost.

SEC. 27. **SEC. 13.** Section 2733 of the Business and Professions Code is amended to read:

2733. (a) (1) (A) Upon approval of an application filed pursuant to subdivision (b) of Section 2732.1, and upon the payment of the fee prescribed by subdivision (k) of Section 2815, the board may issue a temporary license to practice professional nursing, and a temporary certificate to practice as a certified ~~nurse-midwife, certified nurse-practitioner, certified public health nurse, certified clinical nurse specialist, or certified nurse-anesthetist~~ *public health nurse* for a period of six months from the date of issuance.

(B) Upon approval of an application filed pursuant to subdivision (b) of Section 2732.1, and upon the payment of the fee prescribed by subdivision (d) of Section 2838.2, the board may issue a temporary certificate to practice as a certified clinical nurse specialist for a period of six months from the date of issuance.

(C) Upon approval of an application filed pursuant to subdivision (b) of Section 2732.1, and upon the payment of the fee prescribed by subdivision (e) of Section 2815.5, the board may issue a temporary certificate to practice as a certified nurse-midwife for a period of six months from the date of issuance.

(D) Upon approval of an application filed pursuant to subdivision (b) of Section 2732.1, and upon the payment of the fee prescribed by subdivision (d) of Section 2830.7, the board may issue a temporary certificate to practice as a certified nurse anesthetist for a period of six months from the date of issuance.

(E) Upon approval of an application filed pursuant to subdivision (b) of Section 2732.1, and upon the payment of the fee prescribed by subdivision (p) of Section 2815, the board may issue a temporary certificate to practice as a certified nurse practitioner for a period of six months from the date of issuance.

(2) A temporary license or temporary certificate shall terminate upon notice thereof by certified mail, return receipt requested, if it is issued by mistake or if the application for permanent licensure is denied.

(b) Upon written application, the board may reissue a temporary license or temporary certificate to any person who has applied for a regular renewable license pursuant to subdivision (b) of Section 2732.1 and who, in the judgment of the board has been excusably delayed in completing his or her application for or the minimum requirements for a regular renewable license, but the board may not reissue a temporary license or temporary certificate more than twice to any one person.

SEC. 28. **SEC. 14.** Section 2746.51 of the Business and Professions Code is amended to read:

2746.51. (a) Neither this chapter nor any other provision of law shall be construed to prohibit a certified nurse-midwife from furnishing or ordering drugs or devices, including controlled substances classified in Schedule II, III, IV, or V under the California Uniform Controlled Substances Act (Division 10 (commencing with Section 11000) of the Health and Safety Code), when all of the following apply:

(1) The drugs or devices are furnished or ordered incidentally to the provision of any of the following:

(A) Family planning services, as defined in Section 14503 of the Welfare and Institutions Code.

(B) Routine health care or perinatal care, as defined in subdivision (d) of Section 123485 of the Health and Safety Code.

(C) Care rendered, consistent with the certified nurse-midwife's educational preparation or for which clinical competency has been established and maintained, to persons within a facility specified in subdivision (a), (b), (c), (d), (i), or (j) of Section 1206 of the Health and Safety Code, a clinic as specified in Section 1204 of the Health and Safety Code, a general acute care hospital as defined in subdivision (a) of Section 1250 of the Health and Safety Code, a licensed birth center as defined in Section 1204.3 of the Health and Safety Code, or a special hospital specified as a maternity hospital in subdivision (f) of Section 1250 of the Health and Safety Code.

(2) The drugs or devices are furnished or ordered by a certified nurse-midwife in accordance with standardized procedures or protocols. For purposes of this section, standardized procedure means a document, including protocols, developed and approved by the supervising physician and surgeon, the certified nurse-midwife, and the facility administrator or his or her designee. The standardized procedure covering the furnishing or ordering of drugs or devices shall specify all of the following:

(A) Which certified nurse-midwife may furnish or order drugs or devices.

(B) Which drugs or devices may be furnished or ordered and under what circumstances.

(C) The extent of physician and surgeon supervision.

(D) The method of periodic review of the certified nurse-midwife's competence, including peer review, and review of the provisions of the standardized procedure.

(3) If Schedule II or III controlled substances, as defined in Sections 11055 and 11056 of the Health and Safety Code, are furnished or ordered by a certified nurse-midwife, the controlled substances shall be furnished or ordered in accordance with a patient-specific protocol approved by the treating or supervising physician and surgeon. For Schedule II controlled substance protocols, the provision for furnishing the Schedule II controlled substance shall address the diagnosis of the illness, injury, or condition for which the Schedule II controlled substance is to be furnished.

(4) The furnishing or ordering of drugs or devices by a certified nurse-midwife occurs under physician and surgeon supervision. For purposes of this section, no physician and surgeon shall supervise more than four certified nurse-midwives at one time. Physician and surgeon supervision shall not be construed to require the physical presence of the physician, but does include all of the following:

(A) Collaboration on the development of the standardized procedure or protocol.

(B) Approval of the standardized procedure or protocol.

(C) Availability by telephonic contact at the time of patient examination by the certified nurse-midwife.

(b) (1) The furnishing or ordering of drugs or devices by a certified nurse-midwife is conditional on the issuance by the board of a number to the applicant who has successfully completed the requirements of paragraph (2). The number shall be included on all transmittals of orders for drugs or devices by the certified nurse-midwife. The board shall maintain a list of the certified nurse-midwives that it has certified pursuant to this paragraph and the number it has issued to each one. The board shall make the list available to the California State Board of Pharmacy upon its request. Every certified nurse-midwife who is authorized pursuant to this section to furnish or issue a drug order for a controlled substance shall register with the United States Drug Enforcement Administration.

(2) The board has certified in accordance with paragraph (1) that the certified nurse-midwife has satisfactorily completed a course in pharmacology covering the drugs or devices to be furnished or ordered under this section. The board shall establish the requirements for satisfactory completion of this paragraph. *The board may charge the applicant a fee to cover all necessary costs to implement this section, that shall be not less than four hundred dollars (\$400) nor more than one thousand five hundred dollars (\$1,500) for an initial application, nor less than one hundred fifty dollars (\$150) nor more than one thousand dollars (\$1,000) for an application for renewal. The board may charge a penalty fee for failure to renew a furnishing number within the prescribed time that shall be not less than seventy-five dollars (\$75) nor more than five hundred dollars (\$500).*

(3) A physician and surgeon may determine the extent of supervision necessary pursuant to this section in the furnishing or ordering of drugs and devices.

(4) A copy of the standardized procedure or protocol relating to the furnishing or ordering of controlled substances by a certified nurse-midwife shall be provided upon request to any licensed pharmacist who is uncertain of the authority of the certified nurse-midwife to perform these functions.

(5) Certified nurse-midwives who are certified by the board and hold an active furnishing number, who are currently authorized through standardized procedures or protocols to furnish Schedule II controlled substances, and who are registered with the United States Drug Enforcement Administration shall provide documentation of continuing education specific to the use of Schedule II controlled substances in settings other than a hospital based on standards developed by the board.

(c) Drugs or devices furnished or ordered by a certified nurse-midwife may include Schedule II controlled substances under the California Uniform Controlled Substances Act (Division 10 (commencing with Section 11000) of the Health and Safety Code) under the following conditions:

(1) The drugs and devices are furnished or ordered in accordance with requirements referenced in paragraphs (2) to (4), inclusive, of subdivision (a) and in paragraphs (1) to (3), inclusive, of subdivision (b).

(2) When Schedule II controlled substances, as defined in Section 11055 of the Health and Safety Code, are furnished or ordered by a certified nurse-midwife, the controlled substances shall be furnished or ordered in accordance with a patient-specific protocol approved by the treating or supervising physician and surgeon.

(d) Furnishing of drugs or devices by a certified nurse-midwife means the act of making a pharmaceutical agent or agents available to the patient in strict accordance with a standardized procedure or protocol. Use of the term "furnishing" in this section shall include the following:

(1) The ordering of a drug or device in accordance with the standardized procedure or protocol.

(2) Transmitting an order of a supervising physician and surgeon.

(e) "Drug order" or "order" for purposes of this section means an order for medication or for a drug or device that is dispensed to or for an ultimate user, issued by a certified nurse-midwife as an individual practitioner, within the meaning of Section 1306.03 of Title 21 of the Code of Federal Regulations. Notwithstanding any other provision of law, (1) a drug order issued pursuant to this section shall be treated in the same manner as a prescription of the supervising physician; (2) all references to "prescription" in this code and the Health and Safety Code shall include drug orders issued by certified nurse-midwives; and (3) the signature of a certified nurse-midwife on a drug order issued in accordance with this section shall be deemed to be the signature of a prescriber for purposes of this code and the Health and Safety Code.

SEC. 29. SEC. 15. Section 2786.5 of the Business and Professions Code is amended to read:

2786.5. (a) An institution of higher education or a private postsecondary school of nursing approved by the board pursuant to subdivision (b) of Section 2786 shall remit to the board for deposit in the Board of Registered Nursing Fund the following fees, in accordance with the following schedule:

(1) The fee for approval of a school of nursing shall be ~~five thousand dollars (\$5,000)~~; *fixed by the board at not less than forty thousand dollars (\$40,000) nor more than eighty thousand dollars (\$80,000)*.

(2) The fee for continuing approval of a nursing program established after January 1, 2013, shall be ~~three thousand five hundred dollars (\$3,500)~~; *fixed by the board at not less than fifteen thousand dollars (\$15,000) nor more than thirty thousand dollars (\$30,000)*.

(3) The processing fee for authorization of a substantive change to an approval of a school of nursing shall be *fixed by the board at not less than two thousand* five hundred dollars ~~(\$500)~~; *(\$2,500) nor more than five thousand dollars (\$5,000)*.

(b) If the board determines that the annual cost of providing oversight and review of a school of nursing, as required by this article, is less than the amount of any fees required to be paid by that institution pursuant to this article, the board may decrease the fees applicable to that institution to an amount that is proportional to the board's costs associated with that institution.

SEC. 30. SEC. 16. Section 2811 of the Business and Professions Code is amended to read:

2811. (a) Each person holding a regular renewable license under this chapter, whether in an active or inactive status, shall apply for a renewal of his *or her* license and pay the biennial renewal fee required by this chapter each two years on or before the last day of the month following the month in which his *or her* birthday occurs,

beginning with the second birthday following the date on which the license was issued, whereupon the board shall renew the license.

(b) Each such license not renewed in accordance with this section shall expire but may within a period of eight years thereafter be reinstated upon payment of the ~~biennial renewal fee and penalty fee~~ *fee* required by this chapter and upon submission of such proof of the applicant's qualifications as may be required by the board, except that during such eight-year period no examination shall be required as a condition for the reinstatement of any such expired license which has lapsed solely by reason of nonpayment of the renewal fee. After the expiration of such eight-year period the board may require as a condition of reinstatement that the applicant pass such examination as it deems necessary to determine his present fitness to resume the practice of professional nursing.

(c) A license in an inactive status may be restored to an active status if the licensee meets the continuing education standards of Section 2811.5.

~~SEC. 34.~~ **SEC. 17.** Section 2811.5 of the Business and Professions Code is amended to read:

2811.5. (a) Each person renewing his or her license under Section 2811 shall submit proof satisfactory to the board that, during the preceding two-year period, he or she has been informed of the developments in the registered nurse field or in any special area of practice engaged in by the licensee, occurring since the last renewal thereof, either by pursuing a course or courses of continuing education in the registered nurse field or relevant to the practice of the licensee, and approved by the board, or by other means deemed equivalent by the board.

(b) For purposes of this section, the board shall, by regulation, establish standards for continuing education. The standards shall be established in a manner to ~~assure~~ *ensure* that a variety of alternative forms of continuing education are available to licensees, including, but not limited to, academic studies, in-service education, institutes, seminars, lectures, conferences, workshops, extension studies, and home study programs. The standards shall take cognizance of specialized areas of ~~practice~~ *practice, and content shall be relevant to the practice of nursing and shall be related to the scientific knowledge or technical skills required for the practice of nursing or be related to direct or indirect patient or client care*. The continuing education standards established by the board shall not exceed 30 hours of direct participation in a course or courses approved by the board, or its equivalent in the units of measure adopted by the board.

(c) The board shall audit continuing education providers at least once every five years to ensure adherence to regulatory requirements, and shall withhold or rescind approval from any provider that is in violation of the regulatory requirements.

~~(e)~~ *(d)* The board shall encourage continuing education in spousal or partner abuse detection and treatment. In the event the board establishes a requirement for continuing education coursework in spousal or partner abuse detection or treatment, that requirement shall be met by each licensee within no more than four years from the date the requirement is imposed.

~~(d)~~ *(e)* In establishing standards for continuing education, the board shall consider including a course in the special care needs of individuals and their families facing end-of-life issues, including, but not limited to, all of the following:

- (1) Pain and symptom management.
- (2) The psycho-social dynamics of death.
- (3) Dying and bereavement.
- (4) Hospice care.

~~(e)~~ *(f)* In establishing standards for continuing education, the board may include a course on pain management.

~~(f)~~ *(g)* This section shall not apply to licensees during the first two years immediately following their initial licensure in California or any other governmental jurisdiction.

~~(g)~~ *(h)* The board may, in accordance with the intent of this section, make exceptions from continuing education requirements for licensees residing in another state or country, or for reasons of health, military service, or other good cause.

~~SEC. 32.~~**SEC. 18.** Section 2815 of the Business and Professions Code is amended to read:

2815. Subject to the provisions of Section 128.5, the amount of the fees prescribed by this chapter in connection with the issuance of licenses for registered nurses under its provisions is that fixed by the following schedule:

(a) (1) The fee to be paid upon the filing ~~of an~~ *by a graduate of an approved school of nursing in this state of an* application for a licensure by examination shall be fixed by the board at not less than ~~seventy-five three hundred~~ dollars ~~(~~\$75~~)~~ *(\$300)* nor more than one ~~hundred fifty thousand~~ dollars ~~(~~\$150~~)~~ *(\$1,000)*.

(2) *The fee to be paid upon the filing by a graduate of a school of nursing in another state, district, or territory of the United States of an application for a licensure by examination shall be fixed by the board at not less than three hundred fifty dollars (\$350) nor more than one thousand dollars (\$1,000).*

(3) *The fee to be paid upon the filing by a graduate of a school of nursing in another country of an application for a licensure by examination shall be fixed by the board at not less than seven hundred fifty dollars (\$750) nor more than one thousand five hundred dollars (\$1,500).*

(4) *The fee to be paid upon the filing of an application for licensure by a repeat examination shall be fixed by the board at not less than two hundred fifty dollars (\$250) and not more than one thousand dollars (\$1,000).*

(b) The fee to be paid for taking each examination shall be the actual cost to purchase an examination from a vendor approved by the board.

(c) (1) The fee to be paid for application *by a person who is licensed or registered as a nurse in another state, district, or territory of the United States* for licensure by endorsement shall be fixed by the board at not less than ~~three hundred~~ fifty dollars ~~(~~\$50~~)~~ *(\$350)* nor more than one ~~hundred thousand~~ dollars ~~(~~\$100~~)~~ *(\$1,000)*.

(2) *The fee to be paid for application by a person who is licensed or registered as a nurse in another country for licensure by endorsement shall be fixed by the board at not less than seven hundred fifty dollars (\$750) nor more than one thousand five hundred dollars (\$1,500).*

(d) (1) The biennial fee to be paid upon the filing of an application for renewal of the license shall be not less than ~~seventy-five dollars~~ ~~(~~\$75~~)~~ *one hundred eighty dollars (\$180)* nor more than ~~one seven~~ hundred fifty dollars ~~(~~\$150~~)~~ *(\$750)*. In addition, an assessment of ten dollars (\$10) shall be collected and credited to the Registered Nurse Education Fund, pursuant to Section 2815.1.

(2) *The fee to be paid upon the filing of an application for reinstatement pursuant to subdivision (b) of Section 2811 shall be not less than three hundred fifty dollars (\$350) nor more than one thousand dollars (\$1,000).*

(e) The penalty fee for failure to renew a license within the prescribed time shall be fixed by the board at not more than 50 percent of the regular renewal fee, but not less than ~~thirty-seven ninety~~ dollars ~~(~~\$37~~)~~ *(\$90)* nor more than ~~three hundred~~ seventy-five dollars ~~(~~\$75~~)~~ *(\$375)*.

(f) The fee to be paid for approval of a continuing education provider shall be fixed by the board at not less than ~~two five~~ hundred dollars ~~(~~\$200~~)~~ *(\$500)* nor more than ~~three hundred one thousand~~ dollars ~~(~~\$300~~)~~ *(\$1,000)*.

(g) The biennial fee to be paid upon the filing of an application for renewal of provider approval shall be fixed by the board at not less than ~~two seven~~ hundred fifty dollars ~~(~~\$200~~)~~ *(\$750)* nor more than ~~three hundred one thousand~~ dollars ~~(~~\$300~~)~~ *(\$1,000)*.

(h) The penalty fee for failure to renew provider approval within the prescribed time shall be fixed at not more than 50 percent of the regular renewal fee, but not less than one hundred ~~twenty-five~~ dollars ~~(~~\$100~~)~~ *(\$125)* nor more than ~~one five~~ hundred ~~fifty~~ dollars ~~(~~\$150~~)~~ *(\$500)*.

(i) The penalty for submitting insufficient funds or fictitious check, draft or order on any bank or depository for payment of any fee to the board shall be fixed at not less than fifteen dollars (\$15) nor more than thirty dollars (\$30).

(j) The fee to be paid for an interim permit shall be fixed by the board at not less than ~~thirty~~ ~~one hundred~~ dollars ~~(~~\$30~~)~~ *(\$100)* nor more than ~~two hundred~~ fifty dollars ~~(~~\$50~~)~~ *(\$250)*.

(k) The fee to be paid for a temporary license shall be fixed by the board at not less than ~~thirty~~ ~~one hundred~~ dollars ~~(~~\$30~~)~~ *(\$100)* nor more than ~~two hundred~~ fifty dollars ~~(~~\$50~~)~~ *(\$250)*.

(l) The fee to be paid for processing endorsement papers to other states shall be fixed by the board at not less than ~~sixty one hundred~~ dollars ~~(\$60)~~ ~~(\$100)~~ nor more than ~~one two~~ hundred dollars ~~(\$100)~~ ~~(\$200)~~.

(m) The fee to be paid for a certified copy of a school transcript shall be fixed by the board at not less than ~~thirty fifty~~ dollars ~~(\$30)~~ ~~(\$50)~~ nor more than ~~fifty one hundred~~ dollars ~~(\$50)~~ ~~(\$100)~~.

(n) (1) The fee to be paid for a duplicate *pocket* license shall be fixed by the board at not less than ~~thirty fifty~~ dollars ~~(\$30)~~ ~~(\$50)~~ nor more than ~~fifty seventy-five~~ dollars ~~(\$50)~~ ~~(\$75)~~.

(2) *The fee to be paid for a duplicate wall certificate shall be fixed by the board at not less than sixty dollars (\$60) nor more than one hundred dollars (\$100).*

(o) (1) The fee to be paid by a registered nurse for an evaluation of his or her qualifications to use the title "nurse practitioner" shall be fixed by the board at not less than ~~seventy five- five hundred~~ dollars ~~(\$75)~~ ~~(\$500)~~ nor more than one ~~thousand five~~ hundred ~~fifty~~ dollars ~~(\$150)~~ ~~(\$1,500)~~.

(2) *The fee to be paid by a registered nurse for a temporary certificate to practice as a nurse practitioner shall be fixed by the board at not less than one hundred fifty dollars (\$150) nor more than five hundred dollars (\$500).*

(3) *The fee to be paid upon the filing of an application for renewal of a certificate to practice as a nurse practitioner shall be not less than one hundred fifty dollars (\$150) nor more than one thousand dollars (\$1,000).*

(4) *The penalty fee for failure to renew a certificate to practice as a nurse practitioner within the prescribed time shall be not less than seventy-five dollars (\$75) nor more than five hundred dollars (\$500).*

(p) *The fee to be paid by a registered nurse for listing as a "psychiatric mental health nurse" shall be fixed by the board at not less than three hundred fifty dollars (\$350) nor more than seven hundred fifty dollars (\$750).*

(q) *The fee to be paid for duplicate National Council Licensure Examination for registered nurses (NCLEX-RN) examination results shall be not less than sixty dollars (\$60) nor more than one hundred dollars (\$100).*

(r) *The fee to be paid for a letter certifying a license shall be not less than twenty dollars (\$20) nor more than thirty dollars (\$30).*

No further fee shall be required for a license or a renewal thereof other than as prescribed by this chapter.

SEC. 33. SEC. 19. Section 2815.5 of the Business and Professions Code is amended to read:

2815.5. The amount of the fees prescribed by this chapter in connection with the issuance of certificates as nurse-midwives is that fixed by the following schedule:

(a) The fee to be paid upon the filing of an application for a certificate shall be fixed by the board at not less than ~~seventy five- five hundred~~ dollars ~~(\$75)~~ ~~(\$500)~~ nor more than one ~~thousand five~~ hundred ~~fifty~~ dollars ~~(\$150)~~ ~~(\$1,500)~~.

(b) The biennial fee to be paid upon the application for a renewal of a certificate shall be fixed by the board at not less than ~~one hundred~~ fifty dollars ~~(\$50)~~ ~~(\$150)~~ nor more than one ~~hundred thousand~~ dollars ~~(\$100)~~ ~~(\$1,000)~~.

(c) The penalty fee for failure to renew a certificate within the prescribed time shall be 50 percent of the renewal fee in effect on the date of the renewal of the license, but not less than ~~twenty five seventy-five~~ dollars ~~(\$25)~~ ~~(\$75)~~ nor more than ~~fifty- five hundred~~ dollars ~~(\$50)~~ ~~(\$500)~~.

(d) The fee to be paid upon the filing of an application for the nurse-midwife equivalency examination shall be fixed by the board at not less than one hundred dollars (\$100) nor more than two hundred dollars (\$200).

(e) *The fee to be paid for a temporary certificate shall be fixed by the board at not less than one hundred fifty dollars (\$150) nor more than five hundred dollars (\$500).*

SEC. 34. SEC. 20. Section 2816 of the Business and Professions Code is amended to read:

2816. The nonrefundable fee to be paid by a registered nurse for an evaluation of his or her qualifications to use the title "public health nurse" shall be equal to the fees set out in subdivision (o) of Section 2815. *The fee to be paid upon the application for renewal of the certificate to practice as a public health nurse shall be fixed by the*

board at not less than one hundred twenty-five dollars (\$125) and not more than five hundred dollars (\$500).

All fees payable under this section shall be collected by and paid to the Registered Nursing Fund. It is the intention of the Legislature that the costs of carrying out the purposes of this article shall be covered by the revenue collected pursuant to this section.

SEC. 35. SEC. 21. Section 2830.7 of the Business and Professions Code is amended to read:

2830.7. The amount of the fees prescribed by this chapter in connection with the issuance of certificates as nurse anesthetists is that fixed by the following schedule:

(a) The fee to be paid upon the filing of an application for a certificate shall be fixed by the board at not less than ~~seventy-five~~ *five hundred* dollars ~~(\$75)~~ *(\$500)* nor more than one *thousand five* hundred ~~fifty~~ dollars ~~(\$150)~~ *(\$1,500)*.

(b) The biennial fee to be paid upon the application for a renewal of a certificate shall be fixed by the board at not less than *one hundred* fifty dollars ~~(\$50)~~ *(\$150)* nor more than one ~~hundred thousand~~ dollars ~~(\$100)~~ *(\$1,000)*.

(c) The penalty fee for failure to renew a certificate within the prescribed time shall be 50 percent of the renewal fee in effect on the date of the renewal of the license, but not less than ~~twenty-five~~ *seventy-five* dollars ~~(\$25)~~ *(\$75)* nor more than ~~fifty~~ *five hundred* dollars ~~(\$50)~~ *(\$500)*.

(d) The fee to be paid for a temporary certificate shall be fixed by the board at not less than one hundred fifty dollars (\$150) nor more than five hundred dollars (\$500).

SEC. 36. SEC. 22. Section 2836.3 of the Business and Professions Code is amended to read:

2836.3. (a) The furnishing of drugs or devices by nurse practitioners is conditional on issuance by the board of a number to the nurse applicant who has successfully completed the requirements of subdivision (g) of Section 2836.1. The number shall be included on all transmittals of orders for drugs or devices by the nurse practitioner. The board shall make the list of numbers issued available to the Board of Pharmacy. The board may charge the applicant a fee to cover all necessary costs to implement this ~~section~~ *section, that shall be not less than four hundred dollars (\$400) nor more than one thousand five hundred dollars (\$1,500) for an initial application, nor less than one hundred fifty dollars (\$150) nor more than one thousand dollars (\$1,000) for an application for renewal. The board may charge a penalty fee for failure to renew a furnishing number within the prescribed time that shall be not less than seventy-five dollars (\$75) nor more than five hundred dollars (\$500).*

(b) The number shall be renewable at the time of the applicant's registered nurse license renewal.

(c) The board may revoke, suspend, or deny issuance of the numbers for incompetence or gross negligence in the performance of functions specified in Sections 2836.1 and 2836.2.

SEC. 37. SEC. 23. Section 2838.2 of the Business and Professions Code is amended to read:

2838.2. (a) A clinical nurse specialist is a registered nurse with advanced education, who participates in expert clinical practice, education, research, consultation, and clinical leadership as the major components of his or her role.

(b) The board may establish categories of clinical nurse specialists and the standards required to be met for nurses to hold themselves out as clinical nurse specialists in each category. The standards shall take into account the types of advanced levels of nursing practice that are or may be performed and the clinical and didactic education, experience, or both needed to practice safely at those levels. In setting the standards, the board shall consult with clinical nurse specialists, physicians and surgeons appointed by the Medical Board with expertise with clinical nurse specialists, and health care organizations that utilize clinical nurse specialists.

(c) A registered nurse who meets one of the following requirements may apply to become a clinical nurse specialist:

(1) Possession of a master's degree in a clinical field of nursing.

(2) Possession of a master's degree in a clinical field related to nursing with ~~course-work~~ *coursework* in the components referred to in subdivision (a).

(3) On or before July 1, 1998, meets the following requirements:

- (A) Current licensure as a registered nurse.
- (B) Performs the role of a clinical nurse specialist as described in subdivision (a).
- (C) Meets any other criteria established by the board.
- (d) *(1) A nonrefundable fee of not less than ~~seventy five~~ **five hundred** dollars ~~(\$75), (\$500)~~, but not to exceed one **thousand five** hundred ~~fifty~~ dollars ~~(\$150), (\$1,500)~~ shall be paid by a registered nurse applying to be a clinical nurse specialist for the evaluation of his or her qualifications to use the title "clinical nurse specialist." ~~A biennial renewal fee shall be paid upon submission of an application to renew the clinical nurse specialist certificate and shall be established by the board at no less than fifty dollars (\$50) and no more than one hundred dollars (\$100). The penalty fee for failure to renew a certificate within the prescribed time shall be 50 percent of the renewal fee in effect on the date of the renewal of the license, but not less than twenty five dollars (\$25), nor more than fifty dollars (\$50). The fees authorized by this subdivision shall not exceed the amount necessary to cover the costs to the board to administer this section.~~*
- (2) The fee to be paid for a temporary certificate to practice as a clinical nurse specialist shall be not less than thirty dollars (\$30) nor more than fifty dollars (\$50).*
- (3) A biennial renewal fee shall be paid upon submission of an application to renew the clinical nurse specialist certificate and shall be established by the board at no less than one hundred fifty dollars (\$150) and no more than one thousand dollars (\$1,000).*
- (4) The penalty fee for failure to renew a certificate within the prescribed time shall be 50 percent of the renewal fee in effect on the date of the renewal of the license, but not less than seventy-five dollars (\$75) nor more than five hundred dollars (\$500).*
- (5) The fees authorized by this subdivision shall not exceed the amount necessary to cover the costs to the board to administer this section.*

SEC. 38. SEC. 24. Section 4128.2 of the Business and Professions Code is amended to read:

4128.2. (a) In addition to the pharmacy license requirement described in Section 4110, a centralized hospital packaging pharmacy shall obtain a specialty license from the board prior to engaging in the functions described in Section 4128.

(b) An applicant seeking a specialty license pursuant to this article shall apply to the board on forms established by the board.

(c) Before issuing the specialty license, the board shall inspect the pharmacy and ensure that the pharmacy is in compliance with this article and regulations established by the board.

(d) A license to perform the functions described in Section 4128 may only be issued to a pharmacy that is licensed by the board as a hospital pharmacy.

(e) A license issued pursuant to this article shall be renewed annually and is not transferrable.

(f) An applicant seeking renewal of a specialty license shall apply to the board on forms established by the board.

(g) A license to perform the functions described in Section 4128 shall not be renewed until the pharmacy has been inspected by the board and found to be in compliance with this article and regulations established by the board.

(h) ~~The~~ *Until July 1, 2017, the* fee for issuance or annual renewal of a centralized hospital packaging pharmacy license shall be six hundred dollars (\$600) and may be increased by the board to eight hundred dollars (\$800).

SEC. 41. SEC. 25. 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) This section shall become ~~operative~~ *inoperative* on July 1, ~~2014-2017, and as of January 1, 2018, is repealed.~~

SEC. 26. *Section 4400 is added to the Business and Professions Code, 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 five hundred twenty dollars (\$520) and may be increased to five hundred seventy dollars (\$570). 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 six hundred sixty-five dollars (\$665) and may be increased to nine hundred thirty dollars (\$930).

(c) The fee for the pharmacist application and examination shall be two hundred sixty dollars (\$260) and may be increased to two hundred eighty-five dollars (\$285).

(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 shall be one hundred ninety-five dollars (\$195) and may be increased to two hundred fifteen dollars (\$215). The fee for a pharmacist biennial renewal shall be three hundred sixty dollars (\$360) and may be increased to five hundred five dollars (\$505).

(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 increased to eight hundred twenty dollars (\$820). 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 shall be one hundred seventy dollars (\$170) and may be increased to two hundred forty dollars (\$240). The fee for a hypodermic license renewal shall be two hundred dollars (\$200) and may be increased to two hundred eighty dollars (\$280).

(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 one hundred fifty dollars (\$150) and may be increased to two hundred ten dollars (\$210).

(2) The fee for the annual renewal of a license as a designated representative or designated representative-3PL shall be two hundred fifteen dollars (\$215) and may be increased to three hundred dollars (\$300).

(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 one hundred fifty dollars (\$150) and may be increased to two hundred ten dollars (\$210).

(2) The fee for the annual renewal of a license as a designated representative for a veterinary food-animal drug retailer shall be two hundred fifteen dollars (\$215) and may be increased to three hundred dollars (\$300).

(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 increased to eight hundred twenty dollars (\$820).

(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 increased to eight hundred twenty dollars (\$820). 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 increased to eight hundred twenty dollars (\$820).

(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 one hundred sixty-five dollars (\$165) and may be increased to two hundred thirty dollars (\$230). 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 five hundred twenty dollars (\$520) for each license and may be increased to five hundred seventy dollars (\$570). The annual fee for renewal of the license shall be three hundred twenty-five dollars (\$325) for each license and may be increased to three hundred sixty dollars (\$360).

(r) The fee for the issuance of a pharmacy technician license shall be one hundred forty dollars (\$140) and may be increased to one hundred ninety-five dollars (\$195). The fee for renewal of a pharmacy technician license shall be one hundred forty dollars (\$140) and may be increased to one hundred ninety-five dollars (\$195).

(s) The fee for a veterinary food-animal drug retailer license shall be four hundred thirty-five dollars (\$435) and may be increased to six hundred ten dollars (\$610). The annual renewal fee for a veterinary food-animal drug retailer license shall be three hundred thirty dollars (\$330) and may be increased to four hundred sixty dollars (\$460).

(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 of a nongovernmental sterile compounding pharmacy license shall be one thousand six hundred forty-five dollars (\$1,645) and may be increased to two thousand three hundred five dollars (\$2,305). The fee for a temporary license shall be five hundred fifty dollars (\$550) and may be increased to seven hundred fifteen dollars (\$715). The annual renewal fee of the license shall be one thousand three hundred twenty-five dollars (\$1,325) and may be increased to one thousand eight hundred fifty-five dollars (\$1,855).

(v) The fee for the issuance of a nonresident sterile compounding pharmacy license shall be two thousand three hundred eighty dollars (\$2,380) and may be increased to three thousand three hundred thirty-five dollars (\$3,335). The annual renewal of the license shall be two thousand two hundred seventy dollars (\$2,270) and may be increased to three thousand one hundred eighty dollars (\$3,180). 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 of a centralized hospital packaging license shall be eight hundred twenty dollars (\$820) and may be increased to one thousand one hundred fifty dollars (\$1,150). The annual renewal of the license shall be eight hundred five dollars (\$805) and may be increased to one thousand one hundred twenty-five dollars (\$1,125).

(x) This section shall become operative on July 1, 2017.

SEC. 43. **SEC. 27.** 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) (2) Regularly licensed veterinarians actually called from other states to attend cases in this state, but who do not open an office or~~ Veterinarians holding a current, valid license in good standing in another state or country who provide assistance to a California licensed veterinarian and attend on a specific case. The California licensed veterinarian shall maintain a valid veterinarian-client-patient relationship. The veterinarian providing the assistance shall not establish a veterinarian-client-patient relationship with the client by attending the case or at a future time and shall not practice veterinary medicine, open an office, appoint a place to ~~do business within this~~ meet patients, communicate with clients who reside within the limits of this state, give orders, or have ultimate authority over the care or primary diagnosis of a patient that is located within this state.

(3) Veterinarians called into the state by a law enforcement agency or animal control agency pursuant to subdivision (b).

(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) 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) 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) 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. 44. SEC. 28. Section 4999 of the Business and Professions Code is amended to read:

4999. (a) *"Telephone ~~Any~~ medical advice service" means any* business entity that employs, or contracts or subcontracts, directly or indirectly, with, the full-time equivalent of five or more persons functioning as health care professionals, whose primary function is to provide telephone medical advice, that provides telephone medical advice services to a patient at a California ~~address shall be registered with the Telephone Medical Advice Services Bureau.~~ *address. "Telephone medical advice service" does not include a medical group that operates in multiple locations in California if no more than five full-time equivalent persons at any one location*

perform telephone medical advice services and those persons limit the telephone medical advice services to patients being treated at that location.

~~(b) A medical group that operates in multiple locations in California shall not be required to register pursuant to this section if no more than five full time equivalent persons at any one location perform telephone medical advice services and those persons limit the telephone medical advice services to patients being treated at that location.~~

~~(c) Protection of the public shall be the highest priority for the bureau in exercising its registration, regulatory, and disciplinary functions. Whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount.~~

SEC. 46. SEC. 29. Section 4999.1 of the Business and Professions Code is repealed.

~~4999.1. Application for registration as a telephone medical advice service shall be made on a form prescribed by the department, accompanied by the fee prescribed pursuant to Section 4999.5. The department shall make application forms available. Applications shall contain all of the following:~~

~~(a) The signature of the individual owner of the telephone medical advice service, or of all of the partners if the service is a partnership, or of the president or secretary if the service is a corporation. The signature shall be accompanied by a resolution or other written communication identifying the individual whose signature is on the form as owner, partner, president, or secretary.~~

~~(b) The name under which the person applying for the telephone medical advice service proposes to do business.~~

~~(c) The physical address, mailing address, and telephone number of the business entity.~~

~~(d) The designation, including the name and physical address, of an agent for service of process in California.~~

~~(e) A list of all health care professionals providing medical advice services that are required to be licensed, registered, or certified pursuant to this chapter. This list shall be submitted to the department on a form to be prescribed by the department and shall include, but not be limited to, the name, state of licensure, type of license, and license number.~~

~~(f) The department shall be notified within 30 days of any change of name, physical location, mailing address, or telephone number of any business, owner, partner, corporate officer, or agent for service of process in California, together with copies of all resolutions or other written communications that substantiate these changes.~~

SEC. 46. SEC. 30. Section 4999.2 of the Business and Professions Code is amended to read:

~~4999.2. (a) A~~ *In order to obtain and maintain a registration, a* telephone medical advice service shall *comply with the requirements established by the department. Those requirements shall include, but shall not be limited to, all of the following:* *be responsible for complying with the following requirements:*

~~(1)~~ *(a) (A) (1)* Ensuring that all health care professionals who provide medical advice services are appropriately licensed, certified, or registered as a physician and surgeon pursuant to Chapter 5 (commencing with Section 2000) or the Osteopathic Initiative Act, as a dentist, dental hygienist, dental hygienist in alternative practice, or dental hygienist in extended functions pursuant to Chapter 4 (commencing with Section 1600), as an occupational therapist pursuant to Chapter 5.6 (commencing with Section 2570), as a registered nurse pursuant to Chapter 6 (commencing with Section 2700), as a psychologist pursuant to Chapter 6.6 (commencing with Section 2900), as a naturopathic doctor pursuant to Chapter 8.2 (commencing with Section 3610), as a marriage and family therapist pursuant to Chapter 13 (commencing with Section 4980), as a licensed clinical social worker pursuant to Chapter 14 (commencing with Section 4991), as a licensed professional clinical counselor pursuant to Chapter 16 (commencing with Section 4999.10), as an optometrist pursuant to Chapter 7 (commencing with Section 3000), or as a chiropractor pursuant to the Chiropractic Initiative Act, and operating consistent with the laws governing their respective scopes of practice in the state within which they provide telephone medical advice services, except as provided in ~~paragraph (2).~~ *subdivision (b).*

~~(B) (2)~~ *(2)* Ensuring that all health care professionals who provide telephone medical advice services from an out-of-state location, as identified in ~~subparagraph (A), paragraph (1),~~ *are licensed, registered, or certified in the*

state within which they are providing the telephone medical advice services and are operating consistent with the laws governing their respective scopes of practice.

~~(2)~~ (b) Ensuring that the telephone medical advice provided is consistent with good professional practice.

~~(3)~~ (c) Maintaining records of telephone medical advice services, including records of complaints, provided to patients in California for a period of at least five years.

~~(4)~~ (d) Ensuring that no staff member uses a title or designation when speaking to an enrollee, subscriber, or consumer that may cause a reasonable person to believe that the staff member is a licensed, certified, or registered health care professional described in ~~subparagraph (A) of paragraph (1)~~, *paragraph (1) of subdivision (a)*, unless the staff member is a licensed, certified, or registered professional.

~~(5)~~ (e) Complying with all directions and requests for information made by the department.

~~(6)~~ (f) Notifying the department within 30 days of any change of name, physical location, mailing address, or telephone number of any business, owner, partner, corporate officer, or agent for service of process in California, together with copies of all resolutions or other written communications that substantiate these changes.

~~(7) Submitting quarterly reports, on a form prescribed by the department, to the department within 30 days of the end of each calendar quarter.~~

~~(b) To the extent permitted by Article VII of the California Constitution, the department may contract with a private nonprofit accrediting agency to evaluate the qualifications of applicants for registration pursuant to this chapter and to make recommendations to the department.~~

SEC. 47. SEC. 31. Section 4999.3 of the Business and Professions Code is repealed.

~~4999.3. (a) The department may suspend, revoke, or otherwise discipline a registrant or deny an application for registration as a telephone medical advice service based on any of the following:~~

~~(1) Incompetence, gross negligence, or repeated similar negligent acts performed by the registrant or any employee of the registrant.~~

~~(2) An act of dishonesty or fraud by the registrant or any employee of the registrant.~~

~~(3) The commission of any act, or being convicted of a crime, that constitutes grounds for denial or revocation of licensure pursuant to any provision of this division.~~

~~(b) The 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 department shall have all powers granted therein.~~

~~(c) Copies of any complaint against a telephone medical advice service shall be forwarded to the Department of Managed Health Care.~~

~~(d) The department shall forward a copy of any complaint submitted to the department pursuant to this chapter to the entity that issued the license to the licensee involved in the advice provided to the patient.~~

SEC. 48. SEC. 32. Section 4999.4 of the Business and Professions Code is repealed.

~~4999.4. (a) Every registration issued to a telephone medical advice service shall expire 24 months after the initial date of issuance.~~

~~(b) To renew an unexpired registration, the registrant shall, before the time at which the registration would otherwise expire, pay the renewal fee authorized by Section 4999.5.~~

~~(c) An expired registration may be renewed at any time within three years after its expiration upon the filing of an application for renewal on a form prescribed by the bureau and the payment of all fees authorized by Section 4999.5. A registration that is not renewed within three years following its expiration shall not be renewed, restored, or reinstated thereafter, and the delinquent registration shall be canceled immediately upon expiration of the three-year period.~~

SEC. 49. SEC. 33. Section 4999.5 of the Business and Professions Code is repealed.

~~4999.5. The department may set fees for registration and renewal as a telephone medical advice service sufficient to pay the costs of administration of this chapter.~~

SEC. 34. *Section 4999.5 is added to the Business and Professions Code, to read:*

4999.5. *The respective healing arts licensing boards shall be responsible for enforcing this chapter and any other laws and regulations affecting California licensed health care professionals providing telephone medical advice services.*

~~SEC. 51.~~**SEC. 35.** Section 4999.6 of the Business and Professions Code is repealed.

~~4999.6. The department may adopt, amend, or repeal any rules and regulations that are reasonably necessary to carry out this chapter. A telephone medical advice services provider who provides telephone medical advice to a significant total number of charity or medically indigent patients may, at the discretion of the director, be exempt from the fee requirements imposed by this chapter. However, those providers shall comply with all other provisions of this chapter.~~

~~SEC. 52.~~**SEC. 36.** Section 7137 of the Business and Professions Code is amended to read:

7137. The board shall set fees by regulation. These fees shall not exceed the following schedule:

(a) The application fee for an original license in a single classification shall not be more than three hundred dollars (\$300).

The application fee for each additional classification applied for in connection with an original license shall not be more than seventy-five dollars (\$75).

The application fee for each additional classification pursuant to Section 7059 shall not be more than seventy-five dollars (\$75).

The application fee to replace a responsible managing officer, responsible managing manager, responsible managing member, or responsible managing employee pursuant to Section 7068.2 shall not be more than seventy-five dollars (\$75).

(b) The fee for rescheduling an examination for an applicant who has applied for an original license, additional classification, a change of responsible managing officer, responsible managing manager, responsible managing member, or responsible managing employee, or for an asbestos certification or hazardous substance removal certification, shall not be more than sixty dollars (\$60).

(c) The fee for scheduling or rescheduling an examination for a licensee who is required to take the examination as a condition of probation shall not be more than sixty dollars (\$60).

(d) The initial license fee for an active or inactive license shall not be more than one hundred eighty dollars (\$180).

(e) The renewal fee for an active license shall not be more than three hundred sixty dollars (\$360).

The renewal fee for an inactive license shall not be more than one hundred eighty dollars (\$180).

(f) The delinquency fee is an amount equal to 50 percent of the renewal fee, if the license is renewed after its expiration.

(g) The registration fee for a home improvement salesperson shall not be more than seventy-five dollars (\$75).

(h) The renewal fee for a home improvement salesperson registration shall not be more than seventy-five dollars (\$75).

(i) The application fee for an asbestos certification examination shall not be more than seventy-five dollars (\$75).

(j) The application fee for a hazardous substance removal or remedial action certification examination shall not be more than seventy-five dollars (\$75).

(k) In addition to any other fees charged to C-10 and C-7 contractors, the board may charge a fee not to exceed twenty dollars (\$20), which shall be used by the board to enforce provisions of the Labor Code related to electrician certification.

(l) This section shall become inoperative on July 1, 2017, and as of January 1, 2018, is repealed.

SEC. 37. *Section 7137 is added to the Business and Professions Code, to read:*

7137. *The board may set fees by regulation. These fees shall be set according to the following schedule:*

(a) (1) The application fee for an original license in a single classification shall be three hundred thirty dollars (\$330) and may be increased to not more than three hundred seventy-five dollars (\$375).

(2) The application fee for each additional classification applied for in connection with an original license shall not be more than eighty-five dollars (\$85).

(3) The application fee for each additional classification pursuant to Section 7059 shall be one hundred fifty dollars (\$150) and may be increased to not more than one hundred seventy-five dollars (\$175).

(4) The application fee to replace a responsible managing officer, responsible managing manager, responsible managing member, or responsible managing employee pursuant to Section 7068.2 shall be one hundred fifty dollars (\$150) and may be increased to not more than one hundred seventy-five dollars (\$175).

(5) The application fee to add personnel, other than a qualifying individual, to an existing license shall be one hundred dollars (\$100) and may be increased to not more than one hundred fifteen dollars (\$115).

(b) The fee for rescheduling an examination for an applicant who has applied for an original license, additional classification, a change of responsible managing officer, responsible managing manager, responsible managing member, or responsible managing employee, or for an asbestos certification or hazardous substance removal certification, shall not be more than seventy dollars (\$70).

(c) The fee for scheduling or rescheduling an examination for a licensee who is required to take the examination as a condition of probation shall not be more than seventy dollars (\$70).

(d) The initial license fee for an active or inactive license shall be two hundred dollars (\$200) and may be increased to not more than two hundred twenty-five dollars (\$225).

(e) (1) The renewal fee for an active license shall be four hundred dollars (\$400) and may be increased to not more than four hundred fifty dollars (\$450).

(2) The renewal fee for an inactive license shall be two hundred dollars (\$200) and may be increased to not more than two hundred twenty-five dollars (\$225).

(f) The delinquency fee is an amount equal to 50 percent of the renewal fee, if the license is renewed after its expiration.

(g) The registration fee for a home improvement salesperson shall be eighty-three dollars (\$83) and may be increased to not more than ninety-five dollars (\$95).

(h) The renewal fee for a home improvement salesperson registration shall be eighty-three dollars (\$83) and may be increased to not more than ninety-five dollars (\$95).

(i) The application fee for an asbestos certification examination shall be eighty-three dollars (\$83) and may be increased to not more than ninety-five dollars (\$95).

(j) The application fee for a hazardous substance removal or remedial action certification examination shall be eighty-three dollars (\$83) and may be increased to not more than ninety-five dollars (\$95).

(k) In addition to any other fees charged to C-10 and C-7 contractors, the board may charge a fee not to exceed twenty dollars (\$20), which shall be used by the board to enforce provisions of the Labor Code related to electrician certification.

(l) The board shall, by regulation, establish criteria for the approval of expedited processing of applications. Approved expedited processing of applications for licensure or registration, as required by other provisions of law, shall not be subject to this subdivision.

(m) This section shall become operative on July 1, 2017.

SEC. 54. **SEC. 38.** *Section 7153.3 of the Business and Professions Code is amended to read:*

7153.3. (a) To renew a home improvement salesperson registration, which has not expired, the registrant shall before the time at which the registration would otherwise expire, apply for renewal on a form prescribed by the registrar and pay a renewal fee prescribed by this chapter. Renewal of an unexpired registration shall continue the registration in effect for the two-year period following the expiration date of the registration, when it shall expire if it is not again renewed.

(b) An application for renewal of registration is delinquent if the application is not postmarked or received via electronic transmission as authorized by Section 7156.6 by the date on which the registration would otherwise expire. A registration may, however, still be renewed at any time within three years after its expiration upon the filing of an application for renewal on a form prescribed by the registrar and the payment of the renewal fee prescribed by this chapter and a delinquent renewal penalty in the amount of twenty-five dollars (\$25). If a registration is not renewed within three years, the person shall make a new application for registration pursuant to Section 7153.1.

(c) The registrar may refuse to renew a registration for failure by the registrant to complete the application for renewal of registration. If a registrant fails to return the application rejected for insufficiency or incompleteness within 90 days from the original date of rejection, the application and fee shall be deemed abandoned. Any application abandoned may not be reinstated. However, the person may file a new application for registration pursuant to Section 7153.1.

The registrar may review and accept the petition of a person who disputes the abandonment of his or her renewal application upon a showing of good cause. This petition shall be received within 90 days of the date the application for renewal is deemed abandoned.

(d) This section shall become inoperative on July 1, 2017, and as of January 1, 2018, is repealed.

SEC. 39. *Section 7153.3 is added to the Business and Professions Code, to read:*

***7153.3.** (a) To renew a home improvement salesperson registration, which has not expired, the registrant shall before the time at which the registration would otherwise expire, apply for renewal on a form prescribed by the registrar and pay a renewal fee prescribed by this chapter. Renewal of an unexpired registration shall continue the registration in effect for the two-year period following the expiration date of the registration, when it shall expire if it is not again renewed.*

(b) An application for renewal of registration is delinquent if the application is not postmarked or received via electronic transmission as authorized by Section 7156.6 by the date on which the registration would otherwise expire. A registration may, however, still be renewed at any time within three years after its expiration upon the filing of an application for renewal on a form prescribed by the registrar and the payment of the renewal fee prescribed by this chapter and a delinquent renewal penalty equal to 50 percent of the renewal fee. If a registration is not renewed within three years, the person shall make a new application for registration pursuant to Section 7153.1.

(c) (1) The registrar may refuse to renew a registration for failure by the registrant to complete the application for renewal of registration. If a registrant fails to return the application rejected for insufficiency or incompleteness within 90 days from the original date of rejection, the application and fee shall be deemed abandoned. Any application abandoned may not be reinstated. However, the person may file a new application for registration pursuant to Section 7153.1.

(2) The registrar may review and accept the petition of a person who disputes the abandonment of his or her renewal application upon a showing of good cause. This petition shall be received within 90 days of the date the application for renewal is deemed abandoned.

(d) This section shall become operative on July 1, 2017.

~~SEC. 56.~~**SEC. 40.** Section 8516 of the Business and Professions Code is amended to read:

8516. (a) This section, and Section 8519, apply only to wood destroying pests or organisms.

(b) ~~No~~ **A** registered company or licensee shall *not* commence work on a contract, or sign, issue, or deliver any documents expressing an opinion or statement relating to the absence or presence of wood destroying pests or organisms until an inspection has been made by a licensed Branch 3 field representative or ~~operator~~ *operator employed by a registered company, except as provided in Section 8519.5.* The address of each property inspected or upon which work is completed shall be reported on a form prescribed by the board and shall be

filed with the board no later than 10 business days after the commencement of an inspection or upon completed work.

Every property inspected pursuant to this subdivision or Section 8518 shall be assessed a filing fee pursuant to Section 8674.

Failure of a registered company to report and file with the board the address of any property inspected or work completed pursuant to Section 8518 or this section is grounds for disciplinary action and shall subject the registered company to a fine of not more than two thousand five hundred dollars (\$2,500). *The address of an inspection report prepared for use by an attorney for litigation purposes shall not be required to be reported to the board and shall not be assessed a filing fee.*

A written inspection report conforming to this section and a form approved by the board shall be prepared and delivered to the person requesting the inspection *and the property owner*, or to the ~~person's~~ *property owner's* designated ~~agent~~ *agent*, within 10 business days *from the start* of the inspection, except that an inspection report prepared for use by an attorney for litigation purposes is not required to be reported to the ~~board~~ *board or the property owner*. *An inspection report may be a complete, limited, supplemental, or reinspection report, as defined by Section 1993 of Title 16 of the California Code of Regulations.* The report shall be delivered before work is commenced on any property. The registered company shall retain for three years all ~~original~~ inspection reports, field notes, and activity forms.

Reports shall be made available for inspection and reproduction to the executive officer of the board or his or her duly authorized representative during business hours. ~~Original~~ *All* inspection reports or copies thereof shall be submitted to the board upon ~~request~~ *demand* within two business days. The following shall be set forth in the report:

- (1) The *start* date of the inspection and the name of the licensed field representative or operator making the inspection.
- (2) The name and address of the person or firm ordering the report.
- (3) The name and address of *the property owner and* any person who is a party in interest.
- (4) The address or location of the property.
- (5) A general description of the building or premises inspected.
- (6) A foundation diagram or sketch of the structure or structures or portions of the structure or structures inspected, ~~indicating thereon~~ *including* the approximate location of any infested or infected areas evident, and the parts of the structure where conditions that would ordinarily subject those parts to attack by wood destroying pests or organisms exist. *Reporting of the infested or infected wood members, or parts of the structure identified, shall be listed in the inspection report to clearly identify them, as is typical in standard construction components, including, but not limited to, siding, studs, rafters, floor joists, fascia, subfloor, sheathing, and trim boards.*
- (7) Information regarding the substructure, foundation walls and footings, porches, patios and steps, air vents, abutments, attic spaces, roof framing that includes the eaves, rafters, fascias, exposed timbers, exposed sheathing, ceiling joists, and attic walls, or other parts subject to attack by wood destroying pests or organisms. Conditions usually deemed likely to lead to infestation or infection, such as earth-wood contacts, excessive cellulose debris, faulty grade levels, excessive moisture conditions, evidence of roof leaks, and insufficient ventilation are to be reported.
- (8) One of the following statements, as appropriate, printed in bold type:
 - (A) The exterior surface of the roof was not inspected. If you want the water tightness of the roof determined, you should contact a roofing contractor who is licensed by the Contractors' State License Board.
 - (B) The exterior surface of the roof was inspected to determine whether or not wood destroying pests or organisms are present.
- (9) Indication or description of any areas that are inaccessible or not inspected with recommendation for further inspection if practicable. If, after the report has been made in compliance with this section, authority is given later to open inaccessible areas, a supplemental report on conditions in these areas shall be made.
- (10) Recommendations for corrective measures.

(11) Information regarding the pesticide or pesticides to be used for their control *or prevention* as set forth in subdivision (a) of Section 8538.

(12) The inspection report shall clearly disclose that if requested by the person ordering the original report, a reinspection of the structure will be performed if an estimate or bid for making repairs was given with the original inspection report, or thereafter.

~~(13) The inspection report shall contain the following statement, printed in boldface type:~~

~~"NOTICE: Reports on this structure prepared by various registered companies should list the same findings (i.e. termite infestations, termite damage, fungus damage, etc.). However, recommendations to correct these findings may vary from company to company. You have a right to seek a second opinion from another company."~~

An estimate or bid ~~for repairs~~ shall be given separately allocating the costs to perform each and every recommendation for corrective measures as specified in subdivision (c) with the original inspection report if the person who ordered the original inspection report so requests, and if the registered company is regularly in the business of performing *each* corrective ~~measures~~; *measure*.

If no estimate or bid was given with the original inspection report, or thereafter, then the registered company shall not be required to perform a reinspection.

A reinspection shall be an inspection of those items previously listed on an original report to determine if the recommendations have been completed. Each reinspection shall be reported on an original inspection report form and shall be labeled ~~"Reinspection" in capital letters by rubber stamp or typewritten.~~ *"Reinspection."* Each reinspection shall also identify the original report by date.

After four months from an original inspection, all inspections shall be original inspections and not reinspections.

Any reinspection shall be performed for not more than the price of the registered company's original inspection price and shall be completed within 10 *working business* days after a reinspection has been ordered.

(13) The inspection report shall contain the following statement, printed in boldface type:

"NOTICE: Reports on this structure prepared by various registered companies should list the same findings (i.e. termite infestations, termite damage, fungus damage, etc.). However, recommendations to correct these findings may vary from company to company. You have a right to seek a second opinion from another company."

(c) At the time a report is ordered, the registered company or licensee shall inform the person or entity ordering the report, that a ~~separated~~ *separate* report is available pursuant to this subdivision. If a ~~separated~~ *separate* report is requested at the time the inspection report is ordered, the registered company or licensee shall separately identify on the report each recommendation for corrective measures as follows:

(1) The infestation or infection that is evident.

(2) The conditions that are present that are deemed likely to lead to infestation or infection.

If a registered company or licensee fails to inform as required by this subdivision and a dispute arises, or if any other dispute arises as to whether this subdivision has been complied with, a ~~separated~~ *separate* report shall be provided within 24 hours of the request but, in no event, later than the next business day, and at no additional cost.

(d) When a corrective condition is identified, either as paragraph (1) or (2) of subdivision (c), and the ~~responsible party, as negotiated between the buyer and the seller,~~ *property owner or the property owner's designated agent* chooses not to correct those conditions, the registered company or licensee shall not be liable for damages resulting from a failure to correct those conditions or subject to any disciplinary action by the board. Nothing in this subdivision, however, shall relieve a registered company or a licensee of any liability resulting from negligence, fraud, dishonest dealing, other violations pursuant to this chapter, or contractual obligations between the registered company or licensee and the responsible parties.

(e) The inspection report form prescribed by the board shall separately identify the infestation or infection that is evident and the conditions that are present that are deemed likely to lead to infestation or infection. If a ~~separated~~ *separate* form is requested, the form shall explain the infestation or infection that is evident and the

conditions that are present that are deemed likely to lead to infestation or infection and the difference between those conditions. In no event, however, shall conditions deemed likely to lead to infestation or infection be characterized as actual "defects" or as actual "active" infestations or infections or in need of correction as a precondition to issuing a certification pursuant to Section 8519.

(f) The report and any contract entered into shall also state specifically when any guarantee for the work is made, and if so, the specific terms of the guarantee and the period of time for which the guarantee shall be in effect. *If a guarantee extends beyond three years, the registered company shall maintain all original inspection reports, field notes, activity forms, and notices of completion for the duration of the guarantee period and for one year after the guarantee expires.*

(g) ~~Control service is defined as the regular reinspection of a property after a report has been made in compliance with this section and any corrections as have been agreed upon have been completed.~~ *For purposes of this section, "control service agreement" means an agreement, including extended warranties, to have a licensee conduct over a period of time regular inspections and other activities related to the control or eradication of wood destroying pests and organisms.* Under a control service agreement a registered company shall refer to the original report and contract in a manner as to identify them clearly, and the report shall be assumed to be a true report of conditions as originally issued, except it may be modified after a control service inspection. A registered company is not required to issue a report as outlined in paragraphs (1) to (11), inclusive, of subdivision (b) after each control service inspection. If after control service inspection, no modification of the original report is made in writing, then it will be assumed that conditions are as originally reported. A control service contract shall state specifically the particular wood destroying pests or organisms and the portions of the buildings or structures covered by the contract.

(h) A registered company or licensee may enter into and maintain a control service agreement provided the following requirements are met:

(1) The control service agreement shall be in writing, signed by both parties, and shall specifically include the following:

(A) The wood destroying pests and organisms ~~that could infest and infect the structure.~~ *covered by the control service agreement.*

(B) ~~The wood destroying pests and organisms covered by the control service agreement.~~ Any wood destroying pest or organism that is not covered must be specifically listed.

(C) The type and manner of treatment to be used to correct the infestations or infections.

(D) The structures or buildings, or portions thereof, covered by the agreement, including a statement specifying whether the coverage for purposes of periodic inspections is limited or full. Any exclusions from those described in the original report must be specifically listed.

(E) A reference to the original inspection ~~report and agreement.~~ *report.*

(F) The frequency of the inspections to be provided, the fee to be charged for each renewal, and the duration of the agreement.

(G) Whether the fee includes structural repairs.

(H) If the services provided are guaranteed, and, if so, the terms of the guarantee.

(I) A statement that all corrections of infestations or infections covered by the control service agreement shall be completed within six months of discovery, unless otherwise agreed to in writing by both parties.

(2) The original inspection report, the control service agreement, and completion report shall be maintained for three years after the cancellation of the control service agreement.

~~(3)~~ (3) Inspections made pursuant to a control service agreement shall be conducted by a Branch 3 licensee. Section 8506.1 does not modify this provision.

~~(3)~~ (4) A full inspection of the property covered by the control service agreement shall be conducted and a report filed pursuant to subdivision (b) at least once every three years from the date that the agreement was entered into, unless the consumer cancels the contract within three years from the date the agreement was entered into.

~~(4)~~ (5) ~~A~~ Under a control service agreement, a written report shall be required for the correction of any infestation or infection unless all of the following conditions are met:

- (A) The infestation or infection has been previously reported.
- (B) The infestation or infection is covered by the control service agreement.
- (C) There is no additional charge for correcting the infestation or infection.
- (D) Correction of the infestation or infection takes place within 45 days of its discovery.
- (E) Correction of the infestation or infection does not include fumigation.

~~(5)~~ (6) All notice requirements pursuant to Section 8538 shall apply to all pesticide treatments conducted under control service agreements.

~~(6) For purposes of this section, "control service agreement" means any agreement, including extended warranties, to have a licensee conduct over a period of time regular inspections and other activities related to the control or eradication of wood destroying pests and organisms.~~

(i) All work recommended by a registered company, where an estimate or bid for making repairs was given with the original inspection report, or thereafter, shall be recorded on this report or a separate work agreement and shall specify a price for each recommendation. This information shall be provided to the person requesting the inspection, and shall be retained by the registered company with the inspection report copy for three years.

~~SEC. 57.~~ **SEC. 41.** Section 8518 of the Business and Professions Code is amended to read:

8518. (a) When a registered company completes work under a contract, it shall prepare, on a form prescribed by the board, a notice of work completed and not completed, and shall furnish that notice to the owner of the property or the owner's agent within 10 business days after completing the work. The notice shall include a statement of the cost of the completed work and estimated cost of work not completed.

(b) The address of each property inspected or upon which work was completed shall be reported on a form prescribed by the board and shall be filed with the board no later than 10 business days after completed work.

(c) A filing fee shall be assessed pursuant to Section 8674 for every property upon which work is completed.

(d) Failure of a registered company to report and file with the board the address of any property upon which work was completed pursuant to subdivision (b) of Section 8516 or ~~Section 8518~~ *this section* is grounds for disciplinary action and shall subject the registered company to a fine of not more than two thousand five hundred dollars (\$2,500).

(e) The registered company shall retain for three years all original notices of work completed, work not completed, and activity forms.

(f) Notices of work completed and not completed shall be made available for inspection and reproduction to the executive officer of the board or his or her duly authorized representative during business hours. Original notices of work completed or not completed or copies thereof shall be submitted to the board upon request within two business days.

(g) This section shall only apply to work relating to wood destroying pests or organisms.

~~SEC. 59.~~ **SEC. 42.** Section 1348.8 of the Health and Safety Code is amended to read:

1348.8. (a) A health care service plan that provides, operates, or contracts for telephone medical advice services to its enrollees and subscribers shall do all of the following:

(1) Ensure that the in-state or out-of-state telephone medical advice service ~~is registered pursuant to~~ *complies with the requirements of* Chapter 15 (commencing with Section 4999) of Division 2 of the Business and Professions Code.

(2) Ensure that the staff providing telephone medical advice services for the in-state or out-of-state telephone medical advice service are licensed as follows:

(A) For full service health care service plans, the staff hold a valid California license as a registered nurse or a valid license in the state within which they provide telephone medical advice services as a physician and

surgeon or physician assistant, and are operating in compliance with the laws governing their respective scopes of practice.

(B) (i) For specialized health care service plans providing, operating, or contracting with a telephone medical advice service in California, the staff shall be appropriately licensed, registered, or certified as a dentist pursuant to Chapter 4 (commencing with Section 1600) of Division 2 of the Business and Professions Code, as a dental hygienist pursuant to Article 7 (commencing with Section 1740) of Chapter 4 of Division 2 of the Business and Professions Code, as a physician and surgeon pursuant to Chapter 5 (commencing with Section 2000) of Division 2 of the Business and Professions Code or the Osteopathic Initiative Act, as a registered nurse pursuant to Chapter 6 (commencing with Section 2700) of Division 2 of the Business and Professions Code, as a psychologist pursuant to Chapter 6.6 (commencing with Section 2900) of Division 2 of the Business and Professions Code, as an optometrist pursuant to Chapter 7 (commencing with Section 3000) of Division 2 of the Business and Professions Code, as a marriage and family therapist pursuant to Chapter 13 (commencing with Section 4980) of Division 2 of the Business and Professions Code, as a licensed clinical social worker pursuant to Chapter 14 (commencing with Section 4991) of Division 2 of the Business and Professions Code, as a professional clinical counselor pursuant to Chapter 16 (commencing with Section 4999.10) of Division 2 of the Business and Professions Code, or as a chiropractor pursuant to the Chiropractic Initiative Act, and operating in compliance with the laws governing their respective scopes of practice.

(ii) For specialized health care service plans providing, operating, or contracting with an out-of-state telephone medical advice service, the staff shall be health care professionals, as identified in clause (i), who are licensed, registered, or certified in the state within which they are providing the telephone medical advice services and are operating in compliance with the laws governing their respective scopes of practice. All registered nurses providing telephone medical advice services to both in-state and out-of-state business entities registered pursuant to this chapter shall be licensed pursuant to Chapter 6 (commencing with Section 2700) of Division 2 of the Business and Professions Code.

(3) Ensure that every full service health care service plan provides for a physician and surgeon who is available on an on-call basis at all times the service is advertised to be available to enrollees and subscribers.

(4) Ensure that staff members handling enrollee or subscriber calls, who are not licensed, certified, or registered as required by paragraph (2), do not provide telephone medical advice. Those staff members may ask questions on behalf of a staff member who is licensed, certified, or registered as required by paragraph (2), in order to help ascertain the condition of an enrollee or subscriber so that the enrollee or subscriber can be referred to licensed staff. However, under no circumstances shall those staff members use the answers to those questions in an attempt to assess, evaluate, advise, or make any decision regarding the condition of an enrollee or subscriber or determine when an enrollee or subscriber needs to be seen by a licensed medical professional.

(5) Ensure that no staff member uses a title or designation when speaking to an enrollee or subscriber that may cause a reasonable person to believe that the staff member is a licensed, certified, or registered professional described in Section 4999.2 of the Business and Professions Code unless the staff member is a licensed, certified, or registered professional.

(6) Ensure that the in-state or out-of-state telephone medical advice service designates an agent for service of process in California and files this designation with the director.

(7) ~~Requires~~ *Require* that the in-state or out-of-state telephone medical advice service makes and maintains records for a period of five years after the telephone medical advice services are provided, including, but not limited to, oral or written transcripts of all medical advice conversations with the health care service plan's enrollees or subscribers in California and copies of all complaints. If the records of telephone medical advice services are kept out of state, the health care service plan shall, upon the request of the director, provide the records to the director within 10 days of the request.

(8) Ensure that the telephone medical advice services are provided consistent with good professional practice.

(b) The director shall forward to the Department of Consumer Affairs, within 30 days of the end of each calendar quarter, data regarding complaints filed with the department concerning telephone medical advice services.

(c) For purposes of this section, "telephone medical advice" means a telephonic communication between a patient and a health care professional in which the health care professional's primary function is to provide to the patient a telephonic response to the patient's questions regarding his or her or a family member's medical care or treatment. "Telephone medical advice" includes assessment, evaluation, or advice provided to patients or their family members.

~~SEC. 60.~~**SEC. 43.** Section 10279 of the Insurance Code is amended to read:

10279. (a) Every disability insurer that provides group or individual policies of disability, or both, that provides, operates, or contracts for, telephone medical advice services to its insureds shall do all of the following:

(1) Ensure that the in-state or out-of-state telephone medical advice service ~~is registered pursuant to~~ *complies with the requirements of* Chapter 15 (commencing with Section 4999) of Division 2 of the Business and Professions Code.

(2) Ensure that the staff providing telephone medical advice services for the in-state or out-of-state telephone medical advice service hold a valid California license as a registered nurse or a valid license in the state within which they provide telephone medical advice services as a physician and surgeon or physician assistant and are operating consistent with the laws governing their respective scopes of practice.

(3) Ensure that a physician and surgeon is available on an on-call basis at all times the service is advertised to be available to enrollees and subscribers.

(4) Ensure that the in-state or out-of-state telephone medical advice service designates an agent for service of process in California and files this designation with the commissioner.

(5) Require that the in-state or out-of-state telephone medical advice service makes and maintains records for a period of five years after the telephone medical advice services are provided, including, but not limited to, oral or written transcripts of all medical advice conversations with the disability insurer's insureds in California and copies of all complaints. If the records of telephone medical advice services are kept out of state, the insurer shall, upon the request of the director, provide the records to the director within 10 days of the request.

(6) Ensure that the telephone medical advice services are provided consistent with good professional practice.

(b) The commissioner shall forward to the Department of Consumer Affairs, within 30 days of the end of each calendar quarter, data regarding complaints filed with the department concerning telephone medical advice services.

SEC. 44. 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.



Bill Number:	AB 45
Current Version:	January 21, 2016 - Amended
Authors:	Mullin
Topic:	Household Hazardous Waste
Board Position:	Oppose Unless Amended (Ver: 1/21/16)

Affected Section(s):

Adds Article 3.4 Household Hazardous Waste Collection and Reduction to the Public Resources Code

Status: Referred to Senate Environmental Quality

SUMMARY:

Assembly Bill 45 would require the California Department of Resources Recycling and Recovery (CalRecycle) to adopt one or more model ordinances for a comprehensive program for the collection of household hazardous waste; would authorize a local jurisdiction that provides for the residential collection and disposal of solid waste that proposes to enact an ordinance for the collection and diversion of household hazardous waste to adopt one of the model ordinances adopted by CalRecycle; and would define “household hazardous waste,” “home-generated pharmaceutical waste” and other terms.

The bill is contingent on CalRecycle making a determination whether a nonprofit organization has been created and funded to make grants to local jurisdictions for specified purposes relating to household hazardous waste disposal and would specify that if the department does not determine that such a nonprofit organization exists by December 31, 2018, then the bill’s provisions would be repealed by January 1, 2019.

THIS BILL

Adds Article 3.4 Household Hazardous Waste Collection and Reduction to the Public Resources Code.

Section 47120: Establishes various definitions including:

- (a) “Comprehensive program for the collection of household hazardous waste” means a local program that includes several components:
 - a. Utilization of locally sponsored collection sites
 - b. Scheduled and publicly advertised drop off days
 - c. Door-to-door collection programs
 - d. Mobile collection programs

- e. Dissemination of information about how consumers should dispose of the various types of household hazardous waste
- f. Education programs to promote consumer understanding and use of the location components of a comprehensive program.

Other definitions include

- “Household hazardous waste” includes, but is not limited to,
 - Automotive products, garden chemicals, household chemicals, paint products, consumer electronics, swimming pool chemicals, household batteries, fluorescent bulbs, mercury-containing items, as defined, as well as
 - Home-generated sharps waste, as defined in Section 117671 of the Health and Safety Code.
- “Home-generated pharmaceutical waste.” For purposes of this section, “home-generated pharmaceutical waste” means a prescription or nonprescription drug, as specified in Section 4022 or 4025.1 of the Business and Professions Code, that is a waste generated by a household or households. “Home-generated pharmaceutical waste” shall not include drugs for which producers provide a take-back program as a part of a United States Food and Drug Administration-managed risk evaluation and mitigation strategy pursuant to Section 355.1 of Title 21 of the United States Code, or waste generated by a business, corporation, limited partnership, or an entity involved in a wholesale transaction between a distributor and a retailer.

Adds section 47121 to require CalRecycle to adopt one or more model ordinances for a comprehensive program for the collection of household hazardous waste for adoption by any local jurisdiction, as defined, and requires CalRecycle to post the model ordinance(s) on its Internet Web site. The bill provides that after a model ordinance is posted by CalRecycle, the ordinance may be adopted by a local jurisdiction.

Adds section 47122 requires CalRecycle to determine if an appropriate nonprofit organization has been created and funded for the purpose of making grants to local governments to assist them with the following:

- Educating residents of communities on the existence of household hazardous waste disposal programs and how to use them, and
- Defraying the cost of components of local government household hazardous waste programs.

Adds section 47123 to specify that the provisions of the bill are applicable only to a local jurisdiction that provides for the residential collection and disposal of solid waste.

Adds section 47124 to specify that if CalRecycle does not make a determination as to an appropriate nonprofit organization (as specified in section 47122) by December 31, 2018, that the provisions become inoperable on January 1, 2019.

EXISTING LAW:

The federal Secure and Responsible Drug Disposal Act was passed to address the prescription medication epidemic in the US. In 2014 the DEA established requirements for the take back of controlled substances and other drugs. Federal law prescribes for the manner by which pharmaceuticals must be destroyed or disposed of by DEA registrants.

¹Defines “pharmaceutical waste” as a component of “medical waste” and prescribes the manner in which medical waste is to be disposed of.

BOARD REQUESTED AMENDMENTS:

AB 45 continues to allow for the curbside pickup of home-generated pharmaceutical waste without addressing any issues related to the diversion or security of these drugs. The board has reached out to the author’s office at various times to discuss board concerns and requested amendments.

As noted in the board’s position letter, the board strongly supports efforts to establish requirements for the appropriate disposal of prescription drugs. We have requested amendments to provide for disposal of household pharmaceutical waste through use of prescription drug mail back envelopes (which is consistent with federal law) in lieu of curbside pickup.

STAFF COMMENTS / RECOMMENDATION:

The bill remains silent on safety measures to ensure the security of the home-generated pharmaceutical waste as part of a comprehensive program for the collection of household hazardous waste (model ordinance).

Recommendation: Maintain position of Oppose Unless Amended

FISCAL IMPACT ON THE BOARD:

Board staff does not anticipate any major fiscal impact as a result of this measure. Any minor impact could be absorbed within existing resources.

SUPPORT / OPPOSITION**SUPPORT: (8)**

Advanced Medical Technology Association (AdvaMed)
 Biocom
 California Life Science Association
 California Pharmacists Association
 California Retailers Association
 Consumer Healthcare Products Association
 Generic Pharmaceutical Association
 National Association of Chain Drug Stores

¹ Medical Waste Management Act administered by the California Department of Public Health

OPPOSE: (105)

Alameda County Board of Supervisors
Alameda County Hazardous Materials Facility
Alameda County Meds Coalition
Alameda StopWaste
Butte County Board of Supervisors
California Association of Environmental Health Administrators
California Association of Retired Americans
California Environmental Health Directors
California Hepatitis C Task Force
California League of Conservation Voters
California Product Stewardship Council
California Refuse Recycling Council
California Resource Recovery Association
California State Association of Counties
Californian's Against Waste
City and County of San Francisco
City of Burbank
City of Camarillo
City of Chula Vista
City of Claremont
City of Clovis
City of Commerce
City of Culver City
City of Cupertino
City of Diamond Bar
City of Lakewood
City of Mountain View
City of Palo Alto
City of Pasadena
City of Roseville
City of Santa Monica
City of Stockton
City of Sunnyvale
City of Thousand Oaks
City of Torrance
City of West Hollywood
Clean Water Action
Contra Costa County Board of Supervisors
County of Sacramento
Del Norte Solid Waste Management Authority
Delta Diablo
Goodwill Industries of San Francisco, San Mateo, and Marin
Green Sangha of Marin
Health Officers Association of California
Hope2gether Foundation
Kern County Board of Supervisors
Kern County Public Works Department
League of California Cities
League of Women Voters of California
Los Angeles County Board of Supervisors
Los Angeles County Department of Public Works

Los Angeles County Solid Waste Management Committee/Integrated Waste Management Task Force
Marin County Board of Supervisors
Marin County Pharmacist Association
Marin Household Hazardous Waste Facility
Marin Sanitary Service
Mojave Desert and Mountain Recycling Authority
Napa County Board of Supervisors
Napa Recycling and Waste Services
Napa Sanitation District
Napa Upper Valley Waste Management Agency
National Association of Hazardous Materials Managers, California Chapter and National Coalition Against Prescription Drug Abuse
Peninsula Sanitary Service, Inc.
Pharmacy Defense Fund
Pharmacy Planning Service, Inc.
Planning and Conservation League
Recology
Riverside County Department of Waste Resources
Rural County Representatives of California
Russian River Watershed Association
Salinas Valley Recycles
San Joaquin County Public Works
San Luis Obispo County Integrated Waste Management Authority
Sanitation Districts of Los Angeles County
Santa Barbara County
Santa Barbara County Board of Supervisors
Santa Clara County Board of Supervisors
Santa Clara County, Recycling and Waste Reduction Commission
Santa Cruz County Board of Supervisors
Santa Monica Mayor Tony Vazquez
Seventh Generation Advisors
Sierra Club California
Solano County Board of Supervisors
Solid Waste Association of North America
Solid Waste Solutions, Inc.
Sonoma County Board of Supervisors
Sonoma County Waste Management Agency
Sonoma County Water Agency
Stanislaus County
StopWaste
Surfrider Foundation
Teamsters Local 396
Tulare County Board of Supervisors
Upper Valley Waste Management Agency
Urban Counties of California
Waterkeeper
Western Placer Waste Management Authority
Yolo County Board of Supervisors
Zero Waste Marin

HISTORY:

Date	Action
6/8/16	In committee: Set, second hearing. Hearing canceled at the request of author.
5/16/16	In committee: Set, first hearing. Hearing canceled at the request of author.
2/04/16	Referred to Com. on E.Q.
1/27/16	In Senate. Read first time. To Com. on RLS. for assignment.
1/27/16	Read third time. Passed. Ordered to the Senate. (Ayes 50. Noes 18. Page 3507.)
1/25/16	Read second time. Ordered to third reading.
1/21/16	Read second time and amended. Ordered returned to second reading.
1/21/16	From committee: Amend, and do pass as amended. (Ayes 12. Noes 0.) (January 21).
5/28/15	In committee: Hearing postponed by committee.
5/20/15	In committee: Set, first hearing. Referred to APPR. suspense file.
5/04/15	Re-referred to Com. on APPR.
4/30/15	Read second time and amended.
4/29/15	From committee: Amend, and do pass as amended and re-refer to Com. on APPR. (Ayes 4. Noes 2.) (April 28).
4/27/15	Re-referred to Com. on E.S. & T.M.
4/23/15	From committee chair, with author's amendments: Amend, and re-refer to Com. on E.S. & T.M. Read second time and amended.
4/23/15	From committee: Do pass and re-refer to Com. on E.S. & T.M. (Ayes 6. Noes 3.) (April 22). Re-referred to Com. on E.S. & T.M.
4/14/15	Re-referred to Com. on L. GOV.
4/13/15	From committee chair, with author's amendments: Amend, and re-refer to Com. on L. GOV. Read second time and amended.
3/23/15	Re-referred to Com. on L. GOV.
3/19/15	From committee chair, with author's amendments: Amend, and re-refer to Com. on L. GOV. Read second time and amended.
3/19/15	Referred to Coms. on L. GOV. and E.S. & T.M.
12/02/14	From printer. May be heard in committee January 1.
12/01/14	Read first time. To print.



California State Board of Pharmacy

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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

June 2, 2016

The Honorable Kevin Mullin
Member, California State Assembly
State Capitol, Room 3160
Sacramento, CA 95816

RE: Assembly Bill 45 – Oppose Unless Amended

Dear Assembly Member Mullin:

I regret to advise you that the Board of Pharmacy has considered the most recent amendments (A-1/21/16) of Assembly Bill 45 and continues to have a position of "Oppose Unless Amended." The current version of the bill would require CalRecycle to adopt one or more model ordinances for the collection of household hazardous waste, and allows local jurisdictions to thereafter adopt any of those model ordinances. Our issue is that AB 45 continues to allow for the curbside pickup of home-generated pharmaceutical waste without addressing any issues related to the diversion or security of these drugs. Unwanted pharmaceuticals do have street value and placement of these drugs at the curb presents health risks to those who encounter the containers.

The board strongly supports efforts to establish requirements for the appropriate disposal of prescription drugs. The board would support an amendment that would provide for disposal of household pharmaceutical waste through use of prescription drug mail back envelopes in lieu of curbside pickup.

The board welcomes the opportunity to work with you to address the need for safe and convenient alternatives for pharmaceutical take-back. Please do not hesitate to contact me at (916) 574-7913 if you have any questions.

Sincerely,

A handwritten signature in blue ink that reads "Carolyn Klein".

CAROLYN KLEIN

Manager, Licensing and Legislation

cc: Department of Consumer Affairs



AB-45 Household hazardous waste. (2015-2016)

SECTION 1. *The Legislature finds and declares all of the following:*

(a) Household hazardous waste is creating environmental, health, and workplace safety issues. Whether due to unused pharmaceuticals, batteries, medical devices, or other disposable consumer items, effective and efficient disposal remains an extraordinary challenge.

(b) State and local efforts to address disposal of these items have been well intended and, in some cases, effective. However, even the most effective programs have very low consumer participation. Other approaches being promoted throughout the state would fragment the collection of household hazardous waste and move collection away from consumer convenience.

(c) In addition to other programs for the collection of household hazardous waste, a number of cities in California are already using curbside household hazardous waste collection programs, door-to-door household hazardous waste collection programs, and household hazardous waste residential pickup services as mechanisms for collecting and disposing of many commonly used household items for which disposal has been the subject of state legislation and local ordinances. The waste disposal companies and local governments that have implemented these programs have found them to be valuable components of a comprehensive approach to the management of household hazardous waste.

(d) There is also an appropriate role for manufacturers and distributors of these products in comprehensive efforts to more effectively manage household hazardous waste. That role should be based on the ability of manufacturers and distributors to communicate with consumers.

SEC. 2. *Article 3.4 (commencing with Section 47120) is added to Chapter 1 of Part 7 of Division 30 of the Public Resources Code, to read:*

Article 3.4. Household Hazardous Waste Collection and Reduction

47120. *For purposes of this article, the following terms have the following meanings:*

(a) "Comprehensive program for the collection of household hazardous waste" means a local program that may include, but is not limited to, the following components:

(1) Utilization of locally sponsored collection sites.

(2) Scheduled and publicly advertised drop-off days.

(3) Door-to-door collection programs.

(4) Mobile collection programs.

(5) Dissemination of information about how consumers should dispose of the various types of household hazardous waste.

(6) Education programs to promote consumer understanding and use of the local components of a comprehensive program.

(b) "Household hazardous waste" includes, but is not limited to, the following:

(1) Automotive products, including, but not limited to, antifreeze, batteries, brake fluid, motor oil, oil filters, fuels, wax, and polish.

(2) Garden chemicals, including, but not limited to, fertilizers, herbicides, insect sprays, pesticides, and weed killers.

(3) Household chemicals, including, but not limited to, ammonia, cleaners, strippers, and rust removers.

(4) *Paint products, including, but not limited to, paint, caulk, glue, stripper, thinner, and wood preservatives and stain.*

(5) *Consumer electronics, including, but not limited to, televisions, computers, laptops, monitors, keyboards, DVD and CD players, VCRs, MP3 players, cell phones, desktop printers, scanners, fax machines, computer mice, microwaves, and related cords.*

(6) *Swimming pool chemicals, including, but not limited to, chlorine tablets and liquids, pool acids, and stabilizers.*

(7) *Household batteries. For purposes of this section, "household batteries" means batteries that individually weigh two kilograms or less of mercury, alkaline, carbon-zinc, or nickel-cadmium, and any other batteries typically generated as household waste, including, but not limited to, batteries used to provide power for consumer electronic and personal goods often found in a household.*

(8) *Fluorescent tubes and compact fluorescent lamps.*

(9) *Mercury-containing items, including, but not limited to, thermometers, thermostats, and switches.*

(10) *Home-generated sharps waste, as defined in Section 117671 of the Health and Safety Code.*

(11) *Home-generated pharmaceutical waste. For purposes of this section, "home-generated pharmaceutical waste" means a prescription or nonprescription drug, as specified in Section 4022 or 4025.1 of the Business and Professions Code, that is a waste generated by a household or households. "Home-generated pharmaceutical waste" shall not include drugs for which producers provide a take-back program as a part of a United States Food and Drug Administration-managed risk evaluation and mitigation strategy pursuant to Section 355-1 of Title 21 of the United States Code, or waste generated by a business, corporation, limited partnership, or an entity involved in a wholesale transaction between a distributor and a retailer.*

47121. (a) *The department, in consultation with affected industries and stakeholders, shall adopt one or more model ordinances for a comprehensive program for the collection of household hazardous waste for adoption by any local jurisdiction that provides for the residential collection and disposal of solid waste.*

(b) *Upon adoption of the model ordinance or ordinances by the department, the department shall notify the public by posting the model ordinance or ordinances on the department's Internet Web site.*

(c) *After the department posts the model ordinance or ordinances on its Internet Web site, a local jurisdiction that proposes to enact an ordinance governing the collection and diversion of household hazardous waste may adopt one of the department's model ordinances.*

47122. (a) *The department shall determine whether an appropriate nonprofit organization has been created and funded for the purpose of making grants to local governments to assist with both of the following activities:*

(1) *Educating residents of communities on the existence of household hazardous waste disposal programs and how to use them.*

(2) *Defraying the cost of components of local government household hazardous waste programs.*

(b) *In making the determination set forth in subdivision (a), the department shall take all of the following into consideration:*

(1) *Whether the nonprofit organization has, at the time of the determination, a minimum of five million dollars (\$5,000,000) dedicated to grants to local governments for the purposes set forth in subdivision (a).*

(2) *Whether the nonprofit organization will have sufficient funding to allocate grants to local governments throughout the state for five years.*

(3) *Whether the composition of the nonprofit's board of directors is sufficiently diverse and experienced to appropriately consider grant applications that will positively impact efforts to improve disposal of household hazardous waste.*

(4) *Whether the nonprofit organization has appropriate criteria for considering grant applications.*

(c) *Upon making a determination that an appropriate nonprofit organization exists as set forth in subdivision (a), the department shall post the fact that the department has made this determination on the department's Internet Web site.*

47123. This article is applicable only to local jurisdictions that provide for the residential collection and disposal of solid waste.

47124. If the department does not make the determination that there exists an appropriate nonprofit organization, as specified in subdivision (a) of Section 47122, by December 31, 2018, this article shall be repealed on January 1, 2019.



Bill Number:	AB 1069
Current Version:	July 1, 2015 - Amended
Author:	Gordon
	Coauthors: Assembly Members Chu, Low and Mark Stone and Senators Beall and Wieckowski
Topic:	Prescription Drugs: Collection and Distribution Program
Board Position:	Oppose Unless Amended

Affected Sections: Amend section 150204 of the Health and Safety Code (H&SC)

Status: In Senate Appropriations Committee (7/7/15)

SUMMARY: Would expand the provisions under which a county established repository and distribution program allow the transfer of drugs to between counties that are not adjacent, and would allow for the repackaging of donated medications in advance of a prescription.

EXISTING LAW: Authorizes a county to establish a repository and distribution program to allow for the distribution of surplus unused medications to persons in need of financial assistance.

H&SC Section 150201 provides definitions for purposes of the division including

- Donor organization as a health and care facilities that donates centrally stored unused medications including: general acute care hospital, acute psychiatric hospital, skilled nursing facility, intermediate care facility, correctional treatment center, psychiatric health facility, chemical dependency recovery hospital, residential care home, and approved mental health rehabilitation center.
- Eligible Entity which includes a licensed pharmacy as specified
- Medication as a dangerous drug as defined in B&PC 4022
- Participating Entity as an entity eligible that operates a repository and distribution program

H&SC 150202.5 allows for donor organizations to donate unused, unexpired medication if the medication was received directly from a manufacturer or wholesaler or the medication was returned from a health facility to the issuing pharmacy.

H&SC 150203 allows for a wholesaler and drug manufacturer to donate unused medication.

H&SC 150204 sets forth the means by which a county may establish a program, the reporting requirements as well as the written procedures that address the following:

- Establishing eligibility for medically indigent patients who may participate
- Ensuring that eligible patients are not charged for medications received under the program
- Develop a formulary of medications appropriate for the program
- Ensure proper safety and management of any medication collected and maintained
- Ensure the privacy of individuals for whom the medication was originally prescribed

In addition, the section specifies that only medication that is donated in unopened, tamper-evident packaging or modified unit dose containers that meet USP standards for donation, provided lot numbers and expiration dates are affixed.

Further this section also provides that the medication donated to the program shall be maintained in the donated packaging units until dispensed to the eligible patient who presents a valid prescription and allows for donated medication to be transferred to an adjacent county.

Federal law provides a definition of tamper evident packaging as well as the labeling requirements of unit dose medications, including the lot or control number [Ref. 21 CFR 201.100(b), 211.130]

THIS BILL WOULD:

Amend H&SC Section 150204

- a. To allow for the transfer of donated medications from one county entity to entity in another county. It would also allow for a transfer of up to 15% of the donated medications received annually unless a transfer is done that is patient and prescription specific.
- b. To allow for medications to be repackaged into new, properly labeled containers until dispensed and specify that such a medication cannot be repackaged more than two times. The repackaging could be of a supply of no more than 90 days and would allow for the mixing of lot numbers and expiration dates. Such information would be required to be included on the label.

STAFF COMMENTS:

At previous board and committee meetings staff discussed several concerns with the proposed expansion of this program and the conflicts it created with federal and state law. In 2015 staff spent considerable staff time working with the author's office and sponsors to highlight these conflicts and secure amendments to remove the conflicts. Still, the current version (7/1/15) creates new conflicts with federal and state law, including repackaging in entities that are neither pharmacies nor licensed by the State Food and Drug Branch or the FDA. As provided for in the measure, this repackaging could also be performed without pharmacist oversight – and it appears to create conflict with Good Manufacturing Practices, as well as with USP standards.

Staff continues to question the need for expanding the transfer provisions found in current law, given that only one county in California is currently operating a program and staff is unaware of any eminent adoption by other counties.

The bill has not moved since last year, and staff continues to reach out to the author's office in an effort to resolve the conflicts the legislation presents.

FISCAL IMPACT ON THE BOARD:

In its current form, the measure creates significant challenges in monitoring for compliance as well as from an enforcement perspective. Board staff anticipates that an additional inspector will be required to confirm compliance and enforce these provisions. Routine investigations will become far more difficult and there could be significant travel involved depending on the locations of the donating entities as well as the original dispensing pharmacies. For example, confirming the transaction information and pedigree of a repackaged medication would become extremely complicated and resource intensive.

SUPPORT / OPPOSITION: (Based on 7/2/15 Senate BP&ED analysis for text dated 7/1/15)

SUPPORT

California Association of Health Facilities
 California Assisted Living Association
 California Chronic Care Coalition
 Supporting Initiatives to Redistribute Unused Medicine (SIRUM) (Sponsor)

OPPOSE

Board of Pharmacy

HISTORY:

Date	Last 6 Actions
07/07/2015	July 7 From committee: Do pass and re-refer to Com. on APPR. (Ayes 7. Noes 0.) (July 6). Re-referred to Com. on APPR.
07/01/2015	July 1 From committee chair, with author's amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. on B., P. & E.D.
06/15/2015	June 15 In committee: Set, first hearing. Hearing canceled at the request of author.
06/11/2015	June 11 Referred to Com. on B., P. & E.D.
06/01/2015	June 1 In Senate. Read first time. To Com. on RLS. for assignment.
06/01/2015	June 1 Read third time. Passed. Ordered to the Senate. (Ayes 80. Noes 0. Page 1685.)



California State Board of Pharmacy

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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

April 29, 2015

The Honorable Rob Bonta
Chair, Assembly Health Committee
California State Assembly
State Capitol, Room 6005
Sacramento, CA 95814

RE: ~~Assembly Bill 1069 -- Oppose Unless Amended~~

Dear Assembly Member Bonta:

The Board of Pharmacy has taken a position of oppose unless amended on Assembly Bill 1069, which is scheduled to be heard in the Assembly Health Committee on May 5, 2015. Assembly Bill 1069 would make significant changes to the current Surplus Medication Collection and Distribution provisions, a program designed to allow for the redistribution of donated medications to indigent patients in a county-established program. As drafted, this measure creates several conflicts with state and federal law, and also creates several policy concerns for the board. Although the bill in its current form appears to be very straightforward, this is not the case.

Regulation of drug distribution is complex, with a myriad of state and federal laws designed to ensure the safety and efficacy of prescription drugs. The board believes this bill in its current form would create conflicts between state and federal law in several areas including the proposed removal of the lot number requirement, the proposed new definition of tamper-evident packaging and the proposed repackaging provisions.

Board staff have conveyed concerns to the sponsor and identified specific areas where the proposal conflicts with federal and state law. We have been unable to resolve some of these legal concerns with the sponsors and are awaiting information from the sponsors on some additional elements of the bill. It is our understanding that amendments may be offered during the committee hearing, but the board has not received any draft language.

For all of the above reasons, the board respectfully requests a NAY vote when this matter is heard in your committee on May 5, 2015. You are welcome to contact Anne Sodergren at (916) 574-7910 if you have any questions.

Sincerely,

A handwritten signature in black ink that reads "Virginia Herold". The signature is fluid and cursive, with the first name being the most prominent.

VIRGINIA HEROLD
Executive Officer

cc: Department of Consumer Affairs
Assembly Member Gordon
Members, Assembly Health Committee



AB-1069 Prescription drugs: collection and distribution program. (2015-2016)

SECTION 1. Section 150204 of the Health and Safety Code is amended to read:

150204. (a) (1) A county may establish, by an action of the county board of supervisors or by an action of the public health officer of the county, as directed by the county board of supervisors, a repository and distribution program for purposes of this division. The county shall advise the California State Board of Pharmacy within 30 days from the date it establishes a repository and distribution program.

(2) Only an eligible entity, pursuant to ~~subdivision (a) of~~ Section 150201, may participate in this program to dispense medication donated to the drug repository and distribution program.

(3) An eligible entity that seeks to participate in the program shall inform the county health department and the California State Board of Pharmacy in writing of its intent to participate in the program. An eligible entity may not participate in the program until it has received written or electronic documentation from the county health department confirming that the department has received its notice of intent.

(4) (A) A participating entity shall disclose to the county health department on a quarterly basis the name and location of the source of all donated medication it receives.

(B) A participating primary care clinic, as described in ~~paragraph (3) of subdivision (a) of Section 150201~~ *Section 150201*, shall disclose to the county health department the name of the licensed physician who shall be accountable to the California State Board of Pharmacy for the clinic's program operations pursuant to this division. This physician shall be the professional director, as defined in subdivision (c) of Section 4182 of the Business and Professions Code.

(C) The county board of supervisors or public health officer of the county shall, upon request, make available to the California State Board of Pharmacy the information in this division.

(5) The county board of supervisors, the public health officer of the county, and the California State Board of Pharmacy may prohibit an eligible or participating entity from participating in the program if the entity does not comply with the provisions of the program, pursuant to this division. If the county board of supervisors, the public health officer of the county, or the California State Board of Pharmacy prohibits an eligible or participating entity from participating in the program, it shall provide written notice to the prohibited entity within 15 days of making this determination. The county board of supervisors, the public health officer of the county, and the California State Board of Pharmacy shall ensure that this notice also is provided to one another.

(b) A county that elects to establish a repository and distribution program pursuant to this division shall establish written procedures for, at a minimum, all of the following:

(1) Establishing eligibility for medically indigent patients who may participate in the program.

(2) Ensuring that patients eligible for the program shall not be charged for any medications provided under the program.

(3) Developing a formulary of medications appropriate for the repository and distribution program.

(4) Ensuring proper safety and management of any medications collected by and maintained under the authority of a participating entity.

(5) Ensuring the privacy of individuals for whom the medication was originally prescribed.

(c) Any medication donated to the repository and distribution program shall comply with the requirements specified in this division. Medication donated to the repository and distribution program shall meet all of the following criteria:

(1) The medication shall not be a controlled substance.

(2) The medication shall not have been adulterated, misbranded, or stored under conditions contrary to standards set by the United States Pharmacopoeia (USP) or the product manufacturer.

(3) The medication shall not have been in the possession of a patient or any individual member of the public, and in the case of medications donated by a health or care facility, as described in Section 150202, shall have been under the control of a staff member of the health or care facility who is licensed in California as a health care professional or has completed, at a minimum, the training requirements specified in Section 1569.69.

(d) (1) Only medication that is donated in unopened, tamper-evident packaging or modified unit dose containers that meet USP standards is eligible for donation to the repository and distribution program, provided lot numbers and expiration dates are affixed. Medication donated in opened containers shall not be dispensed by the repository and distribution program, and once identified, shall be quarantined immediately and handled and disposed of in accordance with the Medical Waste Management Act (Part 14 (commencing with Section 117600) of Division 104).

(2) (A) A medication that is the subject of a United States Food and Drug Administration managed risk evaluation and mitigation strategy pursuant to Section 355-1 of Title 21 of the United States Code shall not be donated if this inventory transfer is prohibited by that strategy, or if the inventory transfer requires prior authorization from the manufacturer of the medication.

(B) A medication that is the subject of a United States Food and Drug Administration managed risk evaluation and mitigation strategy pursuant to Section 355-1 of Title 21 of the United States Code, the donation of which is not prohibited pursuant to subparagraph (A), shall be managed and dispensed according to the requirements of that strategy.

(e) A pharmacist or physician at a participating entity shall use his or her professional judgment in determining whether donated medication meets the standards of this division before accepting or dispensing any medication under the repository and distribution program.

(f) A pharmacist or physician shall adhere to standard pharmacy practices, as required by state and federal law, when dispensing all medications.

(g) Medication that is donated to the repository and distribution program shall be handled in the following ways:

(1) Dispensed to an eligible patient.

(2) Destroyed.

(3) Returned to a reverse distributor or licensed waste hauler.

(4) (A) Transferred to another participating entity within the county to be dispensed to eligible patients pursuant to this division. Notwithstanding this paragraph, a participating ~~county-owned-pharmacy- entity~~ may transfer eligible donated medication to a participating ~~county-owned-pharmacy- entity~~ within another ~~adjacent~~ county that has adopted a program pursuant to this division, if the ~~pharmacies- participating entities~~ transferring the medication have a written agreement ~~between the entities~~ that outlines protocols and procedures for safe and appropriate drug transfer that are consistent with this division. *A participating entity shall not transfer more than 15 percent of its donated medications annually unless the transfer is performed pursuant to Section 4126.5 of the Business and Professions Code.*

(B) Medication donated under this division shall not be transferred by any participating entity more than once, and after it has been transferred, shall be dispensed to an eligible patient, destroyed, or returned to a reverse distributor or licensed waste hauler.

(C) Medication transferred pursuant to this paragraph shall be transferred with documentation that identifies the drug name, strength, and quantity of the medication, and the donation facility from where the medication originated shall be identified on medication packaging or in accompanying documentation. The document shall include a statement that the medication may not be transferred to another participating entity and must be handled pursuant to subparagraph (B). A copy of this document shall be kept by the participating entity transferring the medication and the participating entity receiving the medication.

(h) Medication that is donated to the repository and distribution program that does not meet the requirements of this division shall not be distributed or transferred under this program and shall be either destroyed or returned to a reverse distributor. ~~This medication-~~ *Donated medication that does not meet the requirements of this division* shall not be sold, dispensed, or otherwise transferred to any other entity.

(i) (1) Medication donated to the repository and distribution program shall be maintained in the donated packaging units *or new, properly labeled containers* until dispensed to an eligible patient under this program, who presents a valid prescription. When dispensed to an eligible patient under this program, the medication shall be in a new and properly labeled container, specific to the eligible patient and ensuring the privacy of the individuals for whom the medication was initially dispensed. Expired medication shall not be dispensed. *Donated medication shall not be repackaged more than two times. Nothing in this section requires donated medication to be repackaged two times.*

(2) All of the following requirements shall be satisfied when repackaging donated medication:

(A) Medication shall be repackaged into a container that holds an individual prescription for a supply of no more than 90 days.

(B) Repackaged medication shall be identifiable as donated medication.

(C) Repackaged medication shall be labeled with all of the following:

(i) All applicable lot numbers.

(ii) The earliest expiration date.

(iii) The number of times that the medication has been repackaged.

(j) Medication donated to the repository and distribution program shall be segregated from the participating entity's other drug stock by physical means, for purposes including, but not limited to, inventory, accounting, and inspection.

(k) A participating entity shall keep complete records of the acquisition and disposition of medication donated to, and transferred, dispensed, and destroyed under, the repository and distribution program. These records shall be kept separate from the participating entity's other acquisition and disposition records and shall conform to the Pharmacy Law (Chapter 9 (commencing with Section 4000) of Division 2 of the Business and Professions Code), including being readily retrievable.

(l) Local and county protocols established pursuant to this division shall conform to the Pharmacy Law regarding packaging, transporting, storing, and dispensing all medications.

(m) County protocols established for packaging, transporting, storing, and dispensing medications that require refrigeration, including, but not limited to, any biological product as defined in Section 351 of the Public Health Service Act (42 U.S.C. Sec. 262), an intravenously injected drug, or an infused drug, shall include specific procedures to ensure that these medications are packaged, transported, stored, and dispensed at appropriate temperatures and in accordance with USP standards and the Pharmacy Law.

(n) Notwithstanding any other provision of law, a participating entity shall follow the same procedural drug pedigree requirements for donated drugs as it would follow for drugs purchased from a wholesaler or directly from a drug manufacturer.



Bill Number:	AB 1386
Current Version:	June 28, 2016
Author:	Low
Topic:	Emergency medical care: epinephrine auto-injectors
Board Position:	Support (ver. 1/13/16)

Affected Sections: Add section 4119.4 to the Business and Professions Code
Amend section 1714.23 of the Civil Code
Amend section 1797.197a of the Health and Safety Code

Status: Hearing: August 1, 2016 – Senate Appropriations

SUMMARY:

This measure would amend Pharmacy Law and other provisions of the Civil Code and Health and Safety Code to authorize a school district, county office of education, or charter school to obtain epinephrine auto-injectors pursuant to a prescription, so long as the epinephrine auto-injectors are furnished exclusively for use at a school district site, county office of education or charter school and where the entity complies with related requirements..

Differences between January 13 and June 28 versions:

The bill has been amended three times since January 2016, with the most recent amendment being June 28, 2016. The differences between the version the board supported (1/13) and the current version are below.

- (Sec. 1) Incorporates a reference to the Health and Safety Code, requires a new prescription for any additional epinephrine auto-injectors, and defines “epinephrine auto-injector”
- (Sec. 2 & 4) Fine-tunes the definition of “Epinephrine auto-injector, to reflect a device that is designed for the automatic injection of a premeasured dose (Civil Code and Health & Safety Code).
- (Sec. 3) Specifies requirements for schools that elect to provide epinephrine auto-injectors at schools.
- (Sec. 4) Requires authorized entities that use epinephrine auto injectors to file a report with the Emergency Medical Services Authority (instead of CDPH) within 30 days of using an emergency epinephrine auto-injector. The bill requires EMSA to annually publish a report that summarizes all reports received pursuant to this provision.

EXISTING LAW:

Current law allows an “authorized entity” to obtain, and a pharmacist to furnish pursuant to a prescription from a physician and surgeon, epinephrine auto-injectors for use by employees, volunteers, or agents (first responders) to render emergency care to another person. Current law also *requires* a school district, county office of education, or charter school, to provide emergency epinephrine auto-injectors to school nurses or trained personnel (volunteers) to treat individuals that are believed to be suffering from an anaphylactic reaction.

Current law provides certain qualified immunities for persons (lay rescuers) who utilize these auto-injectors in accordance with current law (that which is not considered gross negligence or willful misconduct).

Current law requires the Emergency Medical Services Authority (EMSA) to establish and approve authorized training providers and minimum standards for the use and administration of epinephrine auto-injectors.

THIS BILL WOULD:

Specific to **pharmacy law**, this measure would:

Add Section 4119.4 to the Business and Professions Code to

- authorize a pharmacy to dispense epinephrine auto-injectors to an “authorized entity” pursuant to a prescription;
- Requires a new prescription for any additional epinephrine auto injectors to be dispensed;
- Specify labeling requirements for the epinephrine auto-injectors;
- Specify record keeping requirements for the authorized entities
- Define “epinephrine auto-injector”

The bill also would

Amend Health and Safety Code to define an authorized entity as any for-profit, nonprofit, or government entity or organization that employs at least one person or utilizes at least one volunteer or agent that has voluntarily completed a training course that has been approved by the California Emergency Medical Services Authority (EMSA).

Extend certain civil liability protections to entities (school districts, etc.) that *choose* to obtain epinephrine auto-injectors for use by authorized persons, who render emergency care to individuals who may be suffering from anaphylaxis.

Allow an authorized health care provider to issue a prescription for an epinephrine auto-injector to an authorized entity if the entity submits evidence that it employs at least one person, or utilizes at least one volunteer or agent, who is trained and qualified to administer an epinephrine auto-injector, as specified.

Sets forth record-keeping requirements for an authorized entity that receives epinephrine auto-injectors and the content of those records.

Requires that a report be filed with EMSA within 30 days of the use of an emergency epinephrine auto-injector, used pursuant to the authority outlined in the bill, and further requires the Emergency Medical Services Authority to annually publish a report that summarizes and analyzes all reports submitted to it.

STAFF RECOMMENDATION:

Maintain Support position

FISCAL IMPACT ON THE BOARD:

Staff does not anticipate any impact to the board or its operations.

SUPPORT: (6/20/16 version)

California Retailers Association
 Two individuals
 American Red Cross
 American College of Emergency Physicians, California Chapter
 Allergy & Asthma Network
 Food Allergy Research and Education
 California Society of Allergy, Asthma and Immunology
 SF Bay Area Food Allergy Network
 American Latex Allergy Association
 Allergy Station @ SacENT

OPPOSITION:

None

HISTORY:

Date	Last Five Actions
06/28/16	Read second time and amended. Re-referred to Com. on APPR.
06/27/16	From committee: amend, and do pass as amended and re-refer to Com. on APPR. (Ayes 7. Noes 0.)(June 21)
06/13/16	From Committee chair, with author’s amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. on JUD.
06/08/16	From committee: Do pass and re-refer to Com. on JUD (Ayes 7. Noes 0.) (June 8). Re-referred to Com. on JUD.
05/31/16	From committee chair, with author’s amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. on HEALTH.



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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

June 2, 2016

The Honorable Evan Low
Member, California State Assembly
State Capitol, Room 2175
Sacramento, CA 95816

RE: Assembly Bill 1386 – Support (As Amended 1/13/2016)

Dear Assembly Member Low:

I am pleased to advise you that the Board of Pharmacy Supports your Assembly Bill 1386 which would allow an authorized health care provider to issue a prescription for an epinephrine auto-injector (1) to a specified person trained and qualified to administer an epinephrine auto-injector; and (2) to an authorized entity if the entity submits evidence it employs at least one person, or utilizes at least one volunteer or agent, who is trained and qualified to administer an epinephrine auto-injector.

Please do not hesitate to contact me at (916) 574-7913 if you have any questions.

Sincerely,

A handwritten signature in blue ink that reads "Carolyn Klein".

CAROLYN KLEIN

Manager, Licensing and Legislation

cc: Department of Consumer Affairs



AB-1386 Emergency medical care: epinephrine auto-injectors. (2015-2016)

SECTION 1. Section 4119.4 is added to the Business and Professions Code, to read:

4119.4. (a) Notwithstanding any other law, a pharmacy may furnish epinephrine auto-injectors to an authorized entity, for the purpose of rendering emergency care in accordance with Section 1797.197a of the Health and Safety Code, if both of the following requirements are met:

(1) The epinephrine auto-injectors are furnished exclusively for use by, or in connection with, an authorized entity.

(2) An authorized health care provider provides a prescription that specifies the quantity of epinephrine auto-injectors to be furnished to an authorized entity described in subdivision (a) of Section 1797.197a of the Health and Safety Code. A new prescription shall be written for any additional epinephrine auto-injectors required for use.

(b) The pharmacy shall label each epinephrine auto-injector dispensed with all of the following:

(1) The name of the person or entity to whom the prescription was issued.

(2) The designations "Section 1797.197a Responder" and "First Aid Purposes Only."

(3) The dosage, use, and expiration date.

(c) Each dispensed prescription shall include the manufacturer's product information sheet for the epinephrine auto-injector.

(d) Records regarding the acquisition and disposition of epinephrine auto-injectors furnished pursuant to subdivision (a) shall be maintained by the authorized entity for a period of three years from the date the records were created. The authorized entity shall be responsible for monitoring the supply of epinephrine auto-injectors and ensuring the destruction of expired epinephrine auto-injectors.

(e) The epinephrine auto-injector dispensed pursuant to this section may be used only for the purpose, and under the circumstances, described in Section 1797.197a of the Health and Safety Code.

(f) For purposes of this section, "epinephrine auto-injector" means a disposable delivery device designed for the automatic injection of a premeasured dose of epinephrine into the human body to prevent or treat a life-threatening allergic reaction.

SEC. 2. Section 1714.23 of the Civil Code is amended to read:

1714.23. (a) For purposes of this section, the following definitions shall apply:

(1) "Anaphylaxis" means a potentially life-threatening hypersensitivity or allergic reaction to a substance.

(A) Symptoms of anaphylaxis may include shortness of breath, wheezing, difficulty breathing, difficulty talking or swallowing, hives, itching, swelling, shock, or asthma.

(B) Causes of anaphylaxis may include, but are not limited to, insect stings or bites, foods, drugs, and other allergens, as well as idiopathic or exercise-induced anaphylaxis.

(2) "Epinephrine auto-injector" means a disposable ~~drug delivery system with a spring activated concealed needle that is designed for emergency administration of epinephrine to provide rapid, convenient first aid for persons suffering from anaphylaxis.~~ delivery device designed for the automatic injection of a premeasured dose of epinephrine into the human body to prevent or treat a life-threatening allergic reaction.

(b) (1) Any person described in subdivision (b) of Section 1797.197a of the Health and Safety Code who administers an epinephrine auto-injector, in good faith and not for compensation, to another person who

appears to be experiencing anaphylaxis at the scene of an emergency situation is not liable for any civil damages resulting from his or her acts or omissions in administering the epinephrine auto-injector, if that person has complied with the requirements and standards of Section 1797.197a of the Health and Safety Code.

(2) (A) An authorized entity shall not be liable for any civil damages resulting from any act or omission other than an act or omission constituting gross negligence or willful or wanton misconduct connected to the administration of an epinephrine auto-injector by any one of its employees, volunteers, or agents who is a lay rescuer, as defined by paragraph (4) of subdivision (a) of Section 1797.197a of the Health and Safety Code, if the entity has complied with all applicable requirements of Section 1797.197a of the Health and Safety Code.

(B) The failure of an authorized entity to possess or administer an epinephrine auto-injector shall not result in civil liability.

(3) This subdivision does not affect any other immunity or defense that is available under law.

(c) The protection specified in *paragraph (1) of* subdivision (b) shall not apply in a case of personal injury or wrongful death that results from the gross negligence or willful or wanton misconduct of the person who renders emergency care treatment by the use of an epinephrine auto-injector.

(d) Nothing in this section relieves a manufacturer, designer, developer, distributor, or supplier of an epinephrine auto-injector of liability under any other applicable law.

(e) An authorizing physician and surgeon is not subject to professional review, liable in a civil action, or subject to criminal prosecution for the issuance of a prescription or order in accordance with Section 1797.197a of the Health and Safety Code unless the physician and surgeon's issuance of the prescription or order constitutes gross negligence or willful or malicious conduct.

SEC. 3. Section 49414 of the Education Code is amended to read:

49414. (a) School districts, county offices of education, and charter schools shall provide emergency epinephrine auto-injectors to school nurses or trained personnel who have volunteered pursuant to subdivision (d), and school nurses or trained personnel may use epinephrine auto-injectors to provide emergency medical aid to persons suffering, or reasonably believed to be suffering, from an anaphylactic reaction.

(b) For purposes of this section, the following terms have the following meanings:

(1) "Anaphylaxis" means a potentially life-threatening hypersensitivity to a substance.

(A) Symptoms of anaphylaxis may include shortness of breath, wheezing, difficulty breathing, difficulty talking or swallowing, hives, itching, swelling, shock, or asthma.

(B) Causes of anaphylaxis may include, but are not limited to, an insect sting, food allergy, drug reaction, and exercise.

(2) "Authorizing physician and surgeon" may include, but is not limited to, a physician and surgeon employed by, or contracting with, a local educational agency, a medical director of the local health department, or a local emergency medical services director.

(3) "Epinephrine auto-injector" means a disposable ~~drug-delivery system with a spring-activated needle that is designed for emergency administration of epinephrine to provide rapid, convenient first aid for persons suffering a potentially fatal reaction to anaphylaxis.~~ *delivery device designed for the automatic injection of a premeasured dose of epinephrine into the human body to prevent or treat a life-threatening allergic reaction.*

(4) "Qualified supervisor of health" may include, but is not limited to, a school nurse.

(5) "Volunteer" or "trained personnel" means an employee who has volunteered to administer epinephrine auto-injectors to a person if the person is suffering, or reasonably believed to be suffering, from anaphylaxis, has been designated by a school, and has received training pursuant to subdivision (d).

(c) Each private elementary and secondary school in the state may voluntarily determine whether or not to make emergency epinephrine auto-injectors and trained personnel available at its school. In making this determination, a school shall evaluate the emergency medical response time to the school and determine whether initiating emergency medical services is an acceptable alternative to epinephrine auto-injectors and trained personnel. A private elementary or secondary school choosing to exercise the authority provided under this subdivision shall not receive state funds specifically for purposes of this subdivision.

(d) Each public and private elementary and secondary school in the state may designate one or more volunteers to receive initial and annual refresher training, based on the standards developed pursuant to subdivision (e), regarding the storage and emergency use of an epinephrine auto-injector from the school nurse or other qualified person designated by an authorizing physician and surgeon.

(e) (1) Every five years, or sooner as deemed necessary by the Superintendent, the Superintendent shall review minimum standards of training for the administration of epinephrine auto-injectors that satisfy the requirements of paragraph (2). For purposes of this subdivision, the Superintendent shall consult with organizations and providers with expertise in administering epinephrine auto-injectors and administering medication in a school environment, including, but not limited to, the State Department of Public Health, the Emergency Medical Services Authority, the American Academy of Allergy, Asthma and Immunology, the California School Nurses Organization, the California Medical Association, the American Academy of Pediatrics, Food Allergy Research and Education, the California Society of Allergy, Asthma and Immunology, the American College of Allergy, Asthma and Immunology, the Sean N. Parker Center for Allergy Research, and others.

(2) Training established pursuant to this subdivision shall include all of the following:

(A) Techniques for recognizing symptoms of anaphylaxis.

(B) Standards and procedures for the storage, restocking, and emergency use of epinephrine auto-injectors.

(C) Emergency followup procedures, including calling the emergency 911 telephone number and contacting, if possible, the pupil's parent and physician.

(D) Recommendations on the necessity of instruction and certification in cardiopulmonary resuscitation.

(E) Instruction on how to determine whether to use an adult epinephrine auto-injector or a junior epinephrine auto-injector, which shall include consideration of a pupil's grade level or age as a guideline of equivalency for the appropriate pupil weight determination.

(F) Written materials covering the information required under this subdivision.

(3) Training established pursuant to this subdivision shall be consistent with the most recent Voluntary Guidelines for Managing Food Allergies In Schools and Early Care and Education Programs published by the federal Centers for Disease Control and Prevention and the most recent guidelines for medication administration issued by the department.

(4) A school shall retain for reference the written materials prepared under subparagraph (F) of paragraph (2).

(f) A school district, county office of education, or charter school shall distribute a notice at least once per school year to all staff that contains the following information:

(1) A description of the volunteer request stating that the request is for volunteers to be trained to administer an epinephrine auto-injector to a person if the person is suffering, or reasonably believed to be suffering, from anaphylaxis, as specified in subdivision (b).

(2) A description of the training that the volunteer will receive pursuant to subdivision (d).

(g) (1) A qualified supervisor of health at a school district, county office of education, or charter school shall obtain from an authorizing physician and surgeon a prescription for each school for epinephrine auto-injectors that, at a minimum, includes, for elementary schools, one regular epinephrine auto-injector and one junior epinephrine auto-injector, and for junior high schools, middle schools, and high schools, if there are no pupils who require a junior epinephrine auto-injector, one regular epinephrine auto-injector. A qualified supervisor of health at a school district, county office of education, or charter school shall be responsible for stocking the epinephrine auto-injector and restocking it if it is used.

(2) If a school district, county office of education, or charter school does not have a qualified supervisor of health, an administrator at the school district, county office of education, or charter school shall carry out the duties specified in paragraph (1).

(3) A prescription pursuant to this subdivision may be filled by local or mail order pharmacies or epinephrine auto-injector manufacturers.

(4) An authorizing physician and surgeon shall not be subject to professional review, be liable in a civil action, or be subject to criminal prosecution for the issuance of a prescription or order pursuant to this section, unless

the physician and surgeon's issuance of the prescription or order constitutes gross negligence or willful or malicious conduct.

(h) A school nurse or, if the school does not have a school nurse or the school nurse is not onsite or available, a volunteer may administer an epinephrine auto-injector to a person exhibiting potentially life-threatening symptoms of anaphylaxis at school or a school activity when a physician is not immediately available. If the epinephrine auto-injector is used it shall be restocked as soon as reasonably possible, but no later than two weeks after it is used. Epinephrine auto-injectors shall be restocked before their expiration date.

(i) A volunteer shall initiate emergency medical services or other appropriate medical followup in accordance with the training materials retained pursuant to paragraph (4) of subdivision (e).

(j) A school district, county office of education, or charter school shall ensure that each employee who volunteers under this section will be provided defense and indemnification by the school district, county office of education, or charter school for any and all civil liability, in accordance with, but not limited to, that provided in Division 3.6 (commencing with Section 810) of Title 1 of the Government Code. This information shall be reduced to writing, provided to the volunteer, and retained in the volunteer's personnel file.

(k) A state agency, the department, or a public school may accept gifts, grants, and donations from any source for the support of the public school carrying out the provisions of this section, including, but not limited to, the acceptance of epinephrine auto-injectors from a manufacturer or wholesaler.

SEC. 4. Section 1797.197a of the Health and Safety Code is amended to read:

1797.197a. (a) For purposes of this section, the following definitions shall apply:

(1) "Anaphylaxis" means a potentially life-threatening hypersensitivity or allergic reaction to a substance.

(A) Symptoms of anaphylaxis may include shortness of breath, wheezing, difficulty breathing, difficulty talking or swallowing, hives, itching, swelling, shock, or asthma.

(B) Causes of anaphylaxis may include, but are not limited to, insect stings or bites, foods, drugs, and other allergens, as well as idiopathic or exercise-induced anaphylaxis.

(2) "Authorized entity" means any for-profit, nonprofit, or government entity or organization that employs at least one person or utilizes at least one volunteer or agent that has voluntarily completed a training course as described in subdivision (c).

~~(2) (3) "Epinephrine auto-injector" means a disposable drug delivery system with a spring-activated concealed needle that is designed for emergency administration of epinephrine to provide rapid, convenient first aid for persons suffering from anaphylaxis.~~ *delivery device designed for the automatic injection of a premeasured dose of epinephrine into the human body to prevent or treat a life-threatening allergic reaction.*

~~(3) (4) "Lay rescuer" means any person who has met the training standards and other requirements of this section but who is not otherwise licensed or certified to use an epinephrine auto-injector on another person.~~

~~(4) (5) "Prehospital emergency medical care person" has the same meaning as defined in paragraph (2) of subdivision (a) of Section 1797.189.~~

(b) A prehospital emergency medical care person or lay rescuer may use an epinephrine auto-injector to render emergency care to another person if all of the following requirements are met:

(1) The epinephrine auto-injector is legally obtained by prescription from an authorized health care ~~provider. An authorized health care provider may issue a prescription for an epinephrine auto-injector to a person described in this subdivision for the purpose of rendering emergency care to another person, upon presentation of current certification demonstrating that person is trained and qualified to administer an epinephrine auto-injector as a prehospital emergency medical care person or lay rescuer, pursuant to this section or any other statute or regulation.~~ *provider or from an authorized entity that acquired the epinephrine auto-injector pursuant to subdivision (e).*

(2) The epinephrine auto-injector is used on another, with the expressed or implied consent of that person, to treat anaphylaxis.

(3) The epinephrine auto-injector is stored and maintained as directed by the manufacturer's instructions for that product.

(4) The person using the epinephrine auto-injector has successfully completed a course of training with an authorized training provider, as described in subdivision (c), and has current certification of training issued by the provider.

(5) The epinephrine auto-injectors obtained by prehospital emergency medical care personnel pursuant to Section 4119.3 of the Business and Professions Code shall be used only when functioning outside the course of the person's occupational duties, or as a volunteer, pursuant to this section.

(6) The Emergency Medical Services System is activated as soon as practicable when an epinephrine auto-injector is used.

(c) (1) The authorized training providers shall be approved, and the minimum standards for training and the use and administration of epinephrine auto-injectors pursuant to this section shall be established and approved, by the ~~California Emergency Medical Services (EMS) Authority~~ authority. The authority may designate existing training standards for the use and administration of epinephrine auto-injectors by prehospital emergency medical care personnel to satisfy the requirements of this section.

(2) The minimum training and requirements shall include all of the following components:

(A) Techniques for recognizing circumstances, signs, and symptoms of anaphylaxis.

(B) Standards and procedures for proper storage and emergency use of epinephrine auto-injectors.

(C) Emergency followup procedures, including activation of the Emergency Medical Services System, by calling the emergency 9-1-1 telephone number or otherwise alerting and summoning more advanced medical personnel and services.

(D) Compliance with all regulations governing the training, indications, use, and precautions concerning epinephrine auto-injectors.

(E) Written material covering the information required under this provision, including the manufacturer product information sheets on commonly available models of epinephrine auto-injectors.

(F) Completion of a training course in cardiopulmonary resuscitation and the use of an automatic external defibrillator (AED) for infants, children, and adults that complies with regulations adopted by the ~~EMS Authority~~ authority and the standards of the American Heart Association or the American Red Cross, and a current certification for that training.

(3) Training certification shall be valid for no more than two years, after which recertification with an authorized training provider is required.

(4) The director ~~of the authority~~ may, in accordance with regulations adopted by the authority, deny, suspend, or revoke any approval issued under this subdivision or may place any approved training provider on probation upon a finding by the director of an imminent threat to public health and safety, as evidenced by any of the following:

(A) Fraud.

(B) Incompetence.

(C) The commission of any fraudulent, dishonest, or corrupt act that is substantially related to the qualifications, functions, or duties of training program directors or instructors.

(D) Conviction of any crime that is substantially related to the qualifications, functions, or duties of training program directors or instructors. The record of conviction or a certified copy of the record shall be conclusive evidence of the conviction.

(E) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of, or conspiring to violate, any provision of this section or the regulations promulgated by the authority pertaining to the review and approval of training programs in anaphylaxis and the use and administration of epinephrine auto-injectors, as described in this subdivision.

(d) (1) The authority shall assess a fee pursuant to regulation sufficient to cover the reasonable costs incurred by the authority for the ongoing review and approval of training and certification under subdivision (c).

(2) The fees shall be deposited in the Specialized First Aid Training Program Approval Fund, which is hereby created in the State Treasury. All moneys deposited in the fund shall be made available, upon appropriation, to the authority for purposes described in paragraph (1).

(3) The authority may transfer unused portions of the Specialized First Aid Training Program Approval Fund to the Surplus Money Investment Fund. Funds transferred to the Surplus Money Investment Fund shall be placed in a separate trust account, and shall be available for transfer to the Specialized First Aid Training Program Approval Fund, together with the interest earned, when requested by the authority.

(4) The authority shall maintain a reserve balance in the Specialized First Aid Training Program Approval Fund of 5 percent of annual revenues. Any increase in the fees deposited in the Specialized First Aid Training Program Approval Fund shall be effective upon determination by the authority that additional moneys are required to fund expenditures pursuant to subdivision (c).

(e) (1) An authorized health care provider may issue a prescription for an epinephrine auto-injector to a prehospital emergency medical care person or a lay rescuer for the purpose of rendering emergency care to another person upon presentation of a current epinephrine auto-injector certification card issued by the authority demonstrating that the person is trained and qualified to administer an epinephrine auto-injector pursuant to this section or any other law.

(2) An authorized health care provider may issue a prescription for an epinephrine auto-injector to an authorized entity if the authorized entity submits evidence it employs at least one person, or utilizes at least one volunteer or agent, who is trained and has a current epinephrine auto-injector certification card issued by the authority demonstrating that the person is qualified to administer an epinephrine auto-injector pursuant to this section.

(f) An authorized entity that possesses and makes available epinephrine auto-injectors shall do both of the following:

(1) Create and maintain on its premises an operations plan that includes all of the following:

(A) The name and contact number for the authorized health care provider who prescribed the epinephrine auto-injector.

(B) Where and how the epinephrine auto-injector will be stored.

(C) The names of the designated employees or agents who have completed the training program required by this section and who are authorized to administer the epinephrine auto-injector.

(D) How and when the epinephrine auto-injector will be inspected for an expiration date.

(E) The process to replace the expired epinephrine auto-injector, including the proper disposal of the expired epinephrine auto-injector or used epinephrine auto-injector in a sharps container.

(2) Submit to the authority, in a manner identified by the authority, a report of each incident that involves the use of an epinephrine auto-injector, not more than 30 days after each use. The authority shall annually publish a report that summarizes all reports submitted to it under this subdivision.

~~(e)~~ *(g) This section shall not apply to a school district or county office of education, or its personnel, that provides and utilizes epinephrine auto-injectors to provide emergency medical aid pursuant to Section 49414 of the Education Code.*

~~(f)~~ *(h) This section shall not be construed to limit or restrict the ability of prehospital emergency medical care personnel, under any other statute or regulation, to administer epinephrine, including the use of epinephrine auto-injectors, or to require additional training or certification beyond what is already required under the other statute or regulation.*

SEC. 5. 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.



Bill Number:	AB 1748
Current Version:	June 20, 2016
Author:	Mayes
Topic:	Emergency medical care: Naloxone Hydrochloride or other Opioid Antagonist
Board Position:	

Affected Sections: Add section 4119.8 to the Business and Professions Code
Add section 49414.3 to the Education Code

Status: Hearing: August 1, 2016 – Senate Appropriations

SUMMARY:

This bill would provide authorize specified educational agencies to provide an emergency opioid antagonist to school nurses or trained personnel and would authorize a school nurse or trained personnel (volunteers) to administer an opioid antagonist to a person suffering from an opioid overdose, as specified. The author’s office indicated this measure is modeled after provisions that allow a pharmacist to dispense emergency epinephrine auto-injectors to authorized entities for the purpose of providing emergency medical assistance.

EXISTING LAW:

Pursuant to a ¹protocol, a pharmacist may furnish naloxone to an individual without a prescription.

Health and Safety Code section 1797.197a provides that an “authorized entity” may obtain, and a pharmacist may furnish pursuant to a prescription, epinephrine auto-injectors, and further specifies requirements for training, recordkeeping, reporting.

THIS BILL WOULD:

Add Section 4119.8 to Pharmacy Law to specify that a pharmacy may furnish naloxone hydrochloride or other opioid antagonist pursuant to a prescription to a school district, county office of education, or charter school pursuant to specified provisions in the Education code. The pharmacy law provisions also specify record-keeping requirements for those school districts that elect to stock the opioid antagonist.

Amend the Education Code to establish training requirements for schools that elect to utilize naloxone or other opioid antagonist; a timeframe to restock the opioid antagonist when

¹ Authority established via AB 1535 (Bloom), Chapter 326, Statutes of 2014

needed; certain protections for physicians that write the prescriptions for schools to access the opioid antagonist; and requires that schools provide defense and indemnification for volunteers that may administer the naloxone hydrochloride if used in a manner consistent with the bill’s provisions.

The author’s office advised that two of the provisions in the Education Code are expected to be amended: (1) to remove CDPH from the list of entities that the Superintendent shall consult with regard to minimum standards of training, and (2) to strike the second sentence in Section 49414.3(e)(2)(C) regarding the transportation of a pupil to an emergency room.

STAFF RECOMMENDATION:

This measure would seem consistent with the board’s efforts to ensure that persons with the appropriate training have lawful access to naloxone hydrochloride or other opioid antagonist to provide emergency medical aid to persons suffering, or reasonably believed to be suffering, from an opioid overdose.

FISCAL IMPACT ON THE BOARD:

Staff does not anticipate any impact to the board or its operations.

SUPPORT: (For the text dated 5/11/16)

- California School Nurses Organization
- Drug Policy Alliance
- California Society for Addiction Medicine
- American Nurses Association of California
- California Pharmacists Association

OPPOSE:

- California Teachers Association

HISTORY:

Last 5 History Actions	
Date	Action
06/29/16	From committee: Do pass and re-refer to Com. on APPR. (Ayes 7. Noes 0.) (June 28). Re-referred to Com. on APPR.
06/20/16	From committee chair, with author's amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. on JUD.
06/15/16	From committee: Do pass and re-refer to Com. on JUD. (Ayes 9. Noes 0.) (June 15). Re-referred to Com. on JUD.
06/02/16	Referred to Coms. on ED. and JUD.
05/23/16	In Senate. Read first time. To Com. on RLS. for assignment.

CHAD MAYES

ASSEMBLY REPUBLICAN LEADER



AB 1748: Authorizing Schools to Stock and Administer Opioid Overdose Antidotes

SUMMARY

Assembly Bill 1748 would provide the authority for California schools to stock, and for nurses and other trained volunteer employees to administer, opioid overdose antidotes like naloxone.

Recently, the Clinton Health Matters Initiative partnered with Adapt Pharma, the manufacturer of Narcan, to reach a discounted public interest price for the medication. Adapt is also offering a free carton of the medication to every high school in the U.S.

BACKGROUND

According to the Centers for Disease Control and Prevention (CDC), the number of deaths resulting from opioid overdoses has been steadily increasing over the past decade, and now exceeds the number of deaths resulting from automobile accidents.

Naloxone (sold under the brand name Narcan) is a medication that can block the effects of opioid overdoses. In November 2015, the FDA approved an easy-to-use variant, administered by nasal spray.

In January 2016 at the Clinton Health Matters Summit in Indian Wells, CA, Adapt Pharma announced:

- An offer of a free Narcan carton (2 doses) for every high school in the U.S.
- A grant to the National Association of School Nurses (NASN) to develop school directed educational materials about opioid overdose risks and prevention.

AB 559 (Wiggins, 2001) authorized schools to receive, stock, and administer epinephrine, and allowed pharmacies to provide the medication to schools.

SB 1438 (Pavley, 2014) equipped firefighters, police officers and other first responders with naloxone.

PROBLEM

There is no clear statutory authority for schools to accept, stock, or administer opioid overdose antidotes. This medication, which could potentially save lives, should be available to schools that choose to stock it.

SOLUTION

AB 1748 is modeled after existing law regarding “EpiPens,” but does not provide any mandates on schools. This bill would:

- Authorize pharmacies to provide naloxone to schools.
- Authorize schools to stock naloxone.
- Allow school nurses, and other employees who have volunteered and received training, to administer naloxone to someone suffering an overdose.
- Require that schools that opt-in provide defense and indemnification for trained employees acting under the section.
- Provide that an employee acting in good faith is exempt from professional review, or civil or criminal liability.

This bill will provide schools with the authority to stock and administer this crucial medication, potentially saving the lives of Californians.

SUPPORT

- California School Nurses Organization (if amended)
- Drug Policy Alliance

FOR MORE INFORMATION

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AB-1748 Pupils: pupil health: opioid antagonist. (2015-2016)

SECTION 1. *Section 4119.8 is added to the Business and Professions Code, to read:*

4119.8. (a) *Notwithstanding any other law, a pharmacy may furnish naloxone hydrochloride or another opioid antagonist to a school district, county office of education, or charter school pursuant to Section 49414.3 of the Education Code if all of the following are met:*

(1) *The naloxone hydrochloride or another opioid antagonist is furnished exclusively for use at a school district schoolsite, county office of education schoolsite, or charter school.*

(2) *A physician and surgeon provides a written order that specifies the quantity of naloxone hydrochloride or another opioid antagonist to be furnished.*

(b) *Records regarding the acquisition and disposition of naloxone hydrochloride or another opioid antagonist furnished pursuant to subdivision (a) shall be maintained by the school district, county office of education, or charter school for a period of three years from the date the records were created. The school district, county office of education, or charter school shall be responsible for monitoring the supply of naloxone hydrochloride or another opioid antagonist and ensuring the destruction of expired naloxone hydrochloride or another opioid antagonist.*

SEC. 2. *Section 49414.3 is added to the Education Code, to read:*

49414.3. (a) *School districts, county offices of education, and charter schools may provide emergency naloxone hydrochloride or another opioid antagonist to school nurses or trained personnel who have volunteered pursuant to subdivision (d), and school nurses or trained personnel may use naloxone hydrochloride or another opioid antagonist to provide emergency medical aid to persons suffering, or reasonably believed to be suffering, from an opioid overdose.*

(b) *For purposes of this section, the following terms have the following meanings:*

(1) *"Authorizing physician and surgeon" may include, but is not limited to, a physician and surgeon employed by, or contracting with, a local educational agency, a medical director of the local health department, or a local emergency medical services director.*

(2) *"Auto-injector" means a disposable delivery device designed for the automatic injection of a premeasured dose of an opioid antagonist into the human body and approved by the federal Food and Drug Administration for layperson use.*

(3) *"Opioid antagonist" means naloxone hydrochloride or another drug approved by the federal Food and Drug Administration that, when administered, negates or neutralizes in whole or in part the pharmacological effects of an opioid in the body, and has been approved for the treatment of an opioid overdose.*

(4) *"Qualified supervisor of health" may include, but is not limited to, a school nurse.*

(5) *"Volunteer" or "trained personnel" means an employee who has volunteered to administer naloxone hydrochloride or another opioid antagonist to a person if the person is suffering, or reasonably believed to be suffering, from an opioid overdose, has been designated by a school, and has received training pursuant to subdivision (d).*

(c) *Each public and private elementary and secondary school in the state may voluntarily determine whether or not to make emergency naloxone hydrochloride or another opioid antagonist and trained personnel available at its school. In making this determination, a school shall evaluate the emergency medical response time to the school and determine whether initiating emergency medical services is an acceptable alternative to naloxone hydrochloride or another opioid antagonist and trained personnel. A private elementary or secondary school*

choosing to exercise the authority provided under this subdivision shall not receive state funds specifically for purposes of this subdivision.

(d) (1) Each public and private elementary and secondary school in the state may designate one or more volunteers to receive initial and annual refresher training, based on the standards developed pursuant to subdivision (e), regarding the storage and emergency use of naloxone hydrochloride or another opioid antagonist from the school nurse or other qualified person designated by an authorizing physician and surgeon. A benefit shall not be granted to or withheld from any individual based on his or her offer to volunteer and there shall be no retaliation against any individual for rescinding his or her offer to volunteer, including after receiving training. Any school district, county office of education, or charter school choosing to exercise the authority provided under this subdivision shall provide the training for the volunteers at no cost to the volunteer and during the volunteer's regular working hours.

(2) An employee who volunteers pursuant to this section may rescind his or her offer to administer emergency naloxone hydrochloride or another opioid antagonist at any time, including after receipt of training.

(e) (1) The Superintendent shall establish minimum standards of training for the administration of naloxone hydrochloride or another opioid antagonist that satisfies the requirements of paragraph (2). Every five years, or sooner as deemed necessary by the Superintendent, the Superintendent shall review minimum standards of training for the administration of naloxone hydrochloride or other opioid antagonists that satisfy the requirements of paragraph (2). For purposes of this subdivision, the Superintendent shall consult with organizations and providers with expertise in administering naloxone hydrochloride or another opioid antagonist and administering medication in a school environment, including, but not limited to, the State Department of Public Health, the Emergency Medical Services Authority, the California School Nurses Organization, the California Medical Association, the American Academy of Pediatrics, and others.

(2) Training established pursuant to this subdivision shall include all of the following:

(A) Techniques for recognizing symptoms of an opioid overdose.

(B) Standards and procedures for the storage, restocking, and emergency use of naloxone hydrochloride or another opioid antagonist.

(C) Basic emergency followup procedures, including, but not limited to, a requirement for the school or charter school administrator or, if the administrator is not available, another school staff member to call the emergency 911 telephone number and to contact the pupil's parent or guardian. The requirement for the school or charter school administrator or other school staff member to call the emergency 911 telephone number shall not require a pupil to be transported to an emergency room.

(D) Recommendations on the necessity of instruction and certification in cardiopulmonary resuscitation.

(E) Written materials covering the information required under this subdivision.

(3) Training established pursuant to this subdivision shall be consistent with the most recent guidelines for medication administration issued by the department.

(4) A school shall retain for reference the written materials prepared under subparagraph (E) of paragraph (2).

(5) The department shall include on its Internet Web site a clearinghouse for best practices in training nonmedical personnel to administer naloxone hydrochloride or another opioid antagonist to pupils.

(f) Any school district, county office of education, or charter school electing to utilize naloxone hydrochloride or another opioid antagonist for emergency aid shall distribute a notice at least once per school year to all staff that contains the following information:

(1) A description of the volunteer request stating that the request is for volunteers to be trained to administer naloxone hydrochloride or another opioid antagonist to a person if the person is suffering, or reasonably believed to be suffering, from an opioid overdose.

(2) A description of the training that the volunteer will receive pursuant to subdivision (d).

(3) The right of an employee to rescind his or her offer to volunteer pursuant to this section.

(4) A statement that no benefit will be granted to or withheld from any individual based on his or her offer to volunteer and that there will be no retaliation against any individual for rescinding his or her offer to volunteer, including after receiving training.

(g) (1) A qualified supervisor of health at a school district, county office of education, or charter school electing to utilize naloxone hydrochloride or another opioid antagonist for emergency aid shall obtain from an authorizing physician and surgeon a prescription for each school for naloxone hydrochloride or another opioid antagonist. A qualified supervisor of health at a school district, county office of education, or charter school shall be responsible for stocking the naloxone hydrochloride or another opioid antagonist and restocking it if it is used.

(2) If a school district, county office of education, or charter school does not have a qualified supervisor of health, an administrator at the school district, county office of education, or charter school shall carry out the duties specified in paragraph (1).

(3) A prescription pursuant to this subdivision may be filled by local or mail order pharmacies or naloxone hydrochloride or another opioid antagonist manufacturers.

(4) An authorizing physician and surgeon shall not be subject to professional review, be liable in a civil action, or be subject to criminal prosecution for the issuance of a prescription or order pursuant to this section, unless the physician and surgeon's issuance of the prescription or order constitutes gross negligence or willful or malicious conduct.

(h) (1) A school nurse or, if the school does not have a school nurse or the school nurse is not onsite or available, a volunteer may administer naloxone hydrochloride or another opioid antagonist to a person exhibiting potentially life-threatening symptoms of an opioid overdose at school or a school activity when a physician is not immediately available. If the naloxone hydrochloride or another opioid antagonist is used it shall be restocked as soon as reasonably possible, but no later than two weeks after it is used. Naloxone hydrochloride or another opioid antagonist shall be restocked before its expiration date.

(2) Volunteers may administer naloxone hydrochloride or another opioid antagonist only by nasal spray or by auto-injector.

(3) A volunteer shall be allowed to administer naloxone hydrochloride or another opioid antagonist in a form listed in paragraph (2) that the volunteer is most comfortable with.

(i) A school district, county office of education, or charter school electing to utilize naloxone hydrochloride or another opioid antagonist for emergency aid shall ensure that each employee who volunteers under this section will be provided defense and indemnification by the school district, county office of education, or charter school for any and all civil liability, in accordance with, but not limited to, that provided in Division 3.6 (commencing with Section 810) of Title 1 of the Government Code. This information shall be reduced to writing, provided to the volunteer, and retained in the volunteer's personnel file.

(j) (1) Notwithstanding any other law, a person trained as required under subdivision (d), who administers naloxone hydrochloride or another opioid antagonist, in good faith and not for compensation, to a person who appears to be experiencing an opioid overdose shall not be subject to professional review, be liable in a civil action, or be subject to criminal prosecution for his or her acts or omissions in administering the naloxone hydrochloride or another opioid antagonist.

(2) The protection specified in paragraph (1) shall not apply in a case of gross negligence or willful and wanton misconduct of the person who renders emergency care treatment by the use of naloxone hydrochloride or another opioid antagonist.

(3) Any public employee who volunteers to administer naloxone hydrochloride or another opioid antagonist pursuant to subdivision (d) is not providing emergency medical care "for compensation," notwithstanding the fact that he or she is a paid public employee.

(k) A state agency, the department, or a public school may accept gifts, grants, and donations from any source for the support of the public school carrying out the provisions of this section, including, but not limited to, the acceptance of naloxone hydrochloride or another opioid antagonist from a manufacturer or wholesaler.



Bill Number:	SB 482
Current Version:	As Amended June 21, 2016
Author:	Lara
Topic:	Controlled Substances: CURES database
Committee Recommendation:	Support (ver. 4/7/16)

Affected Sections: Amends Section 11165.1 of the Health and Safety Code
Add Section 11165.4 to the Health and Safety Code

Status: Assembly Rules Committee

SUMMARY:

This measure would require a prescriber to access the CURES system under specified conditions, to include checking the system before prescribing a Schedule II, III, or IV medication for the first time and at least every four months. The bill also limits the dispensing of a controlled substance in specified settings to either a 5- or 7-day supply

EXISTING LAW:

Existing law classifies certain controlled substances into designated schedules. Further, existing law requires the Department of Justice to maintain CURES for the electronic monitoring of the prescribing and dispensing of Schedule II, Schedule III, and Schedule IV controlled substances and requires dispensing pharmacies and clinics to report specified information for each prescription of a Schedule II, Schedule III, or Schedule IV controlled substance to the department.

THIS BILL WOULD:

Add Section 11164.5 to do the following:

1. Require a prescribers to
 - a. access and consult the CURES database to obtain an electronic history of a patient's controlled substances dispensing history before prescribing a Schedule II or Schedule III drug the first time for a patient as well as at least every four months.
 - b. Add a definition of "first time"
 - c. Obtain a patient's CS history from CURES no earlier than 24 hours before prescribing a Schedule II, III or IV CS.
2. Exempt Veterinarians from the duty to consult CURES
3. Specify circumstances under which a health care practitioner, as specified, does not need to consult CURES, such as
 - a. In specified settings

- b. When ordering, administering, furnishing or dispensing a CS in the emergency department of a general acute care hospital if the quantity does not exceed a 7-day supply.
 - c. When ordered, administered, furnished or dispensed to a patient as part of the patient's treatment for a surgical procedure, if the quantity does not exceed a nonrefillable 5-day supply in specified settings.
 - d. To an individual patient currently receiving hospice care, as defined.
 - e. If the CURES database is not operational, there are technological limitations, or exceptional circumstances that the CURES database cannot be accessed, as specified.
 - f. Other specified circumstances.
4. If the health care practitioner does not consult CURES, they are to document the reason he or she did not do so in the patient's medical record.
 5. Provide for administrative sanctions, as deemed appropriate by a health care practitioner's board, for knowingly failing to consult CURES.
 6. Provide for applicable state and federal privacy governing the duties required by this section.
 7. Specify that the provisions of this section are severable. If a section is deemed invalid, the remainder of the requirements remains in place.
 8. The provisions do not take effect until the DOJ certifies that the CURES database is ready for statewide use. Notification is required to the Secretary of State and the Office of Legislative Counsel of the date of the certification.

STAFF COMMENTS:

The board has long supported provisions to utilize the CURES to review the dispensing history of a patient prior to prescribing and/or dispensing a Schedule II, Schedule III, or Schedule IV controlled substance to a patient.

FISCAL IMPACT ON THE BOARD:

Board staff does not anticipate any significant impact and believes that any minor impact could be absorbed within existing resources.

HISTORY:

Date	Last Five Actions
06/29/16	June 29 set for first hearing canceled at the request of author.
06/21/16	Read second time and amended. Re-referred to Com. on APPR.
06/20/16	From committee: Do pass as amended and re-refer to Com. on APPR. (Ayes 16. Noes 0.) (June 14).
06/06/16	From committee with author's amendments. Read second time and amended. Re-referred to Com. on B. & P.
05/19/16	From committee: Be re-referred to Com. on B. & P. (Ayes 11. Noes 0.) (May 19). Re-referred to Com. on B. & P.



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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

June 2, 2016

The Honorable Ricardo Lara
Member, California State Senate
State Capitol, Room 5050
Sacramento, CA 95816

RE: SB 482 – Support (As Amended 4/7/2016)

Dear Senator Lara:

I am pleased to advise you that the Board of Pharmacy supports your Senate Bill 482.

The board supports your efforts to require that prescribers access and consult the CURES database to review an electronic history of a patient's controlled substances dispensing history before prescribing a Schedule II or Schedule III drug for the first time for a patient or at least annually.

CURES provides point-of-care system access to California's prescription drug monitoring program for pharmacists and prescribers, which is a valuable tool to identify potential drug-seeking behaviors as well as potential drug diversion. We applaud your efforts to increase use of this system.

Please do not hesitate to contact me at (916) 574-7913 if you have any questions.

Sincerely,

A handwritten signature in blue ink that reads "Carolyn Klein".

CAROLYN KLEIN

Manager, Licensing and Legislation

cc: Department of Consumer Affairs



SB-482 Controlled substances: CURES database. (2015-2016)

SECTION 1. Section 11165.1 of the Health and Safety Code is amended to read:

11165.1. (a) (1) (A) (i) A health care practitioner authorized to prescribe, order, administer, furnish, or dispense Schedule II, Schedule III, or Schedule IV controlled substances pursuant to Section 11150 shall, before July 1, 2016, or upon receipt of a federal Drug Enforcement Administration (DEA) registration, whichever occurs later, submit an application developed by the Department of Justice to obtain approval to access information online regarding the controlled substance history of a patient that is stored on the Internet and maintained within the Department of Justice, and, upon approval, the department shall release to that practitioner the electronic history of controlled substances dispensed to an individual under his or her care based on data contained in the CURES Prescription Drug Monitoring Program (PDMP).

(ii) A pharmacist shall, before July 1, 2016, or upon licensure, whichever occurs later, submit an application developed by the Department of Justice to obtain approval to access information online regarding the controlled substance history of a patient that is stored on the Internet and maintained within the Department of Justice, and, upon approval, the department shall release to that pharmacist the electronic history of controlled substances dispensed to an individual under his or her care based on data contained in the CURES PDMP.

(B) An application may be denied, or a subscriber may be suspended, for reasons which include, but are not limited to, the following:

(i) Materially falsifying an application for a subscriber.

(ii) Failure to maintain effective controls for access to the patient activity report.

(iii) Suspended or revoked federal DEA registration.

(iv) Any subscriber who is arrested for a violation of law governing controlled substances or any other law for which the possession or use of a controlled substance is an element of the crime.

(v) Any subscriber accessing information for any other reason than caring for his or her patients.

(C) Any authorized subscriber shall notify the Department of Justice within 30 days of any changes to the subscriber account.

(2) A health care practitioner authorized to prescribe, order, administer, furnish, or dispense Schedule II, Schedule III, or Schedule IV controlled substances pursuant to Section 11150 or a pharmacist shall be deemed to have complied with paragraph (1) if the licensed health care practitioner or pharmacist has been approved to access the CURES database through the process developed pursuant to subdivision (a) of Section 209 of the Business and Professions Code.

(b) Any request for, or release of, a controlled substance history pursuant to this section shall be made in accordance with guidelines developed by the Department of Justice.

(c) In order to prevent the inappropriate, improper, or illegal use of Schedule II, Schedule III, or Schedule IV controlled substances, the Department of Justice may initiate the referral of the history of controlled substances dispensed to an individual based on data contained in CURES to licensed health care practitioners, pharmacists, or both, providing care or services to the individual.

(d) The history of controlled substances dispensed to an individual based on data contained in CURES that is received by a practitioner or pharmacist from the Department of Justice pursuant to this section ~~shall be considered~~ *is* medical information subject to the provisions of the Confidentiality of Medical Information Act contained in Part 2.6 (commencing with Section 56) of Division 1 of the Civil Code.

(e) Information concerning a patient's controlled substance history provided to a prescriber or pharmacist pursuant to this section shall include prescriptions for controlled substances listed in Sections 1308.12, 1308.13, and 1308.14 of Title 21 of the Code of Federal Regulations.

(f) A health care practitioner, pharmacist, and any person acting on behalf of a health care practitioner or pharmacist, when acting with reasonable care and in good faith, is not subject to civil or administrative liability arising from any false, incomplete, or inaccurate information submitted to, or reported by, the CURES database or for any resulting failure of the CURES database to accurately or timely report that information.

SEC. 2. *Section 11165.4 is added to the Health and Safety Code, to read:*

11165.4. *(a) (1) (A) A health care practitioner authorized to prescribe, order, administer, furnish, or dispense a controlled substance shall consult the CURES database to review a patient's controlled substance history before prescribing a Schedule II, Schedule III, or Schedule IV controlled substance to the patient for the first time and at least once every four months thereafter if the substance remains part of the treatment of the patient.*

(B) For purposes of this paragraph, "first time" means the initial occurrence in which a health care practitioner, in his or her role as a health care practitioner, intends to prescribe, order, administer, furnish, or dispense a Schedule II, Schedule III, or Schedule IV controlled substance to a patient and has not previously prescribed a controlled substance to the patient.

(2) A health care practitioner shall obtain a patient's controlled substance history from the CURES database no earlier than 24 hours before he or she prescribes, orders, administers, furnishes, or dispenses a Schedule II, Schedule III, or Schedule IV controlled substance to the patient.

(b) The duty to consult the CURES database, as described in subdivision (a), does not apply to veterinarians.

(c) The duty to consult the CURES database, as described in subdivision (a), does not apply to a health care practitioner in any of the following circumstances:

(1) If a health care practitioner prescribes, orders, or furnishes a controlled substance to be administered or dispensed to a patient while the patient is admitted to any of the following facilities or during an emergency transfer between any of the following facilities:

(A) A licensed clinic, as described in Chapter 1 (commencing with Section 1200) of Division 2.

(B) An outpatient setting, as described in Chapter 1.3 (commencing with Section 1248) of Division 2.

(C) A health facility, as described in Chapter 2 (commencing with Section 1250) of Division 2.

(D) A county medical facility, as described in Chapter 2.5 (commencing with Section 1440) of Division 2.

(2) When a health care practitioner prescribes, orders, administers, furnishes, or dispenses a controlled substance in the emergency department of a general acute care hospital if the quantity of the controlled substance does not exceed a seven-day supply of the controlled substance to be used in accordance with the directions for use.

(3) If a health care practitioner prescribes, orders, administers, furnishes, or dispenses a controlled substance to a patient as part of the patient's treatment for a surgical procedure, if the quantity of the controlled substance does not exceed a nonrefillable five-day supply of the controlled substance to be used in accordance with the directions for use, in any of the following facilities:

(A) A licensed clinic, as described in Chapter 1 (commencing with Section 1200) of Division 2.

(B) An outpatient setting, as described in Chapter 1.3 (commencing with Section 1248) of Division 2.

(C) A health facility, as described in Chapter 2 (commencing with Section 1250) of Division 2.

(D) A county medical facility, as described in Chapter 2.5 (commencing with Section 1440) of Division 2.

(E) A place of practice, as defined in Section 1658 of the Business and Professions Code.

(4) If a health care practitioner prescribes, orders, administers, furnishes, or dispenses a controlled substance to a patient currently receiving hospice care, as defined in Section 1339.40.

(5) (A) If all of the following circumstances are satisfied:

(i) It is not reasonably possible for a health care practitioner to access the information in the CURES database in a timely manner.

(ii) Another health care practitioner or designee authorized to access the CURES database is not reasonably available.

(iii) The quantity of controlled substance prescribed, ordered, administered, furnished, or dispensed does not exceed a nonrefillable five-day supply of the controlled substance to be used in accordance with the directions for use and no refill of the controlled substance is allowed.

(B) A health care practitioner who does not consult the CURES database under subparagraph (A) shall document the reason he or she did not consult the database in the patient's medical record.

(6) If the CURES database is not operational, as determined by the department, or when it cannot be accessed by a health care practitioner because of a temporary technological or electrical failure. A health care practitioner shall, without undue delay, seek to correct any cause of the temporary technological or electrical failure that is reasonably within his or her control.

(7) If the CURES database cannot be accessed because of technological limitations that are not reasonably within the control of a health care practitioner.

(8) If the CURES database cannot be accessed because of exceptional circumstances, as demonstrated by a health care practitioner.

(d) (1) A health care practitioner who knowingly fails to consult the CURES database, as described in subdivision (a), shall be referred to the appropriate state professional licensing board solely for administrative sanctions, as deemed appropriate by that board.

(2) This section does not create a private cause of action against a health care practitioner. This section does not limit a health care practitioner's liability for the negligent failure to diagnose or treat a patient.

(e) This section is not operative until six months after the Department of Justice certifies that the CURES database is ready for statewide use. The department shall notify the Secretary of State and the office of the Legislative Counsel of the date of that certification.

(f) All applicable state and federal privacy laws govern the duties required by this section.

(g) The provisions of this section are severable. If any provision of this section or its application is held invalid, that invalidity shall not affect other provisions or applications that can be given effect without the invalid provision or application.



Bill Number:	SB 999
Current Version:	Amended June 20, 2016
Author:	Pavley
Topic:	Health Insurance: Contraceptives: Annual Supply
Board Position:	None

Affected Sections: Amends Section 4064.5 of the Business and Professions Code, Section 1367.25 of the Health and Safety Code, and Section 10123.196 of the Insurance Code

Status: Passed out of ASM Business, Professions & Consumer Protection (6/28)
To Assembly Appropriations

SUMMARY:

This bill would authorize a pharmacist to dispense prescribed, FDA-approved, self-administered hormonal contraceptives either as prescribed or, at the patient's request, in a 12-month supply, unless the prescriber specifically indicates no change to quantity. The measure would also require a health care service plan or health insurance policy, on or after January 1, 2017, to cover a 12-month supply of a self-administered hormonal contraception dispensed at one time by a prescriber or dispenser.

EXISTING LAW:

Authorizes a pharmacist to furnish self-administered hormonal contraceptives pursuant to a ¹protocol. The board's Communication and Public Education Committee is working on guidance documents for pharmacists that will be providing hormonal contraception as well as other SB 493 services.

Specific to pharmacy law provisions, existing law authorizes a pharmacist to dispense not more than a 90-day supply of a dangerous drug other than a controlled substance pursuant to a valid prescription that specifies an initial quantity of less than a 90-day supply followed by periodic refills of that amount if the patient has met specified requirements, including having completed an initial 30-day supply of the drug. Existing law prohibits a pharmacist from dispensing a greater supply of a dangerous drug if the prescriber indicates "no change to quantity" on the prescription.

¹ 16 Cal Code Reg § 1746.1 effective April 8, 2016; authority Business and Professions Code § 4052.3

THIS BILL WOULD:

1. Make legislative findings including that California has a long history and commitment to expanding access to services that aim to reduce the risk of unintended pregnancies and improving reproductive health outcomes and that studies support that dispensing a 12-month supply of birth control at one time has numerous benefits.
2. Declare it is the intent of the legislature to expand existing contraceptive coverage policy by requiring all health care service plans and health insurance policies to cover a 12-month supply of specified types of hormonal contraception.
3. Amend Section 4064.5 to
 - a. require a pharmacist to dispense – at a patient’s request – up to a 12-month supply of an FDA-approved, self-administered hormonal contraceptive pursuant to a valid prescription that specifies an initial quantity followed by periodic refills
 - b. allow a pharmacist to dispense up to a 12-month supply of an FDA approved self-administered hormonal contraceptive – at the request of the patient - when dispensing pursuant to a protocol under B&PC Section 4052.3.
 - c. Specify that nothing in the section shall be construed to require a pharmacist to dispense or furnish a drug if it would result in a violation of B&PC Section 733.
4. Make changes to the health and safety code and insurance code to facilitate implementation of the legislative intent.

FISCAL IMPACT ON THE BOARD:

Board staff does not anticipate any significant impact and believes that any minor impact could be absorbed within existing resources.

HISTORY:

Last 5 History Actions	
Date	Action
06/28/16	From committee: Do pass and re-refer to Com. on APPR. (Ayes 13. Noes 2.) (June 28). Re-referred to Com. on APPR.
06/20/16	From committee with author's amendments. Read second time and amended. Re-referred to Com. on B. & P.
06/15/16	From committee: Do pass and re-refer to Com. on B. & P. (Ayes 13. Noes 0.) (June 14). Re-referred to Com. on B. & P.
05/27/16	Referred to Coms. on HEALTH and B. & P.
05/23/16	In Assembly. Read first time. Held at Desk.



SB-999 Health insurance: contraceptives: annual supply. (2015-2016)

SECTION 1. (a) *The Legislature hereby finds all of the following:*

(1) *California has a long history of, and commitment to, expanding access to services that aim to reduce the risk of unintended pregnancies and improving reproductive health outcomes.*

(2) *California's Family Planning, Access, Care, and Treatment (Family PACT) Waiver Program, created in 1999, is viewed nationally as the "gold standard" of publicly funded programs providing access to reproductive health care. The program has long recognized the value and importance of providing women with a year's supply of birth control.*

(3) *The Affordable Care Act (ACA) and subsequent federal regulations made contraceptive coverage a national policy by requiring most private health insurance plans to provide coverage for a broad range of preventive services without cost sharing, including FDA-approved prescription contraceptives.*

(4) *Since the passage of the ACA, many states have passed laws strengthening or expanding this federal contraceptive coverage requirement. In 2014, California passed the Contraceptive Coverage Equity Act of 2014, which requires plans to cover all prescribed FDA-approved contraceptives for women without cost sharing, and requires plans to cover at least one therapeutic equivalent of a prescribed contraceptive drug, device, or product.*

(5) *Numerous studies support what California has determined for decades in the Family PACT program: dispensing a 12-month supply of birth control at one time has numerous benefits, including, but not limited to, reducing a woman's odds of having an unintended pregnancy by 30 percent, increasing contraception continuation rates, and decreasing costs per client to insurers by reducing the number of pregnancy tests and pregnancies.*

(6) *Access to contraception is a key element in shaping women's health and well-being. Nearly all women have used contraceptives at some point in their lives, and 62 percent are currently using at least one method.*

(7) *Several states have mirrored the year-supply requirement for contraceptive coverage in their publicly funded family planning or Medicaid programs, recognizing the health benefits of reducing barriers to continuous and effective use of contraception. Recently, Oregon and Washington D.C. have gone further to require private health care service plans and health insurance policies to also cover a 12-month supply of contraceptives. With California's history of leadership in establishing public policies that increase access to contraceptives, adopting a similar requirement is a natural progression of our state's commitment to reducing unintended pregnancy.*

(b) *It is therefore the intent of the Legislature to expand on California's existing contraceptive coverage policy by requiring all health care service plans and health insurance policies, including both commercial and Medi-Cal managed care plans, to cover a 12-month supply of a prescribed FDA-approved contraceptive, such as the ring, the patch, and oral contraceptives.*

SEC. 2. Section 4064.5 of the Business and Professions Code is amended to read:

4064.5. (a) A pharmacist may dispense not more than a 90-day supply of a dangerous drug other than a controlled substance pursuant to a valid prescription that specifies an initial quantity of less than a 90-day supply followed by periodic refills of that amount if all of the following requirements are satisfied:

(1) The patient has completed an initial 30-day supply of the dangerous drug.

(2) The total quantity of dosage units dispensed does not exceed the total quantity of dosage units authorized by the prescriber on the prescription, including refills.

(3) The prescriber has not specified on the prescription that dispensing the prescription in an initial amount followed by periodic refills is medically necessary.

(4) The pharmacist is exercising his or her professional judgment.

(b) For purposes of this section, if the prescription continues the same medication as previously dispensed in a 90-day supply, the initial 30-day supply under paragraph (1) of subdivision (a) is not required.

(c) A pharmacist dispensing an increased supply of a dangerous drug pursuant to this section shall notify the prescriber of the increase in the quantity of dosage units dispensed.

(d) In no case shall a pharmacist dispense a greater supply of a dangerous drug pursuant to this section if the prescriber personally indicates, either orally or in his or her own handwriting, "No change to quantity," or words of similar meaning. Nothing in this subdivision shall prohibit a prescriber from checking a box on a prescription marked "No change to quantity," provided that the prescriber personally initials the box or checkmark. To indicate that an increased supply shall not be dispensed pursuant to this section for an electronic data transmission prescription as defined in subdivision (c) of Section 4040, a prescriber may indicate "No change to quantity," or words of similar meaning, in the prescription as transmitted by electronic data, or may check a box marked on the prescription "No change to quantity." In either instance, it shall not be required that the prohibition on an increased supply be manually initialed by the prescriber.

(e) This section shall not apply to psychotropic medication or psychotropic drugs as described in subdivision (d) of Section 369.5 of the Welfare and Institutions Code.

(f) Except for the provisions of subdivision (d), this section does not apply to FDA-approved, self-administered hormonal contraceptives.

(1) A pharmacist shall dispense, at a patient's request, up to a 12-month supply of an FDA-approved, self-administered hormonal contraceptive pursuant to a valid prescription that specifies an initial quantity followed by periodic refills.

(2) A pharmacist furnishing an FDA-approved self-administered hormonal contraceptive pursuant to Section 4052.3 under protocols developed by the Board of Pharmacy may furnish, at the patient's request, up to a 12-month supply at one time.

(3) Nothing in this subdivision shall be construed to require a pharmacist to dispense or furnish a drug if it would result in a violation of Section 733.

~~(f)~~ (g) Nothing in this section shall be construed to require a health care service plan, health insurer, workers' compensation insurance plan, pharmacy benefits manager, or any other person or entity, including, but not limited to, a state program or state employer, to provide coverage for a dangerous drug in a manner inconsistent with a beneficiary's plan benefit.

SEC. 3. Section 1367.25 of the Health and Safety Code is amended to read:

1367.25. (a) A group health care service plan contract, except for a specialized health care service plan contract, that is issued, amended, renewed, or delivered on or after January 1, 2000, ~~through to~~ December 31, 2015, inclusive, and an individual health care service plan contract that is amended, renewed, or delivered on or after January 1, 2000, ~~through to~~ December 31, 2015, inclusive, except for a specialized health care service plan contract, shall provide coverage for the following, under general terms and conditions applicable to all benefits:

(1) A health care service plan contract that provides coverage for outpatient prescription drug benefits shall include coverage for a variety of federal Food and Drug Administration (FDA)-approved prescription contraceptive methods designated by the plan. In the event the patient's participating provider, acting within his or her scope of practice, determines that none of the methods designated by the plan is medically appropriate for the patient's medical or personal history, the plan shall also provide coverage for another FDA-approved, medically appropriate prescription contraceptive method prescribed by the patient's provider.

(2) Benefits for an enrollee under this subdivision shall be the same for an enrollee's covered spouse and covered nonspouse dependents.

(b) (1) A health care service plan contract, except for a specialized health care service plan contract, that is issued, amended, renewed, or delivered on or after January 1, 2016, shall provide coverage for all of the following services and contraceptive methods for women:

(A) Except as provided in subparagraphs (B) and (C) of paragraph (2), all FDA-approved contraceptive drugs, devices, and other products for women, including all FDA-approved contraceptive drugs, devices, and products available over the counter, as prescribed by the enrollee's provider.

(B) Voluntary sterilization procedures.

(C) Patient education and counseling on contraception.

(D) Followup services related to the drugs, devices, products, and procedures covered under this subdivision, including, but not limited to, management of side effects, counseling for continued adherence, and device insertion and removal.

(2) (A) Except for a grandfathered health plan, a health care service plan subject to this subdivision shall not impose a deductible, coinsurance, copayment, or any other cost-sharing requirement on the coverage provided pursuant to this subdivision. Cost sharing shall not be imposed on any Medi-Cal beneficiary.

(B) If the FDA has approved one or more therapeutic equivalents of a contraceptive drug, device, or product, a health care service plan is not required to cover all of those therapeutically equivalent versions in accordance with this subdivision, as long as at least one is covered without cost sharing in accordance with this subdivision.

(C) If a covered therapeutic equivalent of a drug, device, or product is not available, or is deemed medically inadvisable by the enrollee's provider, a health care service plan shall provide coverage, subject to a plan's utilization management procedures, for the prescribed contraceptive drug, device, or product without cost sharing. Any request by a contracting provider shall be responded to by the health care service plan in compliance with the Knox-Keene Health Care Service Plan Act of 1975, as set forth in this chapter and, as applicable, with the plan's Medi-Cal managed care contract.

(3) Except as otherwise authorized under this section, a health care service plan shall not impose any restrictions or delays on the coverage required under this subdivision.

(4) Benefits for an enrollee under this subdivision shall be the same for an enrollee's covered spouse and covered nonspouse dependents.

(5) For purposes of paragraphs (2) and (3) of this subdivision, "health care service plan" shall include Medi-Cal managed care plans that contract with the State Department of Health Care Services pursuant to Chapter 7 (commencing with Section 14000) and Chapter 8 (commencing with Section 14200) of Part 3 of Division 9 of the Welfare and Institutions Code.

(c) Notwithstanding any other provision of this section, a religious employer may request a health care service plan contract without coverage for FDA-approved contraceptive methods that are contrary to the religious employer's religious tenets. If so requested, a health care service plan contract shall be provided without coverage for contraceptive methods.

(1) For purposes of this section, a "religious employer" is an entity for which each of the following is true:

(A) The inculcation of religious values is the purpose of the entity.

(B) The entity primarily employs persons who share the religious tenets of the entity.

(C) The entity serves primarily persons who share the religious tenets of the entity.

(D) The entity is a nonprofit organization as described in Section 6033(a)(3)(A)(i) or (iii) of the Internal Revenue Code of 1986, as amended.

(2) Every religious employer that invokes the exemption provided under this section shall provide written notice to prospective enrollees prior to enrollment with the plan, listing the contraceptive health care services the employer refuses to cover for religious reasons.

(d) (1) Every health care service plan contract that is issued, amended, renewed, or delivered on or after January 1, 2017, shall cover up to a 12-month supply of FDA-approved, self-administered hormonal contraceptives when dispensed or furnished at one time for an enrollee by a provider, pharmacist, or at a location licensed or otherwise authorized to dispense drugs or supplies.

(2) Nothing in this subdivision shall be construed to require a health care service plan contract to cover contraceptives provided by an out-of-network provider, pharmacy, or location licensed or otherwise authorized

to dispense drugs or supplies, except as may be otherwise authorized by state or federal law or by the plan's policies governing out-of-network coverage.

(3) Nothing in this subdivision shall be construed to require a provider to prescribe, furnish, or dispense 12 months of self-administered hormonal contraceptives at one time.

(4) A health care service plan subject to this subdivision, in the absence of clinical contraindications, shall not impose utilization controls or other forms of medical management limiting the supply of FDA-approved self-administered hormonal contraceptives that may be dispensed or furnished by a provider or pharmacist, or at a location licensed or otherwise authorized to dispense drugs or supplies to an amount that is less than a 12-month supply.

~~(d)~~ (e) This section shall not be construed to exclude coverage for contraceptive supplies as prescribed by a provider, acting within his or her scope of practice, for reasons other than contraceptive purposes, such as decreasing the risk of ovarian cancer or eliminating symptoms of menopause, or for contraception that is necessary to preserve the life or health of an enrollee.

~~(e)~~ (f) This section shall not be construed to deny or restrict in any way the department's authority to ensure plan compliance with this chapter when a plan provides coverage for contraceptive drugs, devices, and products.

~~(f)~~ (g) This section shall not be construed to require an individual or group health care service plan contract to cover experimental or investigational treatments.

~~(g)~~ (h) For purposes of this section, the following definitions apply:

(1) "Grandfathered health plan" has the meaning set forth in Section 1251 of PPACA.

(2) "PPACA" means the federal Patient Protection and Affordable Care Act (Public Law 111-148), as amended by the federal Health Care and Education Reconciliation Act of 2010 (Public Law 111-152), and any rules, regulations, or guidance issued thereunder.

(3) With respect to health care service plan contracts issued, amended, or renewed on or after January 1, 2016, "provider" means an individual who is certified or licensed pursuant to Division 2 (commencing with Section 500) of the Business and Professions Code, or an initiative act referred to in that division, or Division 2.5 (commencing with Section 1797) of this code.

SEC. 4. Section 10123.196 of the Insurance Code is amended to read:

10123.196. (a) An individual or group policy of disability insurance issued, amended, renewed, or delivered on or after January 1, 2000, through December 31, 2015, inclusive, that provides coverage for hospital, medical, or surgical expenses, shall provide coverage for the following, under the same terms and conditions as applicable to all benefits:

(1) A disability insurance policy that provides coverage for outpatient prescription drug benefits shall include coverage for a variety of federal Food and Drug Administration (FDA)-approved prescription contraceptive methods, as designated by the insurer. If an insured's health care provider determines that none of the methods designated by the disability insurer is medically appropriate for the insured's medical or personal history, the insurer shall, in the alternative, provide coverage for some other FDA-approved prescription contraceptive method prescribed by the patient's health care provider.

(2) Coverage with respect to an insured under this subdivision shall be identical for an insured's covered spouse and covered nonspouse dependents.

(b) (1) A group or individual policy of disability insurance, except for a specialized health insurance policy, that is issued, amended, renewed, or delivered on or after January 1, 2016, shall provide coverage for all of the following services and contraceptive methods for women:

(A) Except as provided in subparagraphs (B) and (C) of paragraph (2), all FDA-approved contraceptive drugs, devices, and other products for women, including all FDA-approved contraceptive drugs, devices, and products available over the counter, as prescribed by the insured's provider.

(B) Voluntary sterilization procedures.

(C) Patient education and counseling on contraception.

(D) Followup services related to the drugs, devices, products, and procedures covered under this subdivision, including, but not limited to, management of side effects, counseling for continued adherence, and device insertion and removal.

(2) (A) Except for a grandfathered health plan, a disability insurer subject to this subdivision shall not impose a deductible, coinsurance, copayment, or any other cost-sharing requirement on the coverage provided pursuant to this subdivision.

(B) If the FDA has approved one or more therapeutic equivalents of a contraceptive drug, device, or product, a disability insurer is not required to cover all of those therapeutically equivalent versions in accordance with this subdivision, as long as at least one is covered without cost sharing in accordance with this subdivision.

(C) If a covered therapeutic equivalent of a drug, device, or product is not available, or is deemed medically inadvisable by the insured's provider, a disability insurer shall provide coverage, subject to an insurer's utilization management procedures, for the prescribed contraceptive drug, device, or product without cost sharing. Any request by a contracting provider shall be responded to by the disability insurer in compliance with Section 10123.191.

(3) Except as otherwise authorized under this section, an insurer shall not impose any restrictions or delays on the coverage required under this subdivision.

(4) Coverage with respect to an insured under this subdivision shall be identical for an insured's covered spouse and covered nonspouse dependents.

(c) This section shall not be construed to deny or restrict in any way any existing right or benefit provided under law or by contract.

(d) This section shall not be construed to require an individual or group disability insurance policy to cover experimental or investigational treatments.

(e) Notwithstanding any other provision of this section, a religious employer may request a disability insurance policy without coverage for contraceptive methods that are contrary to the religious employer's religious tenets. If so requested, a disability insurance policy shall be provided without coverage for contraceptive methods.

(1) For purposes of this section, a "religious employer" is an entity for which each of the following is true:

(A) The inculcation of religious values is the purpose of the entity.

(B) The entity primarily employs persons who share the religious tenets of the entity.

(C) The entity serves primarily persons who share the religious tenets of the entity.

(D) The entity is a nonprofit organization pursuant to Section 6033(a)(3)(A)(i) or (iii) of the Internal Revenue Code of 1986, as amended.

(2) Every religious employer that invokes the exemption provided under this section shall provide written notice to any prospective employee once an offer of employment has been made, and prior to that person commencing that employment, listing the contraceptive health care services the employer refuses to cover for religious reasons.

(f) (1) A group or individual policy of disability insurance, except for a specialized health insurance policy, that is issued, amended, renewed, or delivered on or after January 1, 2017, shall cover up to a 12-month supply of FDA-approved, self-administered hormonal contraceptives when dispensed or furnished at one time for an insured by a provider, pharmacist, or at a location licensed or otherwise authorized to dispense drugs or supplies.

(2) Nothing in this subdivision shall be construed to require a policy to cover contraceptives provided by an out-of-network provider, pharmacy, or location licensed or otherwise authorized to dispense drugs or supplies, except as may be otherwise authorized by state or federal law or by the insurer's policies governing out-of-network coverage.

(3) Nothing in this subdivision shall be construed to require a provider to prescribe, furnish, or dispense 12 months of self-administered hormonal contraceptives at one time.

(4) A health insurer subject to this subdivision, in absence of clinical contraindications, shall not impose utilization controls or other forms of medical management limiting the supply of FDA-approved self-

administered hormonal contraceptives that may be dispensed or furnished by a provider or pharmacist, or at a location licensed or otherwise authorized to dispense drugs or supplies to an amount that is less than a 12-month supply.

~~(f)~~ (g) This section shall not be construed to exclude coverage for contraceptive supplies as prescribed by a provider, acting within his or her scope of practice, for reasons other than contraceptive purposes, such as decreasing the risk of ovarian cancer or eliminating symptoms of menopause, or for contraception that is necessary to preserve the life or health of an insured.

~~(g)~~ (h) This section only applies to disability insurance policies or contracts that are defined as health benefit plans pursuant to subdivision (a) of Section 10198.6, except that for accident only, specified disease, or hospital indemnity coverage, coverage for benefits under this section applies to the extent that the benefits are covered under the general terms and conditions that apply to all other benefits under the policy or contract. This section shall not be construed as imposing a new benefit mandate on accident only, specified disease, or hospital indemnity insurance.

~~(h)~~ (i) For purposes of this section, the following definitions apply:

(1) "Grandfathered health plan" has the meaning set forth in Section 1251 of PPACA.

(2) "PPACA" means the federal Patient Protection and Affordable Care Act (Public Law 111-148), as amended by the federal Health Care and Education Reconciliation Act of 2010 (Public Law 111-152), and any rules, regulations, or guidance issued thereunder.

(3) With respect to policies of disability insurance issued, amended, or renewed on or after January 1, 2016, "health care provider" means an individual who is certified or licensed pursuant to Division 2 (commencing with Section 500) of the Business and Professions Code, or an initiative act referred to in that division, or Division 2.5 (commencing with Section 1797) of the Health and Safety Code.

SEC. 5. *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.*



Bill Number: SB 1229
Current Version: June 27, 2016 - Amended
Authors: Senator Jackson
Assembly Member Stone
Topic: Pharmacies: secure drug take-back bins
Board Position: Support

Affected Section(s):

States Legislative intent and declarations
Add Civil Code section 1714.24

Status: Assembly Floor (as of 6/28)

SUMMARY

Senate Bill 1229, as amended, states the Legislature's intent to encourage good faith participation of federally authorized entities to maintain secure drug take-back bins for the convenience and public health and safety of prescription drug consumers, and for the proper disposal in the waste stream of pharmaceutical waste contained in the bins.

The bill references the Secure and Responsible Drug Disposal Act of 2010 (Public Law 111-273) and states that the provisions of the bill shall be construed in a manner that is consistent with the requirements imposed by the DEA's final rule and any regulations promulgated by the state.

The bill establishes definitions and provides certain protections for a collector that maintains a secure drug take-back bin, unless an injury or harm results from the collector's gross negligence or willful and wanton misconduct.

EXISTING LAW:

Section 4022 of the Business and Professions code defines "Dangerous Drug – Dangerous Device" as that which can be lawfully dispensed pursuant to a prescription.

Section 4025 of the Business and Professions Code defines "drug" to be that which is consistent with the federal Food, Drug and Cosmetic Act; articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals; articles (other than food) intended to affect the structure or any function of the body of humans or other animals; and any component of the aforementioned.

¹“Medical waste” is defined in the California Medical Waste Management Act (MWMA) as any biohazardous, pathology, pharmaceutical, or trace chemotherapy waste not regulated by the federal Resource Conservation and Recovery Act of 1976; . . . waste generated from the consolidation of home-generated sharps, etc. This section incorporates the definition of ²“pharmaceutical” to be a prescription or over-the-counter human or veterinary drug, including, but not limited to, a drug as ³defined in the federal Food, Drug and Cosmetic Act. The MWMA generally prohibits a person from transporting, storing, treating, disposing, or causing the treatment of medical waste in a manner not authorized.

THIS BILL WOULD:

1. State the Legislature’s intent to encourage good faith participation by pharmacies in hosting drug take-back bins as well as its intent to prescribe the standards of reasonable care necessary for such pharmacies, and incorporate provisions of the federal Secure and Responsible Drug Disposal Act of 2010 (Public Law 111-273).
2. Add Section 1714.24 of the Civil Code to set forth steps that a collector shall take to ensure for the safety of consumers and employees and for the proper disposal of the waste, to include:
 - Complying with all applicable state and federal laws
 - Ensure the drug take-back bin is placed in a location that is regularly monitored by employees of the registered collector
 - Ensures that conspicuous signage is posted, as specified
 - Ensures that public access is limited to hours when employees are present and can monitor the operation of the bin
 - Regular inspections of the take-back bin for potential tampering, diversion and for security.
 - That the collector shall notify local law enforcement of suspected or known tampering, theft, or significant loss, and the timeframes for such notice, and
 - Notify local law enforcement of any decision to discontinue the operation of a drug take-back bin.
3. Include provide that such a pharmacy shall not be liable for civil damages arising from the use of the take-back bin if the owner takes reasonable steps to ensure safety to consumers and employees as well as proper disposal.
4. Add definitions to the Civil Code, as follows: “Collector,” “Compensation,” “Home-generated pharmaceutical waste,” “Maintains,” “Pharmaceutical,” and “Secure drug take-back bin.”

¹ Health and Safety Code section 117690

² Health and Safety Code section 11747

³ 21 U.S.C. Sec. 321(g)(1)

Board Efforts

The board has initiated ⁴regulations that would establish requirements for prescription drug take-back programs. This rulemaking is in progress.

Federal Drug Takeback

In 2010 the federal government enacted the Secure and Responsible Drug Disposal Act of 2010. The act was passed in an effort to curtail prescription drug abuse by authorizing regulations that outline methods for ultimate users to dispose of their unused or unwanted pharmaceutical controlled substances.

Federal law allows for current DEA registrants to become authorized collectors of controlled substances. The ⁵Final Rule became operative on October 9, 2014, and authorizes certain DEA registrants (manufacturers, distributors, reverse distributors, narcotic treatment programs, retail pharmacies, and hospitals/clinics with an on-site pharmacy) to modify their registration with the DEA to become authorized collectors. All collectors may operate a collection receptacle at their registered location, and collectors with an on-site means of destruction may operate a mail-back program. Retail pharmacies and hospitals/clinics with an on-site pharmacy may operate collection receptacles at long-term care facilities.

The final rule also establishes ⁶regulations related to each element of the disposal process, including the transfer, delivery, collection, destruction, return and recall of pharmaceutical controlled substances, by both registrants and non-registrants.

STAFF RECOMMENDATION

Continue to support Senate Bill 1229.

HISTORY:

Last 5 History Actions	
Date	Action
06/28/16	Read second time. Ordered to third reading.
06/27/16	Read second time and amended. Ordered to second reading.
06/23/16	From committee: Do pass as amended. (Ayes 9. Noes 0.) (June 21).
06/14/16	From committee with author's amendments. Read second time and amended. Re-referred to Com. on JUD.
06/01/16	June 8 set for first hearing canceled at the request of author.

⁴ Proposal to add Article 9.1, Sections 1776 to 1776.6 to the California Code of Regulations. The 45-day notice for public comment was issued February 12, 2016.

⁵ 21 CFR Parts 1300, 1301, 1304, et al. Disposal of Controlled Substances; Final Rule

⁶ These regulations are incorporated into 21 C.F.R. part 1317 on disposal.



California State Board of Pharmacy

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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

June 2, 2016

The Honorable Hannah-Beth Jackson
Member, California State Senate
State Capitol, Room 2032
Sacramento, CA 95816

RE: SB 1229 – Support

Dear Senator Jackson:

I am pleased to advise you that the Board of Pharmacy supports your Senate Bill 1229 (A-4/19/16), which would encourage good-faith participation of authorized entities to maintain secure drug take-back bins to assist drug consumers with proper and safe disposal of pharmaceutical waste, and to limit the liability of those that provide the secure drug take-back bins, as specified.

The board very much appreciates your efforts to address the issue of consumer drug take-back issues and also appreciates your willingness to work with us to address the important issue of safe, secure and convenient drug take-back.

Please do not hesitate to contact me at (916) 574-7911 or the board's legislative manager, Carolyn Klein at (916) 574-7913 if you have any questions.

A handwritten signature in black ink that reads "Virginia Herold". The signature is fluid and cursive.

VIRGINIA HEROLD
Executive Officer

cc: Department of Consumer Affairs



SB-1229 Home-generated pharmaceutical waste: secure drug take-back bins. (2015-2016)

SECTION 1. (a) *The Legislature finds and declares the following:*

(1) *On October 12, 2010, the federal Secure and Responsible Drug Disposal Act of 2010 (Public Law 111-273; hereafter referred to as the Disposal Act) was enacted. Before the Disposal Act, individuals who wanted to dispose of unused, unwanted, or expired pharmaceutical controlled substances had limited disposal options. The federal Controlled Substances Act (21 U.S.C. Sec. 801 et seq.; hereafter referred to as the CSA) only permitted individuals to destroy those substances themselves (e.g., by flushing or discarding), surrender them to law enforcement, or seek assistance from the federal Drug Enforcement Administration (DEA). These restrictions resulted in the accumulation of pharmaceutical controlled substances in household medicine cabinets that were available for abuse, misuse, diversion, and accidental ingestion. The Disposal Act amended the CSA to authorize specified individuals, referred to as "ultimate users," to deliver their pharmaceutical controlled substances to another person for the purpose of disposal in accordance with regulations promulgated by the United States Attorney General.*

(2) *On September 9, 2014, the DEA issued its final rule governing the secure disposal of controlled substances by registrants and ultimate users. Those regulations implement the Disposal Act by expanding the options available to collect controlled substances from ultimate users for the purpose of disposal, including take-back events, mail-back programs, and collection receptacle locations. Those regulations, among other things, allow authorized manufacturers, distributors, reverse distributors, narcotic treatment programs, hospitals/clinics with an onsite pharmacy, and retail pharmacies to voluntarily administer mail-back programs and maintain collection receptacles.*

(b) *It is the intent of the Legislature, with the enactment of this act, to do both of the following:*

(1) *Encourage the good faith participation of federally authorized entities to maintain secure drug take-back bins on their premises for the convenience and public health and safety of prescription drug consumers and the proper disposal in the waste stream of the pharmaceutical waste contained in the bins.*

(2) *Limit the civil and criminal liability of participating entities that meet certain minimum standards and take reasonable care to ensure the health and safety of consumers and employees when maintaining secure drug take-back bins on their premises.*

(c) *The terms and conditions provided by subdivision (b) of Section 1714.24 of the Civil Code, as added by this act, shall be construed in a manner consistent with the requirements imposed by the DEA's final rule governing the secure disposal of controlled substances (79 Fed. Reg. 53519-70 (September 9, 2014)) and any regulations promulgated by the state.*

SEC. 2. *Section 1714.24 is added to the Civil Code, to read:*

1714.24. (a) *For purposes of this section, the following definitions shall apply:*

(1) *"Collector" includes only those entities authorized by and registered with the federal Drug Enforcement Administration to receive a controlled substance for the purpose of destruction, if the entity is in good standing with any applicable licensing authority.*

(2) *"Compensation" means reimbursement or funds received from a customer to compensate for the cost incurred in obtaining, installing, or maintaining a secure drug take-back bin. "Compensation" does not include reimbursement or funds received from any other person or entity, other than a customer, to compensate for the costs incurred in obtaining, installing, or maintaining a secure drug take-back bin.*

(3) *"Home-generated pharmaceutical waste" means a pharmaceutical that is no longer wanted or needed by the consumer and includes any delivery system, such as pills, liquids, and inhalers.*

(4) "Maintains" includes owning, leasing, operating, or otherwise hosting a secure drug take-back bin on the collector's premises.

(5) "Pharmaceutical" means a prescription or over-the-counter human or veterinary drug, including, but not limited to, a drug as defined in Section 109925 of the Health and Safety Code and Section 321(g)(1) of Title 21 of the United States Code. "Pharmaceutical" includes controlled substances included in Schedule II, III, IV, or V of the California Uniform Controlled Substances Act (Division 10 (commencing with Section 11000) of the Health and Safety Code), but does not include a controlled substance included in Schedule I.

(6) "Secure drug take-back bin" means a collection receptacle as described in Section 1317.75 of Title 21 of the Code of Federal Regulations.

(b) Any collector that maintains a secure drug take-back bin shall not be liable in a civil action, or be subject to criminal prosecution, for any injury or harm that results from the collector maintaining a secure drug take-back bin on its premises provided that the collector, not for compensation, acts in good faith to take all of the following steps to ensure the health and safety of consumers and employees and the proper disposal in the waste stream of the home-generated pharmaceutical waste contained in a secure drug take-back bin, unless the injury or harm results from the collector's gross negligence or willful and wanton misconduct:

(1) Complies with all applicable state and federal laws and regulations relating to the collection of home-generated pharmaceutical waste for disposal in secure drug take-back bins, including, but not limited to, the federal Secure and Responsible Drug Disposal Act of 2010 (Public Law 111-273).

(2) Notifies local law enforcement and any local environmental health department as to the existence and location of any secure drug take-back bin on the collector's premises and the status of the collector's registration as a collector with the federal Drug Enforcement Administration.

(3) Ensures that the secure drug take-back bin is placed in a location that is regularly monitored by employees of the registered collector.

(4) Ensures that conspicuous signage is posted on the secure drug take-back bin that clearly notifies customers as to what controlled and noncontrolled substances are and are not acceptable for deposit into the bin, as well as the hours during which collection is allowed.

(5) Ensures that public access to the secure drug take-back bin is limited to hours in which employees of the registered collector are present and able to monitor the operation of the secure drug take-back bin.

(6) Regularly inspects the area surrounding the secure drug take-back bin for potential tampering or diversion. Record logs of those inspections shall be maintained and retained for two years, reflecting the date and time of the inspection, and the initials of the employee inspecting the area. The logs shall be maintained in writing or electronically and may be combined with logs required by state or federal regulations. The logs may be used to demonstrate regular inspection of the area. Other records or reports mandated by federal or state regulations shall also be retained for a minimum of two years unless regulations mandate a longer period.

(7) Notifies local law enforcement authorities of any suspected or known tampering, theft, or significant loss of controlled substances, within one business day of discovery. If the collector maintains daily business hours, this notification shall be made within one calendar day.

(8) Notify local law enforcement as to any decision to discontinue its voluntary collection of controlled substances and provide documentation of its written notification to the federal Drug Enforcement Administration's Registration Unit as otherwise required under federal laws and regulations.

(c) Nothing in this section shall be construed to require entities that may qualify as a collector to acquire, maintain, or make available to the public a secure drug take-back bin on its premises.



Bill Number:	AB 12
Current Version:	August 19, 2015 Amended
Author:	Cooley
Topic:	State Government, Administration Regulations: Review
Board Position:	Oppose

Affected Sections: Adds Chapter 3.6 to Part 1 of Division 3 of Title 2 of the Government Code.

Status: Last location was Senate Appropriations (8/27/15)

SUMMARY:

AB 12 would require state agencies to review, adopt, amend or repeal any regulations that are duplicative, overlapping, and inconsistent or out-of-date by January 1, 2018, and establish reporting requirements.

The bill has been held on the Appropriations Suspense File since August 2015.

EXISTING LAW:

The Administrative Procedure Act establishes requirements for the adoption, amendment or repeal of regulations.

THIS BILL WOULD:

Require the board to identify all regulations that are duplicative, overlapping, inconsistent or out of date and ensure that necessary changes are made via the rulemaking process to correct any such identified changes. Further, this measure would require that all actions be completed on or before January 1, 2018.

STAFF COMMENTS:

Board staff notes that this measure could have a significant impact to its current operations. Completing the necessary review of its regulations as well as securing the changes within the time allotted (two years) seems extremely challenging. Given the complexity of the board's regulatory structure, board staff has concerns that the board could achieve compliance with this measure in the timeframe allowed without significantly impacting other areas of board operations.

FISCAL IMPACT ON THE BOARD:

Board staff have identified a significant fiscal impact to this measure to ensure the necessary review of its regulations are conducted and necessary changes secured in conformance with this measure.

SUPPORT / OPPOSITION: (According to the Senate Governmental Organization analysis for the 4/22/15 text version)

SUPPORT

- | | |
|--|--|
| American Federation of State, County and Municipal Employees | California Manufacturers & Technology Association |
| Associated Builders and Contractors of California Building Owners and Managers Association of California | California Retailers Association |
| California Asian Pacific Chamber of Commerce | California Taxpayers Association |
| California Association of Bed & Breakfast Inns | Commercial Real Estate Development Association |
| California Building Industry Association | Consumer Specialty Products Association |
| California Business Properties Association | Family Business Association |
| California Business Roundtable | Industrial Environmental Association |
| California Chamber of Commerce | International Council of Shopping Centers |
| California Construction and Industrial Materials Association | National Federation of Independent Business/California |
| California Grocers Association | Small Business California |
| California Hotel & Lodging Association | USANA Health Services, Inc. |
| California League of Food Processors | Western States Petroleum Association |

OPPOSITION:

None

HISTORY:

Date	Last Five Actions
07/14/15	From committee: Do pass and re-refer to Com. on APPR. (Ayes 13. Noes 0.) (July 14). Re-referred to Com. on APPR.
06/11/15	Referred to Com. on G.O.
06/01/15	In Senate. Read first time. To Com. on RLS. for assignment.
06/01/15	Read third time. Passed. Ordered to the Senate. (Ayes 80. Noes 0. Page 1693.)
05/28/15	Read second time. Ordered to third reading.



California State Board of Pharmacy

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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

June 2, 2016

The Honorable Ken Cooley
Member, California State Assembly
State Capitol, Room 3146
Sacramento, CA 95816

RE: AB 12 - Oppose

Dear Assembly Member Cooley:

The Board of Pharmacy regrets to advise you that it opposes your Assembly Bill 12, which would require state agencies to review, adopt, amend or repeal any regulations that are duplicative, overlapping, and inconsistent or out-of-date by January 1, 2018, and establish reporting requirements.

We share your concern that regulations adopted but never reviewed can become outdated, duplicative, and inconsistent and, as such, pose unnecessary costs to businesses and impede consumer protection. Currently, the Administrative Procedure Act requires that the Office of Administrative Law review all proposed regulations and shall make a determination as to standards that must be met – including duplicity. As part of the board's rulemaking activities, we work to ensure that our proposals meet all of the required standards prior to transmission to the Office of Administrative Law.

The Board of Pharmacy also undergoes sunset review by the legislature every four years, and a portion of this review provides an opportunity to identify and discuss regulations needing repeal or modification.

Finally, AB 12 would have a significant impact to the board's current operations in terms of resources needed to complete the necessary review mandated by AB 12 and secure any necessary changes within the time allotted in the measure.

For these reasons, the board opposes Assembly Bill 12. Please do not hesitate to me at (916) 574-7913 if you have any questions.

Sincerely,

A handwritten signature in blue ink that reads "Carolyn Klein".

CAROLYN KLEIN

Manager, Licensing and Legislation

cc: Department of Consumer Affairs

AB 12 (Cooley)

Regulatory Review and Major Regulation Economic Impact Reporting

Bill Summary

AB 12 strengthens the accountability and transparency of the regulatory process by requiring that state agencies complete a top-to-bottom review by January 1, 2018, of all current and new regulations to ensure that they are not duplicative, overlapping, inconsistent, or outdated.

Problem

Numerous economists and business leaders agree that one of the greatest obstacles to California job growth is the "thicket" of government regulations that constrain business owners. Duplicative and inconsistent regulations leave business owners confused and often times out of compliance despite their best efforts. In addition, the burdensome regulatory scheme often discourages innovation and new business ventures.

Solution

California's regulatory system needs careful review and accountability. To that end, AB 12 requires that each state agency initiate a top-to-bottom review of current and new regulations looking for duplicative, inconsistent, overlapping, or outdated regulations. Agencies will have two years to complete this review so that it can be completed in a comprehensive and timely manner.

Background

Under the Administrative Procedures Act (APA), state agencies which wish to promulgate a regulation must first have it reviewed by the OAL and have public notice and input. Additionally, AB 1111 (1979) and SB 1754 (1980) mandated the Office of Administrative Law (OAL) to

oversee an orderly review by each state agency of all the regulations they administered with the purpose of reducing the number of regulations and simplifying and improving quality. Since that time, top-to-bottom reviews of state agencies' regulations have been few and far between, leading to outdated, duplicative or overlapping regulations that are not automatically purged or updated upon the passage of new regulations. The last top-to-bottom review of regulations was in 1995 initiated by Governor Pete Wilson.

Support

California Chamber of Commerce
California Manufacturer's and Technology Association
California Association of Independent Business AFSCME
California Asian Pacific Chamber of Commerce
California Association of Bed and Breakfast Inns
California Building Industry Association
California Construction and Industrial Materials Association
California Business Roundtable
California Hotel and Lodging Association
California League of Food Processors
California Retailers Association
Consumer Specialty Products Association
Industrial Environmental Association
National Federation of Independent Businesses-California
Small Business California
USANA Health Sciences, Inc.
Western States Petroleum Association

For More Information

Amanda Kirchner
Legislative Director
916-319-2008
Amanda.Kirchner@asm.ca.gov



AB-12 State government: administrative regulations: review. (2015-2016)

SECTION 1. Chapter 3.6 (commencing with Section 11366) is added to Part 1 of Division 3 of Title 2 of the Government Code, to read:

CHAPTER 3.6. Regulatory Reform

Article 1. Findings and Declarations

11366. The Legislature finds and declares all of the following:

(a) The Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340), Chapter 4 (commencing with Section 11370), Chapter 4.5 (commencing with Section 11400), and Chapter 5 (commencing with Section 11500)) requires agencies and the Office of Administrative Law to review regulations to ensure their consistency with law and to consider impacts on the state's economy and businesses, including small businesses.

(b) However, the act does not require agencies to individually review their regulations to identify overlapping, inconsistent, duplicative, or out-of-date regulations that may exist.

(c) At a time when the state's economy is slowly recovering, unemployment and underemployment continue to affect all Californians, especially older workers and younger workers who received college degrees in the last seven years but are still awaiting their first great job, and with state government improving but in need of continued fiscal discipline, it is important that state agencies systematically undertake to identify, publicly review, and eliminate overlapping, inconsistent, duplicative, or out-of-date regulations, both to ensure they more efficiently implement and enforce laws and to reduce unnecessary and outdated rules and regulations.

Article 2. Definitions

11366.1. For the purposes of this chapter, the following definitions shall apply:

(a) "State agency" means a state agency, as defined in Section 11000, except those state agencies or activities described in Section 11340.9.

(b) "Regulation" has the same meaning as provided in Section 11342.600.

Article 3. State Agency Duties

11366.2. On or before January 1, 2018, each state agency shall do all of the following:

(a) Review all provisions of the California Code of Regulations adopted by that state agency.

(b) Identify any regulations that are duplicative, overlapping, inconsistent, or out of date.

(c) Adopt, amend, or repeal regulations to reconcile or eliminate any duplication, overlap, inconsistencies, or out-of-date provisions, and shall comply with the process specified in Article 5 (commencing with Section 11346) of Chapter 3.5, unless the addition, revision, or deletion is without regulatory effect and may be done pursuant to Section 100 of Title 1 of the California Code of Regulations.

(d) Hold at least one noticed public hearing, which shall be noticed on the Internet Web site of the state agency, for the purposes of accepting public comment on proposed revisions to its regulations.

(e) Notify the appropriate policy and fiscal committees of each house of the Legislature of the revisions to regulations that the state agency proposes to make at least 30 days prior to initiating the process under Article 5 (commencing with Section 11346) of Chapter 3.5 or Section 100 of Title 1 of the California Code of Regulations.

(g) (1) Report to the Governor and the Legislature on the state agency's compliance with this chapter, including the number and content of regulations the state agency identifies as duplicative, overlapping, inconsistent, or out of date, and the state agency's actions to address those regulations.

(2) The report shall be submitted in compliance with Section 9795 of the Government Code.

11366.3. (a) On or before January 1, 2018, each agency listed in Section 12800 shall notify a department, board, or other unit within that agency of any existing regulations adopted by that department, board, or other unit that the agency has determined may be duplicative, overlapping, or inconsistent with a regulation adopted by another department, board, or other unit within that agency.

(b) A department, board, or other unit within an agency shall notify that agency of revisions to regulations that it proposes to make at least 90 days prior to a noticed public hearing pursuant to subdivision (d) of Section 11366.2 and at least 90 days prior to adoption, amendment, or repeal of the regulations pursuant to subdivision (c) of Section 11366.2. The agency shall review the proposed regulations and make recommendations to the department, board, or other unit within 30 days of receiving the notification regarding any duplicative, overlapping, or inconsistent regulation of another department, board, or other unit within the agency.

11366.4. An agency listed in Section 12800 shall notify a state agency of any existing regulations adopted by that agency that may duplicate, overlap, or be inconsistent with the state agency's regulations.

11366.45. This chapter shall not be construed to weaken or undermine in any manner any human health, public or worker rights, public welfare, environmental, or other protection established under statute. This chapter shall not be construed to affect the authority or requirement for an agency to adopt regulations as provided by statute. Rather, it is the intent of the Legislature to ensure that state agencies focus more efficiently and directly on their duties as prescribed by law so as to use scarce public dollars more efficiently to implement the law, while achieving equal or improved economic and public benefits.

Article 4. Chapter Repeal

11366.5. This chapter shall remain in effect only until January 1, 2019, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2019, deletes or extends that date.



Bill Number:	SB 1155
Current Version:	As Amended June 23, 2016
Author:	Morrell
Topic:	Professions and Vocations: Licenses: Military Service (Fee Waiver)
Board Position	None

Affected Sections: Add section 114.6 to the Business and Professions Code

Status: Passed from Assembly Committee on Veterans Affairs (6/28, vote 7-0) and was re-referred to Assembly Appropriations

SUMMARY:

This measure would allow a veteran who is honorably discharged who served as an active duty member of the California National Guard or the United States Armed Forces to have one fee waiver for the application for an issuance of one license by one of the boards within the Department of Consumer Affairs. The provisions would go into effect on January 1, 2018. The most recent amendment specifies information that would constitute “satisfactory evidence” of being honorably discharged.

The board has not taken a position on this bill.

EXISTING LAW:

Existing Pharmacy Law provides for the licensure of five (5) personal licenses, as follows:

- Pharmacist
- Pharmacist Intern
- Pharmacy Technician
- Designated Representative
- Designated Representative-3PL

The board currently expedites the review of applications from those who are active duty military, honorably discharged veterans, or spouses or partners of active duty military. In fiscal year 2015/16 and for a five-month period, the board received 26 requests for expedite – 23 were for pharmacist applications, and 3 were for designated representative applications.

THIS BILL WOULD:

Add section 114.6 to the Business and professions code to allow a veteran who is honorably discharged who served as an active duty member of the California National Guard or the United

States Armed Forces to have one fee waiver for the application for an issuance of one license from any board within the Department of Consumer Affairs.

The provisions specify that only one waiver shall be granted to a veteran, as specified.

STAFF COMMENTS:

Because the waiver provisions apply to one application across all DCA boards, the board would need to determine how to determine if an applicant has already taken advantage of the one waiver allowance.

FISCAL IMPACT ON THE BOARD:

Using the expedite statistics provided (five-month period), the license fees that may have been waived are as follows:

Category	Fee	No.	Total
Pharmacist Exam	\$260	23	\$5,980
Designated Representative	\$330	3	\$900
			\$6,880

HISTORY:

Last 5 History Actions	
Date	Action
06/29/16	From committee: Do pass and re-refer to Com. on APPR. (Ayes 7. Noes 0.) (June 28). Re-referred to Com. on APPR.
06/23/16	Read second time and amended. Re-referred to Com. on V.A.
06/22/16	From committee: Do pass as amended and re-refer to Com. on V.A. (Ayes 15. Noes 0.) (June 21).
06/09/16	Referred to Coms. on B. & P. and V.A.
06/02/16	In Assembly. Read first time. Held at Desk.



California
LEGISLATIVE INFORMATION

SB-1155 Professions and vocations: licenses: military service. (2015-2016)

SECTION 1. *Section 114.6 is added to the Business and Professions Code, to read:*

114.6. (a) (1) *Notwithstanding any other provision of law, every board within the department shall grant a fee waiver for the application for and issuance of an initial license to an applicant who supplies satisfactory evidence to the board that the applicant has served as an active duty member of the California National Guard or the United States Armed Forces and was honorably discharged.*

(2) *For purposes of this section, "satisfactory evidence" means a completed "Certificate of Release or Discharge from Active Duty" (DD Form 214).*

(b) *Under this program, all of the following apply:*

(1) *A veteran shall be granted only one fee waiver, except as specified in paragraph (2). After a fee waiver has been issued by any board within the department pursuant to this section, the veteran is no longer eligible for a waiver.*

(2) *If a board charges a fee for the application for a license and another fee for the issuance of a license, the veteran shall be granted fee waivers for both the application for and issuance of a license.*

(3) *The fee waiver shall apply only to an application of and a license issued to an individual veteran and not to an application of or a license issued to an individual veteran on behalf of a business or other entity.*

(4) *A waiver shall not be issued for any of the following:*

(A) *Renewal of a license.*

(B) *The application for and issuance of an additional license, a certificate, a registration, or a permit associated with the initial license.*

(C) *The application for an examination.*

(c) *This section shall become operative on January 1, 2018.*

ATTACHMENT 1

Board of Pharmacy
Department of Consumer Affairs

Order of Adoption

Adopt new Article 3.5 of Division 17 of Title 16 of the California Code of Regulations and a new Article title as follows:

Article 3.5. Advanced Practice Pharmacist

Adopt §1730 of Article 3.5 of Division 17 of Title 16 of the California Code of Regulations as follows:

§1730 Acceptable Certification Programs

The board recognizes the pharmacy patient care certification programs that are accredited by the National Commission for Certifying Agencies for purposes of satisfying the requirements in Business and Professions Code section 4210(a)(2)(A).

Note: Authority cited: Section 4005, 4210 and 4400, Business and Professions Code. Reference: Sections 4052.6, 4210 and 4400, Business and Professions Code.

Adopt §1730.1 of Article 3.5 of Division 17 of Title 16 of the California Code of Regulations as follows:

§1730.1 Application Requirements for Advanced Practice Pharmacist Licensure

For purposes of Business and Professions Code section 4210 an applicant for advanced practice pharmacist licensure must satisfy two of the following subdivisions.

(a) Demonstrate possession of a current certification as specified in Business and Professions Code section 4210(a)(2)(A), an applicant shall provide either:

(1) A copy of the certification award that includes the name of the applicant pharmacist, the area of specialty and date of completion, or

(2) A letter from the certification program confirming the award of the certification that includes the name of the applicant pharmacist, the area of specialty and the date of completion.

(b) Demonstrate completion of a postgraduate residency earned in the United States through an accredited postgraduate institution as specified in Business and Professions Code section 4210(a)(2)(B), an applicant shall provide either:

(1) A copy of the residency certificate awarded by the postgraduate institution that includes the name of the applicant pharmacist, the area of specialty, and dates of

participation and completion, or

(2) A letter of completion of a postgraduate residency signed by the dean or residency program director of the postgraduate institution and sent directly to the board from the postgraduate institution that lists the name of the applicant pharmacist, the dates of participation and completion, and area(s) of specialty. For an applicant that cannot satisfy this document requirement, the board may, for good cause shown, grant a waiver for this subsection (2).

(c) Demonstrate that experience earned under a collaborative practice agreement or protocol has been earned within 10 years of the time of application for advanced practice pharmacist licensure. Additionally, the one year of experience must be composed of no fewer than 1,500 hours of experience providing clinical services to patients. The experience earned under a collaborative practice agreement or protocol must include initiating, adjusting, modifying or discontinuing drug therapy of patients as authorized by law. An applicant shall demonstrate possession of experience by providing both of the following:

(1) A written statement from the applicant attesting under penalty of perjury that he or she has:

(A) Earned the clinical experience within the required time frame;

(B) Completed the required number of hours of clinical services to patients, as specified in this subdivision and in Business and Professions Code section 4210 (a)(2)(C), which includes initiating, adjusting, modifying or discontinuing drug therapy of patients; and

(i) The applicant shall provide a copy of the collaborative practice agreement or protocol.

(ii) If a copy of the collaborative practice agreement or protocol is not available, the applicant shall provide a description of the collaborative practice agreement or protocol, including examples of the clinical services the applicant provided to patients.

(2) A written statement from the supervising practitioner, program director or health facility administrator attesting under penalty of perjury that the applicant has completed at least one year of experience providing clinical services to patients. For an applicant that cannot satisfy this document requirement, the board may, for good cause shown, grant a waiver for this subsection (2).

Note: Authority cited: Section 4005, 4210 and 4400, Business and Professions Code. Reference: Section 4052.1, 4052.2, 4052.6, 4210 and 4400, Business and Professions Code.

Amend §1749 of Article 6 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1749 (Fee Schedule)

The fees for the issuance and renewal of licenses, certificates, and permits, and the penalties to be assessed for failure to renew in accordance with sections 163.5, 4110, ~~4210~~, 4127.5, 4128.2, 4196, and 4400 of the Business and Professions Code are hereby fixed as follows:

(a) The fee for the issuance of a pharmacy license is five hundred twenty dollars (\$520). The fee for the annual renewal of pharmacy license is three hundred twenty-five dollars (\$325). The penalty for failure to renew is one hundred fifty dollars (\$150).

(b) The fee for the issuance of a temporary license is three hundred twenty-five dollars (\$325).

(c) The fee for the issuance of a pharmacy technician license shall be one hundred five dollars (\$105). The fee for the biennial renewal of a pharmacy technician license shall be one hundred thirty dollars (\$130). The penalty for failure to renew a pharmacy technician license is sixty-five dollars (\$65).

(d) The fee for application and examination as a pharmacist is two hundred sixty dollars (\$260).

(e) The fee for regrading an examination is one hundred fifteen dollars (\$115).

(f)(1) The fee for the issuance of an original pharmacist license is one hundred ninety-five dollars (\$195).

(2) The fee for application of an advanced practice pharmacist license is three hundred dollars (\$300). If granted, there is no fee for the initial license issued, which will expire at the same time the pharmacist's license expires.

(g)(1) The fee for the biennial renewal of a pharmacist's license is one hundred ninety-five dollars (\$195). The penalty fee for failure to renew is ninety-seven dollars fifty cents (\$97.50).

(2) The fee for the biennial renewal of an advanced practice pharmacist license is three hundred dollars (\$300). The penalty fee for failure to renew is one hundred fifty dollars (\$150). The fees in this paragraph are in addition to the fees required to renew the pharmacist's license as specified in paragraph 1.

(h) The fee for the issuance or renewal of a wholesaler's license is seven hundred eighty dollars (\$780). The penalty for failure to renew is one hundred fifty dollars (\$150).

(i) The fee for the issuance or renewal of a hypodermic license is one hundred sixty five dollars (\$165). The penalty for failure to renew is eighty two dollars fifty cents (\$82.50).

(j) The fee for the issuance of a license as a designated representative pursuant to Section 4053 of the Business and Professions Code shall be three hundred thirty dollars (\$330). The fee for the annual renewal of a license as a designated representative shall be one hundred ninety-five dollars (\$195). The penalty for failure to renew is ninety seven dollars and fifty cents (\$97.50).

(k) The fee for the issuance or renewal of a license as a nonresident wholesaler is seven hundred eighty dollars (\$780). The penalty for failure to renew is one hundred fifty dollars (\$150).

(l) The fee for an intern pharmacist license is one hundred fifteen dollars (\$115). The fee for transfer of intern hours or verification of licensure to another state is thirty dollars (\$30).

(m) The fee for the reissuance of any permit, license, or certificate, or renewal thereof, which must be reissued because of change in the information, other than name change, is one hundred dollars (\$100).

(n) The fee for evaluation of continuing education courses for accreditation is forty dollars (\$40) for each hour of accreditation requested.

(o) The fee for the issuance of a clinic license is five hundred twenty dollars (\$520). The fee for the annual renewal of a clinic license is three hundred twenty-five dollars (\$325). The penalty for failure to renew is one hundred fifty dollars (\$150).

(p) The fee for the issuance of a nongovernmental license, or renewal of a license, to compound sterile drug products is seven hundred eighty dollars (\$780). The penalty for failure to renew is one hundred fifty dollars (\$150).

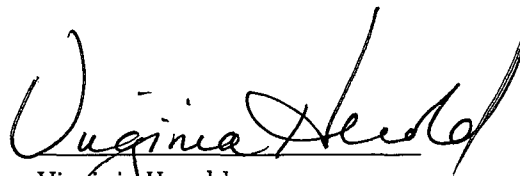
(q) The fee for the issuance of a license as a designated representative for a veterinary food-animal drug retailer shall be three hundred thirty dollars (\$330). The fee for the annual renewal of a license as a designated representative shall be one hundred and ninety-five dollars (\$195). The penalty for failure to renew is ninety-seven dollars and fifty cents (\$97.50).

(r) The fee for a veterinary food-animal drug retailer license is four hundred twenty-five dollars (\$425). The annual renewal fee for a veterinary food-animal drug retailer is three hundred twenty-five dollars (\$325). The fee for the issuance of a temporary license is two hundred and fifty dollars (\$250). The penalty for failure to renew is one hundred twenty-five dollars (\$125).

(s) The fee for the issuance of a retired pharmacist license shall be forty-five dollars (\$45).

(t) The fee for the issuance of a centralized hospital packaging pharmacy license shall be \$800. The annual renewal fee for a centralized hospital packaging pharmacy license shall be \$800. The penalty for failure to renew is one hundred fifty dollars.

Note: Authority cited: Sections 163.5 and 4005, Business and Professions Code. Reference: Sections 163.5, 4005, 4110, 4112(h), 4120, 4128.2, 4196, 4200, 4210, 4400, 4401 and 4403, Business and Professions Code.



Virginia Herold
Executive Officer
Board of Pharmacy

**Title 16. Board of Pharmacy
Order of Adoption**

Add Section 1730.2 of Article 3.5 of Division 17 of Title 16 of the California Code of Regulations as follows:

§ 1730.2 Certification Programs

- (a) For purposes of Business and Professions Code section 4210, subdivision (a)(2)(A), general clinical pharmacy practice is among the relevant areas of practice for which certification may be earned.
- (b) For a pharmacist seeking to demonstrate certification in general clinical pharmacy as a criterion for advanced practice pharmacist licensure by the board, the certification may be earned from an organization recognized as a continuing education provider by the Accreditation Council for Pharmacy Education or accredited by the National Commission for Certifying Agencies as a certification provider, so long as:
 - (1) The certification program includes specified learning objectives in at least five sequentially-ordered education modules, covering the following topics: performing patient assessments; ordering and interpreting drug therapy-related tests; referring patients to other health care providers; participating in the evaluation and management of diseases and health conditions in collaboration with other health care providers; and initiating, adjusting, modifying or discontinuing drug therapy;
 - (2) The certification program requires assessment after completion of each of the education modules in an examination format or by other assessment methodology that confirms the participant's understanding, knowledge, and application of the specified learning objectives for the module, where any failure to successfully complete the assessment in any module prevents advancement to the next module;
 - (3) The certification program requires that instruction and assessments in each of the modules are developed and provided by either:
 - (A) An advanced practice pharmacist licensed by the board or
 - (B) An expert with experience in the respective area(s) of focus specified in subparagraph (1), where "expert" means a person who qualifies to teach at a school of pharmacy recognized by the board.
 - (4) The certification program requires that, upon successful completion of all modules and their respective assessments, each participant shall earn a passing score on a final overall assessment before being awarded certification. The assessment shall be either a final written examination or an objective structured clinical examination developed and administered in collaboration with an accredited school of pharmacy recognized by the board; and
 - (5) The certification program require(s) a minimum of ten hours of continuing education on the topics identified in (b)(1) every two years to maintain certification.

Note: Authority cited: Section 4005 and 4210, Business and Professions Code.

Reference: Sections 4052.6, 4210, and 4233, Business and Professions Code.

Board of Pharmacy

Order of Adoption

To Amend § 1735 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1735. Compounding in Licensed Pharmacies.

(a) "Compounding" means any of the following activities occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a prescription:

- (1) Altering the dosage form or delivery system of a drug
- (2) Altering the strength of a drug
- (3) Combining components or active ingredients
- (4) Preparing a compounded drug product preparation from chemicals or bulk drug substances

(b) "Compounding" does not include reconstitution of a drug pursuant to a manufacturer's direction(s) ~~for oral, rectal, topical, or injectable administration~~, nor does it include the sole act of tablet splitting or crushing, capsule opening, or the addition of flavoring agent(s) to enhance palatability.

~~(c) "Compounding" does not include, except in small quantities under limited circumstances as justified by a specific, documented, medical need, preparation of a compounded drug product that is commercially available in the marketplace or that is essentially a copy of a drug product that is commercially available in the marketplace~~

~~(d)~~(c) The parameters and requirements stated by this Article 4.5 (Section 1735 et seq.) apply to all compounding practices. Additional parameters and requirements applicable solely to sterile ~~injectable~~ compounding are stated by Article 7 (Section 1751 et seq.).

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

To Amend § 1735.1 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1735.1. Compounding Definitions.

(a) “Ante-area” means an area with ISO Class 8 or better air quality where personnel hand hygiene and garbing procedures, staging of components, and other high-particulate-generating activities are performed, that is adjacent to the area designated for sterile compounding. It is a transition area that begins the systematic reduction of particles, prevents large fluctuations in air temperature and pressures in the cleanroom, and maintains air flows from clean to dirty areas. ISO Class 7 or better air quality is required for ante-areas providing air to a negative pressure room.

(b) “Beyond use date” means the date, or date and time, after which administration of a compounded drug preparation shall not begin, the preparation shall not be dispensed, and the preparation shall not be stored (other than for quarantine purposes).

(c) “Biological Safety Cabinet (BSC)” means a ventilated cabinet for compounding sterile drug preparations, having an open front with inward airflow for personnel protection, downward HEPA-filtered laminar airflow for product protection, and HEPA-filtered exhausted air for environmental protection. Where hazardous drugs are prepared, the exhaust air from the biological safety cabinet shall be appropriately removed by properly designed external building ventilation. This external venting should be dedicated to one BSC or CACI.

(d) “Bulk drug substance” means any substance that, when used in the preparation of a compounded drug preparation, processing, or packaging of a drug, is an active ingredient or a finished dosage form of the drug, but the term does not include any intermediate used in the synthesis of such substances.

(e) “Cleanroom or clean area or buffer area” means a room or area with HEPA-filtered air that provides ISO Class 7 or better air quality where the primary engineering control (PEC) is physically located.

(1) For nonhazardous compounding a positive pressure differential of 0.02- to 0.05-inch water column relative to all adjacent spaces is required.

(2) For hazardous compounding at least 30 air changes per hour of HEPA-filtered supply air and a negative pressure of between 0.01 to 0.03 inches of water column relative to all adjacent spaces is required.

(f) "Compounding Aseptic Containment Isolator (CACI)" means a unidirectional HEPA-filtered airflow compounding aseptic isolator (CAI) designed to provide worker protection from exposure to undesirable levels of airborne drug throughout the compounding and material transfer processes and to provide an aseptic environment for compounding sterile preparations. Air exchange with the surrounding environment should not occur unless the air is first passed through a microbial retentive filter (HEPA minimum) system capable of containing airborne concentrations of the physical size and state of the drug being compounded. Where hazardous drugs are prepared, the exhaust air from the isolator shall be appropriately removed by properly designed external building ventilation. This external venting should be dedicated to one BSC or CACI. Air within the CACI shall not be recirculated nor turbulent.

(g) "Compounding Aseptic Isolator (CAI)" means a form of isolator specifically designed for non-hazardous compounding of pharmaceutical ingredients or preparations while bathed with unidirectional HEPA-filtered air. It is designed to maintain an aseptic compounding environment within the isolator throughout the compounding and material transfer processes. Air exchange into the isolator from the surrounding environment should not occur unless the air has first passed through a microbial retentive filter (HEPA minimum) system capable of containing airborne concentrations of the physical size and state of the drug being compounded. Air within the CAI shall not be recirculated nor turbulent.

(h) "Controlled cold temperature" means 2 degrees to 8 degrees C (35 degrees to 46 degrees F).

(i) "Controlled freezer temperature" means -25 degrees to -10 degrees C (-13 degrees to 14 degrees F) or at a range otherwise specified by the pharmaceutical manufacturer(s) for that product.

(j) "Controlled room temperature" means 20 degrees to 25 degrees C (68 degrees to 77 degrees F).

(k) "Copy or essentially a copy" of a commercially available drug product includes all preparations that are comparable in active ingredients to commercially available drug

products, except that it does not include any preparations in which there has been a change, made for an identified individual patient, which produces for that patient a clinically significant difference, as determined by a prescribing practitioner, between that compounded preparation and the comparable commercially available drug product.

(l) "Daily" means occurring every day the pharmacy is operating, except when daily monitoring of refrigerator and freezer temperature are required, then daily means every 24 hours.

(m) "Displacement airflow method" means a concept which utilizes a low pressure differential, high airflow principle to maintain segregation from the adjacent ante-area by means of specific pressure differentials. This principle of displacement airflow shall require an air velocity of 40 ft per minute or more, from floor to ceiling and wall to wall, from the clean area across the line of demarcation into the ante-area. The displacement concept may not be used to maintain clean area requirements for sterile compounds which originate from any ingredient that was at any time non-sterile, regardless of intervening sterilization of the ingredient, or for hazardous compounds.

(n) "Dosage unit" means a quantity sufficient for one administration to one patient.

(o) "Equipment" means items that must be calibrated, maintained or periodically certified.

(p) "First air" means the air exiting the HEPA filter in a unidirectional air stream that is essentially particle free.

(q) "Gloved fingertip sampling" means a process whereby compounding personnel lightly press each fingertip and thumb of each hand onto appropriate growth media, which are then incubated at a temperature and for a time period conducive to multiplication of microorganisms, and then examined for growth of microorganisms.

(r) "Hazardous" means all anti-neoplastic agents identified by the National Institute for Occupational Safety and Health (NIOSH) as meeting the criteria for a hazardous drug and any other drugs, compounds, or materials identified as hazardous by the pharmacist-in-charge.

(s) "Integrity" means retention of potency until the ~~expiration~~ beyond use date ~~noted~~ provided on the label, so long as the preparation is stored and handled according to the label directions.

(t) "Lot" means one or more compounded drug preparation(s) prepared during one uninterrupted continuous cycle of compounding from one or more common active

ingredient(s).

(u) "Media-fill test" means a test used to measure the efficacy of compounding personnel in aseptic techniques whereby compounding procedures are mimicked using a growth-based media and then the resulting preparation is evaluated for sterility. The media-fill test must mimic the most complex compounding procedures performed by the pharmacy.

(v) "Non-sterile-to-sterile batch" means any compounded drug preparation containing two (2) or more dosage units with any ingredient that was at any time non-sterile, regardless of intervening sterilization of that ingredient.

(w) "Parenteral" means a preparation of drugs administered in a manner other than through the digestive tract. It does not include topical, sublingual, rectal or buccal routes of administration.

(x) "Personal protective equipment" means clothing or devices that protect the employee from exposure to compounding ingredients and/or potential toxins and minimize the contamination of compounded preparations. These include shoe covers, head and facial hair covers, face masks, gowns, and gloves.

(y) "Potency" means active ingredient strength within +/- 10% (or the range specified in USP37-NF32, 37th Revision, Through 2nd Supplement Effective December 1, 2014) of the labeled amount. Sterile injectable products compounded solely from commercially manufactured sterile pharmaceutical products in a health care facility licensed under section 1250 of the Health and Safety Code are exempt from this definition. For those exempt, the range shall be calculated and defined in the master formula.

(z) "Preparation" means a drug or nutrient compounded in a licensed pharmacy; the preparation may or may not be sterile.

(aa) "Prescriber's office" or "prescriber office" means an office or suite of offices in which a prescriber regularly sees patients for outpatient diagnosis and treatment. This definition does not include any hospital, pharmacy, or other facility, whether or not separately licensed, that may be affiliated with, adjacent to, or co-owned by, the prescriber's practice environment.

(ab) "Primary Engineering Control (PEC)" means a device that provides an ISO Class 5 or better environment through the use of non-turbulent, unidirectional HEPA-filtered first air for

compounding sterile preparations. Examples of PEC devices include, but are not limited to, laminar airflow workbenches, biological safety cabinets, sterile compounding automated robots, compounding aseptic isolators, and compounding aseptic containment isolators.

(ac) "Process validation" means demonstrating that when a process is repeated within specified limits, the process will consistently produce preparations complying with predetermined requirements. If any aspect of the process is changed, the process would need to be revalidated.

(ad) "Product" means a commercially manufactured drug or nutrient evaluated for safety and efficacy by the FDA.

(ae) "Quality" means the absence of harmful levels of contaminants, including filth, putrid, or decomposed substances, and the absence of active ingredients other than those listed on the label, and the absence of inactive ingredients other than those listed on the master formula document.

(af) "Segregated sterile compounding area" means a designated space for sterile-to-sterile compounding where a PEC is located within either a demarcated area (at least three foot perimeter) or in a separate room. Such area or room shall not contain and shall be void of activities and materials that are extraneous to sterile compounding. The segregated sterile compounding area shall not be in a location that has unsealed windows or doors that connect to the outdoors, in a location with high traffic flow, or in a location that is adjacent to construction sites, warehouses, or food preparation. The segregated sterile compounding area shall not have a sink, other than an emergency eye-washing station, located within three feet of a PEC. The segregated sterile compounding area shall be restricted to preparation of sterile-to-sterile compounded preparations.

(1) The BUD of a sterile drug preparation made in a segregated sterile compounding area is limited to 12 hours or less as defined by section 1751.8(d).

(2) When the PEC in the segregated sterile compounding area is a CAI or a CACI and the documentation provided by the manufacturer shows it meets the requirements listed in section 1751.4(f)(1)-(3), the assigned BUD shall comply with section 1751.8(a-b) or (d).

(ag) "Strength" means amount of active ingredient per unit of a compounded drug product

preparation.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

To Amend § 1735.2 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1735.2. Compounding Limitations and Requirements; Self-Assessment.

(a) Except as specified in (b) and (c), no drug ~~product~~ preparation shall be compounded prior to receipt by a pharmacy of a valid prescription for an individual patient where the prescriber has approved use of a compounded drug ~~product~~ preparation either orally or in writing. Where approval is given orally, that approval shall be noted on the prescription prior to compounding.

(b) A pharmacy may prepare and store a limited quantity of a compounded drug ~~product~~ preparation in advance of receipt of a patient-specific prescription where and solely in such quantity as is necessary to ensure continuity of care for an identified population of patients of the pharmacy based on a documented history of prescriptions for that patient population.

(c) A “reasonable quantity” ~~as used in~~ that may be furnished to a prescriber for office use by the prescriber as authorized by Business and Professions Code section 4052, subdivision (a)(1), means that amount of compounded drug ~~product~~ preparation that:

(1) ~~is~~ ordered by the prescriber or the prescriber’s agent using a purchase order or other documentation received by the pharmacy prior to furnishing that lists the number of patients seen or to be seen in the prescriber’s office for whom the drug is needed or anticipated, and the quantity for each patient that is sufficient for office administration or application to patients in the prescriber’s office, or for distribution of not more than a 72-hour supply to the prescriber’s patients, as estimated by the prescriber; and

(2) Is delivered to the prescriber’s office and signed for by the prescriber or the prescriber’s agent; and

(3) Is sufficient for administration or application to patients solely in the prescriber's office, or

for furnishing of not more than a 120-hour supply for veterinary medical practices, solely to the prescriber's own veterinary patients seen as part of regular treatment in the prescriber's office, as fairly estimated by the prescriber and documented on the purchase order or other documentation submitted to the pharmacy prior to furnishing; and

~~(2)~~(4) That the pharmacist has a credible basis for concluding it is a reasonable quantity for office use ~~is reasonable~~ considering the intended use of the compounded medication and the nature of the prescriber's practice; and

~~(3)~~ (5) for With regard to any individual prescriber to whom the pharmacy furnishes, and with regard to ~~for~~ all prescribers to whom the pharmacy furnishes, taken as a whole, is an amount which the pharmacy is capable of compounding in compliance with pharmaceutical standards for integrity, potency, quality and strength of the compounded drug product preparation; and

(6) Does not exceed an amount the pharmacy can reasonably and safely compound.

(d) No pharmacy or pharmacist shall compound a drug preparation that:

(1) Is classified by the FDA as demonstrably difficult to compound;

(2) Appears on an FDA list of drugs that have been withdrawn or removed from the market because such drugs or components of such drugs have been found to be unsafe or not effective; or

(3) Is a copy or essentially a copy of one or more commercially available drug products, unless that drug product appears on an ASHP (American Society of Health-System Pharmacists) or FDA list of drugs that are in short supply at the time of compounding and at the time of dispense, and the compounding of that drug preparation is justified by a specific, documented medical need made known to the pharmacist prior to compounding. The pharmacy shall retain a copy of the documentation of the shortage and the specific medical need in the pharmacy records for three years from the date of receipt of the documentation.

~~(d)~~(e) A drug product preparation shall not be compounded until the pharmacy has first prepared a written master formula-record document that includes at least the following elements:

(1) Active ingredients to be used.

(2) Equipment to be used.

(3) ~~Expiration dating requirements.~~ The maximum allowable beyond use date for the preparation, and the rationale or reference source justifying its determination.

(4) Inactive ingredients to be used.

(5) ~~Process and/or procedure~~ Specific and essential compounding steps used to prepare the drug.

(6) Quality reviews required at each step in preparation of the drug.

(7) Post-compounding process or procedures required, if any.

(8) Instructions for storage and handling of the compounded drug preparation.

~~(e)(f)~~ Where a pharmacy does not routinely compound a particular drug ~~product~~ preparation, the master formula record for that ~~product~~ preparation may be recorded on the prescription document itself.

~~(f)(g)~~ The pharmacist performing or supervising compounding is responsible for the integrity, potency, quality, and labeled strength of a compounded drug ~~product~~ preparation until ~~it~~ the beyond use date indicated on the label, so long as label instructions for storage and handling are followed after the preparation is dispensed.

~~(g)(h)~~ All chemicals, bulk drug substances, drug products, and other components used for drug compounding shall be stored and used according to compendial and other applicable requirements to maintain their integrity, potency, quality, and labeled strength.

~~(h)(i)~~ Every compounded drug ~~product~~ preparation shall be given an ~~expiration~~ beyond use date representing the date or date and time beyond which the compounded drug preparation should not be used, stored, transported or administered, and determined based on the professional judgment of the pharmacist performing or supervising the compounding. ~~in the professional judgment of the pharmacist performing or supervising the compounding, it should not be used.~~

(1) For non-sterile compounded drug preparation(s), the beyond use date ~~This “beyond use date” of the compounded drug product shall not exceed~~ any of the following: 180 days from preparation or

(A) the shortest expiration date or beyond use date of any component ingredient in the compounded drug ~~product~~ preparation,

- (B) the chemical stability of any one ingredient in the compounded drug preparation;
- (C) the chemical stability of the combination of all ingredients in the compounded drug preparation,
- (D) 180 days for non-aqueous formulations,
- (E) 14 days for water-containing oral formulations, and
- (F) 30 days for water-containing topical/dermal and mucosal liquid and semisolid formulations.

(2) For sterile compounded drug preparations, the beyond use date shall not exceed any of the following:

- (A) The shortest expiration date or beyond use date of any ingredient in the sterile compounded drug product preparation,
- (B) The chemical stability of any one ingredient in the sterile compounded drug preparation,
- (C) The chemical stability of the combination of all ingredients in the sterile compounded drug preparation, and
- (D) The beyond use date assigned for sterility in section 1751.8.

(3) Extension of a beyond use date is only allowable when supported by the following:

- (A) Method Suitability Test,
- (B) Container Closure Integrity Test, and
- (C) Stability Studies

~~unless a longer later date is supported by stability studies of~~

(4) In addition to the requirements of paragraph three (3), the ~~finished~~ drugs or compounded drug ~~products~~ preparations tested and studied shall be using the same identical components in ingredients, specific and essential compounding steps, quality reviews, and packaging as the finished drug or compounded drug preparation.

(5) Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.

~~(j)~~ (j) The pharmacist performing or supervising compounding is responsible for the proper preparation, labeling, storage, and delivery of the compounded drug ~~product~~ preparation.

~~(k)~~ (k) Prior to allowing any drug product preparation to be compounded in a pharmacy, the pharmacist-in-charge shall complete a self-assessment for compounding pharmacies developed

by the board (Incorporated by reference is “Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment” Form 17M-39 Rev. 02/12.) as required by Section 1715 of Title 16, Division 17, of the California Code of Regulations. That form contains a first section applicable to all compounding, and a second section applicable to sterile injectable compounding. The first section must be completed by the pharmacist-in-charge before any compounding is performed in the pharmacy. The second section must be completed by the pharmacist-in-charge before any sterile injectable compounding is performed in the pharmacy. The applicable sections of the self-assessment shall subsequently be completed before July 1 of each odd-numbered year, within 30 days of the start date of a new pharmacist-in-charge or change of location, and within 30 days of the issuance of a new pharmacy license. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

(l) Packages of ingredients, both active and inactive, that lack a supplier’s expiration date are subject to the following limitations:

(1) such ingredients cannot be used for any non-sterile compounded drug preparation more than three (3) years after the date of receipt by the pharmacy.

(2) such ingredients cannot be used for any sterile compounded drug preparation more than one (1) year after the date of receipt by the pharmacy.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code, Sections 1735, 1735.1, 1735.8, and 1751.1-1751.8 of Title 16, Division 17, of the California Code of Regulations.

To Amend § 1735.3 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1735.3. ~~Records~~ Recordkeeping of for Compounded Drug Products Preparations.

(a) For each compounded drug ~~product preparation~~, the pharmacy records shall include:

(1) The master formula ~~record~~ document.

(2) A compounding log consisting of a single document containing all of the following:

(A) Name and Strength of the compounded drug preparation.

(B) The date the drug ~~product preparation~~ was compounded.

~~(3)(C) The identity of the any pharmacy personnel who compounded the~~ engaged in compounding the drug ~~product preparation~~.

~~(4)(D) The identity of the pharmacist reviewing the final drug ~~product preparation~~.~~

~~(5)(E) The quantity of each component ingredient used in compounding the drug ~~product preparation~~.~~

~~(6)(F) The manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. If the manufacturer does not supply an expiration date for any component, the records shall include the date of receipt of the component in the pharmacy, and the limitations of section 1735.2, subdivision (l) shall apply.~~

(i) Exempt from the requirements in this paragraph (1735.3(a)(2)(F)) are sterile ~~products preparations~~ compounded on a one-time basis in a single lot for administration within seventy-two (72) hours to a patient in a health care facility licensed under section 1250 of the Health and Safety Code and stored in accordance with standards for “Redispensed CSPs” found in Chapter 797 of the United States Pharmacopeia – National Formulary (USP37-NF32) Through 2nd Supplement (35 37th Revision, Effective ~~May~~ December 1, 2012-2014), hereby incorporated by reference, to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.

~~(7)(G) A pharmacy-assigned unique reference or lot number for the compounded drug ~~product preparation~~.~~

~~(8)(H)~~ The expiration beyond use date or beyond use date and time of the final compounded drug product preparation, expressed in the compounding record document in a standard date and time format.

~~(9)(I)~~ The final quantity or amount of drug product preparation compounded for dispensing.

(J) Documentation of quality reviews and required post-compounding process and procedures.

(b) Pharmacies shall maintain records of the proper acquisition, storage, and destruction of chemicals, bulk drug substances, drug products, and components used in compounding.

(c) Active ingredients shall be obtained from a supplier registered with the Food and Drug Administration (FDA). All other ~~C~~chemicals, bulk drug substances, and drug products, and ~~and~~ components used to compound drug products preparations shall be obtained, whenever possible, from reliable FDA- registered suppliers. The pharmacy shall acquire and retain any available certificates of purity or analysis, either written in English or translated into English, for chemicals, bulk drug substances, and drug products, and components used in compounding. Certificates of purity or analysis are not required for drug products that are approved by the FDA. Any certificates of purity or analysis acquired by the pharmacy shall be matched to the corresponding chemical, bulk drug substance, or drug products received.

(d) Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was ~~created~~ last in effect. If only recorded and stored electronically, on magnetic media, or in any other computerized form, the records shall be maintained as specified by Business and Professions Code section 4070 subsection (c).

Authority cited: Sections 4005, 4127, and 4169, Business and Professions Code.

Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

To Amend § 1735.4 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1735.4. Labeling of Compounded Drug ~~Products~~ Preparations.

(a) Each compounded drug preparation shall be affixed with a container label prior to dispensing that contains at least:

(1) Name of the compounding pharmacy and dispensing pharmacy (if different);

(2) Name (brand or generic) and strength, volume, or weight of each active ingredient. For admixed IV solutions, the intravenous solution utilized shall be included;

(3) Instructions for storage, handling, and administration. For admixed IV solutions, the rate of infusion shall be included;

(4) The beyond use date for the drug preparation;

(5) The date compounded; and

(6) The lot number or pharmacy reference number.

~~In addition to the labeling information required under Business and Professions Code section 4076 and under California Code of Regulations section 1707.5, the label of a compounded drug product preparation shall contain the generic or brand name(s) of the principal all active ingredient(s).~~

(b) Any compounded drug preparation dispensed to a patient or readied for dispensing to a patient shall also include on the label the information required under Business and Professions Code section 4076 and California Code of Regulations, title 16, section 1707.5.

~~A statement that the drug has been compounded by the pharmacy shall be included on the container or on the receipt provided to the patient.~~

(c) Any compounded drug preparation dispensed to a patient or readied for dispensing to a patient shall also include, on the container label or on a receipt provided to the patient, a statement that the drug has been compounded by the pharmacy. ~~Drug products preparations compounded into unit dose containers that are too small or otherwise impractical for full compliance with subdivisions (a) and (b) shall be labeled with at least the name(s) of the active ingredient(s), concentration or strength, volume or weight of the~~

~~preparation, pharmacy reference or lot number, and expiration date.~~

(d) Prior to dispensing drug preparations compounded into unit-dose containers that are too small or otherwise impractical for full compliance with subdivisions (a), (b), and (c) shall be labeled with at least the name of the compounding pharmacy and dispensing pharmacy, if different, the name(s) of the active ingredient(s), strength, volume or weight of the preparation, pharmacy reference or lot number, and beyond use date, and shall not be subject to minimum font size requirements. Once dispensed, outer packaging must comply with 1735.4(a) – (c).

(e) All hazardous agents shall bear a special label which states “Chemotherapy - Dispose of Properly” or “Hazardous – Dispose of Properly.”

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4076 and 4127, Business and Professions Code.

To Amend § 1735.5 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1735.5. Compounding Policies and Procedures.

(a) Any pharmacy engaged in compounding shall maintain ~~a~~ written policies and procedures ~~manual~~ for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding. Any material failure to follow the pharmacy’s written policies and procedures shall constitute a basis for disciplinary action.

(b) The policies and procedures ~~manual~~ shall be reviewed and such review shall be documented on an annual basis by the pharmacist-in-charge. ~~and~~ The policies and procedures manual shall be updated whenever changes in policies and procedures ~~processes~~ are implemented.

(c) The policies and procedures ~~manual~~ shall include at least the following:

- (1) Procedures for notifying staff assigned to compounding duties of any changes in ~~processes~~ or to the policies or procedures manual.
- (2) ~~Documentation of a~~ A written plan for recall of a dispensed compounded drug product preparation where subsequent verification information demonstrates the potential for adverse effects with continued use of a compounded drug product. The plan shall ensure that all affected doses can be accounted for during the recall and shall provide steps to identify which patients received the affected lot or compounded drug preparation(s).
- (3) ~~The p~~ Procedures for maintaining, storing, calibrating, cleaning, and disinfecting equipment used in compounding, and for training on these procedures as part of the staff training and competency evaluation process.
- (4) Procedures for evaluating, maintaining, certifying, cleaning, and disinfecting the facility (physical plant) used for compounding, and for training on these procedures as part of the staff training and competency evaluation process.
- (45) Documentation of the methodology used to ~~test~~ validate integrity, potency, quality, and labeled strength of compounded drug ~~products~~ preparations. The methodology must be appropriate to compounded drug preparations.
- (56) Documentation of the methodology and rationale or reference source used to determine appropriate ~~expiration~~ beyond use dates for compounded drug ~~products~~ preparations.
- (7) Dates and signatures reflecting all annual reviews of the policies and procedures by the pharmacist-in-charge.
- (8) Dates and signatures accompanying any revisions to the policies and procedures approved by the pharmacist-in-charge.
- (9) Policies and procedures for storage of compounded drug preparations in the pharmacy and daily documentation of all room, refrigerator, and freezer temperatures within the pharmacy.
- (10) Policies and procedures regarding ensuring appropriate functioning of refrigeration devices, monitoring refrigeration device temperatures, and actions to take regarding any out of range temperature variations within the pharmacy.
- (11) Policies and procedures for proper garbing when compounding with hazardous products. This shall include when to utilize double shoe covers.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, ~~and 4127~~, and 4301, Business and Professions Code.

To Amend § 1735.6 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1735.6. Compounding Facilities and Equipment.

(a) Any pharmacy engaged in compounding shall maintain written documentation regarding the facilities and equipment necessary for safe and accurate compounding of compounded drug ~~products~~ preparations. This shall include records of maintenance and cleaning of the facilities and equipment. Where applicable, this shall also include records of certification(s) of facilities or equipment.

(b) Any equipment used to compound drug ~~products~~ preparations shall be stored, used, ~~and~~ maintained, and cleaned in accordance with manufacturers' specifications.

(c) Any equipment that weighs, measures, or transfers ingredients used to compound drug ~~products~~ preparations for which calibration or adjustment is appropriate shall be calibrated prior to use, on a schedule and by a method determined by the manufacturer's specifications, to ensure accuracy. Documentation of each such calibration shall be recorded in writing in a form which is not alterable and these records of calibration shall be maintained and retained in the pharmacy.

(d) Any pharmacy engaged in any hazardous drug compounding shall maintain written documentation regarding appropriate cleaning of facilities and equipment to prevent cross-contamination with non-hazardous drugs.

(e) Hazardous drug compounding shall be completed in an externally vented physically separate room with the following requirements:

(1) Minimum of 30 air changes per hour except that 12 air changes per hour are acceptable for segregated compounding areas with a BSC or CACI when products are assigned a BUD of 12 hrs or less or when non sterile products are compounded; and

(2) Maintained at a negative pressure of 0.01 to 0.03 inches of water column relative to all adjacent spaces (rooms, above ceiling, and corridors); and

(3) Each PEC in the room shall also be externally vented; and

(4) All surfaces within the room shall be smooth, seamless, impervious, and non-shedding.

(f) Where compliance with the January 1, 2017 amendments to Article 4.5 or Article 7, requires physical construction or alteration to a facility or physical environment, the board or its designee may grant a waiver of such compliance for a period of time to permit such physical change(s). Application for any waiver shall be made by the licensee in writing, and the request shall identify the provision(s) requiring physical construction or alteration, and the timeline for any such change(s). The board or its designee may grant the waiver when, in its discretion, good cause is demonstrated for such waiver.

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code.

Reference: Sections 4005, 4036, 4037, 4051, 4052 and 4127, Business and Professions Code.

To Amend § 1735.7 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1735.7. Training of Compounding Staff.

(a) A pharmacy engaged in compounding shall maintain documentation demonstrating that personnel involved in compounding have the skills and training required to properly and accurately perform their assigned responsibilities and documentation demonstrating that all personnel involved in compounding are trained in all aspects of policies and procedures. This training shall include but is not limited to support personnel (e.g. institutional environmental services, housekeeping), maintenance staff, supervising pharmacist and all others whose jobs are related to the compounding process. ~~Any pharmacy engaged in compounding shall maintain written documentation sufficient to demonstrate that pharmacy personnel have the skills and training required to properly and accurately perform their assigned responsibilities relating to compounding.~~

(b) The pharmacy shall develop and maintain an ongoing competency evaluation process for pharmacy personnel involved in compounding, and shall maintain documentation of any and all training related to compounding undertaken by pharmacy personnel.

(c) Pharmacy personnel assigned to compounding duties shall demonstrate knowledge about processes and procedures used in compounding prior to compounding any drug ~~product~~ preparation.

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052 and 4127, Business and Professions Code.

To Amend § 1735.8 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1735.8. Compounding Quality Assurance.

(a) Any pharmacy engaged in compounding shall maintain, as part of its written policies and procedures, a written quality assurance plan designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug ~~products~~ preparations.

(b) The quality assurance plan shall include written procedures for verification, monitoring, and review of the adequacy of the compounding processes and shall also include written documentation of review of those processes by qualified pharmacy personnel.

(c) The quality assurance plan shall include written standards for qualitative and quantitative analysis of compounded drug preparations to ensure integrity, potency, quality, and labeled strength, including the frequency of testing ~~analysis of compounded drug products~~. All qualitative and quantitative analysis reports for compounded drug ~~products~~ preparations shall be retained by the pharmacy and ~~collected~~ maintained along with the compounding log record and master formula document. The quality assurance plan shall include a schedule for routine testing and analysis of specified compounded drug preparations to ensure integrity, potency, quality, and labeled strength, on at least an annual basis.

(d) The quality assurance plan shall include a written procedure for scheduled action in the

event any compounded drug ~~product~~ preparation is ever discovered to be ~~below~~ outside minimum standards for integrity, potency, quality, or labeled strength.

(e) The quality assurance plan shall include a written procedure for responding to out-of-range temperature variations within the pharmacy and within patient care areas of a hospital where furnished drug is returned for redispensing.

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052 and 4127, Business and Professions Code.

To Amend § 1751 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

Article 7. Sterile ~~Injectable~~ Compounding

1751. Sterile ~~Injectable~~ Compounding; Compounding Area; Self-Assessment.

(a) Any pharmacy engaged in compounding sterile ~~injectable~~ drug ~~products~~ preparations shall conform to the parameters and requirements stated by Article 4.5 (Section 1735 et seq.), applicable to all compounding, and shall also conform to the parameters and requirements stated by this Article 7 (Section 1751 et seq.), applicable solely to sterile ~~injectable~~ compounding.

(b) Any pharmacy compounding sterile ~~injectable~~ drug ~~products~~ preparations shall have a ~~designated~~ compounding area designated for the preparation of sterile ~~injectable~~ drug products preparations that is in a restricted location where traffic has no impact on the performance of the PEC(s). The cleanroom, including the walls, ceilings, and floors, shall be constructed in accordance with Section 1250.4 of Title 24, Part 2, Chapter 12, of the California Code of Regulations. The pharmacy shall be ventilated in a manner in accordance with Section 505.5 of Title 24, Part 4, Chapter 5 of the California Code of Regulations. ~~which shall meet the following standards:~~ The environments within the pharmacy shall meet the following standards:

~~(1) Clean Room and Work Station Requirements, shall be in accordance with Section 1250 of Title 24, Part 2, Chapter 12, of the California Code of Regulations.~~

~~(2) Walls, ceilings and floors shall be constructed in accordance with Section 1250 of Title 24, Part 2, Chapter 12, of the California Code of Regulations.~~

~~(3) Be ventilated in a manner in accordance with Section 505.12 of Title 24, Chapter 5 of the California Code of Regulations.~~

~~(4) Be~~ Each ISO environment shall be certified annually at least every six months by a qualified technician ~~who is familiar with the methods and procedures for certifying laminar air flow hoods and clean room requirements, in accordance with standards adopted by the United States General Services Administration~~ in accordance with Section 1751.4. Certification records must be retained ~~for at least 3 years~~ in the pharmacy.

~~(5)-(2) The pharmacy shall be arranged in accordance with Section 1250 of Title 24, Part 2, Chapter 12, of the California Code of Regulations.~~ Items related to the compounding of sterile ~~injectable drug products~~ preparations within the compounding area shall be stored in such a way as to maintain the integrity of an aseptic environment.

~~(6)-(3)~~ A sink shall be included in accordance with Section 1250.4 of Title 24, Part 2, Chapter 12, of the California Code of Regulations. Sinks and drains shall not be present in any ISO Class 7 or better cleanroom, nor in a segregated sterile compounding area within three feet of an ISO Class 5 or better PEC, with the exception of emergency eye-rinsing stations. A sink may be located in an ante-area. When the PEC in the segregated sterile compounding area is a CAI or CACI and the documentation provided by the manufacturer shows it meets the requirements listed in 1751.4(f)(1)-(3) the sterile compounding area is exempt from the room requirement listed in 1751(b)(3).

~~(7)-(4)~~ There shall be a refrigerator and, ~~for~~ where appropriate, a freezer, of sufficient capacity to meet the storage requirements for all material requiring refrigeration or freezing, and a backup plan to ensure continuity of available compounded drug preparations in the event of a power outage.

~~(c) Any pharmacy compounding a sterile injectable drug product preparation from one or more non-sterile ingredients shall comply with Business and Professions Code section 4127.7.~~

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127 and 4127.7, Business and Professions Code; Sections 1735, 1735.1-1735.8., and 1751.1-1751.8. of Title 16, Division 17, of the California Code of

Regulations; and Section 18944, Health and Safety Code.

To Amend § 1751.1 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1751.1. Sterile ~~Injectable~~ Compounding Recordkeeping Requirements.

(a) ~~Pharmacies compounding sterile injectable products for future use pursuant to section 1735.2 shall, in addition to those records required by section 1735.3, make and keep records indicating the name, lot number, amount, and date on which the products were provided to a prescriber.~~

~~(b) In addition to the records required by section 1735.3 and subdivision (a), any pharmacy engaged in any compounding of for sterile drug products preparations compounded from one or more non-sterile ingredients, shall maintain the following records, which must be made and kept by~~ readily retrievable, within the pharmacy:

(1) ~~The~~ Documents evidencing training and competency evaluations of employees in sterile product drug preparation policies and procedures.

(2) Results of hand hygiene and garbing assessments with integrated gloved fingertip testing.

(3) Results of assessments of personnel for aseptic techniques including results of media-fill tests and gloved fingertip testing performed in association with media-fill tests.

(4) Results of viable air and surface sampling.

(5) Video of smoke studies in all ISO certified spaces.

(6) Documents indicating daily documentation of room, R refrigerator, and freezer temperatures appropriate for sterile compounded drug preparations consistent with the temperatures listed in section 1735.1 for:

(A) Controlled room temperature.

(B) Controlled cold temperature.

(C) Controlled freezer temperature.

(7) Certification(s) of the sterile compounding environment(s).

(8) Documents indicating daily documentation of air pressure differentials or air velocity

measurements between all adjoining ISO rooms or areas, including those associated with compounding aseptic (containment) isolators, and air pressure differentials or air velocity measurements between all rooms or spaces with an immediate entry or opening to ISO rooms or areas.

(9) Other facility quality control logs records specific to the pharmacy's policies and procedures (e.g., cleaning logs for facilities and equipment).

(10) Logs or other documentation of inspections for expired or recalled ~~pharmaceutical products or raw ingredients~~ chemicals, bulk drug substances, drug products, or other ingredients.

(11) Preparation records including the master formula document work sheet, the preparation compounding log work sheet, and records of end-product evaluation testing and results.

(b) Pharmacies compounding sterile drug preparations for future use pursuant to section 1735.2 shall, in addition to those records required by section 1735.3, make and keep records indicating the name, lot number, and amount of any drug preparation compounded for future use, the date on which any preparation was provided to a prescriber, and the name, address, license type and number of the prescriber.

(c) Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was created. If only recorded and stored electronically, on magnetic media, or in any other computerized form, the records shall be maintained as specified by Business and Professions Code section 4070 subsection (c).

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

To Amend § 1751.2 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1751.2. Sterile ~~Injectable~~ Compounding Labeling Requirements.

In addition to the labeling information required under Business and Professions Code section 4076 and California Code of Regulations, title 16, sections 1707.5 and 1735.4, a pharmacy ~~which that~~ compounds sterile ~~injectable drug products~~ preparations shall include the following information on the labels for ~~each such those products~~ preparation:

- (a) ~~The~~ Telephone number of the pharmacy. ~~, except~~ The telephone number is not required on the label for sterile injectable drug products preparations dispensed administered for to inpatients of a within the hospital pharmacy.
- ~~(b) Name and concentration of ingredients contained in the sterile injectable drug product.~~
- ~~(c)~~ Instructions for storage, and handling, and administration.;
- ~~(d)~~ All cytotoxic hazardous agents shall bear a special label which states "Chemotherapy - Dispose of Properly" or "Cytotoxic Hazardous – Dispose of Properly."

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4076 and 4127, Business and Professions Code.

To Amend § 1751.3 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1751.3. Sterile ~~Injectable~~ Compounding Policies and Procedures.

(a) Any pharmacy engaged in compounding sterile drug preparations shall maintain written policies and procedures for compounding. Any material failure to follow the pharmacy's written policies and procedures shall constitute a basis for disciplinary action. In addition to the elements required by section 1735.5, there shall be written policies and procedures regarding the following:

- (1) Action levels for colony-forming units (CFUs) detected during viable surface sampling, glove

fingertip, and viable air sampling and actions to be taken when the levels are exceeded.

(2) Airflow considerations and pressure differential monitoring.

(3) An environmental sampling plan and procedures specific to viable air, surface and gloved fingertip sampling as well as nonviable particle sampling.

(4) Cleaning and maintenance of ISO environments and segregated compounding areas.

(5) Compounded sterile drug preparation stability and beyond use dating.

(6) Compounding, filling, and labeling of sterile drug preparations.

(7) Daily and monthly cleaning and disinfection schedule for the controlled areas and any equipment in the controlled area as specified in section 1751.4.

(8) Depyrogenation of glassware (if applicable)

(9) Facility management including certification and maintenance of controlled environments and related equipment.

(10) For compounding aseptic isolators and compounding aseptic containment isolators, documentation of the manufacturer's recommended purge time.

(11) Hand hygiene and garbing.

(12) Labeling of the sterile compounded drug preparations based on the intended route of administration and recommended rate of administration.

(13) Methods by which the supervising pharmacist will fulfill his or her responsibility to ensure the quality of compounded drug preparations.

(14) Orientation, training, and competency evaluation of staff in all aspects of the preparation of sterile drug preparations including didactic training and knowledge/competency assessments that include at minimum: hand hygiene and garbing; decontamination (where applicable); cleaning and disinfection of controlled compounding areas; and proper aseptic technique, demonstrated through the use of a media-fill test performed by applicable personnel; and aseptic area practices.

(15) Preparing sterile compounded drug preparations from non-sterile components (if applicable). This shall include sterilization method suitability testing for each master formula document.

(16) Procedures for handling, compounding and disposal of hazardous agents. The written

policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.

(17) Procedures for handling, compounding and disposal of infectious materials. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.

(18) Proper use of equipment and supplies.

(19) Quality assurance program compliant with sections 1711, 1735.8 and 1751.7.

(20) Record keeping requirements.

(21) Temperature monitoring in compounding and controlled storage areas.

(22) The determination and approval by a pharmacist of ingredients and the compounding process for each preparation before compounding begins.

(23) Use of automated compounding devices (if applicable).

(24) Visual inspection and other final quality checks of sterile drug preparations.

~~(a) Any pharmacy engaged in compounding sterile injectable drug products shall maintain a written policy and procedures manual for compounding that includes, in addition to the elements required by section 1735.5, written policies and procedures regarding the following:~~

~~(1) Compounding, filling, and labeling of sterile injectable compounds.~~

~~(2) Labeling of the sterile injectable product compounded drug preparations based on the intended route of administration and recommended rate of administration.~~

~~(3) Equipment and supplies.~~

~~(4) Training of staff in the preparation of sterile injectable products.~~

~~(5) Procedures for handling cytotoxic agents.~~

~~(6) Quality assurance program.~~

~~(7) Record keeping requirements.~~

~~(b) The ingredients and the compounding process for each preparation must be determined in writing before compounding begins and must be reviewed by a pharmacist.~~

~~(c) Pharmacies compounding sterile injectable drug products preparations shall have written policies and procedures for the disposal of infectious materials and/or materials containing cytotoxic hazardous residues. The written policies and procedures shall describe the pharmacy~~

~~protocols for cleanups and spills in conformity with local health jurisdiction standards.~~

(b) For lot compounding, the pharmacy shall maintain written policies and procedures that includes, in addition to the elements required by section 1735.5 and 1751.3(a), written policies and procedures regarding the following:

(1) Use of master formula documents and compounding logs.

(2) Appropriate documentation.

(3) Appropriate sterility and potency testing.

(c) For non-sterile-to-sterile batch compounding, the pharmacy shall maintain written policies and procedures for compounding that includes, in addition to the elements required by section 1735.5, 1751.3(a), and 1751.7(e), written policies and procedures regarding the following:

(1) Process validation for chosen sterilization methods.

(2) End-product evaluation, quantitative, and qualitative testing.

~~(d)(1) All written p~~olicies and procedures shall be immediately available to all personnel involved in these compounding activities and to board inspectors.

~~(d)(2)(e) All personnel involved must read the policies and procedures before compounding sterile injectable products-drug preparations, and any~~All personnel involved must read all additions, revisions, and deletions to the written policies and procedures-must be communicated to all personnel involved in sterile compounding. Each review must be documented by a signature and date.

~~(3) Policies and procedures must address at least the following:~~

~~(A) Competency evaluation.~~

~~(B) Storage and handling of products and supplies.~~

~~(C) Storage and delivery of final products.~~

~~(D) Process validation.~~

~~(E) Personnel access and movement of materials into and near the controlled area~~

~~(F) Use and maintenance of environmental control devices used to create the critical direct compounding area for manipulation of sterile products (e.g., laminar airflow workstations, biological safety cabinets, class 100 cleanrooms, and barrier isolator~~

workstations).

~~(G) Regular cleaning schedule for the controlled areas and any equipment in the controlled area and the alternation of disinfectants. Pharmacies subject to an institutional infection control policy may follow that policy as it relates to cleaning schedules and the alternation of disinfectants in lieu of complying with this subdivision.~~

~~(H) Disposal of packaging materials, used syringes, containers, and needles to enhance sanitation and avoid accumulation in the controlled area.~~

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

To Amend § 1751.4 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1751.4. Facility and Equipment Standards for Sterile ~~Injectable~~ Compounding.

(a) No sterile ~~injectable drug product~~ preparation shall be compounded if it is known, or reasonably should be known, that the compounding environment fails to meet criteria specified in the pharmacy's written policies and procedures for the safe compounding of sterile ~~injectable drug products~~ preparations.

(b) During the compounding of preparation of sterile ~~injectable drug products~~ preparations, access to the areas designated ~~area or cleanroom~~ for compounding must be limited to those individuals who are properly attired.

(c) All equipment used in the areas designated ~~area or cleanroom~~ for compounding must be made of a material that can be easily cleaned and disinfected.

(d) Cleaning shall be done using a germicidal detergent and sterile water. The use of a sporicidal agent is required to be used at least monthly.

(1) All ISO Class 5 surfaces, work table surfaces, carts, counters, and the cleanroom floor shall be cleaned at least daily. After each cleaning, disinfection using a suitable sterile agent shall occur on all ISO Class 5 surfaces, work table surfaces, carts, and counters.

(2) Walls, ceilings, storage shelving, tables, stools, and all other items in the ISO Class 7 or ISO Class 8 environment shall be cleaned at least monthly.

(3) Cleaning shall also occur after any unanticipated event that could increase the risk of contamination.

(4) All cleaning materials, such as wipers, sponges, and mops, shall be non-shedding and dedicated to use in the cleanroom, or ante-area, and segregated sterile compounding areas and shall not be removed from these areas except for disposal.

(e) Disinfection, using a suitable sterile agent, shall also occur on all surfaces in the ISO Class 5 PEC frequently, including:

(1) At the beginning of each shift;

(2) At least every 30 minutes when compounding involving human staff is occurring or before each lot;

(3) After each spill; and

(4) When surface contamination is known or suspected.

~~(d) Exterior workbench surfaces and other hard surfaces in the designated area, such as walls, floors, ceilings, shelves, tables, and stools, must be disinfected weekly and after any unanticipated event that could increase the risk of contamination.~~

(f) Pharmacies preparing sterile compounded preparations require the use of a PEC that provides ISO Class 5 air or better air quality. Certification and testing of primary and secondary engineering controls shall be performed no less than every six months and whenever the device or area designated for compounding is relocated, altered or a service to the facility is performed that would impact the device or area. Certification must be completed by a qualified technician who is familiar with certification methods and procedures in accordance with CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006-13, Revised May 20, 2015).

Certification records must be retained for at least 3 years. Unidirectional compounding aseptic isolators or compounding aseptic containment isolators may be used outside of an ISO Class 7 cleanroom if the isolator is certified to meet the following criteria:

(1) Particle counts sampled approximately 6-12 inches upstream of the critical exposure site shall maintain ISO Class 5 levels during compounding operations.

(2) Not more than 3520 particles (0.5 um and larger) per cubic meter shall be counted during material transfer, with the particle counter probe located as near to the transfer door as possible without obstructing transfer.

(3) Recovery time to achieve ISO Class 5 air quality shall be documented and internal procedures developed to ensure that adequate recovery time is allowed after material transfer before and during compounding operations.

Compounding aseptic isolators that do not meet the requirements as outlined in this subdivision or are not located within an ISO Class 7 cleanroom may only be used to compound preparations that meet the criteria specified in accordance with subdivision (d) of Section 1751.8 of Title 16, Division 17, of the California Code of Regulations.

(g) Pharmacies preparing parenteral cytotoxic sterile hazardous agents shall do so in accordance with Section 505.125.1 of Title 24, Chapter 5, of the California Code of Regulations, requiring a ~~laminar air flow hood~~ negative pressure PEC. Additionally, each PEC used to compound hazardous agents shall be externally vented. The ~~hood~~ negative pressure PEC must be certified ~~annually~~ every six months by a qualified technician who is familiar with CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006-13, Revised May 20, 2015). ~~the methods and procedures for certifying laminar air flow hoods and cleanroom requirements, in accordance with National Sanitation Foundation Standard 49 for Class II (Laminar Flow) Biohazard Cabinetry, as revised May, 1983 (available from the National Sanitation Foundation, 3475 Plymouth Road, P.O. Box 1468, Ann Arbor, Michigan 48106, phone number (313) 769-8010) or manufacturer's specifications. Certification records must be retained for at least 3 years.~~ Any drug preparation that is compounded in a PEC where hazardous drugs are prepared must be labeled as hazardous, regardless of whether the drug ingredients are considered hazardous.

(1) During the hazardous drug compounding that is performed in a compounding aseptic containment isolator, full hand hygiene and garbing must occur. Garbing shall include hair cover, facemask, beard cover (if applicable), polypropylene or low shedding gown that closes in the back, shoe covers, and two pairs of sterile ASTM D6978-05 standard gloves.

(h) If a compounding aseptic isolator is certified by the manufacturer to maintain ISO Class 5

air quality during dynamic operation conditions during compounding as well as during the transfer of ingredients into and out of the compounding aseptic isolator, then it may be placed into a non-ISO classified room. Individuals that use compounding aseptic isolators in this manner must ensure appropriate garbing, which consists of donning sterile gloves over the isolator gloves immediately before non-hazardous compounding. These sterile gloves must be changed by each individual whenever continuous compounding is ceased and before compounding starts again.

(i) Compounding aseptic isolator and compounding aseptic containment isolator used in the compounding of sterile drug preparations shall use non-turbulent unidirectional air flow patterns. A smoke patterned test shall be used to determine air flow patterns.

(j) Viable surface sampling shall be done at least every six months for all sterile-to-sterile compounding and quarterly for all non-sterile-to-sterile compounding. Viable air sampling shall be done by volumetric air sampling procedures which test a sufficient volume of air (400 to 1,000 liters) at each location and shall be done at least once every six months. Viable surface and viable air sampling shall be performed by a qualified individual who is familiar with the methods and procedures for surface testing and air sampling. Viable air sampling is to be performed under dynamic conditions that simulate actual production. Viable surface sampling is to be performed under dynamic conditions of actual compounding. When the environmental monitoring action levels are exceeded, the pharmacy shall identify the CFUs at least to the genus level in addition to conducting an investigation pursuant to its policies and procedures. Remediation shall include, at minimum, an immediate investigation of cleaning and compounding operations and facility management.

(k) The sterile compounding area in the pharmacy shall have a comfortable and well-lighted working environment, which includes a room temperature of 20-24 degrees Celsius (68-75 degrees Fahrenheit) or cooler to maintain comfortable conditions for compounding personnel when attired in the required compounding garb.

(l) A licensee may request a waiver of these provisions as provided in section 1735.6(f).

Note: Authority Cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052 and 4127, Business and Professions Code; and Section 18944, Health and Safety Code.

To Amend § 1751.5 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1751.5. Sterile ~~Injectable~~ Compounding Attire.

~~(a) When preparing cytotoxic agents, gowns and gloves shall be worn.~~

~~(b) (a)~~ When compounding sterile drug products preparations from one or more non-sterile ingredients the following standards must be met:

(1) ~~Cleanroom garb~~ Personal protective equipment consisting of a ~~low non-~~shedding coverall gown, head cover, face mask, facial hair covers (if applicable), and shoe covers must be worn inside the designated area at all times. For hazardous compounding double shoe covers are required.

(2) ~~Cleanroom garb~~ Personal protective equipment must be donned and removed ~~outside the designated area~~ in an ante-area or immediately outside the segregated compounding area.

(3) Personnel shall don personal protective equipment in an order that proceeds from those activities considered the dirtiest to those considered the cleanest. The following order is to be followed unless the pharmacy has a procedure in place that documents a method equivalent to or superior to the method described here: The donning of shoe covers or dedicated shoes, head and facial hair covers and face masks shall be followed by the washing of hands and forearms up to the elbows for 30 seconds with soap and water, drying hands, and then the donning of a non-shedding gown.

~~(3)~~ (4) Compounding personnel shall not wear any wrist, hand, finger, and or wrist other visible jewelry must be eliminated jewelry, piercing, headphones, earbuds, or personal electronic device. If jewelry cannot be removed then it must be thoroughly cleaned and covered with a sterile glove.

(4) ~~Head and facial hair must be kept out of the critical area or be covered.~~

(5) ~~Gloves made of low-shedding materials are required.~~ Sterile gloves that have been tested for compatibility with disinfection with isopropyl alcohol are required. Hand cleansing with a persistently active alcohol-based product followed by the donning of sterile gloves may occur within the ante or cleanroom. Gloves are to be routinely disinfected with sterile 70 percent isopropyl alcohol before entering or re-entering the PEC and after contact with non-sterile objects. Gloves shall also be routinely inspected for holes, punctures, or tears and replaced immediately if such are detected.

(6) Individuals experiencing exposed rashes, sunburn, weeping sores, conjunctivitis, active respiratory infections or other communicable disease, or those wearing cosmetics, nail polish, or artificial nails shall be excluded from the ISO Class 5 and ISO Class 7 compounding areas until their conditions are remedied.

~~(c) The requirements of subdivision (b) do not apply if a barrier isolator is used to compound sterile injectable products from one or more non-sterile ingredients.~~

(b) When preparing hazardous agents, appropriate gowns and personal protective equipment shall be worn regardless of the PECs used (e.g., biological safety cabinet and compounding aseptic containment isolator).

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

To Amend § 1751.6 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1751.6 Training of Sterile Injectable Compounding Staff, Patient, and Caregiver. Sterile Compounding Consultation; Training of Sterile Compounding Staff.

(a) Consultation shall be available to the patient and/or primary caregiver concerning proper use, storage, handling, and disposal of sterile injectable drug products preparations and related supplies furnished by the pharmacy.

(b) The pharmacist-in-charge shall ~~be responsible to~~ ensure that all pharmacy personnel

engaging in compounding sterile ~~injectable drug products~~ preparations shall have training and demonstrated competence in the safe handling and compounding of sterile ~~injectable drug products~~ preparations, including ~~cytotoxic~~ hazardous agents if the pharmacy compounds products with ~~cytotoxic~~ hazardous agents.

(c) Records of training and demonstrated competence shall be available for each individual and shall be retained for three years beyond the period of employment.

(d) The pharmacist-in-charge shall be responsible to ensure the continuing competence of pharmacy personnel engaged in compounding sterile ~~injectable drug products~~ preparations.

(e) Pharmacies that compound sterile ~~drug products from one or more non-sterile ingredients~~ preparations must comply with the following training requirements:

(1) The pharmacy must establish and follow a written program of training and performance evaluation designed to ensure that each person working in the designated area has the knowledge and skills necessary to perform their assigned tasks properly. This program of training and performance evaluation must address at least the following:

(A) Aseptic technique.

(B) Pharmaceutical calculations and terminology.

(C) Sterile ~~product~~ preparation compounding documentation.

(D) Quality assurance procedures.

(E) Aseptic preparation procedures.

(F) Proper hand hygiene, gowning and gloving technique.

(G) General conduct in the controlled area (aseptic area practices).

(H) Cleaning, sanitizing, and maintaining of the equipment and ~~used in~~ the controlled area.

(I) Sterilization techniques for compounding sterile drug preparations from one or more non-sterile ingredients.

(J) Container, equipment, and closure system selection.

(2) Each person ~~assigned to the controlled area~~ engaged in sterile compounding must successfully complete practical skills training in aseptic technique and aseptic area practices using models that are comparable to the most complex manipulations to be performed by the individual. Each pharmacist responsible for, or directly supervising and controlling, aseptic

techniques or practices, must demonstrate the skills needed to ensure the sterility of compounded drug preparations. Evaluation must include written testing and a written protocol of periodic routine performance checks involving adherence to aseptic area policies and procedures. Each person's proficiency and continuing training needs must be reassessed at least every 12 months. Results of these assessments must be documented and retained in the pharmacy for three years.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

To Amend § 1751.7 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1751.7. Sterile ~~Injectable~~ Compounding Quality Assurance and Process Validation.

(a) Any pharmacy engaged in compounding sterile ~~injectable drug products~~ preparations shall maintain, as part of its written policies and procedures, a written quality assurance plan including, in addition to the elements required by section 1735.8, a documented, ongoing quality assurance program that monitors personnel performance, equipment, and facilities. The end product shall be examined on a periodic sampling basis as determined by the pharmacist-in-charge to assure that it meets required specifications. The ~~Quality Assurance Program~~ shall include at least the following:

(1) Procedures for Cleaning and sanitization of the parenteral medication sterile preparation area.

~~(2) The storage of compounded sterile injectable products in the pharmacy and periodic documentation of refrigerator temperature.~~

~~(3)~~(2) Actions to be taken in the event of a drug recall.

~~(4)~~(3) Written justification of Documentation justifying the chosen expiration beyond use dates for compounded sterile injectable drug products preparations.

(b)(1) The pharmacy and each individual involved in the compounding of sterile drug

preparations must successfully demonstrate competency on aseptic technique and aseptic area practices before being allowed to prepare sterile drug preparations. The validation process shall be carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation. The validation process shall be representative of the types of manipulations, products and batch sizes the individual is expected to prepare and include a media-fill test. The validation process shall be as complicated as the most complex manipulations performed by staff and contain the same amount or greater amount of volume transferred during the compounding process. The same personnel, procedures, equipment, and materials must be used in the testing. Media used must have demonstrated the ability to support and promote growth. Completed medium samples must be incubated in a manner consistent with the manufacturer's recommendations. If microbial growth is detected, then each individual's sterile preparation process must be evaluated, corrective action taken and documented, and the validation process repeated.

(2) Each individual's competency must be revalidated at least every twelve months for sterile to sterile compounding and at least every six months for individuals compounding sterile preparations from non-sterile ingredients.

(3) The pharmacy's validation process on aseptic technique and aseptic area practices must be revalidated whenever:

(A) the quality assurance program yields an unacceptable result,

(B) there is any change in the compounding process, the Primary Engineering Control (PEC), or the compounding environment. For purposes of this subsection, a change includes, but is not limited to, when the PEC is moved, repaired or replaced, when the facility is modified in a manner that affects airflow or traffic patterns, or when improper aseptic techniques are observed.

(4) The pharmacy must document the validation and revalidation process.

~~Each individual involved in the preparation of sterile injectable drug products preparations must first successfully demonstrate competency by successfully performing aseptic media fill tests complete a validation process on technique before being allowed to prepare sterile~~

~~injectable drug products preparations. The validation process shall be carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation. The validation process shall be representative of all types of manipulations, products and batch sizes the individual is expected to prepare. The media fill testing process shall be as complicated as the most complex manipulations performed by staff and contain the same amount or greater of volume transferred during the compounding process. The same personnel, procedures, equipment, and materials must be involved. Media used must have demonstrated the ability to support and promote growth. Completed medium media samples must be incubated in a manner consistent with the manufacturer's recommendations. If microbial growth is detected, then the employee's sterile preparation process must be evaluated, corrective action taken and documented, and the validation process media fill testing repeated. Personnel competency must be revalidated at least every twelve months for sterile to sterile compounding and at least every six months for individuals compounding sterile products from non-sterile ingredients. Aseptic work practice assessments via media fill tests must be revalidated, as appropriate to the circumstance or personnel found to be deficient, whenever the quality assurance program yields an unacceptable result, when the compounding process changes, equipment used in the compounding of sterile injectable drug products preparations is repaired or replaced, the facility is modified in a manner that affects airflow or traffic patterns, or whenever improper aseptic techniques are observed. Revalidation must be documented.~~

(c) All sterile compounding personnel must successfully complete an initial competency evaluation. In addition, immediately following the initial hand hygiene and garbing procedure, each individual who may be required to do so in practice must successfully complete a gloved fingertip (all fingers on both hands) sampling procedure (zero colony forming units for both hands) at least three times before initially being allowed to compound sterile drug preparations.

(d) Re-evaluation of garbing and gloving competency shall occur at least every 12 months for personnel compounding products made from sterile ingredients and at least every six months for personnel compounding products from non-sterile ingredients.

~~(e)~~(e)(1) Batch-produced sterile drug preparations compounded from one or more non-sterile ingredients, except as provided in paragraph (2), shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens. Sterility testing shall be USP chapter 71 compliant and pyrogens testing shall confirm acceptable levels of pyrogens per USP chapter 85 limits, before dispensing. This requirement of end product testing confirming sterility and acceptable levels of pyrogens prior to dispensing shall apply regardless of any sterility or pyrogen testing that may have been conducted on any ingredient or combination of ingredients that were previously non-sterile. Exempt from pyrogen testing are topical ophthalmic and inhalation preparations.

(2) The following non-sterile-to-sterile batch drug preparations do not require end product testing for sterility and pyrogens:

(A) Preparations for self-administered ophthalmic drops in a quantity sufficient for administration to a single patient for 30 days or less pursuant to a prescription.

(B) Preparations for self-administered inhalation in a quantity sufficient for administration to a single patient for 5 days or less pursuant to a prescription.

~~Batch-produced sterile injectable drug products compounded from one or more non-sterile ingredients shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens.~~

~~(d) Batch-produced sterile to sterile transfers shall be subject to periodic testing through process validation for sterility as determined by the pharmacist in charge and described in the written policies and procedures.~~

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

To Amend § 1751.8 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1751.8. Beyond Use Dating for Sterile Compounded Drug Preparations.

In conformity with and in addition to the requirements and limitations of section 1735.2, subdivision (h), every sterile compounded drug preparation shall be given and labeled with a beyond use date that does not exceed the shortest expiration date or beyond use date of any ingredient in sterile compounded drug preparation, nor the chemical stability of any one ingredient in the sterile compounded drug preparation, nor the chemical stability of the combination of all ingredients in the sterile compounded drug preparation, and that, in the absence of passing a sterility test in accordance with standards for sterility testing found in Chapter 797 of the United States Pharmacopeia – National Formulary (USP37-NF32) Through 2nd Supplement (37th Revision, Effective December 1, 2014), hereby incorporated by reference, that would justify an extended beyond use date, conforms to the following limitations:

(a) The beyond use date shall specify that storage and exposure periods cannot exceed 48 hours at controlled room temperature, 14 days at controlled cold temperature, and 45 days in solid frozen state, where the sterile compounded drug preparation is compounded solely with aseptic manipulations and all of the following apply:

(1) The preparation is compounded entirely within an ISO Class 5 PEC located in an ISO Class 7 cleanroom with an ante-area or compounded entirely within a CAI which meets the requirements in 1751.4(f)(1)-(3), using only sterile ingredients, products, components, and devices; and

(2) The compounding process involves transferring, measuring, and mixing manipulations using not more than three commercially manufactured packages of sterile preparations and not more than two entries into any one sterile container or package of sterile preparations or administration containers/devices to prepare the drug preparation; and

(3) Compounding manipulations are limited to aseptically opening ampules, penetrating disinfected stoppers on vials with sterile needles and syringes or spiked transfer devices, and transferring sterile liquids in sterile syringes to sterile administration devices, package

containers of other sterile preparations, and containers for storage dispensing.

(b) The beyond use date shall specify that storage and exposure periods cannot exceed 30 hours at controlled room temperature, 9 days at controlled cold temperature, and 45 days in solid frozen state, where the sterile compounded drug preparation is compounded solely with aseptic manipulations and all of the following apply:

(1) The preparation is compounded entirely within an ISO Class 5 PEC located in an ISO Class 7 cleanroom with an ante-area or compounded entirely within a CAI which meets the requirements in 1751.4(f)(1)-(3), using multiple individual or small doses of sterile preparations combined or pooled to prepare a compounded sterile preparation that will be administered either to multiple patients or to one patient on multiple occasions; and

(2) The compounding process involves complex aseptic manipulations other than the single-volume transfer; and

(3) The compounding process requires unusually long duration such as that required to complete dissolution or homogenous mixing.

(c) The beyond use date shall specify that storage and exposure periods cannot exceed 24 hours at controlled room temperature, 3 days at controlled cold temperature, and 45 days in solid frozen state, where the sterile compounded drug preparation is compounded solely with aseptic manipulations using non-sterile ingredients, regardless of intervening sterilization of that ingredient and the following applies:

(1) The preparation is compounded entirely within an ISO Class 5 PEC located in an ISO Class 7 cleanroom with an ante-area or compounded entirely within a CAI which meets the requirements in 1751.4(f)(1)-(3).

(d) The beyond use date shall specify that storage and exposure periods cannot exceed 12 hours where the sterile compounded drug preparation is compounded solely with aseptic manipulations and all of the following apply:

(1) The preparation was compounded entirely within an ISO Class 5 PEC that is located in a segregated sterile compounding area and restricted to sterile compounding activities, using only sterile ingredients, components, and devices, by personnel properly cleansed and garbed; and

(2) The compounding process involves simple transfer of not more than three commercially manufactured packages of sterile nonhazardous preparations or diagnostic radiopharmaceutical preparations from the manufacturer's original containers; and

(3) The compounding process involves not more than two entries into any one container or package (e.g., bag, vial) of sterile infusion solution or administration container/device.

(e) Where any sterile compounded drug preparation was compounded either outside of an ISO class 5 PEC or under conditions that do not meet all of the requirements for any of subdivisions

(a) through (d), the sterile compounded drug preparation shall be labeled "for immediate use only" and administration shall begin no later than one hour following the start of the compounding process. Unless the "immediate use" preparation is immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, the preparation shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the compounded sterile preparation, and the exact one-hour beyond use date and time. If administration has not begun within one hour following the start of the compounding process, the compounded sterile preparation shall be promptly, properly, entirely, and safely discarded. This provision does not preclude the use of a PEC to compound an "immediate use" preparation. A PEC used solely to compound 'immediate use' preparations need not be placed within an ISO Class 7 cleanroom, with an ante-area. Such "immediate use" preparations shall be compounded only in those limited situations where there is a need for immediate administration of a sterile preparation compounded outside of an ISO class 5 environment and where failure to administer could result in loss of life or intense suffering. Any such compounding shall be only in such quantity as is necessary to meet the immediate need and the circumstance causing the immediate need shall be documented in accordance with policies and procedures.

(f) The beyond use date for any compounded allergen extracts shall be the earliest manufacturer expiration date of the individual allergen extracts.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

To Add § 1751.9 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1751.9 Single-Dose and Multi-Dose Containers; Limitations on Use

(a) Single-dose ampules are for immediate use only, and once opened shall not be stored for any time period.

(b) Unless otherwise specified by the manufacturer, any single-dose container of a compounded sterile drug preparation other than an ampule, such as a bag, bottle, syringe or vial, shall be used in its entirety or its remaining contents shall be labeled with a beyond use date and discarded within the following time limit, depending on the environment:

(1) When needle-punctured in an environment with air quality worse than ISO Class 5, within one (1) hour;

(2) When needle-punctured in an environment with ISO Class 5 or better air quality, within six (6) hours. A container must remain within the ISO Class 5 or better air quality to be used for the full six hours, unless otherwise specified by the manufacturer.

(3) If the puncture time is not noted on the container, the container must immediately be discarded.

(c) Unless otherwise specified by the manufacturer, a multi-dose container stored according to the manufacturer's specifications shall be used in its entirety or its remaining contents shall be labeled with a beyond use date and discarded within twenty eight (28) days from initial opening or puncture. Any multi-dose container not stored according to the manufacturer's specifications shall be discarded immediately upon identification of such storage circumstance. If any open container is not labeled with a beyond use date or the beyond use date is not correct, the container must immediately be discarded.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

To Amend § 1751.10 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

~~1751.8.~~ 1751.10. Sterile ~~Injectable~~ Compounding Reference Materials.

In any pharmacy engaged in compounding sterile ~~injectable drug products~~ preparations, there shall be current and appropriate reference materials regarding the compounding of sterile ~~injectable drug products~~ preparations located in or immediately available to the pharmacy.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

To Add Article 7.5 of Division 17 of Title 16 of the California Code of Regulations to read as follow

Article 7.5 Furnishing for Home Administration

To Amend § 1751.10 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

~~1751.10.~~ 1752. Furnishing to Parenteral Patient at Home.

Subject to all provisions of this article, a pharmacist may carry and furnish to a patient at home dangerous drugs, other than controlled substances, and devices for parenteral therapy when the dangerous drug or device is one currently prescribed for the patient.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code.

To Amend § 1751.11 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

~~1751.11.~~ 1753. Furnishing to Home Health Agencies and Licensed Hospices.

Subject to the following conditions, a licensed pharmacy may furnish to a home health agency licensed under provisions of Chapter 8 (commencing with section 1725 of Division 2 of the Health and Safety Code) or to a hospice licensed under provisions of Chapter 8.5 (commencing with section 1745 of Division 2 of the Health and Safety Code) dangerous drugs for parenteral therapy other than controlled substances, in a portable container for furnishing to patients at home for emergency treatment or adjustment of parenteral drug therapy by the home health agency or licensed hospice.

(a) The pharmacy, having ownership and responsibility for the portable containers, shall ensure that each portable container is:

- (1) furnished by a registered pharmacist;
- (2) sealed in such a manner that a tamper-proof seal must be broken to gain access to the drugs;
- (3) under the effective control of a registered nurse, pharmacist or delivery person at all times when not in the pharmacy;
- (4) labeled on the outside of the container with a list of the contents;
- (5) maintained at an appropriate temperature according to United States Pharmacopeia Standards (1995, 23rd Revision), and protected at all times from extreme temperatures that could damage the contents.

(b) The portable container may contain up to:

- (1) 1000mL of 0.9% sodium chloride intravenous infusion in containers of a size determined by the pharmacy;
- (2) 1000mL of 5% dextrose in water injection in containers of a size determined by the

pharmacy;

(3) two vials of urokinase 5000 units;

(4) Each of the following items shall be in sealed, unused containers; the furnishing pharmacy may select any or all of these dangerous drugs in up to five dosage units for inclusion in the sealed, portable container:

(A) heparin sodium lock flush 100 units/mL;

(B) heparin sodium lock flush 10 units/mL;

(C) epinephrine HCl solution 1:1,000;

(D) epinephrine HCl solution 1:10,000;

(E) diphenhydramine HCl 50mg/mL;

(F) methylprednisolone 125mg/2mL;

(G) normal saline, preserved, up to 30 mL vials;

(H) naloxone 1mg/mL 2 mL;

(I) droperidol 5mg/2mL;

(J) prochlorperazine 10mg/2mL;

(K) promethazine 25mg/mL;

(L) dextrose 25gms/50mL;

(M) glucagon 1mg/mL;

(N) insulin (human) 100 units/mL;

(O) bumetamide 0.5mg/2mL;

(P) furosemide 10mg/mL;

(Q) EMLA Cream 5 gm tube;

(R) Lidocaine 1 percent 30mL vials.

(5) The pharmacy shall ensure that the specific dangerous drugs and quantities to be included in the portable container are listed in the home health agency's or licensed hospice's policies and procedures.

(c) The pharmacy shall not supply a portable container to a home health agency or licensed hospice which does not:

(1) implement and maintain policies and procedures for:

- (A) the storage, temperature stability and transportation of the portable container;
 - (B) the furnishing of dangerous drugs from the portable container upon the written or oral authorization of a prescriber; and
 - (C) a specific treatment protocol for the administration of each medication contained in the portable container.
- (2) have the policies, procedures and protocols reviewed and revised (as needed) annually by a group of professional personnel including a physician and surgeon, a pharmacist and a registered nurse.
- (d) A copy of these policies, procedures and protocols shall be maintained by the furnishing pharmacy from each home health agency or licensed hospice for which the pharmacy furnishes portable containers.
 - (e) In cases where a drug has been administered to a patient pursuant to the oral order of a licensed prescriber, the pharmacy shall ensure that the oral order is immediately written down by the registered nurse or pharmacist and communicated by copy or fax within 24 hours to the furnishing pharmacy, with a copy of the prescriber-signed document forwarded to the dispensing pharmacy within 20 days.
 - (f) The pharmacy shall ensure that within seven days (168 hours) after the seal has been broken on the portable container, the home health agency's director of nursing service or a registered nurse employed by the home health agency or licensed hospice returns the container to the furnishing pharmacy. The furnishing pharmacy shall then perform an inventory of the drugs used from the container, and if the container will be reused, must restock and reseal the container before it is again furnished to the home health agency or licensed hospice.
 - (g) The furnishing pharmacy shall have written policies and procedures for the contents, packaging, inventory monitoring, labeling and storage instructions of the portable container.
 - (h) The furnishing pharmacy shall ensure that the home health agency or licensed hospice returns the portable containers to the furnishing pharmacy at least every 60 days for verification of product quality, quantity, integrity and expiration dates, or within seven days (168 hours) after the seal has been broken.

(i) The furnishing pharmacy shall maintain a current inventory and record of all items placed into and furnished from the portable container.

Note: Authority cited: Sections 4005 and ~~and~~ 4057, Business and Professions Code. Reference: Sections 4040, 4057, 4081 and 4332, Business and Professions Code.

To Amend § 1751.12 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

~~1751.12~~ 1754. Obligations of a Pharmacy Furnishing Portable Containers.

(a) A licensed pharmacy shall not issue portable containers to any home health agency or licensed hospice unless the home health agency or licensed hospice complies with provisions of section ~~1751.11~~ 1753.

(b) A licensed pharmacy shall cease to furnish portable containers to a home health agency or licensed hospice if the home health agency or licensed hospice does not comply with provisions of section ~~1751.11~~ 1753.

Note: Authority cited: Sections 4005 and 4057, Business and Professions Code. Reference: Sections 4040, 4057, 4081 and 4332, Business and Professions Code.

BOARD OF PHARMACY
Order of Adoption

Add §1746.5 to Article 5 of Division 17 of Title 16 of the California Code of Regulations as follows:

§1746.5 Pharmacists Furnishing Travel Medications.

(a) For purposes of Business and Professions Code section 4052(a)(10)(A)(3), prescription medications “not requiring a diagnosis” means a prescription medication that is either:

(1) For a condition that is both self-diagnosable and recognized as self-treatable by the federal Center for Disease Control and Prevention’s (CDC) Health Information for International Travel (commonly called the Yellow Book), or

(2) A prophylactic.

(b) A pharmacist furnishing prescription medications not requiring a diagnosis that are recommended by the CDC for individuals traveling outside the 50 states and the District of Columbia pursuant to section 4052(a)(10) of the Business and Professions Code shall follow the requirements of this section.

(c) Training: A pharmacist who furnishes travel medications shall keep documentation of the following on site and available for inspection by the Board:

(1) Completion of an immunization certificate program that meets the requirements of Business and Professions Code section 4052.8(b)(1),

(2) Completion of an travel medicine training program, which must consist of at least 10 hours of training and cover each medication related element of the International Society of Travel Medicine’s Body of Knowledge for the Practice of Travel Medicine (2012),

(3) Completion of the CDC Yellow Fever Vaccine Course, and

(4) Current basic life support certification.

(d) Continuing Education: Pharmacists must complete two hours of ongoing continuing education focused on travel medicine, separate from continuing education in immunizations and vaccines, from an approved provider once every two years.

(e) Prior to furnishing travel medication, a pharmacist shall perform a good faith evaluation of the patient, including evaluation of a patient travel history using destination-specific travel criteria. The travel history must include all the information necessary for a risk assessment

during pre-travel consultation, as identified in the CDC Yellow Book. An example of an appropriate and comprehensive travel history is available on the Board's website.

(f) Notifications: The pharmacist shall notify the patient's primary care provider of any drugs and/or devices furnished to the patient within 30 days of the date of furnishing, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by the primary care provider. If the patient does not have a primary care provider, or is unable to provide contact information for his or her primary care provider, the pharmacist shall provide the patient with written record of the drugs and/or devices furnished and advise the patient to consult a physician of the patient's choice.

(g) Documentation: For each travel medication furnished by a pharmacist, a patient medication record shall be maintained and securely stored in physical or electronic manner such that the information required by title 42, section 300aa-25 of the United States Code and title 16, sections 1707.1 and 1717 of the California Code of Regulations is readily retrievable during the pharmacy or facility's normal operating hours. A pharmacist shall provide the patient with a progress note, which fully documents the clinical assessment and travel medication plan. An example of an appropriate and comprehensive progress note is available on the Board's website.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Section 4052 and 4052.8, Business and Professions Code.

Virginia Herold
Executive Officer
Board of Pharmacy

ATTACHMENT 2

California State Board of Pharmacy
Specific Language to Amend 16 CCR § 1760

Initial proposed changes indicated with single ~~striketrough~~ for deletions and single underline for additions.

Modified changes indicated with ~~double striketrough~~ for deletions and double underline for additions

Amend Section 1760 to Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1760. Disciplinary Guidelines.

In reaching a decision on a disciplinary action under the Administrative Procedure Act (Government Code section 11400 et seq.) the board shall consider the disciplinary guidelines entitled "Disciplinary Guidelines" (Rev. ~~10/2007-7/2015~~ 10/2015), which are hereby incorporated by reference.

Deviation from these guidelines and orders, including the standard terms of probation, is appropriate where the board, in its sole discretion, determines that the facts of the particular case warrant such a deviation-the presence of mitigating factors; the age of the case; evidentiary problems.

Note: Authority cited: Sections 315, 315.2, 315.4 and 4005, Business and Professions Code; and Section 11400.20, Government Code. Reference: Sections 315, 315.2, 315.4, 4300 - 4313 and ~~4301~~, Business and Professions Code; and Sections 11400.20 and 11425.50(e), Government Code.

BOARD OF PHARMACY

Order of Adoption

Add and Adopt §1746.4, which is new regulation text as follows:

§1746.4 Pharmacists Initiating and Administering Vaccines.

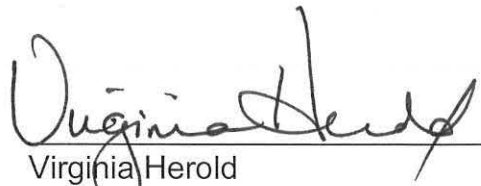
- (a) A pharmacist initiating and/or administering vaccines pursuant to sections 4052 or 4052.8 of the Business and Professions Code shall follow the requirements specified in subdivisions (b) through (f) of this section.
- (b) Training: A pharmacist who initiates and/or administers any vaccine shall keep documentation of:
 - (1) Completion of an approved immunization training program, and
 - (2) Basic life support certification.

This documentation shall be kept on site and available for inspection.

- (c) Continuing Education: Pharmacists must complete one hour of ongoing continuing education focused on immunizations and vaccines from an approved provider once every two years.
- (d) Notifications: The pharmacist shall notify the patient's primary care provider of any vaccines administered to the patient, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by the primary care provider. Primary care provider notification must take place within 14 days of the administration of any vaccine. If the patient does not have a primary care provider, or is unable to provide contact information for his or her primary care provider, the pharmacist shall advise the patient to consult an appropriate health care provider of the patient's choice. If known, notification to the prenatal care provider of immunizations provided to pregnant women must take place within 14 days of the administration of any vaccine.
- (e) Immunization Registry: A pharmacist shall fully report the information described in Section 120440(c) of the Health and Safety Code into one or more state and/or local immunization information systems within 14 days of the administration of any vaccine. The pharmacist shall inform the patient or the patient's guardian of immunization record sharing preferences, detailed in Section 120440(e) of the Health and Safety Code.
- (f) Documentation: For each vaccine administered by a pharmacist, a patient vaccine administration record shall be maintained in an automated data processing or manual record mode such that the required information under title 42, section 300aa-25 of the United States Code is readily retrievable during the pharmacy or facility's normal operating hours. A pharmacist shall provide the patient with a

vaccine administration record, which fully documents the vaccines administered by the pharmacist. An example of an appropriate vaccine administration record is available on the Board of Pharmacy's website.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4052 and 4052.8, Business and Professions Code, Section 120440, Health and Safety Code, and Sections 300aa – 25, Title 42, United States Code.



Virginia Herold
Executive Officer
California State Board of Pharmacy

ATTACHMENT 3

Title 16. Board of Pharmacy

PROPOSED LANGUAGE

Amend Section 1703 of Article 1 of Division 17 of Title 16 of the California Code of Regulations to read:

§ 1703. Delegation of Certain Functions.

The power and discretion conferred by law upon the board to receive and file accusations; issue notices of hearing, statements to respondent and statements of issues; receive and file notices of defense; determine the time and place of hearings under Section 11508 of the Government Code; set and calendar cases for hearing and perform other functions necessary to the business-like dispatch of the business of the board in connection with proceedings under the provisions of Sections 11500 through 11528 of the Government Code, prior to the hearing of such proceedings; the certification and delivery or mailing of copies of decisions under Section 11518 of said code; ~~and~~ issue summary suspension orders or notices of suspension under Section 4311 of the Business and Professions Code; make changes to its regulations without regulatory effect pursuant to Title 1, California Code of Regulations Section 100; and approve waivers pursuant to Section 4076.5(e) are hereby delegated to and conferred upon the executive officer, or, in his or her absence from the office of the board, the acting executive officer.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4003, 4076.5 and 4311, Business and Professions Code.

Title 16. Board of Pharmacy

Modified Language

Changes made to the originally proposed language are shown by ~~double strikethrough~~ for deleted language and double underline for added language. (Additionally, the modified text is listed in red for color printers.)

To Amend Section 1744 of Article 5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1744. Drug Warnings

Pursuant to Business and Professions Code Section 4074, a pharmacist shall inform the patient or his or her representative of the harmful effects of certain drugs dispensed by prescription.

(a) Because ~~the following classes of drugs may impair a person's ability to drive~~ operate a motor vehicle or vessel, ~~operate machinery when taken alone or in combination with alcohol~~ a pharmacist shall include a written label on the drug container indicating that the drug may impair a person's ability to operate a vehicle or vessel:

- (1) Muscle relaxants.
- (2) Analgesics ~~with central nervous system depressant effects.~~
- ~~(3) Antipsychotic drugs with central nervous system depressant effects including phenothiazines~~
- (4) Antidepressants with central nervous system depressant effects.
- (5) Antihistamines, motion sickness agents, antipruritics, antinauseants, anticonvulsants and antihypertensive agents with central nervous system depressant effects.
- (6) All Schedule II, III, IV and V agents with central nervous system depressant effects. ~~or narcotic controlled substances as set forth in Health and Safety Code at Section 11055 et seq. prescribed in doses which could have an adverse effect on a person's ability to operate a motor vehicle.~~
- (7) Anticholinergic agents and other drugs ~~which~~ that may impair vision.
- (7) Any other drug which, based on the pharmacist's professional judgment, may impair a patient's ability to operate a vehicle or vessel.

(b) Because ~~the following are examples classes of drugs pose a substantial risk to the person~~ consuming the drug when taken in combination with alcohol, a pharmacist shall ~~provide a written warning notice on the label to include a written label on the drug container to~~ provide a written warning notice on the label to include a written label on the drug container to alert the patient about possible potentiating effects: ~~which may have harmful effects when taken in combination with alcohol.~~ These may or may not affect a person's ability to operate a motor vehicle:

- (1) Disulfiram and other drugs (e.g., chlorpropamide, metronidazole) which may cause a disulfiram-like reaction.
- (2) Mono amine oxidase inhibitors.
- (3) Nitrates.
- (4) Cycloserine.
- (5) Antidiabetic agents including insulin and sulfonylureas (due to risk of hypoglycemia).
- (6) Any other drug which, based upon a pharmacist's professional judgment, may pose a substantial risk to the person consuming the drug when taken in combination with alcohol.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4022,~~4055~~ and 4074, Business and Professions Code.

Title 16. Board of Pharmacy

Modified Text

Changes made to the originally proposed language are shown by **double strikethrough** for deleted language and **double underline** for added language. (Additionally, the modified text is listed in red for color printers.)

To Amend Section 1707.5 of Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1707.5. Patient-Centered Labels for Prescription Drug Containers; Requirements.

- (a) Labels on drug containers dispensed to patients in California shall conform to the following format:
- (1) Each of the following items, and only these four items, shall be clustered into one area of the label that comprises at least 50 percent of the label. Each item shall be printed in at least a 12-point sans serif typeface, and listed in the following order:
 - (A) Name of the patient
 - (B) Name of the drug and strength of the drug. For the purposes of this section, “name of the drug” means either the manufacturer's trade name of the drug, or the generic name and the statement “generic for _____” where the brand name is inserted ~~into the parentheses. If, it has been at least five years since the expiration of the brand name’s patent or, if~~ in the professional judgment of the pharmacist, the brand name is no longer widely used, the label may list only the generic name of the drug and outside of the patient centered area, the name of the manufacturer.
 - (C) The directions for the use of the drug.
 - (D) The condition or purpose for which the drug was prescribed if the condition or purpose is indicated on the prescription.
 - (2) For added emphasis, the label shall also highlight in bold typeface or color, or use blank space to set off the items listed in subdivision (a)(1).
 - (3) The remaining required elements for the label specified in section 4076 of the Business and Professions Code, as well as any other items of information appearing on the label or the container, shall be printed so as not to interfere with the legibility or emphasis of the primary elements specified in paragraph (1) of subdivision (a). These additional elements may appear in any style, font, and size typeface.
 - (4) When applicable, directions for use shall use one of the following phrases:
 - (A) Take 1 [insert appropriate dosage form] at bedtime
 - (B) Take 2 [insert appropriate dosage form] at bedtime
 - (C) Take 3 [insert appropriate dosage form] at bedtime
 - (D) Take 1 [insert appropriate dosage form] in the morning
 - (E) Take 2 [insert appropriate dosage form] in the morning
 - (F) Take 3 [insert appropriate dosage form] in the morning

- (G) Take 1 [insert appropriate dosage form] in the morning, and Take 1 [insert appropriate dosage form] at bedtime
- (H) Take 2 [insert appropriate dosage form] in the morning, and Take 2 [insert appropriate dosage form] at bedtime
- (I) Take 3 [insert appropriate dosage form] in the morning, and Take 3 [insert appropriate dosage form] at bedtime
- (J) Take 1 [insert appropriate dosage form] in the morning, 1 [insert appropriate dosage form] at noon, and 1 [insert appropriate dosage form] in the evening
- (K) Take 2 [insert appropriate dosage form] in the morning, 2 [insert appropriate dosage form] at noon, and 2 [insert appropriate dosage form] in the evening
- (L) Take 3 [insert appropriate dosage form] in the morning, 3 [insert appropriate dosage form] at noon, and 3 [insert appropriate dosage form] in the evening
- (M) Take 1 [insert appropriate dosage form] in the morning, 1 [insert appropriate dosage form] at noon, 1 [insert appropriate dosage form] in the evening, and 1 [insert appropriate dosage form] at bedtime
- (N) Take 2 [insert appropriate dosage form] in the morning, 2 [insert appropriate dosage form] at noon, 2 [insert appropriate dosage form] in the evening, and 2 [insert appropriate dosage form] at bedtime
- (O) Take 3 [insert appropriate dosage form] in the morning, 3 [insert appropriate dosage form] at noon, 3 [insert appropriate dosage form] in the evening, and 3 [insert appropriate dosage form] at bedtime
- (P) If you have pain, take __ [insert appropriate dosage form] at a time. Wait at least __ hours before taking again. Do not take more than __ [appropriate dosage form] in one day

(b) By October 2011, and updated as necessary, the board shall publish on its Web site translation of the directions for use listed in subdivision (a)(4) into at least five languages other than English, to facilitate the use thereof by California pharmacies.

(c) The board shall collect and publish on its Web site examples of labels conforming to these requirements, to aid pharmacies in label design and compliance.

(d) The pharmacy shall have policies and procedures in place to help patients with limited or no English proficiency understand the information on the label as specified in subdivision (a) in the patient's language. The pharmacy's policies and procedures shall be specified in writing and shall include, at minimum, the selected means to identify the patient's language and to provide interpretive services and translation services in the patient's language. The pharmacy shall, at minimum, provide interpretive services in the patient's language, if interpretive services in such language are available, during all hours that the pharmacy is open, either in person by pharmacy staff or by use of a third-party interpretive service available by telephone at or adjacent to the pharmacy counter.

~~(e) The board shall re-evaluate the requirements of this section by December 2013 to ensure optimal conformance with Business and Professions Code section 4076.5.~~

~~(f)~~ (e) As used in this section, "appropriate dosage form" includes pill, caplet, capsule or tablet.

Note: Authority cited: Sections 4005 and 4076.5, Business and Professions Code. Reference: Sections 4005, 4076 and 4076.5, Business and Professions Code.

Title 16. Board of Pharmacy
Modified Text

Proposal to add new Article 9.1 of Division 17 of Title 16 of the California Code of Regulations and a new Article title as follows:

Article 9.1. Prescription Drug Take-Back Programs

Proposal to add § 1776 of Article 9.1 of Division 17 of Title 16 of the California Code of Regulations as follows:

Section 1776 Prescription Drug Take-Back Programs: Authorization

Pharmacies, hospitals/clinics with onsite pharmacies, distributors and reverse distributors licensed by the board ~~and licensed skilled nursing facilities~~ may offer, under the requirements in this article, specified prescription drug take-back services to the public to provide options for the public to destroy unwanted, unused or outdated prescription drugs. Each of these entities must comply with regulations of the federal Drug Enforcement Administration and the Board of Pharmacy regulations contained in this article.

All board-licensed authorized collectors should be vigilant to prevent the public patients or their agents from disposing of prohibited items through drug take-back collection methods. Federal, state and other laws prohibit the deposit ~~in drug take-back receptacles~~ of the following in pharmaceutical take back receptacles: medical sharps and needles (e.g., insulin syringes), iodine-containing medications, mercury-containing thermometers, radiopharmaceuticals, hazardous medications (cancer chemotherapy drugs, cytotoxic drugs), illicit drugs, and compressed cylinders or aerosols (e.g., asthma inhalers).

Only California-licensed pharmacies, hospitals/clinics with onsite pharmacies, and drug distributors (licensed wholesalers and third- party logistics providers) who are registered with the Drug Enforcement Administration (DEA) as collectors and licensed in good standing with the board ~~and are also registered with the Drug Enforcement Administration as collectors~~ may host a pharmaceutical take-back receptacle ~~as participate in drug take-back programs~~ authorized under this article.

Note: Authority cited: Section 4005, Business and Professions Code.

Reference: Sections 4005, Business and Professions Code and Section 1317.40, Title 21 Code of Federal Regulations.

Proposal to add § 1776.1 of Article 9.1 of Division 17 of Title 16 of the California Code of Regulations as follows:

Section 1776.1 Pharmacies

- ~~(a) Pharmacies may assist patients seeking to destroy unwanted, previously dispensed prescription drugs as provided in this article. Provision of such services is voluntary.~~
- (b) (a) Pharmacies may provide take-back services to the public patients as provided in sections 1776 - 1776.4. Retail pharmacies and hospital/clinics with onsite pharmacies may establish collection receptacles in their facilities. Pharmacies may operate collection receptacles as specified in in section 1776.4 in skilled nursing facilities licensed under California Health and Safety Code section 1250(c).
- ~~(c) (b) There are multiple federal, and state and local requirements governing the collection and destruction of dangerous drugs. Pharmacies are expected to know and adhere to these requirements when operating a prescription drug take-back program.~~
- ~~(d) (c) For purposes of this article, prescription drugs means dangerous drugs as defined by California Business and Professions Code section 4022, which includes including controlled substances. Controlled substances may be commingled in collection receptacles or mail back packages or envelopes with other dangerous drugs. Once drugs are deposited into a collection receptacle or mail back envelope or package by a consumer patient, they are not to be separated by pharmacy staff or others.~~
- (d) (d) The following dangerous drugs and devices are expressly prohibited from collection in a pharmacy's prescription drug take-back collection receptacles: medical sharps and needles (e.g., insulin syringes), iodine-containing medications, mercury-containing thermometers, radiopharmaceuticals, antineoplastic agents (cancer chemotherapy drugs, cytotoxic drugs), and compressed cylinders or aerosols (e.g., asthma inhalers). Signage informing the public of the items prohibited from being deposited shall be placed posted on collection receptacles as referenced in section 1776.3.
- (e) (e) Prescription drugs that are eligible for collection in drug take-back programs operated by pharmacies are only those prescription drugs that have been dispensed by any pharmacy or practitioner to a patient or patient's agent consumer. Dangerous drugs that have not been dispensed to patients consumers for use (such as outdated drug stock in a pharmacy, drug samples provided to a medical practitioner or medical waste) may not be collected in as part of a pharmacy's drug take-back programs.
- (1) Pharmacy staff shall not review, accept, count, sort, or handle any prescription drugs returned from the public.
- (2) A pharmacy shall not accept or possess prescription drugs returned to the pharmacy by skilled nursing homes, residential care homes, other facilities, health care practitioners or other entities.
- (3) A pharmacy shall not dispose of quarantined, recalled or outdated prescription drugs from pharmacy stock in a drug take-back collection receptacle. ~~Instead the pharmacy must return these items to a reverse distributor.~~
- ~~(f) (f) A pharmacy must be registered with the federal Drug Enforcement Administration as a collector for purposes of operating maintaining a prescription drug take-back collection receptacle program. Such pharmacies cannot employ anyone convicted of a felony related to controlled substances, or anyone who has had a DEA permit denied,~~

surrendered or revoked.

- (h) (g) Any pharmacy that ~~operates~~ maintains a drug take-back collection receptacle program as authorized in this article shall notify the board on a form designated by the board within 30 days of establishing the collection program. Additionally:
- (1) Any pharmacy that ceases to ~~operate~~ maintain a drug take-back collection receptacle program shall notify the board within 30 days on a form designated by the board. ~~If the pharmacy later ceased to operate the collection receptacle, the pharmacy must notify the board within 30 days.~~
 - (2) Any pharmacy ~~operating a mail back program or~~ maintaining collection receptacles shall identify to the board that it provides such services annually at the time of renewal of the pharmacy license, and shall identify all locations where its collection receptacles are located.
 - (3) Any tampering with a ~~storage~~ collection receptacle or theft of deposited drugs shall be reported to the board with 14 days.
 - (4) Any tampering, damage or theft of a removed liner shall be reported to the board within 14 days.
- (h) If the pharmacy ~~later ceases to operate~~ maintain ~~the~~ a registered collection receptacle, the pharmacy must notify the Drug Enforcement Administration within 30 days.
- (i) A pharmacy shall not provide take-back services to consumers, as provided in sections 1776 - 1776.4, if, in the professional judgment of the pharmacist in charge, the pharmacy cannot comply with the provisions of this article or the Drug Enforcement Administration rules.
- (j) A pharmacy shall not provide take-back services to consumers, as provided in sections 1776 - 1776.4, if the pharmacy or the pharmacist in charge is on probation with the Board, and, if the pharmacy had previously provided take-back services, the pharmacist in charge shall notify the Board and the Drug Enforcement Administration as required in subsections (h) and (i), above.

Note: Authority cited: Section 4005, Business and Professions Code.

Reference: Section 4005, Business and Professions Code and Sections 1301.71, 1317.30, 1317.40, Title 21 Code of Federal Regulations.

Proposal to add § 1776.2 of Article 9.1 of Division 17 of Title 16 of the California Code of Regulations as follows:

1776.2 Mail Back Package and Envelope Services from Pharmacies

- (a) Pharmacies that provide prescription drug take-back services may do so by ~~establishing providing mail back services, whereby the public may obtain from the pharmacy~~ preaddressed mailing envelopes or packages containers to allow a consumer to for returning prescription drugs to an authorized Drug Enforcement Administration destruction location.
- (b) All envelopes and packages must be preaddressed to a location registered with the Drug Enforcement Administration as a collector ~~that has onsite a method appropriate to destroy the prescription drugs.~~ The pharmacy is responsible for ensuring that all preaddressed

envelopes and packages it makes available to the public are preaddressed to be delivered to facilities that comply with this section.

- (c) ~~The preaddressed envelopes and packages must be water and spill proof, tamper evident, tear resistant and sealable. The exterior shall be nondescript and not include markings that indicate the envelope or package contains prescription drugs. Postage shall be prepaid on each envelope or package.~~
- (d) ~~The preaddressed envelope and package shall contain a unique identification number for each envelope and package, and certain instructions for users to mail back drugs.~~
- (e) ~~The pharmacy distributing mail back envelopes and packages shall create and maintain records required by section 1776.6.~~
- (f) ~~Individuals who mail back prescription drugs as provided in this section do not need to identify themselves as the senders.~~
- (g) ~~Once filled with unwanted prescription drugs, the A pharmacy shall not accept any mail back packages or envelopes that contain drugs. Consumers shall be directed to mail the envelopes or packages or deposit them into a pharmaceutical take-back receptacle. shall be mailed and not accepted by the pharmacy for return, processing or holding.~~

Note: Authority cited: Section 4005, Business and Professions Code.

Reference: Section 4005, Business and Professions Code and Sections 1317.70 and 1317.70, Title 21 Code of Federal Regulations.

Proposal to add § 1776.3 of Article 9.1 of Division 17 of Title 16 of the California Code of Regulations as follows:

1776.3 Collection Receptacles in Pharmacies

- (a) Pharmacies ~~may~~ that provide prescription drug take-back services to the public may do so by establishing a collection receptacle in the pharmacy whereby ~~for~~ the public ~~to~~ may deposit their unwanted prescription drugs for destruction. The receptacle shall be securely locked and substantially constructed, with a permanent outer container and a removable inner liner. ~~In~~ During hours when the pharmacy is closed, the collection receptacle shall not be accessible to the public for deposit of drugs. The pharmacy shall lock the deposit slot on the collection receptacle and physically block ~~the public patients~~ from access to the collection receptacle by some means.
- (b) The pharmacy ~~operating~~ maintaining the collection receptacle must securely install the receptacle so it cannot be moved or removed. The receptacle shall be installed in an inside location within the pharmacy premise, where the receptacle is visible to pharmacy employees, but not located in or near emergency areas.
- (c) In hospitals/clinics with a pharmacy on the premises, the collection receptacle must be located in an area that is regularly monitored by employees and not in the proximity of any emergency or urgent care areas. When the supervising pharmacy is closed, the collection receptacle shall be locked so that drugs may not be deposited into the collection receptacle. When the collection receptacle is locked, the supervising pharmacy shall ensure that the collection receptacle is also physically blocked from public patient access by some means.

- (d) The receptacle shall include a small opening that allows deposit of drugs into the inside of the receptacle directly into the inner liner, but does not allow for an individual to reach into the receptacle's contents.
- (e) The pharmacy is responsible for the management and maintenance of the receptacle. Pharmacy staff shall not accept, count, sort or handle prescription drugs returned from the public, but instead direct the public to deposit the drugs into the collection receptacle themselves.
- (f) A liner as used in this article shall be made of material that is certified by the manufacturer to meet the American Society for Testing Materials (ASTM) D1709 standard test for impact resistance of 165 grams (drop dart test), and the ASTM D1922 standards for tear resistance of 480 grams in both parallel and perpendicular planes.
- (1) The liner shall be waterproof, tamper evident and tear resistant.
- (2) The liner shall be opaque to prevent viewing or removal of any contents once the liner has been removed from a collection receptacle. The liner shall be clearly marked to display the maximum contents (for example, in gallons). The liner shall bear a permanent, unique identification number established by the pharmacy or pre-entered onto the liner by the liner's manufacturer or distributor.
- (g) The liner shall be removable as specified in this section. The receptacle shall allow the public to deposit prescription drugs into the receptacle for containment into the inner liner, without permitting access to or removal of prescription drugs already deposited into the collection receptacle and liner. Once a prescription drug or any other item is placed in the collection receptacle, the prescription drug or item cannot be removed or counted.
- (h) If the liner is not already itself rigid or already inside of a rigid container when as it is removed from the collection receptacle, the liner must be immediately placed in a rigid container for storage, handling and transport. A rigid container may be disposable, reusable, or recyclable. Rigid containers shall be leak resistant, have tight-fitting covers, and be kept clean and in good repair. ~~Rigid containers may be of any color.~~ All rigid containers must meet standards of the United States Department of Transportation for transport of medical waste. The containers shall be capable of being sealed and be kept clean and in good repair.
- (i) The liner may be removed from a locked collection receptacle only by two employees of the pharmacy. Upon removal, these pharmacy employees ~~who~~ shall immediately seal the liner and record, in a written log, their participation in the removal of each liner from a collection receptacle. If the liner is not already contained in a rigid container within the receptacle, the two employees shall immediately place the liner in a rigid container. Liners and their rigid containers shall not be opened, x-rayed, analyzed or penetrated at any time by the pharmacy or pharmacy personnel.
- (j) Liners and their rigid containers that have been filled and removed from a collection receptacle must be stored in a secured, locked location in the pharmacy no longer than ~~three~~ 14 days.
- (k) The pharmacy shall maintain a written log to record information about all liners that have been placed into or removed from a collection receptacle. The log shall contain:
- (1) The unique identification numbers of all unused liners in possession of the pharmacy,
- (2) The unique identification number and dates a liner is placed in the collection receptacle,
- (3) The date the liner is removed from the collection receptacle,

- (4) The names and signatures of the two pharmacy employees who removed and witnessed the removal of a liner from the collection receptacle, and
- (5) The date the liner was provided to a licensed DEA-registered reverse distributor for destruction, and the signature of the two pharmacy employees who witnessed the delivery to the reverse distributor. If a common carrier is used to transport the liner to the reverse distributor, the company used, the signature of the driver, and any related paperwork (invoice, bill of lading) must be recorded.
- (l) The pharmacy shall ensure the sealed inner liners and their contents are shipped to a reverse distributor's registered location by common or contract carrier (such as UPS, FEDEX or USPS) or by licensed reverse distributor pick-up at the licensed pharmacy's premises.
- (m) The collection receptacle shall contain signage developed by the board advising the public that it is ~~permissible to deposit Schedule II-V drugs into the receptacle, but not permissible to deposit any~~ Schedule I drugs into the collection receptacle. ~~Labeling~~ The signage shall also identify that medical sharps and needles (e.g., insulin syringes), iodine-containing medications, mercury-containing thermometers, radiopharmaceuticals, antineoplastic agents (cancer chemotherapy drugs, cytotoxic drugs), and compressed cylinders or aerosols (e.g., asthma inhalers) may not be deposited into the receptacle. The name and phone number of the collector pharmacy responsible for the receptacle shall also be affixed to the collection receptacle.
- (n) The board shall develop signage to appear on the collection receptacle to provide consumer information about the collection process.

Note: Authority cited: Section 4005, Business and Professions Code.

Reference: Section 4005, Business and Professions Code and Sections 1304.22, 1317.05, 1317.60, 1317.75, and 1317.80 Title 21 Code of Federal Regulations.

Proposal to add § 1776.4 of Article 9.1 of Division 17 of Title 16 of the California Code of Regulations as follows:

1776.4 Collection in Skilled Nursing Facilities

Skilled nursing facilities licensed under Health and Safety Code section 1250(c) may participate in drug take-back programs as authorized by this article.

- (a) Skilled nursing facility personnel may dispose of a current resident's unwanted or unused prescription drugs by using mail back packages or envelopes and packages based upon a request by the resident patient. Mail back envelopes and packages shall conform to the requirements specified in section 1776.2. Records shall be kept by the skilled nursing facility noting the specific quantity of each prescription drug mailed back, the unique identification number of the mail back package and the preaddressed location to which the mail back envelope is sent.
- (b) Only retail pharmacies and hospitals/clinics with onsite pharmacies may establish collection receptacles in skilled nursing facilities for the collection and ultimate disposal of unwanted prescription drugs.
 - (1) Any pharmacy and hospital/clinic with an onsite pharmacy ~~operating~~ maintaining collection receptacles in skilled nursing facilities shall be registered and maintain registration with the DEA as collectors.

- (2) Any pharmacy or hospital/clinic with an onsite pharmacy that ~~operates~~ maintains a collection receptacle at a skilled nursing facility shall notify the board within 30 days of establishing a collection receptacle on a form designated by the board.
- (3) Any pharmacy or hospital/clinic with an onsite pharmacy that ceases to ~~operate~~ maintain a collection ~~site~~ receptacle at a skilled nursing facility shall notify the board within 30 days on a form designated by the board.
- (4) Any pharmacy operating a collection receptacle ~~site~~ at a skilled nursing facility shall list all collection receptacles it ~~operates~~ maintains annually at the time of renewal of the pharmacy license.
- (c) When a pharmacy or hospital/clinic with an onsite pharmacy installs a collection receptacle in a skilled nursing facility, only the pharmacy shall remove, seal, transfer, and store or supervise the removal, sealing, transfer and storage of sealed inner liners at long-term care facilities as specified in this section.
- (d) Every pharmacy and hospital/clinic pharmacy that ~~operates~~ maintains a collection ~~site~~ receptacle at any skilled nursing facility shall notify the board within 14 days of any loss or theft from the collection receptacle or secured storage location for the storage of removed liners.
- (e) Within three business days after the permanent discontinuation of use of a medication by a prescriber, as a result of the resident's transfer to another facility or as a result of death, the skilled nursing facility may place the patient's unneeded prescription drugs into a collection receptacle. Records of such deposit shall be made in the patient's records, with the name and signature of the employee discarding the drugs.
- (f) A collection receptacle must be located in a secured area regularly monitored by skilled nursing facility employees.
- (g) The collection receptacle shall be securely fastened to a permanent structure so that it cannot be moved or removed. The collection receptacle shall have a small opening that allows deposit of drugs into the inside of the collection receptacle and directly into the inner liner, but does not allow for an individual to reach into the receptacle's contents.
- (h) The receptacle shall be securely locked and substantially constructed, with a permanent outer container and a removable inner liner.
- (1) The liner shall comply with provisions in this article. The receptacle shall allow deposit of prescription drugs into the receptacle for containment into the inner liner, without permitting access to or removal of prescription drugs already deposited into the collection receptacle and liner. Once a prescription drug or any other item is placed in the collection receptacle, the prescription drug or item cannot be viewed, removed or counted.
- (2) If the liner is not already itself rigid or already inside of a rigid container ~~as~~ when it is removed from the collection receptacle, the liner must be immediately placed in a rigid container for storage, handling and transport. A rigid container may be disposable, reusable, or recyclable. Rigid containers shall be leak resistant, have tight-fitting covers, and be kept clean and in good repair. ~~Rigid containers may be of any color.~~ All rigid containers must meet standards of the United States Department of Transportation for transport of medical waste. The rigid containers shall be capable of being sealed and be kept clean and in good repair.
- (i) A liner as used in this article shall be made of material that is certified by the manufacturer to meet American Society for Testing Materials (ASTM) D1709 standard test for impact

resistance of 165 grams (drop dart test), and the ASTM D1922 standards for tear resistance of 480 grams in both parallel and perpendicular planes.

- (1) The liner shall be waterproof, tamper evident and tear resistant.
 - (2) The liner shall be opaque to prevent viewing or removal of any contents once the liner has been removed from a collection receptacle. The liner shall be clearly marked to display the maximum contents (for example, in gallons). The liner shall bear a permanent, unique identification number established by the pharmacy or pre-entered onto the liner by the liner's manufacturer.
- (j) The collection receptacle shall prominently display a sign indicating that prescription drugs and controlled drugs in Schedules II – V may be deposited. The name and phone number of the collector pharmacy responsible for the receptacle shall also be affixed to the collection receptacle.
- (k) Once deposited, the prescription drugs shall not be handled, counted, inventoried or otherwise individually handled.
- (l) The installation, removal, transfer and storage of inner liners shall be performed only by:
- (1) One employee of the authorized collector pharmacy and one supervisory level employee of the long-term care facility (e.g., a charge nurse or supervisor) designated by the authorized collector, or
 - (2) By or under the supervision of two employees of the authorized collector pharmacy.
- (m) Sealed inner liners that are placed in a container may be stored at the skilled nursing facility for up to three business days in a securely locked, substantially constructed cabinet or a securely locked room with controlled access until transfer to a reverse distributor for destruction.
- (n) Liners still housed in a rigid container may be delivered to a reverse distributor for destruction by two pharmacy employees delivering the sealed inner liners in the rigid containers and their contents directly to a reverse distributor's registered location, or by common or contract carrier or by reverse distributor pickup at the skilled nursing facility.
- (o) Records of the pickup, delivery and destruction shall be maintained that provide the date each sealed inner liner is transferred for destruction, the address and registration number of the reverse distributor or distributor to whom each sealed inner was transferred, the unique identification number and the size (e.g., 5 gallon, 10 gallon) of each liner transferred, and if applicable, the names and signatures of the two employees who transported each liner.

Note: Authority cited: Section 4005, Business and Professions Code.

Reference: Sections 4005, Business and Professions Code and Sections 1304.22, 1317.05, 1317.40, 1317.60, 1317.75, 1317.80, and 1317.95, Title 21 Code of Federal Regulations

Proposal to add § 1776.5 of Article 9.1 of Division 17 of Title 16 of the California Code of Regulations as follows:

1776.5 Reverse Distributors

- (a) A licensed reverse distributor (either a reverse wholesaler or a reverse third-party logistics provider) registered with the DEA as a collector may accept the sealed inner liners of collection receptacles. Once received, the reverse distributor shall establish records required by this section.

- (b) A licensed reverse distributor may not ~~open or survey~~ count, inventory or otherwise sort or ~~x-ray~~ the contents of inner liners. All liners shall be ~~incinerated~~ destroyed by an appropriately licensed and registered DEA reverse distributor in a manner that makes the drugs irretrievable.
- (c) Two employees of the reverse distributor shall pick up or accept the receipt of inner liners from DEA registrants.
- (d) A reverse distributor shall not employ as an agent or employee anyone who has access to or influence over controlled substances, any person who has been convicted of any felony offense related to controlled substances or who at any time had a DEA registration revoked or suspended, or has surrendered a DEA registration for cause.
- (e) Each reverse distributor with an incineration site shall maintain a record of the destruction on DEA form 41. The records shall be complete, accurate, and include the name and signature of the two employees who witness the destruction.
- (f) For each sealed liner or mail back package received from collectors or law enforcement pursuant to federal CFR section 1317.55, the reverse distributor shall maintain records of the number of sealed inner liners or mail back envelopes/package, including the:
 - (1) Date of acquisition;
 - (2) Number and the size (e.g., five 10-gallon liners, etc.);
 - (3) Inventory number of each liner or envelope/package;
 - (4) The method of delivery to the reverse distributor, the signature of the individuals delivering the liners to the reverse distributor, and the reverse distributor's employees who received the sealed liner;
 - (5) The date, place and method of destruction;
 - (6) Number of packages and inner liners received;
 - (7) Number of packages and inner liners destroyed;
 - (8) The number and signature of the two employees of the registrant that witnessed the destruction.

Note: Authority cited: Section 4005, Business and Professions Code.

Reference: Sections 4005, Business and Professions Code and Section 1301.71, 1304.21, 1304.22, 1317.15, and 1317.55 Title 21 Code of Federal Regulations.

Proposal to add § 1776.6 of Article 9.1 of Division 17 of Title 16 of the California Code of Regulations as follows:

1776.6 Record Keeping Requirements for Board Licensees Providing Drug Take-Back Services

Each entity authorized by this article to collect unwanted prescription drugs from patients shall maintain the following records for three years.

- ~~(a) When obtaining unused mail-back packages and envelopes for future distribution:~~
 - ~~(1) The collector pharmacy shall maintain records that identify: the date the envelope or package was obtained by the pharmacy, the number of packages/envelopes made available to the public, and the unique identification number of each package.~~
 - ~~(2) For unused packages and envelopes provided to a skilled nursing facility or third party to make available to patients and other authorized individuals: the name of the third party and physical address of the location receiving the unused packages, date sent,~~

and the number of unused packages sent with the corresponding unique identification number.

- ~~(b) For each mail-back package or envelope distributed by a pharmacy, the pharmacy shall record the serial number of each package or envelope distributed and the date distributed.~~
- ~~(c) For sealed mail-back packages received by the reverse distributor: the date of receipt and the unique identification of the individual package or envelope,~~
- ~~(d) For sealed mail-back packages destroyed onsite by the reverse distributor collector: number of sealed mail-back packages destroyed, the date and method of destruction, the unique identification number of each mail-back package destroyed, and the names and signatures of the two employees of the registrant who witness the destruction.~~
- (e) (a) For pharmacies using collection receptacles, the pharmacy shall maintain the following records for each liner:
 - (1) Date each unused liner is acquired, its unique identification number and size (e.g., five gallon, 10-gallon). The pharmacy shall assign the unique identification number if the liner does not already contain one.
 - (2) Date each liner is installed in a collection receptacle, the address of the location where each liner is installed, the unique identification and size (e.g., five gallon, 10- gallon), the registration number of the collector pharmacy, and the names and signatures of the two employees that witnessed each installation.
 - (3) Date each inner liner is removed and sealed, the address of the location from which each inner liner is removed, the unique identification number and size (e.g., 5 gallon, 10 gallon) of each inner liner removed, the registration number of the collector pharmacy, and the names and signatures of the two employees that witnessed each removal.
 - (4) Date each sealed inner liner is transferred to storage, the unique identification and size (e.g., 5-gallon, 10 gallon) of each inner liner stored, and the names and signatures of the two employees that transferred each sealed inner liner to storage.
 - (5) Date each sealed inner liner is transferred for destruction, the address and registration number of the reverse distributor or distributor to whom each sealed inner was transferred, the unique identification number and the size (e.g., 5 gallon, 10 gallon) of each liner transferred, and the names and signatures of the two employees who transferred each sealed inner liner to the reverse distributor or distributor, or the common carrier who delivered it, and the signature of the driver.
- (b) For each reverse distributor (wholesaler or third-party logistics provider) accepting sealed mail-back packages: the date of receipt and the unique identification of the individual package or envelope.
- (c) For each reverse distributor that will destroy the mail-back packages: the number of sealed mail-back packages destroyed, the date and method of destruction, the unique identification number of each mail-back package destroyed, and the names and signatures of the two employees of the registrant who witness the destruction.
- (d) For each reverse distributor (wholesaler or third-party logistics provider) accepting liners, the following records must be maintained, with recording taking place immediately upon receipt of a liner:
 - (1) The date of receipt of each liner, the unique serial number of the liner, the pharmacy from which the liner was received, the method by which the liner was delivered to the

reverse distributor (e.g., personal delivery by two pharmacy staff, shipping via common carrier).

- (2) For each liner destroyed by the reverse distributor collector: the method and date of destruction, listed by the unique identification number of liner and other items required by (f)(1), and the names and signatures of the two employees of the registrant who witness the destruction.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005, Business and Professions Code and Section 1317.22, Title 21 Code of Federal Regulations

**Title 16. Board of Pharmacy
Proposed Text**

Adopt section 1715.65 in Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1715.65. Reconciliation and Inventory Report of Controlled Substances

- (a) Every pharmacy, and every clinic licensed under sections 4180 or 4190, shall perform reconciliation and inventory functions to prevent the loss of controlled substances.
- (b) The pharmacist-in-charge of a pharmacy or consultant pharmacist for a clinic shall review all reconciliations and inventories taken, and establish and maintain secure methods to prevent losses of controlled drugs. Written policies and procedures shall be developed for performing the reconciliation and inventory reports required by this section.
- (c) Perform a Periodic Inventory: A pharmacy or clinic shall compile an Inventory Report of specific controlled substances at least every three months. The compilation of this Inventory Report shall require a physical count, not an estimate, of all quantities of federal Schedule II controlled substances and at least one additional controlled substance which may be specified by the board each year as based upon loss reports made to the board in the prior year. The Inventory Report shall be dated and signed by the individual(s) performing the inventory, and countersigned by the pharmacist-in-charge or consultant pharmacist.
 - (1) The original or copy of the signed controlled substances Inventory Report shall be kept in the pharmacy or clinic and be readily retrievable for three years.
 - (2) The biennial inventory of controlled substances required by federal law may serve as one of the mandated inventories under this section in the year where the federal biennial inventory is performed, provided:
 - (A) A physical count of all controlled substances is performed, not an estimated count of how much medication is in a container.
 - (B) The federal Drug Enforcement Administration biennial inventory was taken no more than three months from the last inventory required by this section.
- (d) A new pharmacist-in-charge of the pharmacy shall complete an inventory as required by subdivision (c) within 30 days of becoming pharmacist-in-charge. Whenever possible an outgoing pharmacist-in-charge should complete an inventory as required in subdivision (c).
- (e) Reconciliation with Inventory Report: The pharmacy or clinic shall review all acquisitions and dispositions of controlled substances as part of the inventory process to determine the expected stock of each controlled substance on hand, based on the prior Inventory Report. Records used to compile each reconciliation shall be maintained in the pharmacy or clinic for at least three years in a readily retrievable form.
 - (1) Losses shall be identified in writing and reported to the board and, when appropriate, to the Drug Enforcement Administration.
 - (2) Likely causes of overages shall be identified in writing and retained.

- (3) Should the reconciliation identify controlled substances which had been in the inventory of the pharmacy or clinic during the prior six-month period, but for which there is no stock at the time of the physical count, the pharmacist-in-charge or consultant pharmacist shall determine there has been a loss of these controlled substances. These losses shall be reported in the manner specified by paragraph 1.
- (f) Adjustments to the Inventory Report shall be made following reconciliation, only after the reporting and documenting of any losses or accounting made for overages.
- (1) Each adjustment to the Inventory Report made to correct the stock on hand count shall be annotated to show any adjustment in the number of controlled substances on hand in the pharmacy or clinic, and who made the annotation, and the date.
- (2) The pharmacist-in-charge or consultant pharmacist shall countersign the adjusted Inventory Report.
- (3) The original Inventory Report and amended Inventory Report following reconciliation shall be readily retrievable in the pharmacy or clinic for three years.
- (g) The pharmacist-in-charge of a hospital pharmacy or of a pharmacy servicing skilled nursing homes where an automated drug delivery system is in use shall review at least once each month all controlled substances removed from or added into each automated drug delivery machine operated by the pharmacy. Any discrepancy or unusual access identified shall be investigated. Controlled drugs inappropriately accessed or removed from the automated delivery shall be reported to the board within 14 days.
- (h) A pharmacy or clinic identifying losses of controlled drugs but unable to identify the cause within 30 days shall take additional steps to identify the origin of the losses, including installation of cameras, relocation of the controlled drugs to a more secure location within the pharmacy, or daily inventory counts of the drugs where shortages are continuing.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4081, 4104 and 4332, Business and Professions Code.

BOARD OF PHARMACY

Proposal to amend § 1732.05 in Article 4 of Division 17 of Title 16 of the California Code of Regulations to read:

§1732.05. Accreditation Agencies for Continuing Education

(a) The following organizations are approved accreditation agencies:

- (1) The Accreditation Council for Pharmacy Education.
- (2) The ~~Pharmacy Foundation of California~~ California Pharmacists Association.

(b) Accreditation agencies shall:

- (1) Evaluate each continuing education provider seeking accreditation in accordance with the provider's ability to comply with the requirements of section 1732.1 of this Division.
- (2) Maintain a list of the name and address of the person responsible for the provider's continuing education program. The accreditation agency shall require that any change in the responsible person's identity shall be reported to the accreditation agency within 15 days of the effective date of the change.
- (3) Provide the board with the names, addresses and responsible party of each provider, upon request.
- (4) Respond to complaints from the board, providers or from pharmacists concerning activities of any of its accredited providers or their coursework.
- (5) Review at least one course per year offered by each provider accredited by the agency for compliance with the agency's requirements and requirements of the board and, on request, report the findings of such reviews to the board.
- (6) Take such action as is necessary to assure that the continuing education coursework offered by its providers meets the continuing education requirements of the board.
- (7) Verify the completion of a specific continuing education course by an individual pharmacist upon request of the board.

(c) Substantial failure of an approved accreditation agency to evaluate continuing education providers as set forth in subdivision (b) shall constitute cause for revocation of its approval as an accreditation agency by the board.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4232, Business and Professions Code.

Proposal to amend § 1732.2 in Article 4 of Division 17 of Title 16 of the California Code of Regulations to read:

§ 1732.2. Board Accredited Continuing Education

(a) Individuals may petition the board to allow continuing education credit for specific coursework which is not offered by a provider but meets the standards of Section 1732.3.

(b) Notwithstanding subdivision (a) of this section, coursework which meets the standard of relevance to pharmacy practice and has been approved for continuing education by the Medical Board of California, the California Board of Podiatric Medicine, the California Board of Registered Nursing or the Dental Board of California shall, upon satisfactory completion, be considered approved continuing education for pharmacists.

(c) A pharmacist serving on a designated subcommittee of the board for the purpose of developing the California Practice Standards and Jurisprudence Examination for pharmacists pursuant to section 4200.2 of the Business and Professions Code may annually be awarded up to six (6) hours of continuing education for conducting a review of exam test questions. A subcommittee member shall not receive continuing education hours pursuant to this subdivision if that subcommittee member requests reimbursement from the board for time spent conducting a review of exam test questions.

(d) A pharmacist or pharmacy technician who attends a full day board meeting may be awarded six (6) hours of continuing education per renewal period. The board shall designate on its public agenda which day shall be eligible for continuing education credit. A pharmacist or pharmacy technician requesting continuing education pursuant to this subdivision must sign in and out on an attendance sheet at the board meeting that requires the individual to provide his or her first and last name, license number, time of arrival and time of departure from the meeting.

(e) A pharmacist or pharmacy technician who attends a full committee meeting of the board may be awarded two (2) hours of continuing education per renewal period. A pharmacist or pharmacy technician requesting continuing education hours pursuant to this subdivision must sign in and out on an attendance sheet at the committee meeting that requires the individual to provide his or her first and last name, license number, time of arrival and time of departure from the meeting.

(f) An individual may be awarded three (3) hours of continuing education for successfully passing the examination administered by the Commission for Certification in Geriatric Pharmacy.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4232, Business and Professions Code.

Proposal to amend § 1732.5 of Article 4 of Division 17 of Title 16 of the California Code of Regulations to read:

§1732.5 Renewal Requirements for Pharmacists

(a) Except as provided in Section 4234 of the Business and Professions Code and Section 1732.6 of this Division, each applicant for renewal of a pharmacist license shall submit proof satisfactory to the board, that the applicant has completed 30 hours of continuing education in the prior 24 months.

(b) At least six (6) of the thirty (30) hours required for pharmacist license renewal shall be completed in one or more of the following subject areas:

- (1) Emergency/Disaster Response
- (2) Patient Consultation
- (3) Maintaining Control of a Pharmacy's Drug Inventory
- (4) Ethics
- (5) Substance Abuse, Including Indications of Red Flags and a Pharmacist's Corresponding Responsibility
- (6) Compounding

Pharmacists renewing their licenses which expire on or after July 1, 2018, shall be subject to the requirements of this subdivision.

~~(b)~~ (c) All pharmacists shall retain their certificates of completion for four (4) years following completion of a continuing education course.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4231 and 4232, Business and Professions Code.

ATTACHMENT 4

Board of Pharmacy

Amend Section 1702 of Article 5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1702. Pharmacist Renewal Requirements

(a) A pharmacist applicant for renewal who has not previously submitted fingerprints as a condition of licensure or for whom an electronic record of the licensee's fingerprints does not exist in the Department of Justice's criminal offender record identification database shall successfully complete a state and federal level criminal offender record information search conducted through the Department of Justice by the licensee's or registrant's renewal date ~~that occurs on or after December 7, 2010.~~

(1) A pharmacist shall retain for at least three years as evidence of having complied with subdivision (a) either a receipt showing that he or she has electronically transmitted his or her fingerprint images to the Department of Justice or, for those who did not use an electronic fingerprinting system, a receipt evidencing that his or her fingerprints were recorded and submitted to the Board.

(2) A pharmacist applicant for renewal shall pay the actual cost of compliance with subdivision (a).

(3) As a condition of petitioning the board for reinstatement of a revoked or surrendered license, or for restoration of a retired license, an applicant shall comply with subdivision (a).

(4) The board may waive the requirements of this section for licensees who are actively serving in the United States military. The board may not return a license to active status until the licensee has complied with subdivision (a).

(b) As a condition of renewal, a pharmacist applicant shall disclose on the renewal form whether he or she has been convicted, as defined in Section 490 of the Business and Professions Code, of any violation of the law in this or any other state, the United States, or other country, since his or her last renewal . omitting ~~T~~raffic infractions under ~~\$300~~ \$500 not involving alcohol, dangerous drugs, or controlled substances do not need to be disclosed.

(c) As a condition of renewal, a pharmacist applicant shall disclose on the renewal form any disciplinary action against any license issued to the applicant by a government agency. For the purposes of this section, "disciplinary action" means an adverse licensure or certification action that resulted in a restriction or penalty being placed on the license, such as revocation, suspension, probation or public reprimand or reproof.

(d) Failure to provide all of the information required by this section renders an application for renewal incomplete and the board shall not renew the license and shall issue the applicant an inactive pharmacist license. An inactive pharmacist license issued pursuant to this section may only be reactivated after compliance is confirmed for all licensure renewal requirements.

Authority: Sections 4001.1 and 4005, Business and Professions Code.

Reference: Sections 490, 4036, 4200.5, 4207, 4301, 4301.5 and 4400, Business and Professions Code; and Sections 11105(b)(10) and 11105(e), Penal Code.

Board of Pharmacy

Adopt Section 1702.1 of Article 5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1702. 1 Pharmacy Technician Renewal Requirements

(a) A pharmacy technician applicant for renewal who has not previously submitted fingerprints as a condition of licensure or for whom an electronic record of the licensee's fingerprints does not exist in the Department of Justice's criminal offender record identification database shall successfully complete a state and federal level criminal offender record information search conducted through the Department of Justice by the licensee's or registrant's renewal date that occurs on or after July 1, 2014.

(1) A pharmacy technician shall retain for at least three years as evidence of having complied with subdivision (a) either a receipt showing that he or she has electronically transmitted his or her fingerprint images to the Department of Justice or, for those who did not use an electronic fingerprinting system, a receipt evidencing that his or her fingerprints were recorded and submitted to the Board.

(2) A pharmacy technician applicant for renewal shall pay the actual cost of compliance with subdivision (a).

(3) As a condition of petitioning the board for reinstatement of a revoked or surrendered license an applicant shall comply with subdivision (a).

(4) The board may waive the requirements of this section for licensees who are actively serving in the United States military. The board may not return a license to active status until the licensee has complied with subdivision (a).

(b) As a condition of renewal, a pharmacy technician applicant shall disclose on the renewal form whether he or she has been convicted, as defined in Section 490 of the Business and Professions Code, of any violation of the law in this or any other state, the United States, or other country, since his or her last renewal . Traffic infractions under \$500 not involving alcohol, dangerous drugs, or controlled substances do not need to be disclosed.

(c) As a condition of renewal, a pharmacy technician applicant shall disclose on the renewal form any disciplinary action against any license issued to the applicant by a government agency. For the purposes of this section, "disciplinary action" means an adverse licensure or certification action that resulted in a restriction or penalty against the license or certification such as revocation, suspension, probation or public reprimand or reproof.

(d) Failure to provide all of the information required by this section renders an application for renewal incomplete and the board shall not renew the license until the licensee demonstrates compliance with all requirements.

Authority: Sections 4001.1 and 4005, Business and Professions Code.

Reference: Sections 490, 4038, 4115, 4202, 4207, 4301, 4301.5 and 4400, Business and Professions Code; and Sections 11105(b)(10) and 11105(e), Penal Code.

Board of Pharmacy

Adopt Section 1702.2 of Article 5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1702. 2 Designated Representative Renewal Requirements

(a) A designated representative applicant for renewal who has not previously submitted fingerprints as a condition of licensure or for whom an electronic record of the licensee's fingerprints does not exist in the Department of Justice's criminal offender record identification database shall successfully complete a state and federal level criminal offender record information search conducted through the Department of Justice by the licensee's or registrant's renewal date that occurs on or after July 1, 2014.

(1) A designated representative shall retain for at least three years as evidence of having complied with subdivision (a) either a receipt showing that he or she has electronically transmitted his or her fingerprint images to the Department of Justice or, for those who did not use an electronic fingerprinting system, a receipt evidencing that his or her fingerprints were recorded and submitted to the Board.

(2) A designated representative applicant for renewal shall pay the actual cost of compliance with subdivision (a).

(3) As a condition of petitioning the board for reinstatement of a revoked or surrendered license an applicant shall comply with subdivision (a).

(4) The board may waive the requirements of this section for licensees who are actively serving in the United States military. The board may not return a license to active status until the licensee has complied with subdivision (a).

(b) As a condition of renewal, a designated representative applicant shall disclose on the renewal form whether he or she has been convicted, as defined in Section 490 of the Business and Professions Code, of any violation of the law in this or any other state, the United States, or other country, since his or her last renewal. Traffic infractions under \$500 not involving alcohol, dangerous drugs, or controlled substances do not need to be disclosed.

(c) As a condition of renewal, a designated representative applicant shall disclose on the renewal form any disciplinary action against any license issued to the applicant by a government agency. For the purposes of this section, "disciplinary action" means an adverse licensure or certification action that resulted in a restriction or penalty against the license or certification such as revocation, suspension, probation or public reprimand or reproval.

(d) Failure to provide all of the information required by this section renders an application for renewal incomplete and the board shall not renew the license until the licensee demonstrates compliance with all requirements.

Authority : Sections 4001.1 and 4005, Business and Professions Code.

Reference: Sections 490, 4022.5, 4053, 4207, 4301, 4301.5 and 4400, Business and Professions Code; and Sections 11105(b)(10) and 11105(e), Penal Code.

Board of Pharmacy

Adopt Section 1702.5 of Article 5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1702.5. Disclosure of Discipline, Renewal, Nonresident Wholesaler or Nonresident Pharmacy.

(a) As a condition of renewal, an applicant seeking renewal of a license as a nonresident wholesaler or as a nonresident pharmacy shall report to the board any disciplinary action taken by any government agency since the last renewal of the license. An applicant seeking the first renewal of a license as a nonresident wholesaler or a nonresident pharmacy shall report to the board any disciplinary action taken by any government agency since issuance of the license. Failure to provide information required by this section shall render an application for renewal incomplete, and the board shall not renew the license until such time as the information is provided.

(b) For purposes of this section, “disciplinary action” means any adverse licensure or certification action that resulted in a restriction or penalty against the license or certification. Such actions include revocation, suspension, probation or public reprimand or reproof.

Authority: Section 4005, Business and Professions Code.

Reference: Sections 4112, 4161, 4300, and 4301, Business and Professions Code

Title 16. Board of Pharmacy

Proposed Language

To Amend Article 10 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

Article 10. ~~Wholesalers~~ Dangerous Drug Distributors

To Amend Section 1780 of Article 10 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1780. Minimum Standards for ~~Wholesalers~~.

The following minimum standards shall apply to all wholesale and third-party logistics provider establishments for which permits have been issued by the Board:

- (a) A wholesaler and a third-party logistics provider shall store dangerous drugs in a secured and lockable area.
- (b) All wholesaler and third-party logistics provider premises, fixtures and equipment therein shall be maintained in a clean and orderly condition. Wholesale and third-party logistics provider premises shall be well ventilated, free from rodents and insects, and adequately lighted. Plumbing shall be in good repair. Temperature and humidity monitoring shall be conducted to assure compliance with the United States Pharmacopeia Standards (1990, 22nd Revision).
- (c) Entry into areas where prescription drugs are held shall be limited to authorized personnel.
 - (1) All facilities shall be equipped with an alarm system to detect entry after hours.
 - (2) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.
 - (3) The outside perimeter of the wholesaler premises shall be well-lighted.
- (d) All materials must be examined upon receipt or before shipment.
 - (1) Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated prescription drugs or prescription drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.
 - (2) Each outgoing shipment shall be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have been damaged in storage or held under improper conditions.
- (e) The following procedures must be followed for handling returned, damaged and outdated prescription drugs.
 - (1) Prescription drugs that are outdated, damaged, deteriorated, misbranded or adulterated shall be placed in a quarantine area and physically separated from other drugs until they are destroyed or returned to their supplier.
 - (2) Any prescription drugs whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be placed in a quarantine area and physically separated from other prescription drugs until they are either destroyed or returned to the supplier.
 - (3) If the conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality or purity, the drug shall be destroyed or returned to the supplier unless testing or other investigation proves that the drug meets appropriate United States Pharmacopeia Standards (1990, 22nd Revision).
- (f) Policies and procedures must be written and made available upon request by the board.
 - (1) Wholesale and third-party logistics provider drug distributors shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory and distribution of prescription drugs, including policies and procedures for identifying,

recording, and reporting losses or thefts, for correcting all errors and inaccuracies in inventories, and for maintaining records to document proper storage.

- (2) The records required by paragraph (1) shall be in accordance with Title 21, Code of Federal Regulations, Section 205.50(g). These records shall be maintained for three years after disposition of the drugs.
 - (3) Wholesale and third-party logistics provider drug distributors shall establish and maintain lists of officers, directors, managers and other persons in charge of ~~wholesale~~ drug distribution, storage and handling, including a description of their duties and a summary of their qualifications.
 - (4) Each wholesaler and third-party logistics provider shall provide adequate training and experience to assure compliance with licensing requirements by all personnel.
- (g) The board shall require an applicant for a licensed premise or for renewal of that license to certify that it meets the requirements of this section at the time of licensure or renewal.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4043, 4045, 4051, 4053, 4054, 4059, 4120, 4160, 4161 and 4304, Business and Professions Code.

To Amend Section 1781 of Article 10 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1781. Exemption Certificate.

A registered pharmacist, ~~or an~~ designated representative or designated representative –3PL certified in accordance with Section 4053, 4053.1 or 4054 of the Business and Professions Code shall be present and in control of a manufacturer's, ~~or~~ wholesaler's or a third-party logistics provider's licensed premises during the conduct of business.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4053, 4053.1 or 4054, Business and Professions Code.

To Amend Section 1782 of Article 10 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1782. Reporting Sales of Drugs Subject to Abuse.

All manufacturers, ~~and~~ wholesalers and third-party logistics providers shall report to the Board or its designee, up to twelve (12) times a year, all sales of dangerous drugs subject to abuse as designated by the Board for reporting, in excess of amounts to be determined by the Board from time to time. Reports shall be made within thirty (30) days of the request in the form specified by the Board.

Authority cited: Sections 4005 and 4164, Business and Professions Code; ~~and Section 26692, Health and Safety Code.~~ Reference: Sections 4081, 4164, and 4332, Business and Professions Code; ~~and Section 26692, Health and Safety Code.~~

To Amend Section 1786 of Article 10 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1783. Manufacturer, ~~or~~ Wholesaler or Third-Party Logistics Provider Furnishing Drugs and Devices.

- (a) A manufacturer, ~~or~~ wholesaler or third-party logistics provider shall furnish dangerous drugs or devices only to an authorized person; prior to furnishing dangerous drugs and devices to a person not known to the furnisher, the manufacturer, ~~or~~ wholesaler, or third-party logistics provider shall contact the board or, if the person is licensed or registered by another government entity, that entity, to confirm the

recipient is an authorized person.

- (b) “Authorized person” means a person to whom the board has issued a permit which enables the permit holder to purchase dangerous drugs or devices for use within the scope of its permit. “Authorized person” also means any person in this state or in another jurisdiction within the United States to the extent such furnishing is authorized by the law of this state, any applicable federal law, and the law of the jurisdiction in which that person is located. The manufacturer, ~~or wholesaler~~ or third-party logistics provider furnishing to such person shall, prior to furnishing the dangerous drugs and devices, establish the intended recipient is legally authorized to receive the dangerous drugs or devices.
- (c) Dangerous drugs or devices furnished by a manufacturer, ~~or wholesaler~~ or third-party logistics provider shall be delivered only to the premises listed on the permit; provided that a manufacturer, ~~or wholesaler~~ or third-party logistics provider may furnish drugs to an authorized person or an agent of that person at the premises of the manufacturer, ~~or wholesaler~~ or third-party logistics provider if (1) the identity and authorization of the recipient is properly established and (2) this method of receipt is employed only to meet the immediate needs of a particular patient of the authorized person. Dangerous drugs or devices may be furnished to a hospital pharmacy receiving area provided that a pharmacist or authorized receiving personnel signs, at the time of delivery, a receipt showing the type and quantity of the dangerous drugs or devices so received. Any discrepancy between the receipt and the type and quantity of dangerous drugs and devices actually received shall be reported to the delivering manufacturer, ~~or wholesaler~~ or third-party logistics provider by the next business day after the delivery to the pharmacy receiving area.
- (d) A manufacturer, ~~or wholesaler~~ or third-party logistics provider shall not accept payment for or allow the use of an entity's credit to establish an account for the purchase of dangerous drugs or devices from any person other than: (1) the owner(s) of record, chief executive officer, or chief financial officer listed on the permit for the authorized person; and (2) on an account bearing the name of the permittee.
- (e) All records of dangerous drugs or devices furnished by a manufacturer, ~~or wholesaler~~ or third-party logistics provider to an authorized person shall be preserved by the authorized person for at least three years from the date of making and shall, at all times during business hours, be open to inspection by authorized officers of the law at the licensed premises. The manufacturer, ~~or wholesaler~~ or third-party logistics provider shall also maintain all records of dangerous drugs or devices furnished pursuant to this section for at least three years from the date of making and shall, at all times during business hours, keep them open to inspection by authorized officers of the law at the premises from which the dangerous drugs or devices were furnished.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4043, 4059, 4059.5, 4080, 4081, 4120, 4160, 4161, 4163 and 4304, Business and Professions Code; and Section 11209, Health and Safety Code.

To Amend Section 1784 of Article 10 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1784. Self-Assessment of a Wholesaler by the Designated Representative-in-Charge.

- (a) The designated representative-in-charge or responsible manager of each wholesaler or third-party logistics provider as defined under section 4160 of the Business and Professions Code shall complete a self-assessment of the wholesaler's or third-party logistics provider's compliance with federal and state pharmacy law. The assessment shall be performed before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.
- (b) In addition to the self-assessment required in subdivision (a) of this section, the designated representative-in-charge or responsible manager shall complete a self-assessment within 30 days whenever:

- (1) A new wholesaler or third-party logistics provider permit is issued, or
 - (2) There is a change in the designated representative-in-charge or responsible manager. The new designated representative-in-charge or responsible manager of a wholesaler or third-party logistics provider is responsible for compliance with this subdivision.
 - (3) There is a change in the licensed location of a wholesaler or third-party logistics provider to a new address.
- (c) The components of this assessment shall be on Form 17M-26 (Rev. 10/14) entitled “Wholesaler Dangerous Drugs & Dangerous Devices Self-Assessment” which is hereby incorporated by reference to evaluate compliance with federal and state laws and regulations.
 - (d) Each self-assessment shall be kept on file in the licensed wholesale or third-party logistics provider premises for three years after it is completed.
 - (e) The wholesaler or third-party logistics provider is jointly responsible with the designated representative-in-charge or responsible manager for compliance with this section.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4022.5, 4022.7, 4043, 4045, 4053, 4059, 4120, 4160, 4161, 4201, 4301 and 4305.5, Business and Professions Code.