



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
Lavanza Butler, Vice Chairperson, Licensee Member
Amy Gutierrez, Licensee Member
Amjad Khan, Public Member
Albert Wong, Licensee Member
Valerie Muñoz, Public Member

The committee will be meeting immediately before the board meeting. An update on the committee's action will be provided during the board meeting.

I. Call to Order, Establishment of Quorum, and General Announcements

II. Public Comment on Items Not on the Agenda/Agenda Items for Future Meetings

Note: The committee may not discuss or take action on any matter raised during this public comment section that is not included on this agenda, except to decide whether to place the matter on the agenda of a future meeting. [Government Code sections 11125, 11125.7(a)]

III. Legislation for Discussion and Consideration

The first of a two-year legislative session ended on October 15, 2017.

a. Board Sponsored Legislation

Attachment 1

The Governor signed all of the board sponsored measures this year. Below is a brief summary of each of the measures and **Attachment 1** includes a copy of the chaptered language for each proposal.

1. Omnibus Provisions: SB 800 (Chapter 573, Statutes of 2017) Professions and Vocations, Including Changes to Pharmacy Law

Summary: SB 800 contains omnibus provisions for various programs within the Department of Consumer Affairs (DCA). Board specific provisions include:

- 4013, Amend (d)(1) to add designated representative to the list of individuals who need to join the email subscriber list.
- 4316, Clarify the board's authority to issue a cease-and-desist for unlicensed activity and that the issuing of the order will be delegated to the executive officer.

The measure also repeals 4001.5, which established a requirement for the Joint Committee to review the state's shortage of pharmacists and make recommendations on a course of action to alleviate the shortage. The repeal was not board sponsored but rather was included by the Senate Business, Professions, and Economic Development Committee.

2. SB 351 (Chapter 623, Statutes of 2017, Roth) Hospital Satellite Compounding Pharmacy: License: Requirements

Summary: Creates options for hospitals that wish to obtain additional licenses from the board for purposes of providing pharmaceutical care. Specifically, the board can now issue hospital satellite compounding pharmacy licenses that will not need to be located in the acute care hospital building. This measure also allows the board to issue a hospital pharmacy license that can be located outside of the general acute care hospital but in another physical plant regulated under the California Department of Public Health's hospital license.

3. SB 443 (Chapter 647, Statutes of 2017, Hernandez) Pharmacy: Emergency Medical Services Automated Drug Delivery System

Summary: Creates an option for county emergency medical services to restock ambulances through use of an emergency medical services automated drug delivery system (EMADDS) that is located within a county operated fire department. As part of the measure, the board can issue a license for the use of the EMADDS as well as a license to a designated paramedic.

4. SB 510 (Chapter 649, Statutes of 2017, Stone) Pharmacies: Compounding

Summary: Repeals an outdated statutory requirement specifying the environments in which a pharmacy must compound sterile products.

5. SB 752 (Chapter 598, Statutes of 2017, Stone) Designated Representative-Reverse Distributor

Summary: Establishes the creation of a designated representative-reverse distributor license and shortens the waiting period an applicant must wait to retake the pharmacist licensure examination to 45 days.

b. Chaptered Legislation Impacting the Practice of Pharmacy or the Board's Jurisdiction with Board Established Positions

Attachment 2 & 3

The Governor signed several measures impacting the board's jurisdiction where the board had an established position. Below is a summary of each of the measures and the board's position. **Attachment 2** includes a copy of the chaptered language for each measure.

1. AB 40 (Chapter 607, Statutes of 2017, Santiago) CURES Database: Health Information Technology System

Board Position: Support

Summary: Requires the Department of Justice to make CURES available to a practitioner through either an online internet web portal or an authorized health information technology system, as defined. This measure included an urgency provision and took effect immediately upon signature of the governor.

2. AB 208 (Chapter 208, Statutes of 2017, Eggman) Deferred Entry of Judgment: Pretrial Diversion

Board Position: Neutral (after board amendments were accepted)

Summary: Changes the deferred entry of judgment program to a pretrial program. Expands the conditions under which someone is eligible for the program and reduces the conditions under which someone could be removed from the program. Reduces the length of the program compliance to six to 12 months and prohibits information sharing once someone is in the program. Amendments were secured that ensure the board will have access to relevant information relating to the arrest and participation in the program.

3. AB 401 (Chapter 548, Statutes of 2017, Aguiar-Curry) Pharmacy: Remote Dispensing Site Pharmacy: Telepharmacy

Board Position: Support If Amended

Summary: Establishes regulatory framework for telepharmacy and establishes mandatory reporting by wholesalers of suspicious drug orders.

4. AB 602 (Chapter 139, Statutes of 2017, Bonta) Pharmacy: Nonprescription Diabetes Devices

Board Position: Support If Amended

Summary: Requires pharmacies that dispense nonprescription diabetes test devices pursuant to a prescription to retain records; requires the board to post the names of authorized distributors of such test strips; and makes it unprofessional conduct for a licensee to seek reimbursement for such devices under specified conditions. This measure contained an urgency provision and took effect upon signature of the governor.

5. SB 17 (Chapter 603, Statutes of 2017, Hernandez) Prescription Drugs: Pricing: Notification

Board Position: Support

Summary: Aimed at drug price transparency by establishing reporting requirements for prescription drugs cost and volume for health plans and reporting requirements for drug manufacturers regarding rate increases.

6. SB 547 (Chapter 429, Statutes of 2017, Hill) Professions and Vocations

Board Position: Support

Summary: Allows the board to hire its own counsel.

In addition to the above, several other measures were signed by the Governor.

Attachment 3 includes a compilation of all the changes to relevant sections of the Business and Professions Code and Health and Safety Code. This information will also be posted on the board's website.

IV. Regulations for Discussion and Consideration

c. Board Adopted - Approved by the Office of Administrative Law

Proposed Regulations to Amend and/or Add Title 16 CCR sections 1702, 1702.1, 1702.2 and 1702.5 Related to Renewal Requirements

Summary of Regulation:

Effective January 1, 2018, these regulations establish standardized reporting of convictions and discipline at the time of renewal for pharmacists, pharmacy technicians and designated representatives. Additionally, sections 1702.1 and 1702.2 require pharmacy technicians and designated representatives to be fingerprinted as a condition of renewal if the Department of Justice does not have an electronic fingerprint record on file. Section 1702.5 requires nonresident wholesalers and nonresident pharmacies to report disciplinary actions by other entities at the time of renewal.

A copy of the adopted regulation text is posted on the board's website and can be obtained using the following link - - http://www.pharmacy.ca.gov/laws_regs/approved_regs.shtml

d. Board Adopted - Submitted for Administrative Review to the Department of Consumer Affairs or the Office of Administrative Law

Attachment 4

The board currently has three regulations undergoing review by the Department or the Office of Administrative Law including:

1. Proposed Regulations to Amend Title 16 CCR section 1760 Related to the Board's Disciplinary Guidelines
2. Proposed Regulations to Amend Title 16 CCR section 1749 Related to the Board's Fee Schedule
3. Proposed Regulations to Add Title 16 CCR section 1715.65 Related to the Inventory Reconciliation Report of Controlled Substances

Attachment 4 provides a summary of each of the regulation changes as well as the general timeline. The board-adopted text is posted on the board's website and can be obtain using the following link - - http://www.pharmacy.ca.gov/laws_regs/pending_regs.shtml

e. Board Approved to Initiate Rulemaking – Undergoing Pre-Notice Review by the Department of Consumer Affairs or the Business, Consumer Services and Housing Agency, or Returned to Board Staff for Revisions Pursuant to Such Review

Attachment 5

The board has several regulations undergoing pre-notice review by the department, including:

1. Proposed Emergency Regulations to Amend Title 16 CCR section 1735.2 Related to Compounding Beyond Use Dates
2. Proposed Regulations to Amend Title 16 CCR Sections 1780-1783, et seq. Related to Third-Party Logistics Providers and Dangerous Drug Distributors
3. Proposed Regulations to Amend Title 16 CCR Section 1793.5 Related to the Pharmacy Technician Application, Section 1793.6 Related to the Pharmacy Technician Training Requirements, and Section 1793.65 Related to the Pharmacy Technician Certification Programs
4. Proposed Regulations to Amend Title 16 CCR Section 1707 Related to Offsite Storage
5. Proposed Regulations to Amend Title 16 CCR Section 1746.3 Related to the Naloxone Fact Sheet
6. Proposed Regulations to Amend Title 16 CCR Section 1709 Related to Pharmacy Ownership, Management, and Control, Including Trusts. **Note:** This regulation was returned to board staff for changes after pre-notice review was completed. Board staff will be working on making the requested changes as appropriate and will resubmit the regulation materials.

Attachment 5 includes a timeline for each of the proposed regulations as well as the board approved text.

f. Board Approved to Initiate Rulemaking – Board Staff Drafting Rulemaking Documents for Pre-Notice Review by the Department of Consumer Affairs and the Business, Consumer Services and Housing Agency

Attachment 6

The board currently has two proposed regulations packages being prepared by staff for submission to the department for its pre-notice review:

1. Proposed Regulations to Add Title 16 CCR section 1717.5 Related to Automatic Refill Programs
2. Proposed Regulations to Amend Title 16 CCR sections 1735.1, 1735.2, 1735.6, 1751.1, and 1751.4 Related to Compounding

Attachment 6 includes a timeline for each of the proposed regulations as well as the board approved text.

V. Future Committee Meeting Dates

- January 17, 2018
- April 24, 2018
- July 10, 2018
- October 20, 2018

Attachment 1

SB 800

SECTION 1. Section 4001.5 of the Business and Professions Code is repealed.

~~4001.5. The Joint Committee on Boards, Commissions, and Consumer Protection shall review the state's shortage of pharmacists and make recommendations on a course of action to alleviate the shortage, including, but not limited to, a review of the current California pharmacist licensure examination.~~

SEC. 2. Section 4013 of the Business and Professions Code is amended to read:

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

(b) Any facility licensed by the board shall update its email address with the board's email notification list within 30 days of a change in the facility's email address.

(c) An owner of two or more facilities licensed by the board may comply with subdivisions (a) and (b) by subscribing a single email address to the board's email notification list, where the owner maintains an electronic notice system within all of its licensed facilities that, upon receipt of an email notification from the board, immediately transmits electronic notice of the same notification to all of its licensed facilities. If an owner chooses to comply with this section by using such an electronic notice system, the owner shall register the electronic notice system with the board by July 1, 2011, or within 60 days of initial licensure, whichever is later, informing the board of the single email address to be utilized by the owner, describing the electronic notice system, and listing all facilities to which immediate notice will be provided. The owner shall update its email address with the board's email notification list within 30 days of any change in the owner's email address.

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

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

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

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

(5) This subdivision shall become operative on July 1, 2017.

SEC. 3. Section 4316 of the Business and Professions Code is amended to read:

4316. (a) The ~~board~~ *board, through its executive officer*, 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 without obtaining that* 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 facility* pursuant to Section 1094.5 of the Code of Civil Procedure.

SEC. 4. Section 4980.09 of the Business and Professions Code is amended to read:

SB 351**SECTION 1.** Section 4029 of the Business and Professions Code is amended to read:

4029. (a) "Hospital pharmacy" means and includes a pharmacy, licensed by the board, located within any licensed hospital, institution, or establishment that maintains and operates organized facilities for the diagnosis, care, and treatment of human illnesses to which persons may be admitted for overnight stay and that meets all of the requirements of this chapter and the rules and regulations of the board.

(b) A hospital pharmacy ~~also includes~~ *may include* a pharmacy that ~~may be located outside of the hospital in another~~ *is located in any* physical plant that is regulated under ~~a hospital's consolidated license issued pursuant to Section 1250.8~~ *the license of a general acute care hospital as defined in subdivision (a) of Section 1250* of the Health and Safety Code. As a condition of licensure by the board, the pharmacy in another physical plant shall provide pharmaceutical services only to registered hospital patients who are on the premises of the same physical plant in which the pharmacy is located, except as provided in Article 7.6 (commencing with Section 4128). The pharmacy services provided shall be directly related to the services or treatment plan administered in the physical plant. Nothing in this subdivision shall be construed to restrict or expand the services that a hospital pharmacy may provide.

(c) "Hospital satellite compounding pharmacy" means an area licensed by the board to perform sterile compounding that is separately licensed by the board pursuant to Section 4127.15 to perform that compounding and is located outside of the hospital in another physical plant that is regulated as a general acute care hospital as defined in subdivision (a) of Section 1250 of the Health and Safety Code.

SEC. 2. *Section 4127.15 is added to the Business and Professions Code, to read:*

4127.15. Subject to the requirements of this section, the board may issue a license to a hospital satellite compounding pharmacy. The license fee and annual renewal fee shall be in an amount established by the board in subdivision (u) of Section 4400. The license shall not be transferable.

(a) A hospital satellite compounding pharmacy license shall not be issued or renewed until the location is inspected by the board and found to be in compliance with this article and regulations adopted by the board.

(1) A hospital satellite compounding pharmacy shall compound sterile drug products for administration only to registered hospital patients who are on the premises of the same physical plant in which the hospital satellite compounding pharmacy is located.

(2) The services provided shall be directly related to the services or treatment plan administered in the physical plant.

(b) A hospital satellite compounding pharmacy license shall not be issued or renewed until the board does all of the following:

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

(2) Reviews the hospital satellite compounding pharmacy's completed self-assessment form as described in Section 1735.2 of Title 16 of the California Code of Regulations.

(3) Receives a list of all products compounded by the hospital satellite compounding pharmacy since the last license renewal.

(c) A hospital satellite compounding pharmacy shall do all of the following:

(1) Purchase, procure, or otherwise obtain all components through the license of the hospital pharmacy as defined in subdivision (a) of Section 4029.

(2) Satisfy the ratio of not less than one pharmacist on duty for a total of two pharmacy technicians on duty.

(3) Ensure immediate supervision, as defined in Section 70065 of Title 22 of the California Code of Regulations, by a pharmacist of licensed ancillary staff involved in sterile compounding.

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(4) Provide to the board, within 12 hours, any recall notice issued by the hospital satellite compounding pharmacy for sterile drug products it has compounded.

(5) Report to the board, within 12 hours, adverse effects reported or potentially attributable to the sterile drug products compounded by the hospital satellite compounding pharmacy. Unexpected adverse effects shall also be, within 12 hours, reported to the MedWatch program of the federal Food and Drug Administration.

SEC. 3. Section 4400 of the Business and Professions Code, as added by Section 26 of Chapter 799 of the Statutes of 2016, 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 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).

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(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 *or a hospital satellite compounding pharmacy* 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

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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 an outsourcing facility license shall be two thousand two hundred seventy dollars (\$2,270) and may be increased to up to three thousand one hundred eighty dollars (\$3,180) by the board. The fee for the renewal of an outsourcing facility license shall be one thousand three hundred twenty-five dollars (\$1,325) and may be increased to up to one thousand eight hundred fifty-five dollars (\$1,855) by the board. The fee for a temporary outsourcing facility license shall be seven hundred fifteen dollars (\$715).

(x) The fee for the issuance of a nonresident outsourcing facility license shall be two thousand three hundred eighty dollars (\$2,380) and may be increased to up to three thousand three hundred thirty-five dollars (\$3,335) by the board. The fee for the renewal of a nonresident outsourcing facility license shall be two thousand two hundred seventy dollars (\$2,270) and may be increased to up to three thousand one hundred eighty dollars (\$3,180) by the board. 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.

(y) 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).

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

SEC. 3.5. Section 4400 of the Business and Professions Code, as added by Section 26 of Chapter 799 of the Statutes of 2016, 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 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).

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(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, *or as a designated representative-reverse distributor pursuant to Section 4053.2* 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~~ *representative, designated representative-3PL*, or designated ~~representative-3PL~~ *representative-reverse distributor* 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).

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(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 *or a hospital satellite compounding pharmacy* 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 an outsourcing facility license shall be two thousand two hundred seventy dollars (\$2,270) and may be increased to up to three thousand one hundred eighty dollars (\$3,180) by the board. The fee for the renewal of an outsourcing facility license shall be one thousand three hundred twenty-five dollars (\$1,325) and may be increased to up to one thousand eight hundred fifty-five dollars (\$1,855) by the board. The fee for a temporary outsourcing facility license shall be seven hundred fifteen dollars (\$715).

(x) The fee for the issuance of a nonresident outsourcing facility license shall be two thousand three hundred eighty dollars (\$2,380) and may be increased to up to three thousand three hundred thirty-five dollars (\$3,335) by the board. The fee for the renewal of a nonresident outsourcing facility license shall be two thousand two hundred seventy dollars (\$2,270) and may be increased to up to three thousand one hundred eighty dollars (\$3,180) by the board. 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.

(y) 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).

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

sec. 4. Section 3.5 of this bill incorporates amendments to Section 4400 of the Business and Professions Code proposed by both this bill and Senate Bill 752. That section of this bill shall only become operative if (1) both bills are enacted and become effective on or before January 1, 2018, (2) each bill amends Section 4400 of the Business and Professions Code, and (3) this bill is enacted after Senate Bill 752, in which case Section 3 of this bill shall not become operative.

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,

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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.

SB 443**SECTION 1.** *Section 4034.5 is added to the Business and Professions Code, to read:*

4034.5. An “emergency medical services automated drug delivery system” or “EMSADDS” means an automated drug delivery system that stores and distributes drugs for the sole purpose of restocking a secured emergency pharmaceutical supplies container that is used by an emergency medical services agency to provide emergency medical services.

SEC. 2. Section 4119 of the Business and Professions Code is amended to read:

4119. (a) Notwithstanding any other ~~provision of~~ law, a pharmacy may furnish a dangerous drug or dangerous device to a licensed health care facility for storage in a secured emergency pharmaceutical supplies container maintained within the facility in accordance with facility regulations of the State Department of Public Health set forth in Title 22 of the California Code of Regulations and the requirements set forth in Section 1261.5 of the Health and Safety Code. These emergency supplies shall be approved by the facility’s patient care policy committee or pharmaceutical service committee and shall be readily available to each nursing station. Section 1261.5 of the Health and Safety Code limits the number of oral dosage form or suppository form drugs in these emergency supplies to ~~24.~~ **48.**

(b) Notwithstanding any other ~~provision of~~ law, a pharmacy may furnish a dangerous drug or a dangerous device to an approved service provider within an emergency medical services system for storage in a secured emergency pharmaceutical supplies container, in accordance with the policies and procedures of the local emergency medical services agency, if all of the following are met:

(1) The dangerous drug or dangerous device is furnished exclusively for use in conjunction with services provided in an ambulance, or other approved emergency medical services service provider, that provides prehospital emergency medical services.

(2) The requested dangerous drug or dangerous device is within the licensed or certified emergency medical technician’s scope of practice as established by the Emergency Medical Services Authority and set forth in Title 22 of the California Code of Regulations.

(3) The approved service provider within an emergency medical services system provides a written request that specifies the name and quantity of dangerous drugs or dangerous devices.

(4) The approved emergency medical services provider administers dangerous drugs and dangerous devices in accordance with the policies and procedures of the local emergency medical services agency.

(5) The approved emergency medical services provider documents, stores, and restocks dangerous drugs and dangerous devices in accordance with the policies and procedures of the local emergency medical services agency.

Records of each request by, and dangerous drugs or dangerous devices furnished to, an approved service provider within an emergency medical services system, shall be maintained by both the approved service provider and the dispensing pharmacy for a period of at least three years.

The furnishing of controlled substances to an approved emergency medical services provider shall be in accordance with the California Uniform Controlled Substances ~~Act.~~ *Act (Division 10 (commencing with Section 11000) of the Health and Safety Code).*

SEC. 3. *Section 4119.01 is added to the Business and Professions Code, immediately following Section 4119, to read:*

4119.01. (a) Notwithstanding any other law, a pharmacy, or a licensed wholesaler that is also an emergency medical services provider agency, may restock dangerous drugs or dangerous devices into an emergency medical services automated drug delivery system (EMSADDS) that is licensed by the board under this section. Dangerous drugs and dangerous devices stored or maintained in an EMSADDS shall be used for the sole purpose of restocking a secured emergency pharmaceutical supplies container as authorized in subdivision (b) of Section 4119. The EMSADDS may be used only if all of the following conditions are met:

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(1) The emergency medical services provider agency obtains a license from the board to operate the EMSADDS. As a requirement for licensure, the EMSADDS shall be located on the premises of a fire department headquarters, a fire station, or at an emergency medical services provider agency's location. A separate license shall be required for each location.

(A) As part of its license application, the emergency medical services provider agency shall provide: the address where the EMSADDS will be located; the name of the medical director responsible for overseeing the emergency medical services provider agency; the name of any designated pharmacist or licensed designated paramedic who is responsible for performing the duties as required under this section; the policies and procedures detailing the provisions under which the EMSADDS will operate; and the name and license number of the pharmacy or emergency medical services provider agency wholesaler that will furnish the dangerous drugs and dangerous devices through the EMSADDS.

(B) The application and initial license fee to operate EMSADDS shall be one hundred dollars (\$100) per machine. The license shall be renewed annually. The license fee may not be transferred to a different location if the EMSADDS is moved. The penalty fee for failure to renew an EMSADDS license shall be thirty-five dollars (\$35).

(C) The application and renewal fee for a licensed wholesaler that is also an emergency medical services provider agency shall be seven hundred eighty dollars (\$780).

(2) Each EMSADDS shall collect, control, and maintain all transaction information necessary to accurately track the movement of drugs into and out of the system for purposes of security, accuracy, and accountability.

(3) The medical director and designated pharmacist, or the medical director and the licensed designated paramedic, shall develop, adopt, and maintain policies and procedures detailing the provisions under which the EMSADDS will operate. At a minimum, the policies and procedures shall address (A) inventory controls, (B) training, (C) storage and security of the dangerous drugs and dangerous devices, and (D) safeguards to limit access to the EMSADDS to authorized staff only.

(4) The licensed EMSADDS operator shall limit access to the EMSADDS only to employees of the operator who are licensed by the state and as authorized in this section.

(A) An EMSADDS may only be restocked by the medical director, a pharmacist, or a licensed designated paramedic, each of whom may possess and transport dangerous drugs or dangerous devices for that purpose. The transport of dangerous drugs or dangerous devices for restocking into an EMSADDS shall be done in a secured manner to prevent theft or unauthorized access, and shall be done under conditions appropriate to meet storage and handling requirements of the dangerous drugs or dangerous devices. While the dangerous drugs or dangerous devices may be transported, representatives shall not store a dangerous drug or dangerous device at an unlicensed location.

(B) Only a medical director, a pharmacist, or a paramedic may remove dangerous drugs or dangerous devices from an EMSADDS to fill a secured emergency pharmaceutical supplies container. This access shall be observed by a second person who is also a paramedic, a pharmacist, or a medical director. Both the individual who removes dangerous drugs or dangerous devices from the EMSADDS and the observer shall record their participation in the removal of the dangerous drugs or dangerous devices via their signatures or use of biometric identifiers. The restocking of the secured emergency pharmaceutical supplies container from the EMSADDS shall occur at the licensed location of the EMSADDS.

(C) A medical director, a pharmacist, or a licensed designated paramedic may remove outdated dangerous drugs or dangerous devices from an EMSADDS. Any outdated dangerous drugs or dangerous devices shall be provided to a licensed reverse distributor for destruction.

(5) Every EMSADDS operator shall perform monthly inventory and inventory reconciliation functions. The medical director, designated pharmacist, or licensed designated paramedic shall perform a reconciliation and prepare a written report based on written policies and procedures developed to maintain the security and quality of the dangerous drugs and dangerous devices. The written inventory reconciliation report shall include all of the following:

(A) A physical count of all quantities of dangerous drugs and dangerous devices stored in the EMSADDS.

(B) A review of all dangerous drugs and dangerous devices added into and removed from each EMSADDS since the last monthly inventory.

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(C) A comparison of subparagraphs (A) and (B), and identification of any variances.

(D) A review of all individuals who accessed the EMSADDS since the last inventory and identification of unauthorized individuals accessing the EMSADDS or suspicious activity.

(E) Identification of possible causes of shortages and overages.

(6) The medical director and designated pharmacist, or medical director and licensed designated paramedic, shall be jointly responsible for monthly review of the inventory reconciliation report, the training, storage, and security of dangerous drugs and dangerous devices, and the restocking of the EMSADDS. Any inventory losses from an EMSADDS shall be reported to the board within seven days from identification of the loss.

(7) In order for an individual to perform the functions of a licensed designated paramedic described in this section, that individual shall be licensed by the board pursuant to Section 4202.5. A paramedic who only restocks a secured emergency pharmaceutical supplies container from an EMSADDS need not be licensed with the board.

(8) A record of each access to the EMSADDS, as well as all records used to compile an inventory reconciliation report, shall be maintained at the operator's location for at least three years in a readily retrievable form. The records shall include the identity of every individual who accessed the system or witnessed such access; the date of each access; and the drug, dosage, form, strength, and quantity of dangerous drugs or dangerous devices added or removed.

(b) A violation of any of the provisions of this section shall constitute unprofessional conduct and provides the board the authority to take action against the EMSADDS operator's license.

SEC. 4. Section 4202.5 is added to the Business and Professions Code, to read:

4202.5. (a) The board may issue a designated paramedic license to an individual if he or she holds a license as a paramedic in this state and meets the criteria of this section.

(b) The board shall conduct a criminal background check of the applicant to determine if the applicant has committed acts that would constitute grounds for denial of licensure, pursuant to this chapter or Chapter 2 (commencing with Section 480) of Division 1.5.

(c) The board may suspend or revoke a license issued pursuant to this section on any ground specified in Section 4301.

(d) A license issued under this section is dependent on the validity of the holder's paramedic license and shall be automatically suspended if the individual's paramedic license is expired, revoked, or otherwise invalidated by the issuing authority.

(e) The fee for application and issuance of an initial license as a designated paramedic shall be one hundred forty dollars (\$140) for a two-year license. The biennial renewal shall be one hundred forty dollars (\$140). The penalty fee for failure to renew an authorized paramedic license shall be sixty-five dollars (\$65).

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.

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SECTION 1. Section 4127.7 of the Business and Professions Code is repealed.

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

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

~~(b) An ISO class 5 cleanroom.~~

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

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

~~4127.8.~~ **4127.7.** The board may, at its discretion, issue a temporary license to compound 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. 3. Section 4127.9 of the Business and Professions Code is amended and renumbered to read:

~~4127.9.~~ **4127.8.** (a) A pharmacy licensed pursuant to Section 4127.1 or 4127.2 that issues a recall notice regarding a sterile compounded drug shall, in addition to any other duties, contact the recipient pharmacy, prescriber, or patient of the recalled drug and the board as soon as possible within 12 hours of the recall notice if both of the following apply:

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

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

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

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

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

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

SB 752**SECTION 1.** Section 4022.5 of the Business and Professions Code is amended to read:

4022.5. (a) "Designated representative" means an individual to whom a license has been granted pursuant to Section 4053. A pharmacist fulfilling the duties of Section 4053 shall not be required to obtain a license as a designated representative.

(b) "Designated representative-in-charge" means a designated representative or *designated representative-reverse distributor*, or a pharmacist proposed by a wholesaler or veterinary food-animal drug retailer and approved by the board as the supervisor or manager responsible for ensuring the wholesaler's or veterinary food-animal drug retailer's compliance with all state and federal laws and regulations pertaining to practice in the applicable license category.

SEC. 2. Section 4022.6 is added to the Business and Professions Code, to read:

4022.6. "Designated representative-reverse distributor" means an individual to whom a license has been granted pursuant to Section 4053.2, who is responsible for supervision over a licensed wholesaler that only acts as a reverse distributor. A pharmacist fulfilling the duties of Section 4053.2 shall not be required to obtain a license as a designated representative-reverse distributor.

SEC. 3. Section 4040.5 of the Business and Professions Code is amended to read:

4040.5. "Reverse distributor" means every person who acts as an agent for pharmacies, drug wholesalers, third-party logistics providers, manufacturers, and other entities by receiving, inventorying, warehousing, and managing the disposition of outdated or nonsaleable dangerous ~~drugs~~ *drugs or dangerous devices*.

SEC. 4. Section 4053.2 is added to the Business and Professions Code, to read:

4053.2. (a) Notwithstanding Sections 4051 and 4053, the board may issue a designated representative-reverse distributor license to a qualified individual who shall provide sufficient and qualified supervision over a licensed wholesaler that only acts as a reverse distributor. The designated representative-reverse distributor shall protect the public health and safety in the handling, storage, warehousing, and destruction of outdated or nonsaleable dangerous drugs and dangerous devices.

(b) An individual who is at least 18 years of age may apply for a designated representative-reverse distributor license. In order to obtain and maintain that license, the individual shall meet all of the following requirements:

(1) He or she shall be a high school graduate or possess a general education development certificate equivalent.

(2) He or she shall meet one of the following requirements:

(A) Have a minimum of one year of paid work experience in the past three years with a licensed wholesaler, third-party logistics provider, or pharmacy performing duties related to the distribution, dispensing, or destruction of dangerous drugs or dangerous devices.

(B) Have a minimum of one year of paid work experience in the destruction of outdated or nonsaleable dangerous drugs or dangerous devices pharmaceutical waste.

(C) Meet all of the prerequisites to take the examination required for licensure as a pharmacist by the board.

(3) (A) He or she shall complete a training program approved by the board that, at a minimum, addresses each of the following subjects:

(i) Knowledge and understanding of California law and federal law relating to the distribution of dangerous drugs and dangerous devices.

(ii) Knowledge and understanding of California law and federal law relating to the distribution of controlled substances.

(iii) Knowledge and understanding of California law and federal law relating to the removal and destruction of dangerous drugs, dangerous devices, and pharmaceutical waste.

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(iv) Knowledge and understanding of the United States Pharmacopoeia or federal Food and Drug Administration standards relating to the safe storage, handling, and transport of dangerous drugs and dangerous devices.

(B) The board may, by regulation, require the training program required under this paragraph to include additional material.

(C) The board shall not issue a license as a designated representative-reverse distributor until the applicant provides proof of completion of the training required by this paragraph to the board.

(c) A reverse distributor shall not operate without at least one designated representative or designated representative-reverse distributor present at each of its licensed places of business as required under Section 4160.

SEC. 5. Section 4059.5 of the Business and Professions Code is amended to read:

4059.5. (a) Except as otherwise provided in this chapter, dangerous drugs or dangerous devices may only be ordered by an entity licensed by the board and shall be delivered to the licensed premises and signed for and received by a pharmacist. Where a licensee is permitted to operate through a designated representative, ~~the designated representative~~ or in the case of a reverse distributor a designated representative-reverse distributor, that individual shall sign for and receive the delivery.

(b) A dangerous drug or dangerous device transferred, sold, or delivered to a person within this state shall be transferred, sold, or delivered only to an entity licensed by the board, to a manufacturer, or to an ultimate user or the ultimate user's agent.

(c) Notwithstanding subdivisions (a) and (b), deliveries to a hospital pharmacy may be made to a central receiving location within the hospital. However, the dangerous drugs or dangerous devices shall be delivered to the licensed pharmacy premises within one working day following receipt by the hospital, and the pharmacist on duty at that time shall immediately inventory the dangerous drugs or dangerous devices.

(d) Notwithstanding any other ~~provision of~~ law, a dangerous drug or dangerous device may be ordered by and provided to a manufacturer, physician, dentist, podiatrist, optometrist, veterinarian, naturopathic doctor pursuant to Section 3640.7, or laboratory, or a physical therapist acting within the scope of his or her license. A person or entity receiving delivery of a dangerous drug or dangerous device, or a duly authorized representative of the person or entity, shall sign for the receipt of the dangerous drug or dangerous device.

(e) A dangerous drug or dangerous device shall not be transferred, sold, or delivered to a person outside this state, whether foreign or domestic, unless the transferor, seller, or deliverer does so in compliance with the laws of this state and of the United States and of the state or country to which the dangerous drugs or dangerous devices are to be transferred, sold, or delivered. Compliance with the laws of this state and the United States and of the state or country to which the dangerous drugs or dangerous devices are to be delivered shall include, but not be limited to, determining that the recipient of the dangerous drugs or dangerous devices is authorized by law to receive the dangerous drugs or dangerous devices.

(f) Notwithstanding subdivision (a), a pharmacy may take delivery of dangerous drugs and dangerous devices when the pharmacy is closed and no pharmacist is on duty if all of the following requirements are met:

(1) The drugs are placed in a secure storage facility in the same building as the pharmacy.

(2) Only the pharmacist-in-charge or a pharmacist designated by the pharmacist-in-charge has access to the secure storage facility after dangerous drugs or dangerous devices have been delivered.

(3) The secure storage facility has a means of indicating whether it has been entered after dangerous drugs or dangerous devices have been delivered.

(4) The pharmacy maintains written policies and procedures for the delivery of dangerous drugs and dangerous devices to a secure storage facility.

(5) The agent delivering dangerous drugs and dangerous devices pursuant to this subdivision leaves documents indicating the name and amount of each dangerous drug or dangerous device delivered in the secure storage facility.

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The pharmacy shall be responsible for the dangerous drugs and dangerous devices delivered to the secure storage facility. The pharmacy shall also be responsible for obtaining and maintaining records relating to the delivery of dangerous drugs and dangerous devices to a secure storage facility.

SEC. 5.5. Section 4059.5 of the Business and Professions Code is amended to read:

4059.5. (a) Except as otherwise provided in this chapter, dangerous drugs or dangerous devices may only be ordered by an entity licensed by the board and shall be delivered to the licensed premises and signed for and received by a pharmacist. Where a licensee is permitted to operate through a designated representative, ~~the designated representative~~ or in the case of a reverse distributor a designated representative-reverse distributor, *that individual* shall sign for and receive the delivery.

(b) A dangerous drug or dangerous device transferred, sold, or delivered to a person within this state shall be transferred, sold, or delivered only to an entity licensed by the board, to a manufacturer, or to an ultimate user or the ultimate user's agent.

(c) Notwithstanding subdivisions (a) and (b), deliveries to a hospital pharmacy may be made to a central receiving location within the hospital. However, the dangerous drugs or dangerous devices shall be delivered to the licensed pharmacy premises within one working day following receipt by the hospital, and the pharmacist on duty at that time shall immediately inventory the dangerous drugs or dangerous devices.

(d) Notwithstanding any other ~~provision of~~ law, a dangerous drug or dangerous device may be ordered by and provided to a manufacturer, physician, dentist, podiatrist, optometrist, veterinarian, naturopathic doctor pursuant to Section 3640.7, or laboratory, or a physical therapist acting within the scope of his or her license. A person or entity receiving delivery of a dangerous drug or dangerous device, or a duly authorized representative of the person or entity, shall sign for the receipt of the dangerous drug or dangerous device.

(e) A dangerous drug or dangerous device shall not be transferred, sold, or delivered to a person outside this state, whether foreign or domestic, unless the transferor, seller, or deliverer does so in compliance with the laws of this state and of the United States and of the state or country to which the dangerous drugs or dangerous devices are to be transferred, sold, or delivered. Compliance with the laws of this state and the United States and of the state or country to which the dangerous drugs or dangerous devices are to be delivered shall include, but not be limited to, determining that the recipient of the dangerous drugs or dangerous devices is authorized by law to receive the dangerous drugs or dangerous devices.

(f) Notwithstanding subdivision (a), a pharmacy may take delivery of dangerous drugs and dangerous devices when the pharmacy is closed and no pharmacist is on duty if all of the following requirements are met:

(1) The drugs are placed in a secure storage facility in the same building as the pharmacy.

(2) Only the pharmacist-in-charge or a pharmacist designated by the pharmacist-in-charge has access to the secure storage facility after dangerous drugs or dangerous devices have been delivered.

(3) The secure storage facility has a means of indicating whether it has been entered after dangerous drugs or dangerous devices have been delivered.

(4) The pharmacy maintains written policies and procedures for the delivery of dangerous drugs and dangerous devices to a secure storage facility.

(5) The agent delivering dangerous drugs and dangerous devices pursuant to this subdivision leaves documents indicating the name and amount of each dangerous drug or dangerous device delivered in the secure storage facility.

The pharmacy shall be responsible for the dangerous drugs and dangerous devices delivered to the secure storage facility. The pharmacy shall also be responsible for obtaining and maintaining records relating to the delivery of dangerous drugs and dangerous devices to a secure storage facility.

(g) Notwithstanding subdivision (a), dangerous drugs and devices and controlled substances may be ordered by a remote dispensing site pharmacy licensed by the board and may be signed for and received by a registered pharmacy technician, who meets the qualifications of Section 4132, at the remote site. A controlled substance signed for by a pharmacy technician under this section shall be stored separately from existing inventory until the time the controlled substance is reviewed and countersigned by a pharmacist. Any receipt and storage of a

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controlled substance by a pharmacy technician pursuant to this section shall be captured on video, and that video shall be made accessible to the supervising pharmacy and maintained by the remote dispensing site pharmacy for 120 days.

SEC. 6. Section 4100 of the Business and Professions Code is amended to read:

4100. ~~(a)~~ -Within 30 days after changing his or her address of record with the board or after changing his or her name according to law, a pharmacist, intern pharmacist, technician, *designated representative, designated representative-3PL,* or designated ~~representative~~ *representative-reverse distributor* shall notify the executive officer of the board of the change of address or change of name.

~~(b) This section shall become operative on January 1, 2006.~~

SEC. 7. Section 4160 of the Business and Professions Code is amended to read:

4160. (a) A person shall not act as a wholesaler or third-party logistics provider of any dangerous drug or dangerous device unless he or she has obtained a license from the board.

(b) Upon approval by the board and the payment of the required fee, the board shall issue a license to the applicant.

(c) (1) A separate license shall be required for each place of business owned or operated by a wholesaler or third-party logistics provider. Each place of business may only be issued a single license by the board, except as provided in paragraph (2). Each license shall be renewed annually and shall not be transferable. At all times during which a place of business is open for business, at least one designated representative, in the case of a wholesaler, or designated representative-3PL in the case of a third-party logistics provider, shall be present. *A wholesaler that only acts as a reverse distributor may use either a designated representative or a designated representative-reverse distributor to fulfill this requirement.*

(2) A wholesaler and a 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) Every wholesaler shall be supervised or managed by a designated representative-in-charge. The designated representative-in-charge shall be responsible for the wholesaler's compliance with state and federal laws governing wholesalers. As part of its initial application for a license, and for each renewal, each wholesaler shall, on a form designed by the board, provide identifying information and the California license number for a designated representative or pharmacist proposed to serve as the designated representative-in-charge. The proposed designated representative-in-charge shall be subject to approval by the board. The board shall not issue

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or renew a wholesaler license without identification of an approved designated representative-in-charge for the wholesaler. The designated representative-in-charge shall maintain an active license as a designated representative with the board at all times during which he or she is designated as the designated representative-in-charge. *A wholesaler that only acts as a reverse distributor may identify and allow a designated representative-reverse distributor to perform in this capacity. That individual shall maintain an active license as a designated representative-reverse distributor.*

(e) Each place of business of a third-party logistics provider shall be supervised and managed by a responsible manager. The responsible manager shall be responsible for the compliance of the place of business with state and federal laws governing third-party logistics providers and with the third-party logistics provider's customer specifications, except where the customer's specifications conflict with state or federal laws. As part of its initial application for a license, and for each renewal, each third-party logistics provider shall, on a form designated by the board, provide identifying information and the California license number for a designated representative-3PL proposed to serve as the responsible manager. The proposed responsible manager shall be subject to approval by the board. The board shall not issue or renew a third-party logistics provider license without identification of an approved responsible manager for the third-party logistics provider. The responsible manager shall maintain an active license as a designated representative-3PL with the board at all times during which he or she is designated as the responsible manager.

(f) A wholesaler shall notify the board in writing, on a form designed by the board, within 30 days of the date when a designated representative-in-charge ceases to act as the designated representative-in-charge, and shall on the same form propose another ~~designated representative or pharmacist~~ *authorized licensee* to take over as the designated representative-in-charge. The proposed replacement designated representative-in-charge shall be subject to approval by the board. If disapproved, the wholesaler shall propose another replacement within 15 days of the date of disapproval, and shall continue to name proposed replacements until a designated representative-in-charge is approved by the board.

(g) A third-party logistics provider shall notify the board in writing, on a form designed by the board, within 30 days of the date when a responsible manager ceases to act as the responsible manager, and shall on the same form propose another designated representative-3PL to take over as the responsible manager. The proposed replacement responsible manager shall be subject to approval by the board. If disapproved, the third-party logistics provider shall propose another replacement within 15 days of the date of disapproval, and shall continue to name proposed replacements until a responsible manager is approved by the board.

(h) A drug manufacturer premises licensed by the Food and Drug Administration or licensed pursuant to Section 111615 of the Health and Safety Code that only distributes dangerous drugs and dangerous devices of its own manufacture is exempt from this section and Section 4161.

(i) 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 required in an amount established by the board as specified in subdivision (f) of Section 4400. 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~~ *For* purposes of retaining a temporary license, ~~nor~~ *or* for purposes of any disciplinary or license denial proceeding before the board, ~~shall~~ the temporary licenseholder *shall not* be deemed to have a vested property right or interest in the license.

SEC. 8. Section 4200.4 of the Business and Professions Code is amended to read:

4200.4. An applicant who fails ~~the national examination either the North American Pharmacist Licensure Examination or the California Practice Standards and Jurisprudence Examination for Pharmacists~~ may not retake ~~the that~~ examination for at least ~~90 days or for a period established by regulations adopted by the board~~ *45 days*. *The board may, in consultation with the Office of Professional Examination Services of the department, department, adopt a regulation establishing a different waiting period to retake the examination.*

SEC. 9. Section 4331 of the Business and Professions Code is amended to read:

4331. (a) A person ~~who is not a pharmacist, a designated representative in charge, or a designated representative and~~ *not authorized under this chapter* who takes charge of a wholesaler or veterinary food-animal drug retailer or

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who dispenses a prescription or furnishes dangerous devices, except as otherwise provided in this chapter, is guilty of a misdemeanor.

(b) A person who is not a responsible manager or a designated representative-3PL who takes charge of a third-party logistics provider or coordinates the warehousing or distribution of dangerous drugs or dangerous devices within a third-party logistics provider, except as otherwise provided in this chapter, is guilty of a misdemeanor.

(c) A person licensed as a veterinary food-animal drug retailer that fails to place in charge of that veterinary food-animal drug retailer a pharmacist or designated representative, or any person who, by himself or herself, or by any other person, permits the dispensing of prescriptions, except by a pharmacist or designated representative, or as otherwise provided in this chapter, is guilty of a misdemeanor.

(d) A person licensed as a wholesaler that fails to place in charge of that wholesaler a pharmacist or designated representative, or any person who, by himself or herself, or by any other person, permits the furnishing of dangerous drugs or dangerous devices, except by a pharmacist or designated representative, or as otherwise provided in this chapter, is guilty of a misdemeanor.

(e) A person licensed as a third-party logistics provider that fails to place in charge of a licensed place of business of the third-party logistics provider a responsible manager, or any person who, by himself or herself, or by any other person, permits the furnishing of dangerous drugs or dangerous devices, except by a facility manager, or as otherwise provided in this chapter, is guilty of a misdemeanor.

SEC. 10. Section 4400 of the Business and Professions Code, as added by Section 26 of Chapter 799 of the Statutes of 2016, 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 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, *or as a designated representative-reverse distributor pursuant to Section 4053.2* shall be one hundred fifty dollars (\$150) and may be increased to two hundred ten dollars (\$210).

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(2) The fee for the annual renewal of a license as a designated ~~representative~~ *representative, designated representative-3PL*, or designated ~~representative-3PL~~ *representative-reverse distributor* 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).

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(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 an outsourcing facility license shall be two thousand two hundred seventy dollars (\$2,270) and may be increased to up to three thousand one hundred eighty dollars (\$3,180) by the board. The fee for the renewal of an outsourcing facility license shall be one thousand three hundred twenty-five dollars (\$1,325) and may be increased to up to one thousand eight hundred fifty-five dollars (\$1,855) by the board. The fee for a temporary outsourcing facility license shall be seven hundred fifteen dollars (\$715).

(x) The fee for the issuance of a nonresident outsourcing facility license shall be two thousand three hundred eighty dollars (\$2,380) and may be increased to up to three thousand three hundred thirty-five dollars (\$3,335) by the board. The fee for the renewal of a nonresident outsourcing facility license shall be two thousand two hundred seventy dollars (\$2,270) and may be increased to up to three thousand one hundred eighty dollars (\$3,180) by the board. 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.

(y) 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).

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

SEC. 10.5. Section 4400 of the Business and Professions Code, as added by Section 26 of Chapter 799 of the Statutes of 2016, 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 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).

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(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, *or as a designated representative-reverse distributor pursuant to Section 4053.2* 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~~ *representative, designated representative-3PL*, or designated ~~representative-3PL~~ *representative-reverse distributor* 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).

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- (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 *or a hospital satellite compounding pharmacy* 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 an outsourcing facility license shall be two thousand two hundred seventy dollars (\$2,270) and may be increased to up to three thousand one hundred eighty dollars (\$3,180) by the board. The fee for the renewal of an outsourcing facility license shall be one thousand three hundred twenty-five dollars (\$1,325) and may be increased to up to one thousand eight hundred fifty-five dollars (\$1,855) by the board. The fee for a temporary outsourcing facility license shall be seven hundred fifteen dollars (\$715).
- (x) The fee for the issuance of a nonresident outsourcing facility license shall be two thousand three hundred eighty dollars (\$2,380) and may be increased to up to three thousand three hundred thirty-five dollars (\$3,335) by the board. The fee for the renewal of a nonresident outsourcing facility license shall be two thousand two hundred seventy dollars (\$2,270) and may be increased to up to three thousand one hundred eighty dollars (\$3,180) by the board. 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.
- (y) 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

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license shall be eight hundred five dollars (\$805) and may be increased to one thousand one hundred twenty-five dollars (\$1,125).

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

sec. 11. Section 5.5 of this bill incorporates amendments to Section 4059.5 of the Business and Professions Code proposed by both this bill and Assembly Bill 401. That section shall only become operative if (1) both bills are enacted and become effective on or before January 1, 2018, (2) each bill amends Section 4059.5 of the Business and Professions Code, and (3) this bill is enacted after Assembly Bill 401, in which case Section 5 of this bill shall not become operative.

sec. 12. Section 10.5 of this bill incorporates amendments to Section 4400 of the Business and Professions Code proposed by both this bill and Senate Bill 351. That section shall only become operative if (1) both bills are enacted and become effective on or before January 1, 2018, (2) each bill amends Section 4400 of the Business and Professions Code, and (3) this bill is enacted after Senate Bill 351, in which case Section 10 of this bill shall not become operative.

sec. 13. 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.

Attachment 2

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SECTION 1. Section 11165.1 of the Health and Safety Code, as amended by Section 2 of Chapter 708 of the Statutes of 2016, 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~~ department to obtain approval to *electronically* 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~~ *maintained by the department*. 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~~ department to obtain approval to *electronically* 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~~ *maintained by the department*. 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~~ *to access information contained in the CURES database*.

(ii) ~~Failure~~ *Failing* to maintain effective controls for access to the patient activity report.

(iii) ~~Suspended~~ *Having his* or ~~revoked her~~ federal DEA ~~registration~~ *registration suspended or revoked*.

(iv) ~~Any subscriber who is arrested for a violation of~~ *Violating a* 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~~ *Accessing* information for ~~any~~ *a reason* other ~~reason than caring for~~ *than to diagnose or treat* his or her ~~patients~~ *patients, or to document compliance with the law*.

(C) ~~Any An~~ authorized subscriber shall notify the ~~Department of Justice~~ department within 30 days of any changes to the subscriber account.

(D) Commencing no later than October 1, 2018, an approved health care practitioner, pharmacist, and any person acting on behalf of a health care practitioner or pharmacist pursuant to subdivision (b) of Section 209 of the Business and Professions Code may use the department's online portal or a health information technology system that meets the criteria required in subparagraph (E) to access information in the CURES database pursuant to this section. A subscriber who uses a health information technology system that meets the criteria required in subparagraph (E) to access the CURES database may submit automated queries to the CURES database that are triggered by predetermined criteria.

(E) Commencing no later than October 1, 2018, an approved health care practitioner or pharmacist may submit queries to the CURES database through a health information technology system if the entity that operates the health information technology system can certify all of the following:

(i) The entity will not use or disclose data received from the CURES database for any purpose other than delivering the data to an approved health care practitioner or pharmacist or performing data processing activities that may be necessary to enable the delivery unless authorized by, and pursuant to, state and federal privacy and security laws and regulations.

(ii) The health information technology system will authenticate the identity of an authorized health care practitioner or pharmacist initiating queries to the CURES database and, at the time of the query to the CURES database, the health information technology system submits the following data regarding the query to CURES:

(I) The date of the query.

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(II) *The time of the query.*

(III) *The first and last name of the patient queried.*

(IV) *The date of birth of the patient queried.*

(V) *The identification of the CURES user for whom the system is making the query.*

(iii) *The health information technology system meets applicable patient privacy and information security requirements of state and federal law.*

(iv) *The entity has entered into a memorandum of understanding with the department that solely addresses the technical specifications of the health information technology system to ensure the security of the data in the CURES database and the secure transfer of data from the CURES database. The technical specifications shall be universal for all health information technology systems that establish a method of system integration to retrieve information from the CURES database. The memorandum of understanding shall not govern, or in any way impact or restrict, the use of data received from the CURES database or impose any additional burdens on covered entities in compliance with the regulations promulgated pursuant to the federal Health Insurance Portability and Accountability Act of 1996 found in Parts 160 and 164 of Title 45 of the Code of Federal Regulations.*

(F) *No later than October 1, 2018, the department shall develop a programming interface or other method of system integration to allow health information technology systems that meet the requirements in subparagraph (E) to retrieve information in the CURES database on behalf of an authorized health care practitioner or pharmacist.*

(G) *The department shall not access patient-identifiable information in an entity's health information technology system.*

(H) *An entity that operates a health information technology system that is requesting to establish an integration with the CURES database shall pay a reasonable fee to cover the cost of establishing and maintaining integration with the CURES database.*

(I) *The department may prohibit integration or terminate a health information technology system's ability to retrieve information in the CURES database if the health information technology system fails to meet the requirements of subparagraph (E), or the entity operating the health information technology system does not fulfill its obligation under subparagraph (H).*

(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 A~~ 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~~ department.

(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~~ department 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~~ department pursuant to this section 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~~ practitioner 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

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arising from any false, incomplete, inaccurate, or misattributed information submitted to, reported by, or relied upon in the CURES database or for any resulting failure of the CURES database to accurately or timely report that information.

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

(1) "Automated basis" means using predefined criteria to trigger an automated query to the CURES database, which can be attributed to a specific health care practitioner or pharmacist.

(2) "Department" means the Department of Justice.

(3) "Entity" means an organization that operates, or provides or makes available, a health information technology system to a health care practitioner or pharmacist.

(4) "Health information technology system" means an information processing application using hardware and software for the storage, retrieval, sharing of or use of patient data for communication, decisionmaking, coordination of care, or the quality, safety, or efficiency of the practice of medicine or delivery of health care services, including, but not limited to, electronic medical record applications, health information exchange systems, or other interoperable clinical or health care information system.

(5) "User-initiated basis" means an authorized health care practitioner or pharmacist has taken an action to initiate the query to the CURES database, such as clicking a button, issuing a voice command, or taking some other action that can be attributed to a specific health care practitioner or pharmacist.

sec. 2. This act is an urgency statute necessary for the immediate preservation of the public peace, health, or safety within the meaning of Article IV of the California Constitution and shall go into immediate effect. The facts constituting the necessity are:

In order to enable the Department of Justice to ensure that information in the CURES database will be made available to prescribing physicians no later than October 1, 2018, so they may prevent the dangerous abuse of prescription drugs and to safeguard the health and safety of the people of this state, it is necessary that this act take effect immediately.

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SECTION 1. Section 1000 of the Penal Code is amended to read:

1000. (a) This chapter shall apply whenever a case is before any court upon an accusatory pleading for a violation of Section 11350, 11357, 11364, or 11365, paragraph (2) of subdivision (b) of Section 11375, Section 11377, or Section 11550 of the Health and Safety Code, or subdivision (b) of Section 23222 of the Vehicle Code, or Section 11358 of the Health and Safety Code if the marijuana planted, cultivated, harvested, dried, or processed is for personal use, or Section 11368 of the Health and Safety Code if the narcotic drug was secured by a fictitious prescription and is for the personal use of the defendant and was not sold or furnished to another, or subdivision (d) of Section 653f if the solicitation was for acts directed to personal use only, or Section 381 or subdivision (f) of Section 647 of the Penal Code, if for being under the influence of a controlled substance, or Section 4060 of the Business and Professions Code, and it appears to the prosecuting attorney that, except as provided in subdivision (b) of Section 11357 of the Health and Safety Code, all of the following apply to the defendant:

(1) ~~The defendant has no~~ *Within five years prior to the alleged commission of the charged offense, the defendant has not suffered a* conviction for any offense involving controlled substances ~~prior to the alleged commission of the charged offense.~~ *other than the offenses listed in this subdivision.*

(2) The offense charged did not involve a crime of violence or threatened violence.

(3) There is no evidence of a *contemporaneous* violation relating to narcotics or restricted dangerous drugs other than a violation of the ~~sections offenses~~ listed in this subdivision.

~~(4) The defendant's record does not indicate that probation or parole has ever been revoked without thereafter being completed.~~

~~(5) The defendant's record does not indicate that he or she has successfully completed or been terminated from diversion or deferred entry of judgment pursuant to this chapter within five years prior to the alleged commission of the charged offense.~~

~~(6)~~ (4) The defendant has no prior felony conviction within five years prior to the alleged commission of the charged offense.

(b) The prosecuting attorney shall review his or her file to determine whether or not paragraphs (1) to ~~(6)~~, (4), inclusive, of subdivision (a) apply to the defendant. ~~Upon the agreement of the prosecuting attorney, law enforcement, the public defender, and the presiding judge of the criminal division of the superior court, or a judge designated by the presiding judge, this procedure shall be completed as soon as possible after the initial filing of the charges.~~ If the defendant is found eligible, the prosecuting attorney shall file with the court a declaration in writing or state for the record the grounds upon which the determination is based, and shall make this information available to the defendant and his or her attorney. This procedure is intended to allow the court to set the hearing for ~~deferred entry of judgment~~ *pretrial diversion* at the arraignment. If the defendant is found ineligible for ~~deferred entry of judgment~~, *pretrial diversion*, the prosecuting attorney shall file with the court a declaration in writing or state for the record the grounds upon which the determination is based, and shall make this information available to the defendant and his or her attorney. The sole remedy of a defendant who is found ineligible for ~~deferred entry of judgment~~ *pretrial diversion* is a postconviction appeal.

(c) All referrals for ~~deferred entry of judgment~~ *pretrial diversion* granted by the court pursuant to this chapter shall be made only to programs that have been certified by the county drug program administrator pursuant to Chapter 1.5 (commencing with Section 1211) of Title 8, or to programs that provide services at no cost to the participant and have been deemed by the court and the county drug program administrator to be credible and effective. The defendant may request to be referred to a program in any county, as long as that program meets the criteria set forth in this subdivision.

(d) ~~Deferred entry of judgment for a~~ *Pretrial diversion for an alleged* violation of Section 11368 of the Health and Safety Code shall not prohibit any administrative agency from taking disciplinary action against a licensee or from denying a license. ~~Nothing in this subdivision shall be construed to~~ *This subdivision does not* expand or restrict the provisions of Section 1000.4.

(e) Any defendant who is participating in a program ~~referred to~~ *authorized* in this section may be required to undergo analysis of his or her urine for the purpose of testing for the presence of any drug as part of the program.

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However, ~~urine analysis- urinalysis~~ results shall not be admissible as a basis for any new criminal prosecution or proceeding.

SEC. 2. Section 1000.1 of the Penal Code is amended to read:

1000.1. (a) If the prosecuting attorney determines that this chapter may be applicable to the defendant, he or she shall advise the defendant and his or her attorney in writing of that determination. This notification shall include all of the following:

(1) A full description of the procedures for ~~deferred entry of judgment-~~ *pretrial diversion*.

(2) A general explanation of the roles and authorities of the probation department, the prosecuting attorney, the program, and the court in the process.

(3) A clear statement that ~~in lieu of trial-~~ the court may grant ~~deferred entry of judgment-~~ *pretrial diversion* with respect to any *crime offense* specified in subdivision (a) of Section 1000 that is charged, provided that the defendant pleads ~~guilty to each of these charges and waives time for the pronouncement of judgment,~~ *not guilty to the charge or charges, waives the right to a speedy trial, to a speedy preliminary hearing, and to a trial by jury, if applicable,* and that upon the defendant's successful completion of a program, as specified in subdivision (c) of Section 1000, the positive recommendation of the program authority and the motion of the *defendant,* prosecuting attorney, the court, or the probation department, but no sooner than ~~18~~ *12* months and no later than ~~three years~~ *18 months* from the date of the defendant's referral to the program, the court shall dismiss the charge or charges against the defendant.

(4) A clear statement that upon any failure of treatment or condition under the program, or any circumstance specified in Section 1000.3, the prosecuting attorney or the probation department or the court on its own may make a motion to the court ~~for entry of judgment and the court shall render a finding of guilt to the charge or charges pled, enter judgment, and schedule a sentencing hearing-~~ *to terminate pretrial diversion and schedule further proceedings* as otherwise provided in this code.

(5) An explanation of criminal record retention and disposition resulting from participation in the ~~deferred entry of judgment-~~ *pretrial diversion* program and the defendant's rights relative to answering questions about his or her arrest and ~~deferred entry of judgment-~~ *pretrial diversion* following successful completion of the program.

(b) If the defendant consents and waives his or her right to a speedy ~~trial or-~~ *trial,* a speedy preliminary hearing, *and to a trial by jury, if applicable,* the court may refer the case to the probation department or the court may summarily grant ~~deferred entry of judgment if the defendant pleads guilty to the charge or charges and waives time for the pronouncement of judgment-~~ *pretrial diversion*. When directed by the court, the probation department shall make an investigation and take into consideration the defendant's age, employment and service records, educational background, community and family ties, prior controlled substance use, treatment history, if any, demonstrable motivation, and other mitigating factors in determining whether the defendant is a person who would be benefited by education, treatment, or rehabilitation. The probation department shall also determine which programs the defendant would benefit from and which programs would accept the defendant. The probation department shall report its findings and recommendations to the court. The court shall make the final determination regarding education, treatment, or rehabilitation for the defendant. If the court determines that it is appropriate, the court shall grant ~~deferred entry of judgment-~~ *pretrial diversion* if the defendant pleads *not* guilty to the charge or charges and waives ~~time for the pronouncement of judgment-~~ *the right to a speedy trial, to a speedy preliminary hearing, and to a trial by jury, if applicable.*

(c) (1) No statement, or any information procured therefrom, made by the defendant to any probation officer or drug treatment worker, that is made during the course of any investigation conducted by the probation department or treatment program pursuant to subdivision (b), and prior to the reporting of the probation department's findings and recommendations to the court, shall be admissible in any action or proceeding brought subsequent to the investigation.

(2) No statement, or any information procured therefrom, with respect to the specific offense with which the defendant is charged, that is made to any probation officer or drug program worker subsequent to the granting of ~~deferred entry of judgment-~~ *pretrial diversion* shall be admissible in any action or ~~proceeding, including a sentencing hearing-~~ *proceeding.*

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(d) A defendant's ~~plea of guilty participation in pretrial diversion~~ pursuant to this chapter shall not constitute a conviction ~~for any purpose unless a judgment of guilty is entered pursuant to Section 1000.3. or an admission of guilt for any purpose.~~

SEC. 3. Section 1000.2 of the Penal Code is amended to read:

1000.2. (a) The court shall hold a hearing and, after consideration of any information relevant to its decision, shall determine if the defendant consents to further proceedings under this chapter and if the defendant should be granted ~~deferred entry of judgment. If the court does not deem the defendant a person who would be benefited by deferred entry of judgment, or if the defendant~~ *pretrial diversion*. If the defendant does not consent to ~~participate, participate in pretrial diversion~~, the proceedings shall continue as in any other case.

(b) At the time that ~~deferred entry of judgment pretrial diversion~~ is granted, any bail bond or undertaking, or deposit in lieu thereof, on file by or on behalf of the defendant shall be exonerated, and the court shall enter an order so directing.

(c) The period during which ~~deferred entry of judgment pretrial diversion~~ is granted shall be for no less than ~~18 12~~ months nor longer than ~~three years. 18 months. However, the defendant may request, and the court shall grant, for good cause shown, an extension of time to complete a program specified in subdivision (c) of Section 1000.~~ Progress reports shall be filed by the probation department with the court as directed by the court.

SEC. 4. Section 1000.3 of the Penal Code is amended to read:

1000.3. (a) If it appears to the prosecuting attorney, the court, or the probation department that the defendant is performing unsatisfactorily in the assigned program, ~~or that the defendant is not benefiting from education, treatment, or rehabilitation, or that the defendant is convicted of a misdemeanor~~ *convicted of an offense* that reflects the defendant's propensity for violence, or ~~that the defendant is convicted of a felony, or the defendant has engaged in criminal conduct rendering him or her unsuitable for deferred entry of judgment, the~~ the prosecuting attorney, the court on its own, or the probation department may make a motion for ~~entry of judgment. termination from pretrial diversion.~~

(b) After notice to the defendant, the court shall hold a hearing to determine whether ~~judgment should be entered. pretrial diversion shall be terminated.~~

(c) If the court finds that the defendant is not performing satisfactorily in the assigned program, or ~~that the defendant is not benefiting from education, treatment, or rehabilitation, or the~~ the court finds that the defendant has been convicted of a crime as indicated ~~above, or that the defendant has engaged in criminal conduct rendering him or her unsuitable for deferred entry of judgment, in subdivision (a),~~ the court shall ~~render a finding of guilt to the charge or charges pled, enter judgment, and schedule a sentencing hearing. schedule the matter for further proceedings~~ as otherwise provided in this code.

(d) If the defendant has ~~performed satisfactorily during the period in which deferred entry of judgment was granted, completed pretrial diversion,~~ at the end of that period, the criminal charge or charges shall be dismissed.

(e) Prior to dismissing the charge or charges or ~~rendering a finding of guilt and entering judgment, terminating pretrial diversion,~~ the court shall consider the defendant's ability to pay and whether the defendant has paid a diversion restitution fee pursuant to Section 1001.90, if ordered, and has met his or her financial obligation to the program, if any. As provided in Section 1203.1b, the defendant shall reimburse the probation department for the reasonable cost of any program investigation or progress report filed with the court as directed pursuant to Sections 1000.1 and 1000.2.

SEC. 5. Section 1000.4 of the Penal Code is amended to read:

1000.4. (a) Any record filed with the Department of Justice shall indicate the disposition in those cases ~~deferred referred to pretrial diversion~~ pursuant to this chapter. Upon successful completion of a ~~deferred entry of judgment pretrial diversion~~ program, the arrest upon which the ~~judgment defendant~~ was ~~deferred diverted~~ shall be deemed to have never occurred. The defendant may indicate in response to any question concerning his or her prior criminal record that he or she was not arrested or granted ~~deferred entry of judgment pretrial diversion~~ for the offense, except as specified in subdivision ~~(b).~~ (c). A record pertaining to an arrest resulting in successful completion of a ~~deferred entry of judgment pretrial diversion~~ program shall not, without the defendant's consent,

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be used in any way that could result in the denial of any employment, benefit, license, or ~~certificate~~. *certificate, except that, as specified in Section 492 of the Business and Professions Code, successful completion of a pretrial diversion program does not prohibit any agency established under Division 2 (commencing with Section 500) of the Business and Professions Code, or under any initiative act referred to in that division, from taking disciplinary action against a licensee or from denying a license for professional misconduct, notwithstanding that evidence of that misconduct may be contained in a record pertaining to an arrest leading to successful completion of a pretrial diversion program.*

(b) Notwithstanding any other law, any licensing agency listed in Section 144 of the Business and Professions Code may request, and is authorized to receive, from a local or state agency certified records regarding referral to, participation in, successful completion of, and termination from, diversion programs described in this section.

~~(b)~~ (c) The defendant shall be advised that, regardless of his or her successful completion of the ~~deferred entry of judgment- pretrial diversion~~ program, the arrest upon which the ~~judgment- pretrial diversion~~ was ~~deferred based~~ may be disclosed by the Department of Justice in response to any peace officer application request and that, notwithstanding subdivision (a), this section does not relieve him or her of the obligation to disclose the arrest in response to any direct question contained in any questionnaire or application for a position as a peace officer, as defined in Section 830.

SEC. 5.5. Section 1000.4 of the Penal Code is amended to read:

1000.4. (a) Any record filed with the Department of Justice shall indicate the disposition in those cases ~~deferred referred to pretrial diversion~~ pursuant to this chapter. Upon successful completion of a ~~deferred entry of judgment- pretrial diversion~~ program, the arrest upon which the ~~judgment- pretrial diversion~~ defendant was ~~deferred diverted~~ shall be deemed to have never ~~occurred- occurred and the court may issue an order to seal the records pertaining to the arrest as described in Section 851.92~~. The defendant may indicate in response to any question concerning his or her prior criminal record that he or she was not arrested or granted ~~deferred entry of judgment- pretrial diversion~~ for the offense, except as specified in subdivision ~~(b)- (c)~~. A record pertaining to an arrest resulting in successful completion of a ~~deferred entry of judgment- pretrial diversion~~ program shall not, without the defendant's consent, be used in any way that could result in the denial of any employment, benefit, license, or ~~certificate~~. *certificate, except that, as specified in Section 492 of the Business and Professions Code, successful completion of a pretrial diversion program shall not prohibit any agency established under Division 2 (commencing with Section 500) of the Business and Professions Code, or under any initiative act referred to in that division, from taking disciplinary action against a licensee or from denying a license for professional misconduct, notwithstanding that evidence of that misconduct may be recorded in a record pertaining to an arrest leading to successful completion of a pretrial diversion program.*

(b) Notwithstanding any other law, any licensing agency listed in Section 144 of the Business and Professions Code may request, and is authorized to receive, from a local or state agency certified records regarding referral to, participation in, successful completion of, and termination from, diversion programs described in this section.

~~(b)~~ (c) The defendant shall be advised that, regardless of his or her successful completion of the ~~deferred entry of judgment- pretrial diversion~~ program, the arrest upon which the ~~judgment- pretrial diversion~~ was ~~deferred based~~ may be disclosed by the Department of Justice in response to any peace officer application request and that, notwithstanding subdivision (a), this section does not relieve him or her of the obligation to disclose the arrest in response to any direct question contained in any questionnaire or application for a position as a peace officer, as defined in Section 830.

(d) The defendant shall be advised that, regardless of the defendant's successful completion of a pretrial diversion program, an order to seal records pertaining to an arrest made pursuant to this section has no effect on a criminal justice agency's ability to access and use those sealed records and information regarding sealed arrests, as described in Section 851.92.

SEC. 6. Section 1000.5 of the Penal Code is amended to read:

1000.5. (a) (1) The presiding judge of the superior court, or a judge designated by the presiding judge, together with the district attorney and the public defender, may agree in writing to establish and conduct a preguilty plea drug court program pursuant to the provisions of this chapter, wherein criminal proceedings are suspended without a plea of guilty for designated defendants. The drug court program shall include a regimen of graduated sanctions and rewards, individual and group therapy, ~~urine analysis- urinalysis~~ testing commensurate with treatment needs, close court monitoring and supervision of progress, educational or vocational counseling as appropriate, and

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other requirements as agreed to by the presiding judge or his or her designee, the district attorney, and the public defender. If there is no agreement in writing for a preguilty plea program by the presiding judge or his or her designee, the district attorney, and the public defender, the program shall be operated as a ~~deferred entry of judgment~~ *pretrial diversion* program as provided in this chapter.

(2) A person charged with a misdemeanor under paragraph (3) of subdivision (b) of Section 11357.5 or paragraph (3) of subdivision (b) of *Section* 11375.5 of the Health and Safety Code shall be eligible to participate in a preguilty plea drug court program established pursuant to this chapter, as set forth in Section 11375.7 of the Health and Safety Code.

(b) The provisions of Section 1000.3 and Section 1000.4 regarding satisfactory and unsatisfactory performance in a program shall apply to preguilty plea programs, except as provided in Section 11375.7 of the Health and Safety Code. If the court finds that (1) the defendant is not performing satisfactorily in the assigned program, (2) the defendant is not benefiting from education, treatment, or rehabilitation, (3) the defendant has been convicted of a crime specified in Section 1000.3, or (4) the defendant has engaged in criminal conduct rendering him or her unsuitable for the preguilty plea program, the court shall reinstate the criminal charge or charges. If the defendant has performed satisfactorily during the period of the preguilty plea program, at the end of that period, the criminal charge or charges shall be dismissed and the provisions of Section 1000.4 shall apply.

SEC. 7. Section 1000.6 of the Penal Code is amended to read:

~~1000.6. (a) Where a person is participating in a deferred entry of judgment program or a preguilty plea program pursuant to this chapter, the person may also participate in a licensed methadone or levoalphacetylmethadol (LAAM) program if the following conditions are met:~~

~~(1) The sheriff allows a methadone program to operate in the county jail.~~

~~(2) (a) The~~ *A person who is participating in a pretrial diversion program or a preguilty plea program pursuant to this chapter is authorized under the direction of a licensed health care practitioner, to use medications including, but not limited to, methadone, buprenorphine, or levoalphacetylmethadol (LAAM) to treat substance use disorders if the participant allows release of his or her medical records to the court presiding over the participant's preguilty plea or ~~deferred entry pretrial diversion~~ program for the limited purpose of determining whether or not the participant is ~~duly enrolled in the licensed methadone or LAAM program~~ using such medications under the direction of a licensed health care practitioner and is in compliance with ~~deferred entry~~ the pretrial diversion or preguilty plea program rules.*

~~(b) If the conditions specified in paragraphs (1) and (2) of subdivision (a) are met, participation in a methadone or LAAM treatment program the use by a participant of medications to treat substance use disorders shall not be the sole reason for exclusion from a ~~deferred entry pretrial diversion~~ or preguilty plea program. A ~~methadone or LAAM patient who~~ *patient who uses medications to treat substance use disorders and* participates in a preguilty plea or ~~deferred entry pretrial diversion~~ program shall comply with all court program rules.~~

~~(c) A person who is participating in a ~~deferred entry of judgment~~ *pretrial diversion* program or preguilty plea program pursuant to this chapter who ~~participates in a licensed methadone or LAAM program~~ *uses medications to treat substance use disorders* shall present to the court a declaration from ~~the director of the methadone or LAAM program, or the director's~~ *his or her health care practitioner, or his or her health care practitioner's* authorized representative, that the person is currently ~~enrolled and in good standing in the program.~~ *under their care.*~~

~~(d) Urinalysis results that only establish that a person described in this section has ingested or taken the methadone administered or prescribed by a licensed methadone or LAAM program medication duly prescribed to that person by his or her physician or psychiatrist, or medications used to treat substance use disorders, shall not be considered a violation of the terms of the ~~deferred entry of judgment~~ *pretrial diversion* or preguilty plea program under this chapter.~~

~~(e) Except as provided in subdivisions (a) to (d), inclusive, this section shall not be interpreted to amend any provisions governing deferred entry and does not affect any other law governing diversion programs.~~

SEC. 8. *Section 1000.65 is added to the Penal Code, immediately following Section 1000.6, to read:*

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1000.65. This chapter does not affect a pretrial diversion program provided pursuant to Chapter 2.7 (commencing with Section 1001).

sec. 9. Section 5.5 of this bill incorporates amendments to Section 1000.4 of the Penal Code proposed by both this bill and Senate Bill 393. That section shall only become operative if (1) both bills are enacted and become effective on or before January 1, 2018, (2) each bill amends Section 1000.4 of the Penal Code, and (3) this bill is enacted after Senate Bill 393, in which case Section 5 of this bill shall not become operative.

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SECTION 1. (a) The Legislature hereby finds and declares all of the following:

(1) Greater access to health care professionals improves patient outcomes. Patients see their pharmacist more often than any other health care professional. Making pharmacists readily available should be a top priority of the state.

(2) Health care delivery and technology are evolving. Utilizing technology to connect patients to pharmacists in areas where there is no access will improve medication adherence and outcomes.

(3) Over 30 percent of patients never fill their prescriptions. According to a study by Kaiser, this number drops to 5 percent when patients have more convenient access to a pharmacy. Lack of convenient access to a pharmacy leads to lower rates of medication adherence and, according to the New England Healthcare Institute, nonadherence leads to over \$290 billion in avoidable medial spending each year.

(4) Seventy-seven percent of rural counties are designated as health professional shortage areas. In California there are 115 identified areas located in 47 counties where the closest pharmacy is more than 10 miles away.

(5) In rural communities, the geographic and economic realities make it difficult to maintain a pharmacy. Between 2003 and 2013, there was a 12.1-percent decrease in rural pharmacies. Remote dispensing site pharmacies create an economically feasible way to bring pharmacy access to these underserved areas through the use of technology.

(b) The Legislature further finds and declares both of the following:

(1) Section 4001.1 of the Business and Professions Code establishes public protection as the highest priority of the California State Board of Pharmacy in exercising its licensing, regulatory, and disciplinary functions. That section further provides that whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount.

(2) Public protection requires the California State Board of Pharmacy to enforce the laws related to a supervising pharmacy, as defined by Section 4044.6 of the Business and Professions Code, and a remote dispensing site pharmacy, as defined in Section 4044.3 of the Business and Professions Code, through licensure.

(c) It is the intent of the Legislature to enact legislation that will promote policies to allow all California patients, regardless of location, to have access to a pharmacist, thereby increasing medication adherence.

SEC. 2. *Section 4044.3 is added to the Business and Professions Code, to read:*

4044.3. (a) "Remote dispensing site pharmacy" means a licensed pharmacy located in this state that is exclusively overseen and operated by a supervising pharmacy and staffed by one or more qualified registered pharmacy technicians, as defined in Section 4132, where pharmaceutical care services, including, but not limited to, the storage and dispensing of prescription drugs and controlled substances, drug regimen review, and patient counseling, are remotely monitored or provided, or both, by a licensed pharmacist through the use of telepharmacy technology.

(b) Unless otherwise specified in this chapter, a remote dispensing site pharmacy shall comply with all state and federal laws regulating the practice of pharmacy.

SEC. 3. *Section 4044.6 is added to the Business and Professions Code, to read:*

4044.6. (a) "Supervising pharmacy" means a licensed pharmacy located in this state that is owned and operated by a person or persons where the majority of the beneficial interest in, as well as the management and control, resides with at least one board-licensed pharmacist, as defined in Section 4036, that exclusively oversees the operations of a remote dispensing site pharmacy.

(b) A supervising pharmacy shall be exclusively responsible for the operation of the remote dispensing site pharmacy and its employees pursuant to Section 4131.

SEC. 4. *Section 4044.7 is added to the Business and Professions Code, to read:*

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4044.7. "Telepharmacy" means a system that is used by a supervising pharmacy for the purpose of monitoring the dispensing of prescription drugs by a remote dispensing site pharmacy and provides for related drug regimen review and patient counseling by an electronic method, including, but not limited to, the use of audio, visual, still image capture, and store and forward technology.

SEC. 5. Section 4059.5 of the Business and Professions Code is amended to read:

4059.5. (a) Except as otherwise provided in this chapter, dangerous drugs or dangerous devices may only be ordered by an entity licensed by the board and shall be delivered to the licensed premises and signed for and received by a pharmacist. Where a licensee is permitted to operate through a designated representative, the designated representative shall sign for and receive the delivery.

(b) A dangerous drug or dangerous device transferred, sold, or delivered to a person within this state shall be transferred, sold, or delivered only to an entity licensed by the board, to a manufacturer, or to an ultimate user or the ultimate user's agent.

(c) Notwithstanding subdivisions (a) and (b), deliveries to a hospital pharmacy may be made to a central receiving location within the hospital. However, the dangerous drugs or dangerous devices shall be delivered to the licensed pharmacy premises within one working day following receipt by the hospital, and the pharmacist on duty at that time shall immediately inventory the dangerous drugs or dangerous devices.

(d) Notwithstanding any other ~~provision of~~ law, a dangerous drug or dangerous device may be ordered by and provided to a manufacturer, physician, dentist, podiatrist, optometrist, veterinarian, naturopathic doctor pursuant to Section 3640.7, or laboratory, or a physical therapist acting within the scope of his or her license. A person or entity receiving delivery of a dangerous drug or dangerous device, or a duly authorized representative of the person or entity, shall sign for the receipt of the dangerous drug or dangerous device.

(e) A dangerous drug or dangerous device shall not be transferred, sold, or delivered to a person outside this state, whether foreign or domestic, unless the transferor, seller, or deliverer does so in compliance with the laws of this state and of the United States and of the state or country to which the dangerous drugs or dangerous devices are to be transferred, sold, or delivered. Compliance with the laws of this state and the United States and of the state or country to which the dangerous drugs or dangerous devices are to be delivered shall include, but not be limited to, determining that the recipient of the dangerous drugs or dangerous devices is authorized by law to receive the dangerous drugs or dangerous devices.

(f) Notwithstanding subdivision (a), a pharmacy may take delivery of dangerous drugs and dangerous devices when the pharmacy is closed and no pharmacist is on duty if all of the following requirements are met:

(1) The drugs are placed in a secure storage facility in the same building as the pharmacy.

(2) Only the pharmacist-in-charge or a pharmacist designated by the pharmacist-in-charge has access to the secure storage facility after dangerous drugs or dangerous devices have been delivered.

(3) The secure storage facility has a means of indicating whether it has been entered after dangerous drugs or dangerous devices have been delivered.

(4) The pharmacy maintains written policies and procedures for the delivery of dangerous drugs and dangerous devices to a secure storage facility.

(5) The agent delivering dangerous drugs and dangerous devices pursuant to this subdivision leaves documents indicating the name and amount of each dangerous drug or dangerous device delivered in the secure storage facility.

The pharmacy shall be responsible for the dangerous drugs and dangerous devices delivered to the secure storage facility. The pharmacy shall also be responsible for obtaining and maintaining records relating to the delivery of dangerous drugs and dangerous devices to a secure storage facility.

(g) Notwithstanding subdivision (a), dangerous drugs and devices and controlled substances may be ordered by a remote dispensing site pharmacy licensed by the board and may be signed for and received by a registered pharmacy technician, who meets the qualifications of Section 4132, at the remote site. A controlled substance signed for by a pharmacy technician under this section shall be stored separately from existing inventory until the time the controlled substance is reviewed and countersigned by a pharmacist. Any receipt and storage of a

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controlled substance by a pharmacy technician pursuant to this section shall be captured on video, and that video shall be made accessible to the supervising pharmacy and maintained by the remote dispensing site pharmacy for 120 days.

SEC. 5.5. Section 4059.5 of the Business and Professions Code is amended to read:

4059.5. (a) Except as otherwise provided in this chapter, dangerous drugs or dangerous devices may only be ordered by an entity licensed by the board and shall be delivered to the licensed premises and signed for and received by a pharmacist. Where a licensee is permitted to operate through a designated representative, ~~the designated representative~~ *or in the case of a reverse distributor a designated representative-reverse distributor, that individual* shall sign for and receive the delivery.

(b) A dangerous drug or dangerous device transferred, sold, or delivered to a person within this state shall be transferred, sold, or delivered only to an entity licensed by the board, to a manufacturer, or to an ultimate user or the ultimate user's agent.

(c) Notwithstanding subdivisions (a) and (b), deliveries to a hospital pharmacy may be made to a central receiving location within the hospital. However, the dangerous drugs or dangerous devices shall be delivered to the licensed pharmacy premises within one working day following receipt by the hospital, and the pharmacist on duty at that time shall immediately inventory the dangerous drugs or dangerous devices.

(d) Notwithstanding any other ~~provision of~~ law, a dangerous drug or dangerous device may be ordered by and provided to a manufacturer, physician, dentist, podiatrist, optometrist, veterinarian, naturopathic doctor pursuant to Section 3640.7, or laboratory, or a physical therapist acting within the scope of his or her license. A person or entity receiving delivery of a dangerous drug or dangerous device, or a duly authorized representative of the person or entity, shall sign for the receipt of the dangerous drug or dangerous device.

(e) A dangerous drug or dangerous device shall not be transferred, sold, or delivered to a person outside this state, whether foreign or domestic, unless the transferor, seller, or deliverer does so in compliance with the laws of this state and of the United States and of the state or country to which the dangerous drugs or dangerous devices are to be transferred, sold, or delivered. Compliance with the laws of this state and the United States and of the state or country to which the dangerous drugs or dangerous devices are to be delivered shall include, but not be limited to, determining that the recipient of the dangerous drugs or dangerous devices is authorized by law to receive the dangerous drugs or dangerous devices.

(f) Notwithstanding subdivision (a), a pharmacy may take delivery of dangerous drugs and dangerous devices when the pharmacy is closed and no pharmacist is on duty if all of the following requirements are met:

(1) The drugs are placed in a secure storage facility in the same building as the pharmacy.

(2) Only the pharmacist-in-charge or a pharmacist designated by the pharmacist-in-charge has access to the secure storage facility after dangerous drugs or dangerous devices have been delivered.

(3) The secure storage facility has a means of indicating whether it has been entered after dangerous drugs or dangerous devices have been delivered.

(4) The pharmacy maintains written policies and procedures for the delivery of dangerous drugs and dangerous devices to a secure storage facility.

(5) The agent delivering dangerous drugs and dangerous devices pursuant to this subdivision leaves documents indicating the name and amount of each dangerous drug or dangerous device delivered in the secure storage facility.

The pharmacy shall be responsible for the dangerous drugs and dangerous devices delivered to the secure storage facility. The pharmacy shall also be responsible for obtaining and maintaining records relating to the delivery of dangerous drugs and dangerous devices to a secure storage facility.

(g) Notwithstanding subdivision (a), dangerous drugs and devices and controlled substances may be ordered by a remote dispensing site pharmacy licensed by the board and may be signed for and received by a registered pharmacy technician, who meets the qualifications of Section 4132, at the remote site. A controlled substance signed for by a pharmacy technician under this section shall be stored separately from existing inventory until the time the controlled substance is reviewed and countersigned by a pharmacist. Any receipt and storage of a

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controlled substance by a pharmacy technician pursuant to this section shall be captured on video, and that video shall be made accessible to the supervising pharmacy and maintained by the remote dispensing site pharmacy for 120 days.

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

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

- (1) To issue a veterinary food-animal drug retailer license to a wholesaler pursuant to Section 4196.
- (2) To issue a license to compound sterile drugs to a pharmacy pursuant to Section 4127.1 or 4127.2.
- (3) To issue a centralized hospital packaging license pursuant to Section 4128.
- (4) *To issue licenses to two independently owned clinics that share a clinic office space pursuant to Section 4180.5.*

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

SEC. 7. *Article 8 (commencing with Section 4130) is added to Chapter 9 of Division 2 of the Business and Professions Code, to read:*

Article 8. Telepharmacy Systems and Remote Dispensing Site Pharmacies

4130. (a) *A telepharmacy system shall be used for the dispensing of prescription drugs and providing related drug regimen review and patient counseling services at a remote dispensing site pharmacy.*

(b) *If all of the requirements of this article and other relevant provisions of this chapter are met, the board shall issue a remote dispensing site pharmacy license for the purpose of increasing access to dispensing or pharmaceutical care services in the geographic area in which the remote dispensing site pharmacy is to be located.*

(c) (1) *A remote dispensing site pharmacy shall only be located in a medically underserved area unless otherwise approved by the board. For purposes of this section, a "medically underserved area" means a location that does not have a pharmacy that serves the general public within 10 road miles of the remote dispensing site.*

(2) *Notwithstanding paragraph (1), if a pharmacy serving the general public is later established within 10 road miles of a remote dispensing site pharmacy, the remote dispensing site pharmacy may continue to operate.*

(d) *A remote dispensing site pharmacy shall only be staffed by pharmacists or pharmacy technicians, or both, and shall not employ any unlicensed personnel.*

(e) *A remote dispensing site pharmacy license shall be issued only to the supervising pharmacy. A supervising pharmacy shall not obtain more than one remote dispensing site pharmacy license.*

(f) *A remote dispensing site pharmacy shall not be operated by the state and shall not be located in any state facility, including, but not limited to, correctional facilities, state hospitals, or developmental centers. This section shall not be construed to preclude a pharmacist who is otherwise eligible to operate a remote dispensing site pharmacy pursuant to this section from leasing space in property owned by the state, provided it is not for the purpose of serving individuals otherwise served by pharmacists and pharmacy technicians employed by the state.*

(g) *A remote dispensing site pharmacy shall not be located or operated for the purpose of displacing state employees.*

(h) *If a remote dispensing site pharmacy dispenses more than 225 prescriptions per day, calculated each calendar year, it shall cease to be a remote dispensing site pharmacy and may become a full-service pharmacy licensed under Section 4110 with a pharmacist onsite if it meets all the requirements for licensure for a pharmacy.*

4131. (a) *A supervising pharmacy shall provide telepharmacy services for only one remote dispensing site pharmacy.*

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(b) A supervising pharmacy shall not be located greater than 150 road miles from a remote dispensing site pharmacy, unless otherwise approved by the board.

(c) A supervising pharmacy and remote dispensing site pharmacy shall be under common ownership.

(d) Unless staffed by a pharmacist, a remote dispensing site pharmacy shall be staffed by at least one registered pharmacy technician meeting the qualifications of Section 4132. A technician shall remain under the direct supervision and control of a pharmacist at the supervising pharmacy at all times that the remote dispensing site pharmacy is operational. For the purposes of this article, direct supervision and control does not require the pharmacist to be physically present at the remote dispensing site pharmacy, but the pharmacist shall use a telepharmacy system to supervise operations through audio and visual technology from the supervising pharmacy.

(e) Notwithstanding any other law, a pharmacist may serve as the pharmacist-in-charge for a pharmacy in addition to serving as pharmacist-in-charge of a supervising pharmacy. The designated pharmacist-in-charge of the supervising pharmacy shall also serve as the designated pharmacist-in-charge at the remote dispensing site pharmacy.

(f) Notwithstanding any other law, the pharmacist-in-charge of the remote dispensing site pharmacy and the pharmacist-on-duty at the supervising pharmacy shall be responsible for ensuring that both the supervising pharmacy and remote dispensing site pharmacy are sufficiently staffed to allow for appropriate supervision, which is supervision that would not be reasonably expected to result in an unreasonable risk of harm to public health, safety, or welfare.

4132. (a) In addition to the requirements of Section 4202, a pharmacy technician working at a remote dispensing site pharmacy shall meet the qualifications promulgated by the board. The regulations developed by the board shall only apply to pharmacy technicians working at remote dispensing sites.

(b) Notwithstanding Section 4115, a registered pharmacy technician may perform order entry, packaging, manipulative, repetitive, and other nondiscretionary tasks at a remote dispensing site pharmacy under the supervision of a pharmacist at a supervising pharmacy using a telepharmacy system.

(c) A pharmacy technician at a remote dispensing site pharmacy shall not do any of the following:

(1) Receive a new prescription order orally from a prescriber or other person authorized to prescribe by law.

(2) Consult with a patient or his or her agent regarding a prescription, either prior to or after dispensing, or regarding any medical information contained in a patient medication record system or patient chart.

(3) Identify, evaluate, or interpret a prescription.

(4) Interpret the clinical data in a patient medication record system or patient chart.

(5) Consult with any prescriber, nurse, or other health care professional or authorized agent thereof.

(6) Supervise the packaging of drugs and check the packaging procedure and product upon completion.

(7) Perform any function that requires the professional judgment of a licensed pharmacist.

(8) Compound drug preparations.

(d) Notwithstanding Section 4115, a pharmacist at a supervising pharmacy may supervise up to two pharmacy technicians at each remote dispensing site pharmacy. This subdivision shall not be construed to alter a pharmacist's ability to also supervise pharmacy technicians at the supervising pharmacy.

4133. (a) A telepharmacy system shall maintain a video and audio communication system that provides for effective communication between the supervising pharmacy and the remote dispensing site pharmacy's personnel and patients.

(b) A telepharmacy system shall facilitate adequate pharmacist supervision and allow the appropriate exchange of visual, verbal, and written communications for patient counseling and other matters involved in the lawful dispensing of drugs.

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(c) Patient counseling shall be provided using audio-visual communication prior to all prescriptions being dispensed from a remote dispensing site pharmacy.

(d) A telepharmacy system shall be able to do all of the following:

(1) Identify and record the pharmacy technician preparing each prescription and the supervising pharmacist who reviewed and authorized the dispensing of the prescription.

(2) Require a pharmacist to review and compare the electronic image of any new prescription presented at the remote dispensing site pharmacy with the data entry record of the prescription.

(3) Require the pharmacy technician to use barcode technology to verify the accuracy of the drug to be dispensed.

(4) Require remote visual confirmation by a pharmacist at the supervising pharmacy of the drug stock bottle and the drug to be dispensed prior to dispensing.

(5) Ensure that a prescription is not sold or delivered to a patient prior to a pharmacist performing final verification of the accuracy of the prescription and releasing the prescription for sale and delivery.

(e) The video and audio communication system used to counsel and interact with each patient or patient's caregiver shall be secure and compliant with the federal Health Insurance Portability and Accountability Act (Public Law 104-191).

(f) All records of prescriptions dispensed including the records of the actions performed through the telepharmacy system shall be maintained at the remote dispensing site pharmacy and shall be maintained for three years after the filling of the prescription.

4134. (a) A pharmacist from the supervising pharmacy shall complete a monthly in-person, self-inspection of each remote dispensing site pharmacy using a form designated by the board and shall retain all inspection reports.

(b) A perpetual inventory shall be kept for all controlled substances stored at a remote dispensing site pharmacy.

(c) All controlled substances at a remote dispensing site pharmacy shall be stored in a secure cabinet or safe that is locked.

(d) A pharmacist from the supervising pharmacy shall perform inventory and inventory reconciliation functions at a remote dispensing site pharmacy to detect and prevent the loss of any controlled substance.

(e) The pharmacist-in-charge of a remote dispensing site pharmacy shall review all inventory and inventory reconciliation reports taken and shall establish and maintain secure methods to prevent losses of any controlled substance. The board shall develop written policies and procedures for performing the inventory reconciliation reports required by this section.

(f) A pharmacist from the supervising pharmacy shall compile an inventory reconciliation report of all Schedule II controlled substances at a remote dispensing site pharmacy at least once every three months. This compilation shall require all of the following:

(1) A physical count, not an estimate, of all quantities of Schedule II controlled substances at the remote dispensing site pharmacy. The biennial inventory of controlled substances as required under federal law may serve as one of the mandated inventories under this section in the year that the federal biennial inventory is performed, provided that the biennial inventory was taken no more than three months from the last inventory required by this section.

(2) A review of all acquisitions and dispositions of Schedule II controlled substances since the last inventory reconciliation report.

(3) A comparison of paragraphs (1) and (2) in order to determine if there are any variances.

(4) All records used to compile each inventory reconciliation report shall be maintained in the remote dispensing site pharmacy for at least three years in a readily retrievable form.

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(g) A remote dispensing site pharmacy shall report to the board, in writing, any identified losses of controlled substances and possible causes of the loss within 30 days of discovering the loss unless the cause of loss is theft, diversion, or self-use in which case the report shall be made within 14 days of discovering the loss. If the remote dispensing site pharmacy is unable to identify the cause of the loss, the remote dispensing site pharmacy shall undertake further investigation to identify the cause of the loss and security improvements necessary to prevent any additional losses of controlled substances. The pharmacist-in-charge shall be responsible for submitting the report to the board.

(h) Possible causes of overages shall be identified in writing and incorporated into the inventory reconciliation report.

(i) The inventory reconciliation report shall be dated and signed by the individual or individuals performing the inventory and countersigned by the pharmacist-in-charge of the remote dispensing site pharmacy. A countersignature shall not be required if the pharmacist-in-charge personally completed the inventory reconciliation report. The inventory reconciliation report shall be maintained in the remote dispensing site pharmacy for at least three years in a readily retrievable form.

4135. (a) While closed, a remote dispensing site pharmacy shall utilize an alarm or other comparable monitoring system to protect its equipment, records, and supply of drugs, devices, and other restricted sale items from unauthorized access, acquisition, or use.

(b) Unless a pharmacist is present at the remote dispensing site pharmacy, a remote dispensing site pharmacy shall not be open or its employees allowed access to it during times the supervising pharmacy is closed. The security system shall allow for tracking of entries into the remote dispensing site pharmacy and the pharmacist-in-charge shall periodically review the record of entries. Pharmacy services shall not be provided at a remote dispensing site pharmacy if the telepharmacy system is unavailable.

(c) The remote dispensing site pharmacy shall retain a recording of facility surveillance, excluding patient communications, for a minimum of 120 days.

SEC. 8. Section 4169.1 is added to the Business and Professions Code, immediately following Section 4169, to read:

4169.1. A wholesaler, upon discovery, shall notify the board in writing of any suspicious orders of controlled substances placed by a California-licensed pharmacy or wholesaler by providing the board a copy of the information that the wholesaler provides to the United States Drug Enforcement Administration. Suspicious orders include, but are not limited to, orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

SEC. 9. Section 4180.5 is added to the Business and Professions Code, to read:

4180.5. (a) The board may issue licenses authorized under Section 4180 to two independently owned clinics that share a clinic office space, provided that the clinics comply with the following:

(1) Each clinic maintains a separate clinic license with the board with its own professional directors, administrators, owners, and officers.

(2) Each clinic maintains physically separate and locked drug stocks.

(3) Each clinic separately maintains all records required by this article, including acquisition and disposition records.

(4) Dangerous drugs and dangerous devices shall not be loaned between the two licensed clinics.

(b) Dangerous drugs and dangerous device losses at the shared clinic office shall be reported to the board as required by law. Each clinic may be jointly and severally responsible for the drug losses.

(c) The applicants shall also provide the board with a copy of the co-location agreement and a one-time application fee of seven hundred fifty dollars (\$750) for the licenses.

(d) Any change in ownership in either clinic shall require a new application under this section and fees as required by subdivision (q) of Section 4400 and subdivision (c) of this section.

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(e) The board shall not issue licenses authorized under Section 4180 to two independently owned clinics that share a clinic office space pursuant to this section until the board is provided with documentation from the Director of the Department of Health Care Services that any Medi-Cal financing issues, including the ability to claim associated federal financial participation or 340(b) program participation, have been sufficiently addressed to the director's satisfaction. The Department of Health Care Services may seek any federal approvals it deems necessary to implement this section.

(f) The board shall not issue licenses authorized under Section 4180 to two independently owned clinics that share a clinic office space pursuant to the section until the board is provided with documentation from the Director of the Department of Public Health that any licensing and regulatory issues have been sufficiently addressed to the director's satisfaction.

(g) This section shall become inoperative on January 1, 2021, and as of that date is repealed.

SEC. 10. Section 1211 is added to the Health and Safety Code, to read:

1211. (a) Notwithstanding any other law, a clinic licensed pursuant to Section 1204 may operate in shared clinic space with a clinic exempt from licensure pursuant to subdivision (b) of Section 1206 under the following conditions:

(1) Each clinic uses signage that clearly identifies which clinic is operating during the hours of operation.

(2) The licensed clinic reports the operating hours of both clinics.

(3) Each clinic maintains separate medical records.

(4) Each clinic maintains separate drug storage.

(5) Both clinics are licensed by the California State Board of Pharmacy pursuant to Section 4180.5 of the Business and Professions Code.

(b) The department may enter and inspect the shared space at any time pursuant to Section 1227 of the Health and Safety Code, including accessing records. The exempt clinic shall allow the department to access and inspect its records.

(c) The licensed clinic shall be responsible for any statutory or regulatory violations occurring on the premises.

(d) Notwithstanding the rulemaking provisions of the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code), the department may implement, interpret, or make specific this section by means of all-facility letters, or similar instructions, without taking regulatory action.

(e) This section shall become inoperative on January 1, 2021, and as of that date is repealed.

sec. 11. Section 5.5 of this bill incorporates amendments to Section 4059.5 of the Business and Professions Code proposed by both this bill and Senate Bill 752. That section shall only become operative if (1) both bills are enacted and become effective on or before January 1, 2018, (2) each bill amends Section 4059.5 of the Business and Professions Code, and (3) this bill is enacted after Senate Bill 752, in which case Section 5 of this bill shall not become operative.

sec. 12. 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.

AB 602**SECTION 1.** *Section 4025.2 is added to the Business and Professions Code, to read:*

4025.2. "Nonprescription diabetes test device" means a glucose meter or test strip for use in the treatment of prediabetic or diabetic individuals that may be sold without a prescription and that is labeled for use by the consumer in accordance with the requirements of the laws and rules of this state and the federal government.

SEC. 2. Section 4057 of the Business and Professions Code is amended to read:

4057. (a) Except as provided in ~~Sections 4006, 4240, and~~ *Section 4006, subdivision (d) of Section 4081, Section 4240, subdivisions (t) and (u) of Section 4301, and Section 4342*, this chapter does not apply to the retail sale of nonprescription drugs that are not subject to Section 4022 and that are packaged or bottled in the manufacturer's or distributor's container and labeled in accordance with applicable federal and state drug labeling requirements.

(b) This chapter does not apply to specific dangerous drugs and dangerous devices listed in board regulations, where the sale or furnishing is made to any of the following:

(1) A physician, dentist, podiatrist, pharmacist, medical technician, medical technologist, optometrist, or chiropractor holding a currently valid and unrevoked license and acting within the scope of his or her profession.

(2) A clinic, hospital, institution, or establishment holding a currently valid and unrevoked license or permit under Division 2 (commencing with Section 1200) of the Health and Safety Code, or Chapter 2 (commencing with Section 3300) of Division 3 of, or Part 2 (commencing with Section 6250) of Division 6 of, the Welfare and Institutions Code.

(c) This chapter shall not apply to a home health agency licensed under Chapter 8 (commencing with Section 1725) of, or a hospice licensed under Chapter 8.5 (commencing with Section 1745) of, Division 2 of, the Health and Safety Code, when it purchases, stores, furnishes, or transports specific dangerous drugs and dangerous devices listed in board regulations in compliance with applicable law and regulations including:

(1) Dangerous devices described in subdivision (b) of Section 4022, as long as these dangerous devices are furnished only upon the prescription or order of a physician, dentist, or podiatrist.

(2) Hypodermic needles and syringes.

(3) Irrigation solutions of 50 cubic centimeters or greater.

(d) This chapter does not apply to the storage of devices in secure central or ward supply areas of a clinic, hospital, institution, or establishment holding a currently valid and unrevoked license or permit pursuant to Division 2 (commencing with Section 1200) of the Health and Safety Code, or pursuant to Chapter 2 (commencing with Section 3300) of Division 3 of, or Part 2 (commencing with Section 6250) of Division 6 of, the Welfare and Institutions Code.

(e) This chapter does not apply to the retail sale of vitamins, mineral products, or combinations thereof or to foods, supplements, or nutrients used to fortify the diet of humans or other animals or poultry and labeled as such that are not subject to Section 4022 and that are packaged or bottled in the manufacturer's or distributor's container and labeled in accordance with applicable federal and state labeling requirements.

(f) This chapter does not apply to the furnishing of dangerous drugs and dangerous devices to recognized schools of nursing. These dangerous drugs and dangerous devices shall not include controlled substances. The dangerous drugs and dangerous devices shall be used for training purposes only, and not for the cure, mitigation, or treatment of disease in humans. Recognized schools of nursing for purposes of this subdivision are those schools recognized as training facilities by the California Board of Registered Nursing.

SEC. 3. 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

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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.

(d) Pharmacies that dispense nonprescription diabetes test devices pursuant to prescriptions shall retain records of acquisition and sale of those nonprescription diabetes test devices for at least three years from the date of making. The records shall be at all times during business hours open to inspection by authorized officers of the law.

SEC. 4. *Section 4084.1 is added to the Business and Professions Code, to read:*

4084.1. The board may embargo any nonprescription diabetes test device that a board inspector finds or has probable cause to believe was not purchased either directly from the manufacturer or from the nonprescription diabetes test device manufacturer's authorized distributors as identified in Section 4160.5. For the purposes of this section, the board shall embargo these products following the same procedures and protections used for adulterated, misbranded, or counterfeit drugs or dangerous devices in Sections 4084, 4085, and 4086.

SEC. 5. *Section 4160.5 is added to the Business and Professions Code, to read:*

4160.5. Within 30 days of the effective date of the act adding this section, a manufacturer of a nonprescription diabetes test device shall make the names of its authorized distributors available on its Internet Web site and shall provide the board with the names of its authorized distributors. Within 30 days of receiving that information from a manufacturer of a nonprescription diabetes test device, the board shall post the names of authorized distributors of nonprescription diabetes test devices on the board's Internet Web site. A manufacturer of a nonprescription diabetes test device shall, within 30 days of making changes to its authorized distributors, update its Internet Web site and inform the board of changes to its authorized distributors. Within 30 days of receiving notice of any change from a manufacturer of a nonprescription diabetes test device, the board shall post the updated list of the manufacturer's authorized distributors on its Internet Web site.

SEC. 6. Section 4301 of the Business and Professions Code is amended to read:

4301. The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

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

(b) Incompetence.

(c) Gross negligence.

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

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

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- (f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is committed in the course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not.
- (g) Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts.
- (h) The administering to oneself, of any controlled substance, or the use of any dangerous drug or of alcoholic beverages to the extent or in a manner as to be dangerous or injurious to oneself, to a person holding a license under this chapter, or to any other person or to the public, or to the extent that the use impairs the ability of the person to conduct with safety to the public the practice authorized by the license.
- (i) Except as otherwise authorized by law, knowingly selling, furnishing, giving away, or administering, or offering to sell, furnish, give away, or administer, any controlled substance to an addict.
- (j) The violation of any of the statutes of this state, of any other state, or of the United States regulating controlled substances and dangerous drugs.
- (k) The conviction of more than one misdemeanor or any felony involving the use, consumption, or self-administration of any dangerous drug or alcoholic beverage, or any combination of those substances.
- (l) The conviction of a crime substantially related to the qualifications, functions, and duties of a licensee under this chapter. The record of conviction of a violation of Chapter 13 (commencing with Section 801) of Title 21 of the United States Code regulating controlled substances or of a violation of the statutes of this state regulating controlled substances or dangerous drugs shall be conclusive evidence of unprofessional conduct. In all other cases, the record of conviction shall be conclusive evidence only of the fact that the conviction occurred. The board may inquire into the circumstances surrounding the commission of the crime, in order to fix the degree of discipline or, in the case of a conviction not involving controlled substances or dangerous drugs, to determine if the conviction is of an offense substantially related to the qualifications, functions, and duties of a licensee under this chapter. A plea or verdict of guilty or a conviction following a plea of nolo contendere is deemed to be a conviction within the meaning of this provision. The board may take action when the time for appeal has elapsed, or the judgment of conviction has been affirmed on appeal or when an order granting probation is made suspending the imposition of sentence, irrespective of a subsequent order under Section 1203.4 of the Penal Code allowing the person to withdraw his or her plea of guilty and to enter a plea of not guilty, or setting aside the verdict of guilty, or dismissing the accusation, information, or indictment.
- (m) The cash compromise of a charge of violation of Chapter 13 (commencing with Section 801) of Title 21 of the United States Code regulating controlled substances or of Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code relating to the Medi-Cal program.
- (n) The revocation, suspension, or other discipline by another state of a license to practice pharmacy, operate a pharmacy, or do any other act for which a license is required by this chapter that would be grounds for revocation, suspension, or other discipline under this chapter. Any disciplinary action taken by the board pursuant to this section shall be coterminous with action taken by another state, except that the term of any discipline taken by the board may exceed that of another state, consistent with the board's enforcement guidelines. The evidence of discipline by another state is conclusive proof of unprofessional conduct.
- (o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency.
- (p) Actions or conduct that would have warranted denial of a license.
- (q) Engaging in any conduct that subverts or attempts to subvert an investigation of the board.
- (r) The selling, trading, transferring, or furnishing of drugs obtained pursuant to Section 256b of Title 42 of the United States Code to any person a licensee knows or reasonably should have known, not to be a patient of a covered entity, as defined in paragraph (4) of subsection (a) of Section 256b of Title 42 of the United States Code.
- (s) The clearly excessive furnishing of dangerous drugs by a wholesaler to a pharmacy that primarily or solely dispenses prescription drugs to patients of long-term care facilities. Factors to be considered in determining whether the furnishing of dangerous drugs is clearly excessive shall include, but not be limited to, the amount of

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dangerous drugs furnished to a pharmacy that primarily or solely dispenses prescription drugs to patients of long-term care facilities, the previous ordering pattern of the pharmacy, and the general patient population to whom the pharmacy distributes the dangerous drugs. That a wholesaler has established, and employs, a tracking system that complies with the requirements of subdivision (b) of Section 4164 shall be considered in determining whether there has been a violation of this subdivision. This provision shall not be interpreted to require a wholesaler to obtain personal medical information or be authorized to permit a wholesaler to have access to personal medical information except as otherwise authorized by Section 56 and following of the Civil Code. For purposes of this section, "long-term care facility" shall have the same meaning given the term in Section 1418 of the Health and Safety Code.

(t) The acquisition of a nonprescription diabetes test device from a person that the licensee knew or should have known was not the nonprescription diabetes test device's manufacturer or the manufacturer's authorized distributors as identified in Section 4160.5.

(u) The submission of a reimbursement claim for a nonprescription diabetes test device to a pharmaceutical benefit manager, health insurer, government agency, or other third-party payor when the licensee knew or reasonably should have known that the diabetes test device was not purchased either directly from the manufacturer or from the nonprescription diabetes test device manufacturer's authorized distributors as identified in Section 4160.5.

sec. 7. 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.

sec. 8. This act is an urgency statute necessary for the immediate preservation of the public peace, health, or safety within the meaning of Article IV of the California Constitution and shall go into immediate effect. The facts constituting the necessity are:

In order to immediately prevent the sale of nonprescription diabetes test devices that may have been tampered with or improperly stored, it is necessary that this act take effect immediately.

SB 17**SECTION 1.** Section 1367.243 is added to the Health and Safety Code, to read:

1367.243. (a) (1) A health care service plan that reports rate information pursuant to Section 1385.03 or 1385.045 shall report the information described in paragraph (2) to the department no later than October 1 of each year, beginning October 1, 2018.

(2) For all covered prescription drugs, including generic drugs, brand name drugs, and specialty drugs dispensed at a plan pharmacy, network pharmacy, or mail order pharmacy for outpatient use, all of the following shall be reported:

(A) The 25 most frequently prescribed drugs.

(B) The 25 most costly drugs by total annual plan spending.

(C) The 25 drugs with the highest year-over-year increase in total annual plan spending.

(b) The department shall compile the information reported pursuant to subdivision (a) into a report for the public and legislators that demonstrates the overall impact of drug costs on health care premiums. The data in the report shall be aggregated and shall not reveal information specific to individual health care service plans.

(c) For the purposes of this section, a "specialty drug" is one that exceeds the threshold for a specialty drug under the Medicare Part D program (Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108-173)).

(d) By January 1 of each year, beginning January 1, 2019, the department shall publish on its Internet Web site the report required pursuant to subdivision (b).

(e) After the report required in subdivision (b) is released, the department shall include the report as part of the public meeting required pursuant to subdivision (b) of Section 1385.045.

(f) Except for the report required pursuant to subdivision (b), the department shall keep confidential all of the information provided to the department pursuant to this section, and the information shall be protected from public disclosure.

SEC. 2. Section 1385.045 of the Health and Safety Code is amended to read:

1385.045. (a) For large group health care service plan contracts, each health plan shall file with the department the weighted average rate increase for all large group benefit designs during the 12-month period ending January 1 of the following calendar year. The average shall be weighted by the number of enrollees in each large group benefit design in the plan's large group market and adjusted to the most commonly sold large group benefit design by enrollment during the 12-month period. For the purposes of this section, the large group benefit design includes, but is not limited to, benefits such as basic health care services and prescription drugs. The large group benefit design shall not include cost sharing, including, but not limited to, deductibles, copays, and coinsurance.

(b) (1) A plan shall also submit any other information required pursuant to any regulation adopted by the department to comply with this article.

(2) The department shall conduct an annual public meeting regarding large group rates within **three four** months of posting the aggregate information described in this section in order to permit a public discussion of the reasons for the changes in the rates, benefits, and cost sharing in the large group market. The meeting shall be held in either the Los Angeles area or the San Francisco Bay area.

(c) A health care service plan subject to subdivision (a) shall also disclose the following for the aggregate rate information for the large group market submitted under this section:

(1) For rates effective during the 12-month period ending January 1 of the following year, number and percentage of rate changes reviewed by the following:

(A) Plan year.

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- (B) Segment type, including whether the rate is community rated, in whole or in part.
- (C) Product type.
- (D) Number of enrollees.
- (E) The number of products sold that have materially different benefits, cost sharing, or other elements of benefit design.
- (2) For rates effective during the 12-month period ending January 1 of the following year, any factors affecting the base rate, and the actuarial basis for those factors, including all of the following:
- (A) Geographic region.
- (B) Age, including age rating factors.
- (C) Occupation.
- (D) Industry.
- (E) Health status factors, including, but not limited to, experience and utilization.
- (F) Employee, and employee and dependents, including a description of the family composition used.
- (G) Enrollees' share of premiums.
- (H) Enrollees' cost ~~sharing~~ *sharing, including cost sharing for prescription drugs*.
- (I) Covered benefits in addition to basic health care services, as defined in Section 1345, and other benefits mandated under this article.
- (J) Which market segment, if any, is fully experience rated and which market segment, if any, is in part experience rated and in part community rated.
- (K) Any other factor that affects the rate that is not otherwise specified.
- (3) (A) The plan's overall annual medical trend factor assumptions for all benefits and by aggregate benefit category, including hospital inpatient, hospital outpatient, physician services, prescription drugs and other ancillary services, laboratory, and radiology for the applicable 12-month period ending January 1 of the following year. A health plan that exclusively contracts with no more than two medical groups in the state to provide or arrange for professional medical services for the enrollees of the plan shall instead disclose the amount of its actual trend experience for the prior contract year by aggregate benefit category, using benefit categories, to the maximum extent possible, that are the same as, or similar to, those used by other plans.
- (B) The amount of the projected trend separately attributable to the use of services, price inflation, and fees and risk for annual plan contract trends by aggregate benefit category, including hospital inpatient, hospital outpatient, physician services, prescription drugs and other ancillary services, laboratory, and radiology. A health plan that exclusively contracts with no more than two medical groups in the state to provide or arrange for professional medical services for the enrollees of the plan shall instead disclose the amount of its actual trend experience for the prior contract year by aggregate benefit category, using benefit categories that are, to the maximum extent possible, the same or similar to those used by other plans.
- (C) A comparison of the aggregate per enrollee per month costs and rate of changes over the last five years for each of the following:
- (i) Premiums.
- (ii) Claims costs, if any.
- (iii) Administrative expenses.
- (iv) Taxes and fees.

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(D) Any changes in enrollee cost sharing over the prior year associated with the submitted rate information, including both of the following:

(i) Actual copays, coinsurance, deductibles, annual out of pocket maximums, and any other cost sharing by the benefit categories determined by the department.

(ii) Any aggregate changes in enrollee cost sharing over the prior years as measured by the weighted average actuarial value, weighted by the number of enrollees.

(E) Any changes in enrollee benefits over the prior year, including a description of benefits added or eliminated, as well as any aggregate changes, as measured as a percentage of the aggregate claims costs, listed by the categories determined by the department.

(F) Any cost containment and quality improvement efforts since the plan's prior year's information pursuant to this section for the same category of health benefit plan. To the extent possible, the plan shall describe any significant new health care cost containment and quality improvement efforts and provide an estimate of potential savings together with an estimated cost or savings for the projection period.

(G) The number of products covered by the information that incurred the excise tax paid by the health plan.

(4) (A) For covered prescription generic drugs excluding specialty generic drugs, prescription brand name drugs excluding specialty drugs, and prescription brand name and generic specialty drugs dispensed at a plan pharmacy, network pharmacy, or mail order pharmacy for outpatient use, all of the following shall be disclosed:

(i) The percentage of the premium attributable to prescription drug costs for the prior year for each category of prescription drugs as defined in this subparagraph.

(ii) The year-over-year increase, as a percentage, in per-member, per-month total health plan spending for each category of prescription drugs as defined in this subparagraph.

(iii) The year-over-year increase in per-member, per-month costs for drug prices compared to other components of the health care premium.

(iv) The specialty tier formulary list.

(B) The plan shall include the percentage of the premium attributable to prescription drugs administered in a doctor's office that are covered under the medical benefit as separate from the pharmacy benefit, if available.

(C) (i) The plan shall include information on its use of a pharmacy benefit manager, if any, including which components of the prescription drug coverage described in subparagraphs (A) and (B) are managed by the pharmacy benefit manager.

(ii) The plan shall also include the name or names of the pharmacy benefit manager, or managers if the plan uses more than one.

(d) The information required pursuant to this section shall be submitted to the department on or before October 1, ~~2016, 2018~~, and on or before October 1 annually thereafter. Information submitted pursuant to this section is subject to Section 1385.07.

(e) For the purposes of this section, a "specialty drug" is one that exceeds the threshold for a specialty drug under the Medicare Part D program (Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108-173)).

SEC. 3. Section 127280 of the Health and Safety Code is amended to read:

127280. (a) Every health facility licensed pursuant to Chapter 2 (commencing with Section 1250) of Division 2, except a health facility owned and operated by the state, shall each year be charged a fee established by the office consistent with the requirements of this section.

(b) Commencing in calendar year 2004, every freestanding ambulatory surgery clinic as defined in Section 128700, shall each year be charged a fee established by the office consistent with the requirements of this section.

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(c) The fee structure shall be established each year by the office to produce revenues equal to the appropriation made in the annual Budget Act or another statute to pay for the functions required to be performed by the office pursuant to this chapter, Article 2 (commencing with Section 127340) of Chapter 2, or Chapter 1 (commencing with Section 128675) of Part 5, and to pay for any other health-related programs administered by the office. The fee shall be due on July 1 and delinquent on July 31 of each year.

(d) The fee for a health facility that is not a hospital, as defined in subdivision (c) of Section 128700, shall be not more than 0.035 percent of the gross operating cost of the facility for the provision of health care services for its last fiscal year that ended on or before June 30 of the preceding calendar year.

(e) The fee for a hospital, as defined in subdivision (c) of Section 128700, shall be not more than 0.035 percent of the gross operating cost of the facility for the provision of health care services for its last fiscal year that ended on or before June 30 of the preceding calendar year.

(f) (1) The fee for a freestanding ambulatory surgery clinic shall be established at an amount equal to the number of ambulatory surgery data records submitted to the office pursuant to Section 128737 for encounters in the preceding calendar year multiplied by not more than fifty cents (\$0.50).

(2) (A) For the calendar year 2004 only, a freestanding ambulatory surgery clinic shall estimate the number of records it will file pursuant to Section 128737 for the calendar year 2004 and shall report that number to the office by March 12, 2004. The estimate shall be as accurate as possible. The fee in the calendar year 2004 shall be established initially at an amount equal to the estimated number of records reported multiplied by fifty cents (\$0.50) and shall be due on July 1 and delinquent on July 31, 2004.

(B) The office shall compare the actual number of records filed by each freestanding clinic for the calendar year 2004 pursuant to Section 128737 with the estimated number of records reported pursuant to subparagraph (A). If the actual number reported is less than the estimated number reported, the office shall reduce the fee of the clinic for calendar year 2005 by the amount of the difference multiplied by fifty cents (\$0.50). If the actual number reported exceeds the estimated number reported, the office shall increase the fee of the clinic for calendar year 2005 by the amount of the difference multiplied by fifty cents (\$0.50) unless the actual number reported is greater than 120 percent of the estimated number reported, in which case the office shall increase the fee of the clinic for calendar year 2005 by the amount of the difference, up to and including 120 percent of the estimated number, multiplied by fifty cents (\$0.50), and by the amount of the difference in excess of 120 percent of the estimated number multiplied by one dollar (\$1).

(g) There is hereby established the California Health Data and Planning Fund within the office for the purpose of receiving and expending fee revenues collected pursuant to this chapter.

(h) Any amounts raised by the collection of the special fees provided for by subdivisions (d), (e), and (f) that are not required to meet appropriations in the Budget Act for the current fiscal year shall remain in the California Health Data and Planning Fund and shall be available to the office in succeeding years when appropriated by the Legislature in the annual Budget Act or another statute, for expenditure under the provisions of this chapter, Article 2 (commencing with Section 127340) of Chapter 2, and Chapter 1 (commencing with Section 128675) of Part 5, or for any other health-related programs administered by the office, and shall reduce the amount of the special fees that the office is authorized to establish and charge. *In no event, however, shall those amounts be used for programs administered by the office pursuant to Sections 127676, 127679, 127681, 127683, and 127685, that become effective on or after January 1, 2019.*

(i) (1) No health facility liable for the payment of fees required by this section shall be issued a license or have an existing license renewed unless the fees are paid. A new, previously unlicensed, health facility shall be charged a pro rata fee to be established by the office during the first year of operation.

(2) The license of any health facility, against which the fees required by this section are charged, shall be revoked, after notice and hearing, if it is determined by the office that the fees required were not paid within the time prescribed by subdivision (c).

(j) This section shall become operative on January 1, 2002.

SEC. 4. *Chapter 9 (commencing with Section 127675) is added to Part 2 of Division 107 of the Health and Safety Code, to read:*

SB 17**CHAPTER 9. Prescription Drug Pricing for Purchasers**

127675. (a) This chapter shall apply to a manufacturer of a prescription drug that is purchased or reimbursed by any of the following:

(1) A state purchaser in California, including, but not limited to, the Public Employees' Retirement System, the State Department of Health Care Services, the Department of General Services, and the Department of Corrections and Rehabilitation, or an entity acting on behalf of a state purchaser.

(2) A licensed health care service plan.

(3) A health insurer holding a valid outstanding certificate of authority from the Insurance Commissioner.

(4) A pharmacy benefit manager as defined in subdivision (j) of Section 4430 of the Business and Professions Code.

(b) For the purposes of this chapter, the term "office" shall mean the Office of Statewide Health Planning and Development.

127676. (a) The Legislature finds and declares that the State of California has a substantial public interest in the price and cost of prescription drugs. California is a major purchaser through the Public Employees' Retirement System, the State Department of Health Care Services, the Department of General Services, the Department of Corrections and Rehabilitation, and other entities acting on behalf of a state purchaser. California also provides major tax expenditures through the tax exclusion of employer sponsored coverage and tax deductibility of coverage purchased by individuals, as well as tax deductibility of excess health care costs for individuals and families.

(b) (1) It is the intent of the Legislature in enacting this chapter to provide notice and disclosure of information relating to the cost and pricing of prescription drugs in order to provide accountability to the state for prescription drug pricing.

(2) It is further the intent of the Legislature to permit a manufacturer of a prescription drug to voluntarily make pricing decisions regarding a prescription drug, including any price increases. It is further the intent of the Legislature to permit purchasers, both public and private, as well as pharmacy benefit managers, to negotiate discounts and rebates consistent with existing state and federal law.

127677. (a) A manufacturer of a prescription drug with a wholesale acquisition cost of more than forty dollars (\$40) for a course of therapy shall notify each purchaser described in Section 127675 if the increase in the wholesale acquisition cost of a prescription drug is more than 16 percent, including the proposed increase and the cumulative increases that occurred within the previous two calendar years prior to the current year. For purposes of this section, a "course of therapy" is defined as either of the following:

(1) The recommended daily dosage units of a prescription drug pursuant to its prescribing label as approved by the federal Food and Drug Administration for 30 days.

(2) The recommended daily dosage units of a prescription drug pursuant to its prescribing label as approved by the federal Food and Drug Administration for a normal course of treatment that is less than 30 days.

(b) The notice required by subdivision (a) shall be provided in writing at least 60 days prior to the planned effective date of the increase.

(c) (1) The notice required by subdivision (a) shall include the date of the increase, the current wholesale acquisition cost of the prescription drug, and the dollar amount of the future increase in the wholesale acquisition cost of the prescription drug.

(2) The notice required by subdivision (a) shall include a statement regarding whether a change or improvement in the drug necessitates the price increase. If so, the manufacturer shall describe the change or improvement.

(d) The notice required by subdivision (a) shall be provided to each state purchaser and other purchasers described in paragraphs (2) to (4), inclusive, of subdivision (a) of Section 127675 if a purchaser registers with the office for the purpose of this notification. The office shall make available to manufacturers a list of registered purchasers for the purpose of this notification.

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(e) If a pharmacy benefit manager receives a notice of an increase in wholesale acquisition cost consistent with subdivision (a), it shall notify its large contracting public and private purchasers of the increase. For the purposes of this section, a "large purchaser" means a purchaser that provides coverage to more than 500 covered lives.

127679. (a) On a quarterly basis at a time prescribed by the office and in a format prescribed by the office, commencing no earlier than January 1, 2019, a manufacturer shall report to the office all of the following information for each drug for which an increase in wholesale acquisition cost is described in Section 127677:

(1) A description of the specific financial and nonfinancial factors used to make the decision to increase the wholesale acquisition cost of the drug and the amount of the increase, including, but not limited to, an explanation of how these factors explain the increase in the wholesale acquisition cost of the drug.

(2) A schedule of wholesale acquisition cost increases for the drug for the previous five years if the drug was manufactured by the company.

(3) If the drug was acquired by the manufacturer within the previous five years, all of the following information:

(A) The wholesale acquisition cost of the drug at the time of acquisition and in the calendar year prior to acquisition.

(B) The name of the company from which the drug was acquired, the date acquired, and the purchase price.

(C) The year the drug was introduced to market and the wholesale acquisition cost of the drug at the time of introduction.

(4) The patent expiration date of the drug if it is under patent.

(5) If the drug is a multiple source drug, an innovator multiple source drug, a noninnovator multiple source drug, or a single source drug, as defined in subparagraph (A) of paragraph (7) of subdivision (k) of Section 1396r-8 of Title 42 of the United States Code.

(6) A description of the change or improvement in the drug, if any, that necessitates the price increase.

(7) Volume of sales of the manufacturer's drug in the United States for the previous year.

(b) The manufacturer may limit the information reported pursuant to subdivision (a) to that which is otherwise in the public domain or publicly available.

(c) The office shall publish the information provided to it pursuant to this section on its Internet Web site on no less than a quarterly basis. The information shall be published within 60 days of receipt from a manufacturer. The information shall be published in a manner that identifies the information that is disclosed on a per-drug basis and shall not be aggregated in a manner that would not allow identification of the drug.

(d) The office shall be responsible for the enforcement of this section.

(e) A manufacturer of a prescription drug subject to this chapter that does not report the information required pursuant to this section is liable for a civil penalty of one thousand dollars (\$1,000) per day for every day after the reporting period described in this section that the required information is not reported.

(f) A civil penalty shall be assessed and recovered in a civil action brought by the office in the name of the people of the State of California. Assessment of a civil penalty may, at the request of any manufacturer of a prescription drug subject to this section, be reviewed on appeal, and the penalty may be reduced or waived for good cause.

(g) Any money received by the office pursuant to this section shall be paid into the Managed Care Fund.

127681. (a) A manufacturer of a prescription drug shall notify the office in writing if it is introducing a new prescription drug to market at a wholesale acquisition cost that exceeds the threshold set for a specialty drug under the Medicare Part D program (Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108-173)). The notice shall be provided in writing within three days after the release of the drug in the commercial market. A manufacturer may make this notification pending approval by the federal Food and Drug Administration, if commercial availability is expected within three days of approval.

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(b) No later than 30 days after notification pursuant to this section, a manufacturer shall report all of the following information to the office in a format prescribed by the office:

(1) A description of the marketing and pricing plans used in the launch of the new drug in the United States and internationally.

(2) The estimated volume of patients that may be prescribed the drug.

(3) If the drug was granted breakthrough therapy designation or priority review by the federal Food and Drug Administration prior to final approval.

(4) The date and price of acquisition if the drug was not developed by the manufacturer.

(c) The manufacturer may limit the information reported pursuant to subdivision (b) to that which is otherwise in the public domain or publicly available.

(d) The office shall publish the information provided to it pursuant to this section on its Internet Web site on no less than a quarterly basis. The information shall be published in a manner that identifies the information that is disclosed on a per-drug basis and shall not be aggregated in a manner that would not allow identification of the drug.

(e) The office shall be responsible for the enforcement of this section.

(f) A manufacturer of a prescription drug subject to this chapter that does not report the information required pursuant to this section is liable for a civil penalty of one thousand dollars (\$1,000) per day for every day after the notification period described in this section that the required information is not reported.

(g) A civil penalty shall be assessed and recovered in a civil action brought by the office in the name of the people of the State of California. Assessment of a civil penalty may, at the request of any manufacturer of a prescription drug subject to this section, be reviewed on appeal, and the penalty may be reduced or waived for good cause.

(h) Any money received by the office pursuant to this section shall be paid into the Managed Care Fund.

127683. (a) Funding for the actual and necessary expenses of the office to conduct the activities described in this section and in Sections 127676, 127679, 127681, and 127685, shall be provided, subject to appropriation by the Legislature, from transfers of moneys from the Managed Care Fund and the Insurance Fund.

(b) The share of funding from the Managed Care Fund shall be based on the number of covered lives in the state that are covered under plans regulated by the Department of Managed Health Care, including covered lives under Medi-Cal managed care, as determined by the Department of Managed Health Care, in proportion to the total number of all covered lives in the state.

(c) The share of funding to be provided from the Insurance Fund shall be based on the number of covered lives in the state that are covered under health insurance policies and benefit plans regulated by the Department of Insurance, including covered lives under Medicare supplement plans, as determined by the Department of Insurance, in proportion to the total number of all covered lives in the state.

127685. (a) The office may adopt regulations or issue guidance for the implementation of this chapter. All information that is required to be reported to the office pursuant to this chapter shall be reported in a form prescribed by the office, commencing in the first calendar quarter of 2019.

(b) The office may consult with the Department of Managed Health Care, the Department of Insurance, the California State Board of Pharmacy, and any state purchaser of prescription drugs, or an entity acting on behalf of a state purchaser, in issuing guidance or adopting necessary regulations pursuant to subdivision (a), in posting information on its Internet Web site pursuant to this chapter, and in taking any other action for the purpose of implementing this chapter.

127686. (a) By January 1, 2022, the California Research Bureau shall report to the Legislature on the implementation of this chapter, including, but not limited to, this chapter's effectiveness in addressing the following goals:

(1) Promoting transparency in pharmaceutical pricing for the state and other payers.

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(2) Enhancing understanding about pharmaceutical spending trends.

(3) Assisting the state and other payers in management of pharmaceutical drug costs.

(b) A report submitted pursuant to subdivision (a) shall be submitted in compliance with Section 9795 of the Government Code.

(c) Notwithstanding any other law, implementation of this chapter shall be subject to review by the appropriate policy committees of the Legislature. The review shall be performed as if this chapter were scheduled to be repealed on January 1, 2023.

(d) This section shall remain in effect only until January 1, 2024, and as of that date is repealed.

SEC. 5. Section 10123.205 is added to the Insurance Code, to read:

10123.205. (a) (1) A health insurer that reports rate information pursuant to Section 10181.3 or 10181.45 shall report the information described in paragraph (2) to the department no later than October 1 of each year, beginning October 1, 2018.

(2) For all covered prescription drugs, including generic drugs, brand name drugs, and specialty drugs dispensed at a plan pharmacy, network pharmacy, or mail order pharmacy for outpatient use, all of the following shall be reported:

(A) The 25 most frequently prescribed drugs.

(B) The 25 most costly drugs by total annual plan spending.

(C) The 25 drugs with the highest year-over-year increase in total annual plan spending.

(b) The department shall compile the information reported pursuant to subdivision (a) into a report for the public and legislators that demonstrates the overall impact of drug costs on health care premiums. The data in the report shall be aggregated and shall not reveal information specific to individual health insurers.

(c) For the purposes of this section, a "specialty drug" is one that exceeds the threshold for a specialty drug under the Medicare Part D program (Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108-173)).

(d) By January 1 of each year, beginning January 1, 2018, the department shall publish on its Internet Web site the report required pursuant to subdivision (b).

(e) After the report required in subdivision (b) is released, the department shall include the report as part of the public meeting required pursuant to subdivision (b) of Section 10181.45.

(f) Except for the report required pursuant to subdivision (b), the department shall keep confidential all of the information provided to the department pursuant to this section, and the information shall be protected from public disclosure.

SEC. 6. Section 10181.45 of the Insurance Code is amended to read:

10181.45. (a) For large group health insurance policies, each health insurer shall file with the department the weighted average rate increase for all large group benefit designs during the 12-month period ending January 1 of the following calendar year. The average shall be weighted by the number of insureds in each large group benefit design in the insurer's large group market and adjusted to the most commonly sold large group benefit design by enrollment during the 12-month period. For the purposes of this section, the large group benefit design includes, but is not limited to, benefits such as basic health care services and prescription drugs. The large group benefit design shall not include cost sharing, including, but not limited to, deductibles, copays, and coinsurance.

(b) (1) A health insurer shall also submit any other information required pursuant to any regulation adopted by the department to comply with this article.

*(2) The department shall conduct an annual public meeting regarding large group rates within ~~three~~ **four** months of posting the aggregate information described in this section in order to permit a public discussion of the reasons*

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for the changes in the rates, benefits, and cost sharing in the large group market. The meeting shall be held in either the Los Angeles area or the San Francisco Bay area.

(c) A health insurer subject to subdivision (a) shall also disclose the following for the aggregate rate information for the large group market submitted under this section:

(1) For rates effective during the 12-month period ending January 1 of the following year, number and percentage of rate changes reviewed by the following:

(A) Plan year.

(B) Segment type, including whether the rate is community rated, in whole or in part.

(C) Product type.

(D) Number of insureds.

(E) The number of products sold that have materially different benefits, cost sharing, or other elements of benefit design.

(2) For rates effective during the 12-month period ending January 1 of the following year, any factors affecting the base rate, and the actuarial basis for those factors, including all of the following:

(A) Geographic region.

(B) Age, including age rating factors.

(C) Occupation.

(D) Industry.

(E) Health status factors, including, but not limited to, experience and utilization.

(F) Employee, and employee and dependents, including a description of the family composition used.

(G) Insureds' share of premiums.

(H) Insureds' cost ~~sharing-~~ *sharing, including cost sharing for prescription drugs.*

(I) Covered benefits in addition to basic health care services, as defined in Section 1345 of the Health and Safety Code, and other benefits mandated under this article.

(J) Which market segment, if any, is fully experience rated and which market segment, if any, is in part experience rated and in part community rated.

(K) Any other factor that affects the rate that is not otherwise specified.

(3) (A) The insurer's overall annual medical trend factor assumptions for all benefits and by aggregate benefit category, including hospital inpatient, hospital outpatient, physician services, prescription drugs and other ancillary services, laboratory, and radiology for the applicable 12-month period ending January 1 of the following year. A health insurer that exclusively contracts with no more than two medical groups in the state to provide or arrange for professional medical services for the health insurer's insureds shall instead disclose the amount of its actual trend experience for the prior contract year by aggregate benefit category, using benefit categories, to the maximum extent possible, that are the same or similar to those used by other insurers.

(B) The amount of the projected trend separately attributable to the use of services, price inflation, and fees and risk for annual policy trends by aggregate benefit category, including hospital inpatient, hospital outpatient, physician services, prescription drugs and other ancillary services, laboratory, and radiology. A health insurer that exclusively contracts with no more than two medical groups in the state to provide or arrange for professional medical services for the insureds shall instead disclose the amount of its actual trend experience for the prior contract year by aggregate benefit category, using benefit categories that are, to the maximum extent possible, the same or similar to those used by other insurers.

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(C) A comparison of the aggregate per insured per month costs and rate of changes over the last five years for each of the following:

- (i) Premiums.
- (ii) Claims costs, if any.
- (iii) Administrative expenses.
- (iv) Taxes and fees.

(D) Any changes in insured cost sharing over the prior year associated with the submitted rate information, including both of the following:

- (i) Actual copays, coinsurance, deductibles, annual out of pocket maximums, and any other cost sharing by the benefit categories determined by the department.
- (ii) Any aggregate changes in insured cost sharing over the prior years as measured by the weighted average actuarial value, weighted by the number of insureds.

(E) Any changes in insured benefits over the prior year, including a description of benefits added or eliminated as well as any aggregate changes as measured as a percentage of the aggregate claims costs, listed by the categories determined by the department.

(F) Any cost containment and quality improvement efforts made since the insurer's prior year's information pursuant to this section for the same category of health insurer. To the extent possible, the insurer shall describe any significant new health care cost containment and quality improvement efforts and provide an estimate of potential savings together with an estimated cost or savings for the projection period.

(G) The number of products covered by the information that incurred the excise tax paid by the health insurer.

(4) (A) For covered prescription generic drugs excluding specialty generic drugs, prescription brand name drugs excluding specialty drugs, and prescription brand name and generic specialty drugs dispensed at a pharmacy, network pharmacy, or mail order pharmacy for outpatient use, all of the following shall be disclosed:

- (i) The percentage of the premium attributable to prescription drug costs for the prior year for each category of prescription drugs as defined in this subparagraph.*
- (ii) The year-over-year increase, as a percentage, in per-member, per-month total health insurer spending for each category of prescription drugs as defined in this subparagraph.*
- (iii) The year-over-year increase in per-member, per-month costs for drug prices compared to other components of the health care premium.*
- (iv) The specialty tier formulary list.*

(B) The insurer shall include the percentage of the premium attributable to prescription drugs administered in a doctor's office that are covered under the medical benefit as separate from the pharmacy benefit, if available.

(C) (i) The insurer shall include information on its use of a pharmacy benefit manager, if any, including which components of the prescription drug coverage described in subparagraphs (A) and (B) are managed by the pharmacy benefit manager.

(ii) The insurer shall also include the name or names of the pharmacy benefit manager, or managers if the insurer uses more than one.

(d) The information required pursuant to this section shall be submitted to the department on or before October 1, 2016, and on or before October 1 annually thereafter. Information submitted pursuant to this section is subject to Section 10181.7.

(e) For the purposes of this section, a "specialty drug" is one that exceeds the threshold for a specialty drug under the Medicare Part D program (Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108-173)).

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sec. 7. The provisions of this act are severable. If any provision of this act 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.

sec. 8. The Legislature finds and declares that Sections 1 and 5 of this act, which add Section 1367.243 to the Health and Safety Code and Section 10123.205 to the Insurance Code, respectively, impose a limitation on the public's right of access to the meetings of public bodies or the writings of public officials and agencies within the meaning of Section 3 of Article I of the California Constitution. Pursuant to that constitutional provision, the Legislature makes the following findings to demonstrate the interest protected by this limitation and the need for protecting that interest:

In order to protect proprietary, confidential information regarding health care service plan and health insurer prescription drug utilization and spending information that is specific to the plan or insurer and to protect the integrity of the competitive market, it is necessary that this act limit the public's right of access to that information.

sec. 9. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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(2) If the board assigns the petition to an administrative law judge, the administrative law judge shall submit a proposed decision, as specified in Section 11517 of the Government Code, to the board for its consideration, which shall include reasons supporting the proposed decision.

(e) The board may grant or deny the petition, or may impose any terms and conditions that it reasonably deems appropriate as a condition of reinstatement or reduction of penalty.

(f) In considering a petition for reinstatement or modification of a penalty, the board or the administrative law judge shall evaluate and consider evidence of rehabilitation submitted by the petitioner using criteria specified in regulations promulgated by the board.

(g) The board may impose, or the administrative law judge may recommend, terms and conditions on the petitioner in reinstating a license, certificate, or permit or in modifying a penalty.

~~(f)~~ (h) The petitioner shall provide a current set of fingerprints accompanied by the necessary fingerprinting fee.

~~(g)~~ (i) No petition shall be considered while the petitioner is under sentence for any criminal offense, including any period during which the petitioner is on court-imposed probation or parole, or subject to an order of registration pursuant to Section 290 of the Penal Code. No petition shall be considered while there is an accusation or petition to revoke probation pending against the petitioner.

~~(h)~~ (j) Except in those cases where the petitioner has been disciplined pursuant to Section 822, the board may in its discretion deny without hearing or argument any petition that is filed pursuant to this section within a period of two years from the effective date of a prior decision following a hearing under this section.

SEC. 9. Section 2987 of the Business and Professions Code is amended to read:

2987. The amount of the fees prescribed by this chapter shall be determined by the board, and shall be as follows:

(a) The application fee for a psychologist shall not be more than fifty dollars (\$50).

(b) The examination and reexamination fees for the examinations shall be the actual cost to the board of developing, purchasing, and grading of each examination, plus the actual cost to the board of administering each examination.

(c) The initial license fee is an amount equal to the renewal fee in effect on the last regular renewal date before the date on which the license is issued.

(d) The biennial renewal fee for a psychologist shall be four hundred dollars (\$400). The board may increase the renewal fee to an amount not to exceed five hundred dollars (\$500).

(e) The application fee for registration ~~and supervision of~~ as a psychological assistant ~~by a supervisor under Section 2913, which is payable by that supervisor,~~ *under Section 2913* shall not be more than seventy-five dollars (\$75).

(f) The annual renewal fee for registration of a psychological assistant shall not be more than seventy-five dollars (\$75).

(g) The duplicate license or registration fee is five dollars (\$5).

(h) The delinquency fee is ~~twenty-five dollars (\$25).~~ *50 percent of the renewal fee for each license type, not to exceed one hundred fifty dollars (\$150).*

(i) The endorsement fee is five dollars (\$5).

Notwithstanding any other provision of law, the board may reduce any fee prescribed by this section, when, in its discretion, the board deems it administratively appropriate.

SEC. 10. Section 4008 of the Business and Professions Code is amended to read:

4008. (a) Except as provided by Section 159.5, the board may employ *legal counsel and* inspectors of pharmacy. The inspectors, whether the inspectors are employed by the board or the department's Division of Investigation,

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may inspect during business hours all pharmacies, wholesalers, dispensaries, stores, or places where drugs or devices are compounded, prepared, furnished, dispensed, or stored.

(b) Notwithstanding subdivision (a), a pharmacy inspector may inspect or examine a physician's office or clinic that does not have a permit under Section 4180 or 4190 only to the extent necessary to determine compliance with and to enforce either Section 4080 or 4081.

(c) (1) (A) A pharmacy inspector employed by the board or in the department's Division of Investigation shall have the authority, as a public officer, to arrest, without warrant, any person whenever the officer has reasonable cause to believe that the person to be arrested has, in his or her presence, violated a provision of this chapter or of Division 10 (commencing with Section 11000) of the Health and Safety Code.

(B) If the violation is a felony, or if the arresting officer has reasonable cause to believe that the person to be arrested has violated any provision that is declared to be a felony, although no felony has in fact been committed, he or she may make an arrest although the violation or suspected violation did not occur in his or her presence.

(2) In any case in which an arrest authorized by this subdivision is made for an offense declared to be a misdemeanor, and the person arrested does not demand to be taken before a magistrate, the arresting inspector may, instead of taking the person before a magistrate, follow the procedure prescribed by Chapter 5C (commencing with Section 853.5) of Title 3 of Part 2 of the Penal Code. That chapter shall thereafter apply with reference to any proceeding based upon the issuance of a citation pursuant to this authority.

(d) There shall be no civil liability on the part of, and no cause of action shall arise against, a person, acting pursuant to subdivision (a) within the scope of his or her authority, for false arrest or false imprisonment arising out of an arrest that is lawful, or that the arresting officer, at the time of the arrest, had reasonable cause to believe was lawful. An inspector shall not be deemed an aggressor or lose his or her right to self-defense by the use of reasonable force to effect the arrest, to prevent escape, or to overcome resistance.

(e) Any inspector may serve all processes and notices throughout the state.

(f) A pharmacy inspector employed by the board may enter a facility licensed pursuant to subdivision (c) or (d) of Section 1250 of the Health and Safety Code to inspect an automated drug delivery system operated pursuant to Section 4119 or 4119.1.

SEC. 11. Section 4840.5 of the Business and Professions Code is amended to read:

4840.5. Under conditions of an emergency, a registered veterinary technician may render such lifesaving aid and treatment as may be prescribed under regulations adopted by the board pursuant to Section 4836. Such emergency aid and treatment if rendered to an animal patient not in the presence of a licensed veterinarian may only be continued under the direction of a licensed veterinarian. "Emergency" for the purpose of this section, means that the animal has been placed in a life-threatening condition where immediate treatment is ~~necessary to sustain life.~~ *necessary.*

SEC. 12. Section 4887 of the Business and Professions Code is amended to read:

4887. (a) (1) A person whose license or registration has been revoked or who has been placed on probation may petition the board for reinstatement or modification of penalty including modification or termination of probation after ~~a period of not less than one year~~ *the period as described below in subparagraphs (A) to (C), inclusive,* has elapsed from the effective date of the decision ordering the disciplinary action. The petition shall state ~~such~~ facts as ~~may be~~ required by the board. *The period shall be as follows:*

(A) At least three years for reinstatement of a surrendered or revoked license.

(B) At least two years for early termination or modification of probation of three years or more.

(C) At least one year for modification of a condition or termination of probation of less than three years.

(2) Notwithstanding paragraph (1), the board may, upon a showing of good cause, specify in a revocation order, a surrender order, or an order imposing probation of more than three years that the person may petition the board for reinstatement or modification or termination of probation after one year.

Attachment 3

Statutory Changes to Pharmacy Law

Unless otherwise noted, the provisions take effect January 1, 2018

Business and Professions Code Changes

Section 4001.5 of the Business and Professions Code is repealed.

~~The Joint Committee on Boards, Commissions, and Consumer Protection shall review the state's shortage of pharmacists and make recommendations on a course of action to alleviate the shortage, including, but not limited to, a review of the current California pharmacist licensure examination.~~

Section 4008 of the Business and Professions Code is amended to read:

(a) Except as provided by Section 159.5, the board may employ *legal counsel and* inspectors of pharmacy. The inspectors, whether the inspectors are employed by the board or the department's Division of Investigation, may inspect during business hours all pharmacies, wholesalers, dispensaries, stores, or places where drugs or devices are compounded, prepared, furnished, dispensed, or stored.

(b) Notwithstanding subdivision (a), a pharmacy inspector may inspect or examine a physician's office or clinic that does not have a permit under Section 4180 or 4190 only to the extent necessary to determine compliance with and to enforce either Section 4080 or 4081.

(c) (1) (A) A pharmacy inspector employed by the board or in the department's Division of Investigation shall have the authority, as a public officer, to arrest, without warrant, any person whenever the officer has reasonable cause to believe that the person to be arrested has, in his or her presence, violated a provision of this chapter or of Division 10 (commencing with Section 11000) of the Health and Safety Code.

(B) If the violation is a felony, or if the arresting officer has reasonable cause to believe that the person to be arrested has violated any provision that is declared to be a felony, although no felony has in fact been committed, he or she may make an arrest although the violation or suspected violation did not occur in his or her presence.

(2) In any case in which an arrest authorized by this subdivision is made for an offense declared to be a misdemeanor, and the person arrested does not demand to be taken before a magistrate, the arresting inspector may, instead of taking the person before a magistrate, follow the procedure prescribed by Chapter 5C (commencing with Section 853.5) of Title 3 of Part 2 of the Penal Code. That chapter shall thereafter apply with reference to any proceeding based upon the issuance of a citation pursuant to this authority.

(d) There shall be no civil liability on the part of, and no cause of action shall arise against, a person, acting pursuant to subdivision (a) within the scope of his or her authority, for false arrest or false imprisonment arising out of an arrest that is lawful, or that the arresting officer, at the time of the arrest, had reasonable cause to believe was lawful. An inspector shall not be deemed an aggressor or lose his or her right to self-defense by the use of reasonable force to effect the arrest, to prevent escape, or to overcome resistance.

(e) Any inspector may serve all processes and notices throughout the state.

(f) A pharmacy inspector employed by the board may enter a facility licensed pursuant to subdivision (c) or (d) of Section 1250 of the Health and Safety Code to inspect an automated drug delivery system operated pursuant to Section 4119 or 4119.1.

Section 4013 of the Business and Professions Code is amended to read:

(a) Any facility licensed by the board shall join the board's email notification list within 60 days of obtaining a license or at the time of license renewal.

(b) Any facility licensed by the board shall update its email address with the board's email notification list within 30 days of a change in the facility's email address.

(c) An owner of two or more facilities licensed by the board may comply with subdivisions (a) and (b) by subscribing a single email address to the board's email notification list, where the owner maintains an electronic notice system within all of its licensed facilities that, upon receipt of an email notification from the board, immediately transmits electronic notice of the same notification to all of its licensed facilities. If an owner chooses to comply with this section by using such an electronic notice system, the owner shall register the electronic notice system with the board by July 1, 2011, or within 60 days of initial licensure, whichever is later, informing the board of the single email address to be utilized by the owner, describing the electronic notice system, and listing all facilities to which immediate notice will be provided. The owner shall update its email address with the board's email notification list within 30 days of any change in the owner's email address.

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

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

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

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

(5) This subdivision shall become operative on July 1, 2017.

Section 4022.5 of the Business and Professions Code is amended to read:

(a) "Designated representative" means an individual to whom a license has been granted pursuant to Section 4053. A pharmacist fulfilling the duties of Section 4053 shall not be required to obtain a license as a designated representative.

(b) “Designated representative-in-charge” means a designated representative or designated representative-reverse distributor, or a pharmacist proposed by a wholesaler or veterinary food-animal drug retailer and approved by the board as the supervisor or manager responsible for ensuring the wholesaler’s or veterinary food-animal drug retailer’s compliance with all state and federal laws and regulations pertaining to practice in the applicable license category.

Section 4022.6 is added to the Business and Professions Code, to read:

“Designated representative-reverse distributor” means an individual to whom a license has been granted pursuant to Section 4053.2, who is responsible for supervision over a licensed wholesaler that only acts as a reverse distributor. A pharmacist fulfilling the duties of Section 4053.2 shall not be required to obtain a license as a designated representative-reverse distributor.

Section 4029 of the Business and Professions Code is amended to read:

(a) “Hospital pharmacy” means and includes a pharmacy, licensed by the board, located within any licensed hospital, institution, or establishment that maintains and operates organized facilities for the diagnosis, care, and treatment of human illnesses to which persons may be admitted for overnight stay and that meets all of the requirements of this chapter and the rules and regulations of the board.

(b) A hospital pharmacy ~~also includes~~ may include a pharmacy that ~~may be located outside of the hospital in another~~ is located in any physical plant that is regulated under ~~a hospital’s consolidated license issued pursuant to Section 1250.8~~ the license of a general acute care hospital as defined in subdivision (a) of Section 1250 of the Health and Safety Code. As a condition of licensure by the board, the pharmacy in another physical plant shall provide pharmaceutical services only to registered hospital patients who are on the premises of the same physical plant in which the pharmacy is located, except as provided in Article 7.6 (commencing with Section 4128). The pharmacy services provided shall be directly related to the services or treatment plan administered in the physical plant. Nothing in this subdivision shall be construed to restrict or expand the services that a hospital pharmacy may provide.

(c) “Hospital satellite compounding pharmacy” means an area licensed by the board to perform sterile compounding that is separately licensed by the board pursuant to Section 4127.15 to perform that compounding and is located outside of the hospital in another physical plant that is regulated as a general acute care hospital as defined in subdivision (a) of Section 1250 of the Health and Safety Code.

Section 4034.5 is added to the Business and Professions Code, to read:

An “emergency medical services automated drug delivery system” or “EMSADDS” means an automated drug delivery system that stores and distributes drugs for the sole purpose of restocking a secured emergency pharmaceutical supplies container that is used by an emergency medical services agency to provide emergency medical services.

Section 4040.5 of the Business and Professions Code is amended to read:

“Reverse distributor” means every person who acts as an agent for pharmacies, drug wholesalers, third-party logistics providers, manufacturers, and other entities by receiving, inventorying, warehousing, and managing the disposition of outdated or nonsaleable dangerous ~~drugs~~. drugs or dangerous devices.

Section 4044.3 is added to the Business and Professions Code, to read:

(a) “Remote dispensing site pharmacy” means a licensed pharmacy located in this state that is exclusively overseen and operated by a supervising pharmacy and staffed by one or more qualified registered pharmacy technicians, as defined in Section 4132, where pharmaceutical care services, including, but not limited to, the storage and dispensing of prescription drugs and controlled substances, drug regimen review, and patient counseling, are remotely monitored or provided, or both, by a licensed pharmacist through the use of telepharmacy technology.

(b) Unless otherwise specified in this chapter, a remote dispensing site pharmacy shall comply with all state and federal laws regulating the practice of pharmacy.

Section 4044.6 is added to the Business and Professions Code, to read:

(a) “Supervising pharmacy” means a licensed pharmacy located in this state that is owned and operated by a person or persons where the majority of the beneficial interest in, as well as the management and control, resides with at least one board-licensed pharmacist, as defined in Section 4036, that exclusively oversees the operations of a remote dispensing site pharmacy.

(b) A supervising pharmacy shall be exclusively responsible for the operation of the remote dispensing site pharmacy and its employees pursuant to Section 4131.

Section 4044.7 is added to the Business and Professions Code, to read:

“Telepharmacy” means a system that is used by a supervising pharmacy for the purpose of monitoring the dispensing of prescription drugs by a remote dispensing site pharmacy and provides for related drug regimen review and patient counseling by an electronic method, including, but not limited to, the use of audio, visual, still image capture, and store and forward technology.

Section 4052.10 is added to the Business and Professions Code, to read:

(a) A pharmacist may dispense a Schedule II controlled substance, as listed in Section 11055 of the Health and Safety Code, as a partial fill if requested by the patient or the prescriber.

(b) If a pharmacist dispenses a partial fill on a prescription pursuant to this section, the pharmacy shall retain the original prescription, with a notation of how much of the prescription has been filled, until the prescription has been fully dispensed. The total quantity dispensed shall not exceed the total quantity prescribed.

(c) Subsequent fills, until the original prescription is completely dispensed, shall occur at the pharmacy where the original prescription was partially filled. The full prescription shall be dispensed not more than 30 days after the date on which the prescription was written. Thirty-one days after the date on which the prescription was written, the prescription shall expire and no more of the drug shall be dispensed without a subsequent prescription.

(d) The pharmacist shall record in the state prescription drug monitoring program only the actual amounts of the drug dispensed.

(e) The pharmacist shall record the date and amount of each partial fill in a readily retrievable form and on the original prescription, and shall include the initials of the pharmacist who dispensed each partial fill.

(f) A pharmacist may charge a professional dispensing fee to cover the actual supply and labor costs associated with dispensing each partial fill associated with the original prescription.

(g) This section shall not be construed to limit the authority of the Department of Managed Health Care, pursuant to Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code.

(h) This section is not intended to conflict with or supersede any other requirement established for the prescription of a Schedule II controlled substance.

(i) For purposes of this section, the following definitions apply:

(1) "Original prescription" means the prescription presented by the patient to the pharmacy or submitted electronically to the pharmacy.

(2) "Partial fill" means a part of a prescription filled that is of a quantity less than the entire prescription.

(j) This section shall become operative on July 1, 2018.

Section 4053.2 is added to the Business and Professions Code, to read:

(a) Notwithstanding Sections 4051 and 4053, the board may issue a designated representative-reverse distributor license to a qualified individual who shall provide sufficient and qualified supervision over a licensed wholesaler that only acts as a reverse distributor. The designated representative-reverse distributor shall protect the public health and safety in the handling, storage, warehousing, and destruction of outdated or nonsaleable dangerous drugs and dangerous devices.

(b) An individual who is at least 18 years of age may apply for a designated representative-reverse distributor license. In order to obtain and maintain that license, the individual shall meet all of the following requirements:

(1) He or she shall be a high school graduate or possess a general education development certificate equivalent.

(2) He or she shall meet one of the following requirements:

(A) Have a minimum of one year of paid work experience in the past three years with a licensed wholesaler, third-party logistics provider, or pharmacy performing duties related to the distribution, dispensing, or destruction of dangerous drugs or dangerous devices.

(B) Have a minimum of one year of paid work experience in the destruction of outdated or nonsaleable dangerous drugs or dangerous devices pharmaceutical waste.

(C) Meet all of the prerequisites to take the examination required for licensure as a pharmacist by the board.

(3) (A) He or she shall complete a training program approved by the board that, at a minimum, addresses each of the following subjects:

(i) Knowledge and understanding of California law and federal law relating to the distribution of dangerous drugs and dangerous devices.

(ii) Knowledge and understanding of California law and federal law relating to the distribution of controlled substances.

(iii) Knowledge and understanding of California law and federal law relating to the removal and destruction of dangerous drugs, dangerous devices, and pharmaceutical waste.

(iv) Knowledge and understanding of the United States Pharmacopoeia or federal Food and Drug Administration standards relating to the safe storage, handling, and transport of dangerous drugs and dangerous devices.

(B) The board may, by regulation, require the training program required under this paragraph to include additional material.

(C) The board shall not issue a license as a designated representative-reverse distributor until the applicant provides proof of completion of the training required by this paragraph to the board.

(c) A reverse distributor shall not operate without at least one designated representative or designated representative-reverse distributor present at each of its licensed places of business as required under Section 4160.

Section 4057 of the Business and Professions Code is amended to read:

(a) Except as provided in ~~Sections 4006, 4240, and Section 4006, subdivision (d) of Section 4081, Section 4240, subdivisions (t) and (u) of Section 4301, and Section 4342,~~ this chapter does not apply to the retail sale of nonprescription drugs that are not subject to Section 4022 and that are packaged or bottled in the manufacturer's or distributor's container and labeled in accordance with applicable federal and state drug labeling requirements.

(b) This chapter does not apply to specific dangerous drugs and dangerous devices listed in board regulations, where the sale or furnishing is made to any of the following:

(1) A physician, dentist, podiatrist, pharmacist, medical technician, medical technologist, optometrist, or chiropractor holding a currently valid and unrevoked license and acting within the scope of his or her profession.

(2) A clinic, hospital, institution, or establishment holding a currently valid and unrevoked license or permit under Division 2 (commencing with Section 1200) of the Health and Safety Code, or Chapter 2 (commencing with Section 3300) of Division 3 of, or Part 2 (commencing with Section 6250) of Division 6 of, the Welfare and Institutions Code.

(c) This chapter shall not apply to a home health agency licensed under Chapter 8 (commencing with Section 1725) of, or a hospice licensed under Chapter 8.5 (commencing with Section 1745) of, Division 2 of, the Health and Safety Code, when it purchases, stores, furnishes, or transports specific dangerous drugs and dangerous devices listed in board regulations in compliance with applicable law and regulations including:

(1) Dangerous devices described in subdivision (b) of Section 4022, as long as these dangerous devices are furnished only upon the prescription or order of a physician, dentist, or podiatrist.

(2) Hypodermic needles and syringes.

(3) Irrigation solutions of 50 cubic centimeters or greater.

(d) This chapter does not apply to the storage of devices in secure central or ward supply areas of a clinic, hospital, institution, or establishment holding a currently valid and unrevoked license or permit pursuant to Division 2 (commencing with Section 1200) of the Health and Safety Code, or pursuant to Chapter 2 (commencing with Section 3300) of Division 3 of, or Part 2 (commencing with Section 6250) of Division 6 of, the Welfare and Institutions Code.

(e) This chapter does not apply to the retail sale of vitamins, mineral products, or combinations thereof or to foods, supplements, or nutrients used to fortify the diet of humans or other animals or poultry and labeled as such that are not subject to Section 4022 and that are packaged or bottled in the manufacturer's or distributor's container and labeled in accordance with applicable federal and state labeling requirements.

(f) This chapter does not apply to the furnishing of dangerous drugs and dangerous devices to recognized schools of nursing. These dangerous drugs and dangerous devices shall not include controlled substances. The dangerous drugs and dangerous devices shall be used for training purposes only, and not for the cure, mitigation, or treatment of disease in humans. Recognized schools of nursing for purposes of this subdivision are those schools recognized as training facilities by the California Board of Registered Nursing.

Section 4059.5 of the Business and Professions Code is amended to read:

(a) Except as otherwise provided in this chapter, dangerous drugs or dangerous devices may only be ordered by an entity licensed by the board and shall be delivered to the licensed premises and signed for and received by a pharmacist. Where a licensee is permitted to operate through a designated representative, ~~the designated representative~~ or in the case of a reverse distributor a designated representative-reverse distributor, that individual shall sign for and receive the delivery.

(b) A dangerous drug or dangerous device transferred, sold, or delivered to a person within this state shall be transferred, sold, or delivered only to an entity licensed by the board, to a manufacturer, or to an ultimate user or the ultimate user's agent.

(c) Notwithstanding subdivisions (a) and (b), deliveries to a hospital pharmacy may be made to a central receiving location within the hospital. However, the dangerous drugs or dangerous devices shall be delivered to the licensed pharmacy premises within one working day following

receipt by the hospital, and the pharmacist on duty at that time shall immediately inventory the dangerous drugs or dangerous devices.

(d) Notwithstanding any other ~~provision of~~ law, a dangerous drug or dangerous device may be ordered by and provided to a manufacturer, physician, dentist, podiatrist, optometrist, veterinarian, naturopathic doctor pursuant to Section 3640.7, or laboratory, or a physical therapist acting within the scope of his or her license. A person or entity receiving delivery of a dangerous drug or dangerous device, or a duly authorized representative of the person or entity, shall sign for the receipt of the dangerous drug or dangerous device.

(e) A dangerous drug or dangerous device shall not be transferred, sold, or delivered to a person outside this state, whether foreign or domestic, unless the transferor, seller, or deliverer does so in compliance with the laws of this state and of the United States and of the state or country to which the dangerous drugs or dangerous devices are to be transferred, sold, or delivered. Compliance with the laws of this state and the United States and of the state or country to which the dangerous drugs or dangerous devices are to be delivered shall include, but not be limited to, determining that the recipient of the dangerous drugs or dangerous devices is authorized by law to receive the dangerous drugs or dangerous devices.

(f) Notwithstanding subdivision (a), a pharmacy may take delivery of dangerous drugs and dangerous devices when the pharmacy is closed and no pharmacist is on duty if all of the following requirements are met:

(1) The drugs are placed in a secure storage facility in the same building as the pharmacy.

(2) Only the pharmacist-in-charge or a pharmacist designated by the pharmacist-in-charge has access to the secure storage facility after dangerous drugs or dangerous devices have been delivered.

(3) The secure storage facility has a means of indicating whether it has been entered after dangerous drugs or dangerous devices have been delivered.

(4) The pharmacy maintains written policies and procedures for the delivery of dangerous drugs and dangerous devices to a secure storage facility.

(5) The agent delivering dangerous drugs and dangerous devices pursuant to this subdivision leaves documents indicating the name and amount of each dangerous drug or dangerous device delivered in the secure storage facility.

The pharmacy shall be responsible for the dangerous drugs and dangerous devices delivered to the secure storage facility. The pharmacy shall also be responsible for obtaining and maintaining records relating to the delivery of dangerous drugs and dangerous devices to a secure storage facility.

(g) Notwithstanding subdivision (a), dangerous drugs and devices and controlled substances may be ordered by a remote dispensing site pharmacy licensed by the board and may be signed for and received by a registered pharmacy technician, who meets the qualifications of Section 4132, at the remote site. A controlled substance signed for by a pharmacy technician under this

section shall be stored separately from existing inventory until the time the controlled substance is reviewed and countersigned by a pharmacist. Any receipt and storage of a controlled substance by a pharmacy technician pursuant to this section shall be captured on video, and that video shall be made accessible to the supervising pharmacy and maintained by the remote dispensing site pharmacy for 120 days.

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

(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.

(d) Pharmacies that dispense nonprescription diabetes test devices pursuant to prescriptions shall retain records of acquisition and sale of those nonprescription diabetes test devices for at least three years from the date of making. The records shall be at all times during business hours open to inspection by authorized officers of the law.

Section 4084.1 is added to the Business and Professions Code, to read:

The board may embargo any nonprescription diabetes test device that a board inspector finds or has probable cause to believe was not purchased either directly from the manufacturer or from the nonprescription diabetes test device manufacturer's authorized distributors as identified in Section 4160.5. For the purposes of this section, the board shall embargo these products following the same procedures and protections used for adulterated, misbranded, or counterfeit drugs or dangerous devices in Sections 4084, 4085, and 4086.

Section 4100 of the Business and Professions Code is amended to read:

~~(a)~~ -Within 30 days after changing his or her address of record with the board or after changing his or her name according to law, a pharmacist, intern pharmacist, technician, designated

representative, designated representative-3PL, or designated representative-representative-reverse distributor shall notify the executive officer of the board of the change of address or change of name.

~~(b) This section shall become operative on January 1, 2006.~~

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

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

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

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

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

(4) To issue licenses to two independently owned clinics that share a clinic office space pursuant to Section 4180.5.

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

Section 4119 of the Business and Professions Code is amended to read:

(a) Notwithstanding any other ~~provision of~~ law, a pharmacy may furnish a dangerous drug or dangerous device to a licensed health care facility for storage in a secured emergency pharmaceutical supplies container maintained within the facility in accordance with facility regulations of the State Department of Public Health set forth in Title 22 of the California Code of Regulations and the requirements set forth in Section 1261.5 of the Health and Safety Code. These emergency supplies shall be approved by the facility's patient care policy committee or pharmaceutical service committee and shall be readily available to each nursing station. Section 1261.5 of the Health and Safety Code limits the number of oral dosage form or suppository form drugs in these emergency supplies to ~~24~~ 48.

(b) Notwithstanding any other ~~provision of~~ law, a pharmacy may furnish a dangerous drug or a dangerous device to an approved service provider within an emergency medical services system for storage in a secured emergency pharmaceutical supplies container, in accordance with the policies and procedures of the local emergency medical services agency, if all of the following are met:

(1) The dangerous drug or dangerous device is furnished exclusively for use in conjunction with services provided in an ambulance, or other approved emergency medical services service provider, that provides prehospital emergency medical services.

(2) The requested dangerous drug or dangerous device is within the licensed or certified emergency medical technician's scope of practice as established by the Emergency Medical Services Authority and set forth in Title 22 of the California Code of Regulations.

(3) The approved service provider within an emergency medical services system provides a written request that specifies the name and quantity of dangerous drugs or dangerous devices.

(4) The approved emergency medical services provider administers dangerous drugs and dangerous devices in accordance with the policies and procedures of the local emergency medical services agency.

(5) The approved emergency medical services provider documents, stores, and restocks dangerous drugs and dangerous devices in accordance with the policies and procedures of the local emergency medical services agency.

Records of each request by, and dangerous drugs or dangerous devices furnished to, an approved service provider within an emergency medical services system, shall be maintained by both the approved service provider and the dispensing pharmacy for a period of at least three years.

The furnishing of controlled substances to an approved emergency medical services provider shall be in accordance with the California Uniform Controlled Substances ~~Act~~. Act (Division 10 commencing with Section 11000) of the Health and Safety Code).

Section 4119.01 is added to the Business and Professions Code, to read:

(a) Notwithstanding any other law, a pharmacy, or a licensed wholesaler that is also an emergency medical services provider agency, may restock dangerous drugs or dangerous devices into an emergency medical services automated drug delivery system (EMSADDS) that is licensed by the board under this section. Dangerous drugs and dangerous devices stored or maintained in an EMSADDS shall be used for the sole purpose of restocking a secured emergency pharmaceutical supplies container as authorized in subdivision (b) of Section 4119. The EMSADDS may be used only if all of the following conditions are met:

(1) The emergency medical services provider agency obtains a license from the board to operate the EMSADDS. As a requirement for licensure, the EMSADDS shall be located on the premises of a fire department headquarters, a fire station, or at an emergency medical services provider agency's location. A separate license shall be required for each location.

(A) As part of its license application, the emergency medical services provider agency shall provide: the address where the EMSADDS will be located; the name of the medical director responsible for overseeing the emergency medical services provider agency; the name of any designated pharmacist or licensed designated paramedic who is responsible for performing the duties as required under this section; the policies and procedures detailing the provisions under which the EMSADDS will operate; and the name and license number of the pharmacy or emergency medical services provider agency wholesaler that will furnish the dangerous drugs and dangerous devices through the EMSADDS.

(B) The application and initial license fee to operate EMSADDS shall be one hundred dollars (\$100) per machine. The license shall be renewed annually. The license fee may not be transferred to a different location if the EMSADDS is moved. The penalty fee for failure to renew an EMSADDS license shall be thirty-five dollars (\$35).

(C) The application and renewal fee for a licensed wholesaler that is also an emergency medical services provider agency shall be seven hundred eighty dollars (\$780).

(2) Each EMSADDS shall collect, control, and maintain all transaction information necessary to accurately track the movement of drugs into and out of the system for purposes of security, accuracy, and accountability.

(3) The medical director and designated pharmacist, or the medical director and the licensed designated paramedic, shall develop, adopt, and maintain policies and procedures detailing the provisions under which the EMSADDS will operate. At a minimum, the policies and procedures shall address (A) inventory controls, (B) training, (C) storage and security of the dangerous drugs and dangerous devices, and (D) safeguards to limit access to the EMSADDS to authorized staff only.

(4) The licensed EMSADDS operator shall limit access to the EMSADDS only to employees of the operator who are licensed by the state and as authorized in this section.

(A) An EMSADDS may only be restocked by the medical director, a pharmacist, or a licensed designated paramedic, each of whom may possess and transport dangerous drugs or dangerous devices for that purpose. The transport of dangerous drugs or dangerous devices for restocking into an EMSADDS shall be done in a secured manner to prevent theft or unauthorized access, and shall be done under conditions appropriate to meet storage and handling requirements of the dangerous drugs or dangerous devices. While the dangerous drugs or dangerous devices may be transported, representatives shall not store a dangerous drug or dangerous device at an unlicensed location.

(B) Only a medical director, a pharmacist, or a paramedic may remove dangerous drugs or dangerous devices from an EMSADDS to fill a secured emergency pharmaceutical supplies container. This access shall be observed by a second person who is also a paramedic, a pharmacist, or a medical director. Both the individual who removes dangerous drugs or dangerous devices from the EMSADDS and the observer shall record their participation in the removal of the dangerous drugs or dangerous devices via their signatures or use of biometric identifiers. The restocking of the secured emergency pharmaceutical supplies container from the EMSADDS shall occur at the licensed location of the EMSADDS.

(C) A medical director, a pharmacist, or a licensed designated paramedic may remove outdated dangerous drugs or dangerous devices from an EMSADDS. Any outdated dangerous drugs or dangerous devices shall be provided to a licensed reverse distributor for destruction.

(5) Every EMSADDS operator shall perform monthly inventory and inventory reconciliation functions. The medical director, designated pharmacist, or licensed designated paramedic shall perform a reconciliation and prepare a written report based on written policies and procedures developed to maintain the security and quality of the dangerous drugs and dangerous devices. The written inventory reconciliation report shall include all of the following:

(A) A physical count of all quantities of dangerous drugs and dangerous devices stored in the EMSADDS.

(B) A review of all dangerous drugs and dangerous devices added into and removed from each EMSADDS since the last monthly inventory.

(C) A comparison of subparagraphs (A) and (B), and identification of any variances.

(D) A review of all individuals who accessed the EMSADDS since the last inventory and identification of unauthorized individuals accessing the EMSADDS or suspicious activity.

(E) Identification of possible causes of shortages and overages.

(6) The medical director and designated pharmacist, or medical director and licensed designated paramedic, shall be jointly responsible for monthly review of the inventory reconciliation report, the training, storage, and security of dangerous drugs and dangerous devices, and the restocking of the EMSADDS. Any inventory losses from an EMSADDS shall be reported to the board within seven days from identification of the loss.

(7) In order for an individual to perform the functions of a licensed designated paramedic described in this section, that individual shall be licensed by the board pursuant to Section 4202.5. A paramedic who only restocks a secured emergency pharmaceutical supplies container from an EMSADDS need not be licensed with the board.

(8) A record of each access to the EMSADDS, as well as all records used to compile an inventory reconciliation report, shall be maintained at the operator's location for at least three years in a readily retrievable form. The records shall include the identity of every individual who accessed the system or witnessed such access; the date of each access; and the drug, dosage, form, strength, and quantity of dangerous drugs or dangerous devices added or removed.

(b) A violation of any of the provisions of this section shall constitute unprofessional conduct and provides the board the authority to take action against the EMSADDS operator's license.

Section 4127.15 is added to the Business and Professions Code, to read:

Subject to the requirements of this section, the board may issue a license to a hospital satellite compounding pharmacy. The license fee and annual renewal fee shall be in an amount established by the board in subdivision (u) of Section 4400. The license shall not be transferable.

(a) A hospital satellite compounding pharmacy license shall not be issued or renewed until the location is inspected by the board and found to be in compliance with this article and regulations adopted by the board.

(1) A hospital satellite compounding pharmacy shall compound sterile drug products for administration only to registered hospital patients who are on the premises of the same physical plant in which the hospital satellite compounding pharmacy is located.

(2) The services provided shall be directly related to the services or treatment plan administered in the physical plant.

(b) A hospital satellite compounding pharmacy license shall not be issued or renewed until the board does all of the following:

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

(2) Reviews the hospital satellite compounding pharmacy's completed self-assessment form as described in Section 1735.2 of Title 16 of the California Code of Regulations.

(3) Receives a list of all products compounded by the hospital satellite compounding pharmacy since the last license renewal.

(c) A hospital satellite compounding pharmacy shall do all of the following:

(1) Purchase, procure, or otherwise obtain all components through the license of the hospital pharmacy as defined in subdivision (a) of Section 4029.

(2) Satisfy the ratio of not less than one pharmacist on duty for a total of two pharmacy technicians on duty.

(3) Ensure immediate supervision, as defined in Section 70065 of Title 22 of the California Code of Regulations, by a pharmacist of licensed ancillary staff involved in sterile compounding.

(4) Provide to the board, within 12 hours, any recall notice issued by the hospital satellite compounding pharmacy for sterile drug products it has compounded.

(5) Report to the board, within 12 hours, adverse effects reported or potentially attributable to the sterile drug products compounded by the hospital satellite compounding pharmacy. Unexpected adverse effects shall also be, within 12 hours, reported to the MedWatch program of the federal Food and Drug Administration.

Section 4127.7 of the Business and Professions Code is repealed.

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

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

~~(b) An ISO class 5 cleanroom.~~

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

Article 8. Telepharmacy Systems and Remote Dispensing Site Pharmacies

Section 4130 is added to the Business and Professions Code, to read:

(a) A telepharmacy system shall be used for the dispensing of prescription drugs and providing related drug regimen review and patient counseling services at a remote dispensing site pharmacy.

(b) If all of the requirements of this article and other relevant provisions of this chapter are met, the board shall issue a remote dispensing site pharmacy license for the purpose of increasing

access to dispensing or pharmaceutical care services in the geographic area in which the remote dispensing site pharmacy is to be located.

(c) (1) A remote dispensing site pharmacy shall only be located in a medically underserved area unless otherwise approved by the board. For purposes of this section, a "medically underserved area" means a location that does not have a pharmacy that serves the general public within 10 road miles of the remote dispensing site.

(2) Notwithstanding paragraph (1), if a pharmacy serving the general public is later established within 10 road miles of a remote dispensing site pharmacy, the remote dispensing site pharmacy may continue to operate.

(d) A remote dispensing site pharmacy shall only be staffed by pharmacists or pharmacy technicians, or both, and shall not employ any unlicensed personnel.

(e) A remote dispensing site pharmacy license shall be issued only to the supervising pharmacy. A supervising pharmacy shall not obtain more than one remote dispensing site pharmacy license.

(f) A remote dispensing site pharmacy shall not be operated by the state and shall not be located in any state facility, including, but not limited to, correctional facilities, state hospitals, or developmental centers. This section shall not be construed to preclude a pharmacist who is otherwise eligible to operate a remote dispensing site pharmacy pursuant to this section from leasing space in property owned by the state, provided it is not for the purpose of serving individuals otherwise served by pharmacists and pharmacy technicians employed by the state.

(g) A remote dispensing site pharmacy shall not be located or operated for the purpose of displacing state employees.

(h) If a remote dispensing site pharmacy dispenses more than 225 prescriptions per day, calculated each calendar year, it shall cease to be a remote dispensing site pharmacy and may become a full-service pharmacy licensed under Section 4110 with a pharmacist onsite if it meets all the requirements for licensure for a pharmacy.

Section 4131 is added to the Business and Professions Code, to read:

(a) A supervising pharmacy shall provide telepharmacy services for only one remote dispensing site pharmacy.

(b) A supervising pharmacy shall not be located greater than 150 road miles from a remote dispensing site pharmacy, unless otherwise approved by the board.

(c) A supervising pharmacy and remote dispensing site pharmacy shall be under common ownership.

(d) Unless staffed by a pharmacist, a remote dispensing site pharmacy shall be staffed by at least one registered pharmacy technician meeting the qualifications of Section 4132. A technician shall remain under the direct supervision and control of a pharmacist at the

supervising pharmacy at all times that the remote dispensing site pharmacy is operational. For the purposes of this article, direct supervision and control does not require the pharmacist to be physically present at the remote dispensing site pharmacy, but the pharmacist shall use a telepharmacy system to supervise operations through audio and visual technology from the supervising pharmacy.

(e) Notwithstanding any other law, a pharmacist may serve as the pharmacist-in-charge for a pharmacy in addition to serving as pharmacist-in-charge of a supervising pharmacy. The designated pharmacist-in-charge of the supervising pharmacy shall also serve as the designated pharmacist-in-charge at the remote dispensing site pharmacy.

(f) Notwithstanding any other law, the pharmacist-in-charge of the remote dispensing site pharmacy and the pharmacist-on-duty at the supervising pharmacy shall be responsible for ensuring that both the supervising pharmacy and remote dispensing site pharmacy are sufficiently staffed to allow for appropriate supervision, which is supervision that would not be reasonably expected to result in an unreasonable risk of harm to public health, safety, or welfare.

Section 4132 is added to the Business and Professions Code, to read.

(a) In addition to the requirements of Section 4202, a pharmacy technician working at a remote dispensing site pharmacy shall meet the qualifications promulgated by the board. The regulations developed by the board shall only apply to pharmacy technicians working at remote dispensing sites.

(b) Notwithstanding Section 4115, a registered pharmacy technician may perform order entry, packaging, manipulative, repetitive, and other nondiscretionary tasks at a remote dispensing site pharmacy under the supervision of a pharmacist at a supervising pharmacy using a telepharmacy system.

(c) A pharmacy technician at a remote dispensing site pharmacy shall not do any of the following:

(1) Receive a new prescription order orally from a prescriber or other person authorized to prescribe by law.

(2) Consult with a patient or his or her agent regarding a prescription, either prior to or after dispensing, or regarding any medical information contained in a patient medication record system or patient chart.

(3) Identify, evaluate, or interpret a prescription.

(4) Interpret the clinical data in a patient medication record system or patient chart.

(5) Consult with any prescriber, nurse, or other health care professional or authorized agent thereof.

(6) Supervise the packaging of drugs and check the packaging procedure and product upon completion.

(7) Perform any function that requires the professional judgment of a licensed pharmacist.

(8) Compound drug preparations.

(d) Notwithstanding Section 4115, a pharmacist at a supervising pharmacy may supervise up to two pharmacy technicians at each remote dispensing site pharmacy. This subdivision shall not be construed to alter a pharmacist's ability to also supervise pharmacy technicians at the supervising pharmacy.

Section 4133 is added to the Business and Professions Code, to read:

(a) A telepharmacy system shall maintain a video and audio communication system that provides for effective communication between the supervising pharmacy and the remote dispensing site pharmacy's personnel and patients.

(b) A telepharmacy system shall facilitate adequate pharmacist supervision and allow the appropriate exchange of visual, verbal, and written communications for patient counseling and other matters involved in the lawful dispensing of drugs.

(c) Patient counseling shall be provided using audio-visual communication prior to all prescriptions being dispensed from a remote dispensing site pharmacy.

(d) A telepharmacy system shall be able to do all of the following:

(1) Identify and record the pharmacy technician preparing each prescription and the supervising pharmacist who reviewed and authorized the dispensing of the prescription.

(2) Require a pharmacist to review and compare the electronic image of any new prescription presented at the remote dispensing site pharmacy with the data entry record of the prescription.

(3) Require the pharmacy technician to use barcode technology to verify the accuracy of the drug to be dispensed.

(4) Require remote visual confirmation by a pharmacist at the supervising pharmacy of the drug stock bottle and the drug to be dispensed prior to dispensing.

(5) Ensure that a prescription is not sold or delivered to a patient prior to a pharmacist performing final verification of the accuracy of the prescription and releasing the prescription for sale and delivery.

(e) The video and audio communication system used to counsel and interact with each patient or patient's caregiver shall be secure and compliant with the federal Health Insurance Portability and Accountability Act (Public Law 104-191).

(f) All records of prescriptions dispensed including the records of the actions performed through the telepharmacy system shall be maintained at the remote dispensing site pharmacy and shall be maintained for three years after the filling of the prescription.

Section 4134 is added to the Business and Professions Code, to read:

(a) A pharmacist from the supervising pharmacy shall complete a monthly in-person, self-inspection of each remote dispensing site pharmacy using a form designated by the board and shall retain all inspection reports.

(b) A perpetual inventory shall be kept for all controlled substances stored at a remote dispensing site pharmacy.

(c) All controlled substances at a remote dispensing site pharmacy shall be stored in a secure cabinet or safe that is locked.

(d) A pharmacist from the supervising pharmacy shall perform inventory and inventory reconciliation functions at a remote dispensing site pharmacy to detect and prevent the loss of any controlled substance.

(e) The pharmacist-in-charge of a remote dispensing site pharmacy shall review all inventory and inventory reconciliation reports taken and shall establish and maintain secure methods to prevent losses of any controlled substance. The board shall develop written policies and procedures for performing the inventory reconciliation reports required by this section.

(f) A pharmacist from the supervising pharmacy shall compile an inventory reconciliation report of all Schedule II controlled substances at a remote dispensing site pharmacy at least once every three months. This compilation shall require all of the following:

(1) A physical count, not an estimate, of all quantities of Schedule II controlled substances at the remote dispensing site pharmacy. The biennial inventory of controlled substances as required under federal law may serve as one of the mandated inventories under this section in the year that the federal biennial inventory is performed, provided that the biennial inventory was taken no more than three months from the last inventory required by this section.

(2) A review of all acquisitions and dispositions of Schedule II controlled substances since the last inventory reconciliation report.

(3) A comparison of paragraphs (1) and (2) in order to determine if there are any variances.

(4) All records used to compile each inventory reconciliation report shall be maintained in the remote dispensing site pharmacy for at least three years in a readily retrievable form.

(g) A remote dispensing site pharmacy shall report to the board, in writing, any identified losses of controlled substances and possible causes of the loss within 30 days of discovering the loss unless the cause of loss is theft, diversion, or self-use in which case the report shall be made within 14 days of discovering the loss. If the remote dispensing site pharmacy is unable to identify the cause of the loss, the remote dispensing site pharmacy shall undertake further

investigation to identify the cause of the loss and security improvements necessary to prevent any additional losses of controlled substances. The pharmacist-in-charge shall be responsible for submitting the report to the board.

(h) Possible causes of overages shall be identified in writing and incorporated into the inventory reconciliation report.

(i) The inventory reconciliation report shall be dated and signed by the individual or individuals performing the inventory and countersigned by the pharmacist-in-charge of the remote dispensing site pharmacy. A countersignature shall not be required if the pharmacist-in-charge personally completed the inventory reconciliation report. The inventory reconciliation report shall be maintained in the remote dispensing site pharmacy for at least three years in a readily retrievable form.

Section 4135 is added to the Business and Professions Code, to read

(a) While closed, a remote dispensing site pharmacy shall utilize an alarm or other comparable monitoring system to protect its equipment, records, and supply of drugs, devices, and other restricted sale items from unauthorized access, acquisition, or use.

(b) Unless a pharmacist is present at the remote dispensing site pharmacy, a remote dispensing site pharmacy shall not be open or its employees allowed access to it during times the supervising pharmacy is closed. The security system shall allow for tracking of entries into the remote dispensing site pharmacy and the pharmacist-in-charge shall periodically review the record of entries. Pharmacy services shall not be provided at a remote dispensing site pharmacy if the telepharmacy system is unavailable.

(c) The remote dispensing site pharmacy shall retain a recording of facility surveillance, excluding patient communications, for a minimum of 120 days.

Section 4160 of the Business and Professions Code is amended to read:

(a) A person shall not act as a wholesaler or third-party logistics provider of any dangerous drug or dangerous device unless he or she has obtained a license from the board.

(b) Upon approval by the board and the payment of the required fee, the board shall issue a license to the applicant.

(c) (1) A separate license shall be required for each place of business owned or operated by a wholesaler or third-party logistics provider. Each place of business may only be issued a single license by the board, except as provided in paragraph (2). Each license shall be renewed annually and shall not be transferable. At all times during which a place of business is open for business, at least one designated representative, in the case of a wholesaler, or designated representative-3PL in the case of a third-party logistics provider, shall be present. A wholesaler that only acts as a reverse distributor may use either a designated representative or a designated representative-reverse distributor to fulfill this requirement.

(2) A wholesaler and a 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) Every wholesaler shall be supervised or managed by a designated representative-in-charge. The designated representative-in-charge shall be responsible for the wholesaler's compliance with state and federal laws governing wholesalers. As part of its initial application for a license, and for each renewal, each wholesaler shall, on a form designed by the board, provide identifying information and the California license number for a designated representative or pharmacist proposed to serve as the designated representative-in-charge. The proposed designated representative-in-charge shall be subject to approval by the board. The board shall not issue or renew a wholesaler license without identification of an approved designated representative-in-charge for the wholesaler. The designated representative-in-charge shall maintain an active license as a designated representative with the board at all times during which he or she is designated as the designated representative-in-charge. *A wholesaler that only acts as a reverse distributor may identify and allow a designated representative-reverse distributor to perform in this capacity. That individual shall maintain an active license as a designated representative-reverse distributor.*

(e) Each place of business of a third-party logistics provider shall be supervised and managed by a responsible manager. The responsible manager shall be responsible for the compliance of the place of business with state and federal laws governing third-party logistics providers and with the third-party logistics provider's customer specifications, except where the customer's

specifications conflict with state or federal laws. As part of its initial application for a license, and for each renewal, each third-party logistics provider shall, on a form designated by the board, provide identifying information and the California license number for a designated representative-3PL proposed to serve as the responsible manager. The proposed responsible manager shall be subject to approval by the board. The board shall not issue or renew a third-party logistics provider license without identification of an approved responsible manager for the third-party logistics provider. The responsible manager shall maintain an active license as a designated representative-3PL with the board at all times during which he or she is designated as the responsible manager.

(f) A wholesaler shall notify the board in writing, on a form designed by the board, within 30 days of the date when a designated representative-in-charge ceases to act as the designated representative-in-charge, and shall on the same form propose another ~~designated representative or pharmacist~~ authorized licensee to take over as the designated representative-in-charge. The proposed replacement designated representative-in-charge shall be subject to approval by the board. If disapproved, the wholesaler shall propose another replacement within 15 days of the date of disapproval, and shall continue to name proposed replacements until a designated representative-in-charge is approved by the board.

(g) A third-party logistics provider shall notify the board in writing, on a form designed by the board, within 30 days of the date when a responsible manager ceases to act as the responsible manager, and shall on the same form propose another designated representative-3PL to take over as the responsible manager. The proposed replacement responsible manager shall be subject to approval by the board. If disapproved, the third-party logistics provider shall propose another replacement within 15 days of the date of disapproval, and shall continue to name proposed replacements until a responsible manager is approved by the board.

(h) A drug manufacturer premises licensed by the Food and Drug Administration or licensed pursuant to Section 111615 of the Health and Safety Code that only distributes dangerous drugs and dangerous devices of its own manufacture is exempt from this section and Section 4161.

(i) 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 required in an amount established by the board as specified in subdivision (f) of Section 4400. 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~~ For purposes of retaining a temporary license, ~~nor or~~ for purposes of any disciplinary or license denial proceeding before the board, ~~shall~~ the temporary licenseholder shall not be deemed to have a vested property right or interest in the license.

Section 4160.5 is added to the Business and Professions Code, to read:

Within 30 days of the effective date of the act adding this section, a manufacturer of a nonprescription diabetes test device shall make the names of its authorized distributors available on its Internet Web site and shall provide the board with the names of its authorized distributors. Within 30 days of receiving that information from a manufacturer of a nonprescription diabetes test device, the board shall post the names of authorized distributors of nonprescription diabetes test devices on the board's Internet Web site. A manufacturer of a nonprescription diabetes test device shall, within 30 days of making changes to its authorized distributors, update its Internet Web site and inform the board of changes to its authorized distributors. Within 30 days of receiving notice of any change from a manufacturer of a nonprescription diabetes test device, the board shall post the updated list of the manufacturer's authorized distributors on its Internet Web site.

Section 4169.1 is added to the Business and Professions Code, to read:

A wholesaler, upon discovery, shall notify the board in writing of any suspicious orders of controlled substances placed by a California-licensed pharmacy or wholesaler by providing the board a copy of the information that the wholesaler provides to the United States Drug Enforcement Administration. Suspicious orders include, but are not limited to, orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

Section 4170 of the Business and Professions Code is amended to read:

(a) No prescriber shall dispense drugs or dangerous devices to patients in his or her office or place of practice unless all of the following conditions are met:

- (1) The dangerous drugs or dangerous devices are dispensed to the prescriber's own patient, and the drugs or dangerous devices are not furnished by a nurse or physician attendant.
- (2) The dangerous drugs or dangerous devices are necessary in the treatment of the condition for which the prescriber is attending the patient.
- (3) The prescriber does not keep a pharmacy, open shop, or drugstore, advertised or otherwise, for the retailing of dangerous drugs, dangerous devices, or poisons.
- (4) The prescriber fulfills all of the labeling requirements imposed upon pharmacists by Section 4076, all of the recordkeeping requirements of this chapter, and all of the packaging requirements of good pharmaceutical practice, including the use of childproof containers.
- (5) The prescriber does not use a dispensing device unless he or she personally owns the device and the contents of the device, and personally dispenses the dangerous drugs or dangerous devices to the patient packaged, labeled, and recorded in accordance with paragraph (4).
- (6) The prescriber, prior to dispensing, offers to give a written prescription to the patient that the patient may elect to have filled by the prescriber or by any pharmacy.
- (7) The prescriber provides the patient with written disclosure that the patient has a choice between obtaining the prescription from the dispensing prescriber or obtaining the prescription at a pharmacy of the patient's choice.

(8) A certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, a nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, a physician assistant who functions pursuant to Section 3502.1, or a naturopathic doctor who functions pursuant to Section 3640.5, may hand to a patient of the supervising physician and surgeon a properly labeled prescription drug prepackaged by a physician and surgeon, a manufacturer as defined in this chapter, or a pharmacist.

(b) The Medical Board of California, the State Board of Optometry, the Bureau of Naturopathic Medicine, the Dental Board of California, the California Board of Podiatric Medicine, ~~the~~ Osteopathic Medical Board of California, the Board of Registered Nursing, the Veterinary Medical Board, and the Physician Assistant Committee shall have authority with the California State Board of Pharmacy to ensure compliance with this section, and those boards are specifically charged with the enforcement of this chapter with respect to their respective licensees.

(c) "Prescriber," as used in this section, means a person, who holds a physician's and surgeon's certificate, a license to practice optometry, a license to practice naturopathic medicine, a license to practice dentistry, a license to practice veterinary medicine, or a certificate to practice podiatry, and who is duly registered by the Medical Board of California, the Osteopathic Medical Board of California, the State Board of Optometry, the Bureau of Naturopathic Medicine, the Dental Board of California, the Veterinary Medical Board, or the California Board of ~~Osteopathic Examiners of this state~~. Podiatric Medicine.

Section 4175 of the Business and Professions Code is amended to read:

(a) The California State Board of Pharmacy shall promptly forward to the appropriate licensing entity, including the Medical Board of California, the Veterinary Medical Board, the Dental Board of California, the State Board of Optometry, the California Board of Podiatric Medicine, ~~the~~ Osteopathic Medical Board of California, the Board of Registered Nursing, the Bureau of Naturopathic Medicine, or the Physician Assistant Committee, all complaints received related to dangerous drugs or dangerous devices dispensed by a prescriber, certified nurse-midwife, nurse practitioner, naturopathic doctor, or physician assistant pursuant to Section 4170.

(b) All complaints involving serious bodily injury due to dangerous drugs or dangerous devices dispensed by prescribers, certified nurse-midwives, nurse practitioners, naturopathic doctors, or physician assistants pursuant to Section 4170 shall be handled by the Medical Board of California, the Dental Board of California, the State Board of Optometry, the California Board of Podiatric Medicine, ~~the~~ Osteopathic Medical Board of California, the Bureau of Naturopathic Medicine, the Board of Registered Nursing, the Veterinary Medical Board, or the Physician Assistant Committee as a case of greatest potential harm to a patient.

Section 4180.5 is added to the Business and Professions Code, to read:

(a) The board may issue licenses authorized under Section 4180 to two independently owned clinics that share a clinic office space, provided that the clinics comply with the following:

(1) Each clinic maintains a separate clinic license with the board with its own professional directors, administrators, owners, and officers.

(2) Each clinic maintains physically separate and locked drug stocks.

(3) Each clinic separately maintains all records required by this article, including acquisition and disposition records.

(4) Dangerous drugs and dangerous devices shall not be loaned between the two licensed clinics.

(b) Dangerous drugs and dangerous device losses at the shared clinic office shall be reported to the board as required by law. Each clinic may be jointly and severally responsible for the drug losses.

(c) The applicants shall also provide the board with a copy of the co-location agreement and a one-time application fee of seven hundred fifty dollars (\$750) for the licenses.

(d) Any change in ownership in either clinic shall require a new application under this section and fees as required by subdivision (a) of Section 4400 and subdivision (c) of this section.

(e) The board shall not issue licenses authorized under Section 4180 to two independently owned clinics that share a clinic office space pursuant to this section until the board is provided with documentation from the Director of the Department of Health Care Services that any Medi-Cal financing issues, including the ability to claim associated federal financial participation or 340(b) program participation, have been sufficiently addressed to the director's satisfaction. The Department of Health Care Services may seek any federal approvals it deems necessary to implement this section.

(f) The board shall not issue licenses authorized under Section 4180 to two independently owned clinics that share a clinic office space pursuant to the section until the board is provided with documentation from the Director of the Department of Public Health that any licensing and regulatory issues have been sufficiently addressed to the director's satisfaction.

(g) This section shall become inoperative on January 1, 2021, and as of that date is repealed.

Section 4200.4 of the Business and Professions Code is amended to read:

An applicant who fails ~~the national examination~~ either the North American Pharmacist Licensure Examination or the California Practice Standards and Jurisprudence Examination for Pharmacists may not retake ~~the that~~ the examination for at least ~~90 days or for a period established by regulations adopted by the board~~ 45 days. The board may, in consultation with the Office of Professional Examination Services of the department, adopt a regulation establishing a different waiting period to retake the examination.

Section 4202.5 is added to the Business and Professions Code, to read:

(a) The board may issue a designated paramedic license to an individual if he or she holds a license as a paramedic in this state and meets the criteria of this section.

(b) The board shall conduct a criminal background check of the applicant to determine if the applicant has committed acts that would constitute grounds for denial of licensure, pursuant to this chapter or Chapter 2 (commencing with Section 480) of Division 1.5.

(c) The board may suspend or revoke a license issued pursuant to this section on any ground specified in Section 4301.

(d) A license issued under this section is dependent on the validity of the holder's paramedic license and shall be automatically suspended if the individual's paramedic license is expired, revoked, or otherwise invalidated by the issuing authority.

(e) The fee for application and issuance of an initial license as a designated paramedic shall be one hundred forty dollars (\$140) for a two-year license. The biennial renewal shall be one hundred forty dollars (\$140). The penalty fee for failure to renew an authorized paramedic license shall be sixty-five dollars (\$65).

Section 4301 of the Business and Professions Code is amended to read:

The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

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

(b) Incompetence.

(c) Gross negligence.

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

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

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

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

(h) The administering to oneself, of any controlled substance, or the use of any dangerous drug or of alcoholic beverages to the extent or in a manner as to be dangerous or injurious to

oneself, to a person holding a license under this chapter, or to any other person or to the public, or to the extent that the use impairs the ability of the person to conduct with safety to the public the practice authorized by the license.

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

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

(k) The conviction of more than one misdemeanor or any felony involving the use, consumption, or self-administration of any dangerous drug or alcoholic beverage, or any combination of those substances.

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

(m) The cash compromise of a charge of violation of Chapter 13 (commencing with Section 801) of Title 21 of the United States Code regulating controlled substances or of Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code relating to the Medi-Cal program.

(n) The revocation, suspension, or other discipline by another state of a license to practice pharmacy, operate a pharmacy, or do any other act for which a license is required by this chapter that would be grounds for revocation, suspension, or other discipline under this chapter. Any disciplinary action taken by the board pursuant to this section shall be coterminous with action taken by another state, except that the term of any discipline taken by the board may exceed that of another state, consistent with the board's enforcement guidelines. The evidence of discipline by another state is conclusive proof of unprofessional conduct.

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

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

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

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

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

(t) The acquisition of a nonprescription diabetes test device from a person that the licensee knew or should have known was not the nonprescription diabetes test device's manufacturer or the manufacturer's authorized distributors as identified in Section 4160.5.

(u) The submission of a reimbursement claim for a nonprescription diabetes test device to a pharmaceutical benefit manager, health insurer, government agency, or other third-party payor when the licensee knew or reasonably should have known that the diabetes test device was not purchased either directly from the manufacturer or from the nonprescription diabetes test device manufacturer's authorized distributors as identified in Section 4160.5.

Section 4316 of the Business and Professions Code is amended to read:

(a) The ~~board~~ board, through its executive officer, 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 without obtaining that 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~~ facility pursuant to Section 1094.5 of the Code of Civil Procedure.

Section 4331 of the Business and Professions Code is amended to read:

(a) A person ~~who is not a pharmacist, a designated representative in charge, or a designated representative and~~ not authorized under this chapter who takes charge of a wholesaler or veterinary food-animal drug retailer or who dispenses a prescription or furnishes dangerous devices, except as otherwise provided in this chapter, is guilty of a misdemeanor.

(b) A person who is not a responsible manager or a designated representative-3PL who takes charge of a third-party logistics provider or coordinates the warehousing or distribution of dangerous drugs or dangerous devices within a third-party logistics provider, except as otherwise provided in this chapter, is guilty of a misdemeanor.

(c) A person licensed as a veterinary food-animal drug retailer that fails to place in charge of that veterinary food-animal drug retailer a pharmacist or designated representative, or any person who, by himself or herself, or by any other person, permits the dispensing of prescriptions, except by a pharmacist or designated representative, or as otherwise provided in this chapter, is guilty of a misdemeanor.

(d) A person licensed as a wholesaler that fails to place in charge of that wholesaler a pharmacist or designated representative, or any person who, by himself or herself, or by any other person, permits the furnishing of dangerous drugs or dangerous devices, except by a pharmacist or designated representative, or as otherwise provided in this chapter, is guilty of a misdemeanor.

(e) A person licensed as a third-party logistics provider that fails to place in charge of a licensed place of business of the third-party logistics provider a responsible manager, or any person who, by himself or herself, or by any other person, permits the furnishing of dangerous drugs or dangerous devices, except by a facility manager, or as otherwise provided in this chapter, is guilty of a misdemeanor.

Section 4400 of the Business and Professions Code, is amended to read:

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, or as a designated representative-reverse distributor pursuant to Section 4053.2 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~~ representative, designated representative-3PL, or designated ~~representative-3PL~~ representative-reverse distributor 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 or a hospital satellite compounding pharmacy 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 an outsourcing facility license shall be two thousand two hundred seventy dollars (\$2,270) and may be increased to up to three thousand one hundred eighty dollars (\$3,180) by the board. The fee for the renewal of an outsourcing facility license shall be one thousand three hundred twenty-five dollars (\$1,325) and may be increased to up to one thousand eight hundred fifty-five dollars (\$1,855) by the board. The fee for a temporary outsourcing facility license shall be seven hundred fifteen dollars (\$715).

(x) The fee for the issuance of a nonresident outsourcing facility license shall be two thousand three hundred eighty dollars (\$2,380) and may be increased to up to three thousand three hundred thirty-five dollars (\$3,335) by the board. The fee for the renewal of a nonresident outsourcing facility license shall be two thousand two hundred seventy dollars (\$2,270) and

may be increased to up to three thousand one hundred eighty dollars (\$3,180) by the board. 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.

(y) 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).

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

Health and Safety Code Section Changes

Section 11054 of the Health and Safety Code is amended to read:

(a) The controlled substances listed in this section are included in Schedule I.

(b) Opiates. Unless specifically excepted or unless listed in another schedule, any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of those isomers, esters, ethers, and salts is possible within the specific chemical designation:

(1) Acetylmethadol.

(2) Allylprodine.

(3) Alphacetylmethadol (except levoalphacetylmethadol, also known as levo-alpha-acetylmethadol, levomethadyl acetate, or LAAM).

(4) Alphameprodine.

(5) Alphamethadol.

(6) Benzethidine.

(7) Betacetylmethadol.

(8) Betameprodine.

(9) Betamethadol.

(10) Betaprodine.

- (11) Clonitazene.
- (12) Dextromoramide.
- (13) Diampromide.
- (14) Diethylthiambutene.
- (15) Difenoxin.
- (16) Dimenoxadol.
- (17) Dimepheptanol.
- (18) Dimethylthiambutene.
- (19) Dioxaphetyl butyrate.
- (20) Dipipanone.
- (21) Ethylmethylthiambutene.
- (22) Etonitazene.
- (23) Etoxidine.
- (24) Furethidine.
- (25) Hydroxypethidine.
- (26) Ketobemidone.
- (27) Levomoramide.
- (28) Levophenacymorphan.
- (29) Morpheridine.
- (30) Noracymethadol.
- (31) Norlevorphanol.
- (32) Normethadone.
- (33) Norpipanone.
- (34) Phenadoxone.
- (35) Phenampromide.
- (36) Phenomorphan.
- (37) Phenoperidine.
- (38) Piritramide.

(39) Proheptazine.

(40) Properidine.

(41) Propiram.

(42) Racemoramide.

(43) Tilidine.

(44) Trimeperidine.

(45) Any substance which contains any quantity of acetylfentanyl (N-[1-phenethyl-4-piperidinyl] acetanilide) or a derivative thereof.

(46) Any substance which contains any quantity of the thiophene analog of acetylfentanyl (N-[1-[2-(2-thienyl)ethyl]-4-piperidinyl] acetanilide) or a derivative thereof.

(47) 1-Methyl-4-Phenyl-4-Propionoxypiperidine (MPPP).

(48) 1-(2-Phenethyl)-4-Phenyl-4-Acetyloxypiperidine (PEPAP).

(c) Opium derivatives. Unless specifically excepted or unless listed in another schedule, any of the following opium derivatives, its salts, isomers, and salts of isomers whenever the existence of those salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Acetorphine.

(2) Acetyldihydrocodeine.

(3) Benzylmorphine.

(4) Codeine methylbromide.

(5) Codeine-N-Oxide.

(6) Cyprenorphine.

(7) Desomorphine.

(8) Dihydromorphine.

(9) Drotebanol.

(10) Etorphine (except hydrochloride salt).

(11) Heroin.

(12) Hydromorphenol.

(13) Methyldesorphine.

(14) Methyldihydromorphine.

(15) Morphine methylbromide.

(16) Morphine methylsulfonate.

(17) Morphine-N-Oxide.

(18) Myrophine.

(19) Nicocodeine.

(20) Nicomorphine.

(21) Normorphine.

(22) Pholcodine.

(23) Thebacon.

(d) Hallucinogenic substances. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation, which contains any quantity of the following hallucinogenic substances, or which contains any of its salts, isomers, and salts of isomers whenever the existence of those salts, isomers, and salts of isomers is possible within the specific chemical designation (for purposes of this subdivision only, the term "isomer" includes the optical, position, and geometric isomers):

(1) 4-bromo-2,5-dimethoxy-amphetamine—Some trade or other names: 4-bromo-2,5-dimethoxy-alpha-methylphenethylamine; 4-bromo-2,5-DMA.

(2) 2,5-dimethoxyamphetamine—Some trade or other names: 2,5-dimethoxy-alpha-methylphenethylamine; 2,5-DMA.

(3) 4-methoxyamphetamine—Some trade or other names: 4-methoxy-alpha-methylphenethylamine, paramethoxyamphetamine, PMA.

(4) 5-methoxy-3,4-methylenedioxy-amphetamine.

(5) 4-methyl-2,5-dimethoxy-amphetamine—Some trade or other names: 4-methyl-2,5-dimethoxy-alpha-methylphenethylamine; "DOM"; and "STP."

(6) 3,4-methylenedioxy amphetamine.

(7) 3,4,5-trimethoxy amphetamine.

(8) Bufotenine—Some trade or other names: 3-(beta-dimethylaminoethyl)-5-hydroxyindole; 3-(2-dimethylaminoethyl)-5 indolol; N,N-dimethylserolonin, 5-hydroxy-N,N-dimethyltryptamine; mappine.

(9) Diethyltryptamine—Some trade or other names: N,N-Diethyltryptamine; DET.

(10) Dimethyltryptamine—Some trade or other names: DMT.

(11) Ibogaine—Some trade or other names: 7-Ethyl-6,6beta, 7,8,9,10,12,13-octahydro-2-methoxy-6,9-methano-5H-pyrido [1',2':1,2] azepino [5,4-b] indole; Tabernantheiboga.

(12) Lysergic acid diethylamide.

(13) ~~Marijuana~~ Cannabis.

(14) Mescaline.

(15) Peyote—Meaning all parts of the plant presently classified botanically as *Lophophora williamsii* Lemaire, whether growing or not, the seeds thereof, any extract from any part of the plant, and every compound, manufacture, salts, derivative, mixture, or preparation of the plant, its seeds or extracts (interprets 21 U.S.C. Sec. 812(c), Schedule 1(c)(12)).

(16) N-ethyl-3-piperidyl benzilate.

(17) N-methyl-3-piperidyl benzilate.

(18) Psilocybin.

(19) Psilocyn.

(20) Tetrahydrocannabinols. Synthetic equivalents of the substances contained in the plant, or in the resinous extractives of *Cannabis*, sp. and/or synthetic substances, derivatives, and their isomers with similar chemical structure and pharmacological activity such as the following: delta 1 cis or trans tetrahydrocannabinol, and their optical isomers; delta 6 cis or trans tetrahydrocannabinol, and their optical isomers; delta 3,4 cis or trans tetrahydrocannabinol, and its optical isomers.

~~(Since Because nomenclature of these substances is not internationally standardized, compounds of these structures, regardless of numerical designation of atomic positions covered).~~ covered.

(21) Ethylamine analog of phencyclidine—Some trade or other names: N-ethyl-1-phenylcyclohexylamine, (1-phenylcyclohexyl) ethylamine, N-(1-phenylcyclohexyl) ethylamine, cyclohexamine, PCE.

(22) Pyrrolidine analog of phencyclidine—Some trade or other names: 1-(1-phenylcyclohexyl)-pyrrolidine, PCP, PHP.

(23) Thiophene analog of phencyclidine—Some trade or other names: 1-[1-(2 thienyl)-cyclohexyl]-piperidine, 2-thienyl analog of phencyclidine, TPCP, TCP.

(e) Depressants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers whenever the existence of those salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Mecloqualone.

(2) Methaqualone.

(3) Gamma hydroxybutyric acid (also known by other names such as GHB; gamma hydroxy butyrate; 4-hydroxybutyrate; 4-hydroxybutanoic acid; sodium oxybate; sodium oxybutyrate), including its immediate precursors, isomers, esters, ethers, salts, and salts of isomers, esters,

and ethers, including, but not limited to, gammabutyrolactone, for which an application has not been approved under Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 355).

(f) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its isomers:

(1) Cocaine base.

(2) Fenethylamine, including its salts.

(3) N-Ethylamphetamine, including its salts.

Section 11165.1 of the Health and Safety Code, is amended to read:

(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~~ department to obtain approval to electronically 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~~ maintained by the department. 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~~ department to obtain approval to electronically 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~~ maintained by the department. 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~~ to access information contained in the CURES database.

(ii) ~~Failure~~ Failing to maintain effective controls for access to the patient activity report.

(iii) ~~Suspended~~ Having his or revoked her federal DEA ~~registration~~ registration suspended or revoked.

(iv) ~~Any subscriber who is arrested for a violation of~~ Violating a 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~~ Accessing information for ~~any a reason~~ other reason than caring for than to diagnose or treat his or her patients, patients, or to document compliance with the law.

~~(C) Any An~~ authorized subscriber shall notify the ~~Department of Justice~~ department within 30 days of any changes to the subscriber account.

(D) Commencing no later than October 1, 2018, an approved health care practitioner, pharmacist, and any person acting on behalf of a health care practitioner or pharmacist pursuant to subdivision (b) of Section 209 of the Business and Professions Code may use the department's online portal or a health information technology system that meets the criteria required in subparagraph (E) to access information in the CURES database pursuant to this section. A subscriber who uses a health information technology system that meets the criteria required in subparagraph (E) to access the CURES database may submit automated queries to the CURES database that are triggered by predetermined criteria.

(E) Commencing no later than October 1, 2018, an approved health care practitioner or pharmacist may submit queries to the CURES database through a health information technology system if the entity that operates the health information technology system can certify all of the following:

(i) The entity will not use or disclose data received from the CURES database for any purpose other than delivering the data to an approved health care practitioner or pharmacist or performing data processing activities that may be necessary to enable the delivery unless authorized by, and pursuant to, state and federal privacy and security laws and regulations.

(ii) The health information technology system will authenticate the identity of an authorized health care practitioner or pharmacist initiating queries to the CURES database and, at the time of the query to the CURES database, the health information technology system submits the following data regarding the query to CURES:

(I) The date of the query.

(II) The time of the query.

(III) The first and last name of the patient queried.

(IV) The date of birth of the patient queried.

(V) The identification of the CURES user for whom the system is making the query.

(iii) The health information technology system meets applicable patient privacy and information security requirements of state and federal law.

(iv) The entity has entered into a memorandum of understanding with the department that solely addresses the technical specifications of the health information technology system to ensure the security of the data in the CURES database and the secure transfer of data from the CURES database. The technical specifications shall be universal for all health information technology systems that establish a method of system integration to retrieve information from

the CURES database. The memorandum of understanding shall not govern, or in any way impact or restrict, the use of data received from the CURES database or impose any additional burdens on covered entities in compliance with the regulations promulgated pursuant to the federal Health Insurance Portability and Accountability Act of 1996 found in Parts 160 and 164 of Title 45 of the Code of Federal Regulations.

(F) No later than October 1, 2018, the department shall develop a programming interface or other method of system integration to allow health information technology systems that meet the requirements in subparagraph (E) to retrieve information in the CURES database on behalf of an authorized health care practitioner or pharmacist.

(G) The department shall not access patient-identifiable information in an entity's health information technology system.

(H) An entity that operates a health information technology system that is requesting to establish an integration with the CURES database shall pay a reasonable fee to cover the cost of establishing and maintaining integration with the CURES database.

(I) The department may prohibit integration or terminate a health information technology system's ability to retrieve information in the CURES database if the health information technology system fails to meet the requirements of subparagraph (E), or the entity operating the health information technology system does not fulfill its obligation under subparagraph (H).

(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 A~~ 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~~ department.

(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~~ department 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~~ department pursuant to this section 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~~ practitioner 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, inaccurate, or misattributed information submitted to, reported by, or relied upon in the CURES database or for any resulting failure of the CURES database to accurately or timely report that information.

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

(1) "Automated basis" means using predefined criteria to trigger an automated query to the CURES database, which can be attributed to a specific health care practitioner or pharmacist.

(2) "Department" means the Department of Justice.

(3) "Entity" means an organization that operates, or provides or makes available, a health information technology system to a health care practitioner or pharmacist.

(4) "Health information technology system" means an information processing application using hardware and software for the storage, retrieval, sharing of or use of patient data for communication, decisionmaking, coordination of care, or the quality, safety, or efficiency of the practice of medicine or delivery of health care services, including, but not limited to, electronic medical record applications, health information exchange systems, or other interoperable clinical or health care information system.

(5) "User-initiated basis" means an authorized health care practitioner or pharmacist has taken an action to initiate the query to the CURES database, such as clicking a button, issuing a voice command, or taking some other action that can be attributed to a specific health care practitioner or pharmacist.

Section 11220 of the Health and Safety Code is amended to read:

At the end of 30 days from the first treatment, the prescribing or furnishing of controlled substances, except ~~methadone or LAAM,~~ medications approved by the federal Food and Drug Administration for the purpose of narcotic replacement treatment or medication-assisted treatment of substance use disorders, shall be discontinued.

Attachment 4

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

Timeline:

Approved by Board: July 29, 2015
Rulemaking Initiated: September 4, 2015
Adopted by Board: April 27, 2016
Submitted to DCA: August 4, 2016
Submitted to OAL: November 30, 2016
Disapproved by OAL: January 13, 2017
Modified Text Approved by Board: February 17, 2017
Re-Submitted to DCA: April 27, 2017

Summary of Regulation:

This regulation updates the board's disciplinary guidelines that are incorporated by reference. The updated disciplinary guidelines incorporate changes to pharmacy law that occurred between October 2007 and July 2015 and implement SB 1441 (Ridley-Thomas, Chapter 548, Statutes of 2008).

2. Proposed Regulations to Amend Title 16 CCR section 1749 Related to the Board's Fee Schedule

Timeline:

Approved by Board: October 27, 2016
Submitted to DCA for Pre-Notice Review: November 4, 2016
Rulemaking Initiated: April 14, 2017
Adopted by Board: July 26, 2017
Submitted to DCA: October 10, 2017

Summary of Regulation:

This regulation updates the board's fee schedule to incorporate changes made to pharmacy law in Business and Professions Code section 4400 on July 1, 2017.

3. Proposed Regulations to Add Title 16 CCR section 1715.65 Related to the Inventory Reconciliation Report of Controlled Substances

Timeline:

Approved by Board: July 28, 2016
Rulemaking Initiated: September 16, 2016
Adopted by Board: July 26, 2017
Submitted to DCA: September 5, 2017

Summary of Regulation:

This regulation establishes the regulatory requirement to conduct a quarterly inventory and compile an inventory reconciliation report of federal Schedule II Controlled Substances.

Attachment 5

1. Proposed Emergency Regulations to Amend Title 16 CCR section 1735.2 Related to Compounding Beyond Use Dates

Timeline:

Approved by Board: July 25, 2017

Submitted to DCA for Pre-Notice Review: August 15, 2017

Summary of Regulation:

This emergency regulation amends the board's regulation regarding the establishment of compounding beyond use dates as it relates to sterile and non-sterile compounded drug preparations.

2. Proposed Regulations to Amend Title 16 CCR Sections 1780-1783, et seq. Related to Third-Party Logistics Providers and Dangerous Drug Distributors

Timeline:

Approved by Board: October 26, 2016

Submitted to DCA for Pre-Notice Review: February 9, 2017

Returned to the Board on: February 28, 2017

Re-submitted to DCA for Pre-Notice Review: October 25, 2017

Summary of Regulation:

This regulation establishes the regulatory framework for third-party logistics providers.

This package has been returned to Board staff. Board staff is working to review the scope of the changes to determine the next course of action for this regulation package.

3. Proposed Regulations to Amend Title 16 CCR Section 1793.5 Related to the Pharmacy Technician Application, Section 1793.6 Related to the Pharmacy Technician Training Requirements, and Section 1793.65 Related to the Pharmacy Technician Certification Programs

Timeline:

Approved by Board: October 26, 2016

Submitted to DCA for Pre-Notice Review: January 23, 2017

Returned to the Board on: March 28, 2017

Re-submitted to DCA for Pre-Notice Review: August 23, 2017

Summary of Regulation:

This regulation establishes the training requirements and certification programs and updates the application for licensure for pharmacy technicians.

4. Proposed Regulations to Amend Title 16 CCR Section 1707 Related to Offsite Storage

Timeline:

Approved by Board: January 24, 2017

Submitted to DCA for Pre-Notice Review: April 27, 2017

Summary of Regulation:

This regulation amends the board's regulations regarding the waiver requirements for off-site storage of records to allow those cited for a records violation to receive a waiver to store records off-site.

5. Proposed Regulations to Amend Title 16 CCR Section 1746.3 Related to the Naloxone Fact Sheet

Timeline:

Approved by Board: May 4, 2017

Submitted to DCA for Pre-Notice Review: May 31, 2017

Summary of Regulation:

This regulation amends the board's regulations regarding the naloxone fact sheet that must be provided to consumers upon furnishing naloxone hydrochloride.

6. Proposed Regulations to Amend Title 16 CCR Section 1709 Related to Pharmacy Ownership, Management, and Control, Including Through Trusts

Timeline:

Approved by Board: October 27, 2016

Submitted to DCA for Pre-Notice Review: January 26, 2017

Returned to the Board on: March 28, 2017

Summary of Regulation:

This regulation amends the board's regulations regarding ownership to include provisions relating to trust ownership of pharmacies

**Compounding
Beyond Use Dates
16 CCR § 1735.2**

Title 16. Board of Pharmacy

Changes made to the current regulation language are shown by strikethrough for deleted language and underline for added language. Additionally, [Brackets] indicates language that is not being amended.

Amend section 1735.2, subdivision (i) in Article 4.5 of Division 17 of Title 16 California Code of Regulations to read as follows:

1735.2. Compounding Limitations and Requirements; Self-Assessment.

[.....]

- (i) Every compounded drug preparation shall be given 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.
 - (1) For non-sterile compounded drug preparation(s), 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 compounded drug 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, 180 days or an extended date established by the pharmacist's research, analysis, and documentation,
 - (E) ~~14 days~~ for water-containing oral formulations, 14 days or an extended date established by the pharmacist's research, analysis, and documentation, and
 - (F) ~~30 days~~ for water-containing topical/dermal and mucosal liquid and semisolid formulations, 30 days or an extended date established by the pharmacist's research, analysis, and documentation.
 - (G) A pharmacist, using his or her professional judgment may establish an extended date as provided in (D), (E), and (F), if the pharmacist researches by consulting and applying drug-specific and general stability documentation and literature; analyzes such documentation and literature as well as the other factors set forth in this subdivision, and maintains documentation of the research, analysis and conclusion. The factors the pharmacist must analyze include:
 - (i) the nature of the drug and its degradation mechanism,
 - (ii) the dosage form and its components,
 - (iii) the potential for microbial proliferation in the preparation,
 - (iv) the container in which it is packaged,
 - (v) the expected storage conditions, and
 - (vi) the intended duration of therapy.

Documentation of the pharmacist's research and analysis supporting an extension must be maintained in a readily retrievable format as part of the master formula.

- (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) For sterile compounded drug preparations, ~~E~~-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
- (4) In addition to the requirements of paragraph three (3), the drugs or compounded drug preparations tested and studied shall be identical 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.

[.....]

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

**Third-Party Logistics
Providers and
Dangerous Drug
Distributors
§§ 1780-1783**

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 Dangerous Drug Distributors. ~~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 standards set forth in the latest edition of 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 and/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 the standards set forth in the latest edition of the ~~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) Each ~~W~~ wholesaler 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) Each ~~W~~ wholesaler 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, 4053.1, 4054, 4059, 4120, 4160, 4161 ~~and~~ 4304, ~~and~~ 4342 of the Business and Professions Code; Sections 109985 and 111280 of the Health and Safety Code; Section 321 of Title 21, U.S. Code; and Section 205.50 of Title 21, Code of Federal Regulations.

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 Designated Representative.

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~~ Each manufacturers, ~~and~~ wholesalers and third-party logistics provider 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 4053.1, 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, 4053.1, 4059, 4059.5, 4080, 4081, 4120, 4160, 4161, 4163 and 4304, Business and Professions Code; and Section 11209, Health and Safety Code.

Pharmacy Technician

**16 CCR § 1793.5,
1793.6, and 1793.65**

Title 16. Board of Pharmacy Proposed Regulation

Proposal to amend §1793.5 of Article 11 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1793.5. Pharmacy Technician Application.

The "Pharmacy Technician Application" (Form 17A-5 (Rev. ~~10/15~~ 10/2016)), incorporated by reference herein, required by this section is available from the Board of Pharmacy upon request.

(a) Each application for a pharmacy technician license shall include:

(1) Information sufficient to identify the applicant.

(2) A description of the applicant's qualifications and supporting documentation for those qualifications.

(3) A criminal background check that will require submission of fingerprints in a manner specified by the board and the fee authorized in Penal Code section 11105(e).

(4) A sealed, original Self-Query from the National Practitioner Data Bank (NPDB) dated no earlier than 60 days of the date an application is submitted to the board.

(b) The applicant shall sign the application under penalty of perjury and shall submit it to the Board of Pharmacy.

(c) The board shall notify the applicant within 30 days if an application is deficient; and what is needed to correct the deficiency. Once the application is complete, and upon completion of any investigation conducted pursuant to section 4207 of the Business and Professions Code, the board will notify the applicant within 60 days of a license decision.

(d) Before expiration of a pharmacy technician license, a pharmacy technician must renew that license by payment of the fee specified in subdivision (r) of section 4400 of the Business and Professions Code.

Note: Authority cited: Sections 144, 163.5, 4005, 4007, 4038, 4115, 4202, 4207 and 4400, Business and Professions Code. Reference: Sections 163.5, 4005, 4007, 4038, 4115, 4202, 4207, 4400 and 4402 ~~and 4400~~, Business and Professions Code; and Section 11105, Penal Code.

Proposal to amend §1793.6 of Article 11 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1793.6. Training Courses Specified by the Board.

A course of training that meets the requirements of Business and Professions Code section 4202

(a)(2) is:

(a) Any pharmacy technician training program accredited by the American Society of Health--System Pharmacists,

(b) Any pharmacy technician training program provided by a branch of the federal armed services for which the applicant possesses a certificate of completion, or

(c) (1) Any other course that provides a training period of at least 240 hours of instruction covering at least the following:

(± A) Knowledge and understanding of different pharmacy practice settings.

(2 B) Knowledge and understanding of the duties and responsibilities of a pharmacy technician in relationship to other pharmacy personnel and knowledge of standards and ethics, laws and regulations governing the practice of pharmacy.

(3 C) Knowledge and ability to identify and employ pharmaceutical and medical terms, abbreviations and symbols commonly used in prescribing, dispensing and record keeping of medications.

(4 D) Knowledge of and the ability to carry out calculations required for common dosage determination, employing both the metric and apothecary systems.

(5 E) Knowledge and understanding of the identification of drugs, drug dosages, routes of administration, dosage forms and storage requirements.

(6 F) Knowledge of and ability to perform the manipulative and record-keeping functions involved in and related to dispensing prescriptions.

(7 G) Knowledge of and ability to perform procedures and techniques relating to manufacturing, packaging, and labeling of drug products.

(2) In addition to the content of coursework specified in subdivision (c)(1), the course of training must also satisfy all of the following:

(A) Prior to admission to the course of training, an administrator or instructor must conduct a criminal background check and counsel applicants to the program about the negative impact to securing licensure if the background check reveals criminal history.

(B) Administer at least one drug screening to evaluate use of illicit drugs or use of drugs without a prescription. The results of any screen shall be considered as part of the evaluation criteria to determine acceptance into the course of training or appropriateness for continuation in the course of training. An administrator or instructor shall counsel students about the negative impact of a positive drug screen on eligibility for licensure.

(C) Require students to be at least 18 years of age prior to the beginning of instruction.

(D) Require a final examination that demonstrates students' understanding and ability to perform or apply each subject area identified in subsection (1) above.

Authority cited: Sections 4005, 4007, 4038, 4115, 4115.5, and 4202, Business and Professions Code.

Reference: Sections 4005, 4007, 4038, 4115 and 4202, Business and Professions Code.

Proposal to add §1793.65 of Article 11 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1793.65 Pharmacy Technician Certification Programs Approved by the Board.

(a) Pursuant to Business and Professions Code section 4202(a)(4), the board approves the following pharmacy technician certification programs until January 1, 2021:

(1) Pharmacy Technician Certification Board, and

(2) National Healthcareer Association's Examination for the Certification of Pharmacy Technicians Program.

(b) Approval of these programs is valid through December 31, 2020.

Note: Authority cited: Business and Professions Code Sections 4005 and 4202. Reference: Business and Professions Code Sections 4005, 4038 and 4202.

Offsite Storage

16 CCR § 1707

Proposal to Amend 16 CCR § 1707

§ 1707. Waiver Requirements for Off-Site Storage of Records.

(a) Pursuant to subdivision (e) of Section 4105 of the Business and Professions Code and subdivision (c) of Section 4333 of the Business and Professions Code, a waiver shall may be granted to any entity licensed by the board for ~~off-site~~ storage of the records outside the licensed area of the pharmacy described in subdivisions (a), (b) and (c) of Section 4105 of the Business and Professions Code ~~unless the applicant has, within the preceding five years, failed to produce records pursuant to Section 4081 of the Business and Professions Code or has falsified records covered by Section 4081 of the Business and Professions Code.~~

(b) An entity that is granted a waiver pursuant to subdivision (a) shall:

(1) maintain the storage area so that the records are secure, including from unauthorized access; and

(2) be able to produce the records within two business days upon the request of the board or an authorized officer of the law.

(c) In the event that a licensee fails to comply with the conditions set forth in subdivision (b), the board may cancel the waiver without a hearing. Upon notification by the board of cancellation of the waiver, the licensee shall maintain all records at the licensed premises.

(d) A licensee whose waiver has been cancelled pursuant to the provisions set forth in subsection (c) may reapply to the board when compliance with the conditions set forth in subsection (b) can be confirmed by the board.

(e) Notwithstanding any waiver granted pursuant to subdivision (a), all prescription records for non controlled substances shall be maintained on the licensed premises for a period of one year from the date of dispensing.

(f) Notwithstanding any waiver granted pursuant to subdivision (a), all prescription records for controlled substances shall be maintained on the licensed premises for a period of two years from the date of dispensing.

(g) Notwithstanding the requirements of this section, any entity licensed by the board may store the records described in subdivisions (a), (b) and (c) of Section 4105 of the Business and Professions Code in a storage area at the same address or adjoining the licensed premises without obtaining a waiver from the board if the following conditions are met:

(1) The records are readily accessible to the pharmacist-in-charge (or other pharmacist on duty, or designated representative) and upon request to the board or any authorized officer of the law.

(2) The storage area is maintained so that the records are secure and so that the confidentiality of any patient-related information is maintained.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4081, 4105 and 4333, Business and Professions Code.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4081, 4105 and 4333, Business and Professions Code.

Naloxone Fact Sheet

16 CCR § 1746.3

BOARD OF PHARMACY

Proposal to amend § 1746.3 in Article 5 of Division 17 of Title 16 of the California Code of Regulations to read:

§ 1746.3. Protocol for Pharmacists Furnishing Naloxone Hydrochloride.

A pharmacist furnishing naloxone hydrochloride pursuant to section 4052.01 of the Business and Professions Code shall satisfy the requirements of this section.

(a) As used in this section:

(1) "Opioid" means naturally derived opiates as well as synthetic and semi-synthetic opioids.

(2) "Recipient" means the person to whom naloxone hydrochloride is furnished.

(b) Training. Prior to furnishing naloxone hydrochloride, pharmacists who use this protocol must have successfully completed a minimum of one hour of an approved continuing education program specific to the use of naloxone hydrochloride in all routes of administration recognized in subsection (c)(4) of this protocol, or an equivalent curriculum-based training program completed in a board recognized school of pharmacy.

(c) Protocol for Pharmacists Furnishing Naloxone Hydrochloride.

Before providing naloxone hydrochloride, the pharmacist shall:

(1) Screen the potential recipient by asking the following questions:

(A) Whether the potential recipient currently uses or has a history of using illicit or prescription opioids. (If the recipient answers yes, the pharmacist may skip screening question B.);

(B) Whether the potential recipient is in contact with anyone who uses or has a history of using illicit or prescription opioids. (If the recipient answers yes, the pharmacist may continue.);

(C) Whether the person to whom the naloxone hydrochloride would be administered has a known hypersensitivity to naloxone. (If the recipient answers yes, the pharmacist may not provide naloxone. If the recipient responds no, the pharmacist may continue.)

The screening questions shall be made available on the Board of Pharmacy's website in alternate languages for patients whose primary language is not English.

(2) Provide the recipient training in opioid overdose prevention, recognition, response, and administration of the antidote naloxone.

(3) When naloxone hydrochloride is furnished:

(A) The pharmacist shall provide the recipient with appropriate counseling and information on the product furnished, including dosing, effectiveness, adverse effects, storage conditions, shelf-life, and safety. The recipient is not permitted to waive the required consultation.

(B) The pharmacist shall provide the recipient with any informational resources on hand and/or referrals to appropriate resources if the recipient indicates interest in addiction treatment, recovery services, or medication disposal resources at this time.

(C) The pharmacist shall answer any questions the recipient may have regarding naloxone hydrochloride.

(4) Product Selection: A pharmacist shall advise the recipient on how to choose the route of administration based on the formulation available, how well it can likely be administered, the setting, and local context. A pharmacist may supply naloxone hydrochloride as an intramuscular injection, intranasal spray, auto-injector or in another FDA-approved product form. A pharmacist may also recommend optional items when appropriate, including alcohol pads, rescue breathing masks, and rubber gloves.

(5) Labeling: A pharmacist shall label the naloxone hydrochloride consistent with law and regulations. Labels shall include an expiration date for the naloxone hydrochloride furnished. An example of appropriate labeling is available on the Board of Pharmacy's website.

(6) Fact Sheet: The pharmacist shall provide the recipient a copy of the current naloxone fact sheet approved by the Board of Pharmacy or substantively similar fact sheet approved by the executive officer. This fact sheet shall be made available on the Board of Pharmacy's website in alternate languages for patients whose primary language is not English.

(7) Notifications: If the recipient of the naloxone hydrochloride is also the person to whom the naloxone hydrochloride would be administered, then the naloxone recipient is considered a patient for purposes of this protocol and notification may be required under this section.

If the patient gives verbal or written consent, then the pharmacist shall notify the patient's primary care provider of any drug(s) and/or device(s) furnished, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by the patient and that primary care provider.

If the patient does not have a primary care provider, or chooses not to give notification consent, then the pharmacist shall provide a written record of the drug(s) and/or device(s) furnished and advise the patient to consult an appropriate health care provider of the patient's choice.

(8) Documentation: Each naloxone hydrochloride product furnished by a pharmacist pursuant to this protocol shall be documented in a medication record for the naloxone recipient, and securely stored within the originating pharmacy or health care facility for a period of at least three years from the date of dispense. The medication record shall be maintained in an automated data or manual record mode such that the required information under 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.

(9) Privacy: All pharmacists furnishing naloxone hydrochloride in a pharmacy or health care facility shall operate under the pharmacy or facility's policies and procedures to ensure that recipient confidentiality and privacy are maintained.

Note: Authority cited: Section 4052.01, Business and Professions Code. Reference: Section 4052.01, Business and Professions Code.

**Pharmacy Ownership,
Management, and
Control, Including
Through Trusts
16 CCR § 1709**

**Title 16. Board of Pharmacy
Proposed Text**

To Amend Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1709. ~~Names of Owners and Pharmacist In Charge~~ Disclosure and Notification Requirements

- (a) Each ~~permit~~ license issued by the board to operate a pharmacy shall reflect ~~show~~ the name and address of the pharmacy, the form of ownership (~~individual, partnership or corporation~~) and the pharmacist-in-charge. Each pharmacy shall, in its initial application and on the annual renewal form, report the name of the pharmacist-in-charge, the names of all owners and the names of the corporate officers (if a corporation). Any changes in the pharmacist-in-charge, or the owners, or corporate officers shall be reported to the ~~B~~board within 30 days.
- (b) Any transfer, in a single transaction or in a series of transactions, of 10 percent or more of the beneficial interest in a business entity licensed by the board to a person or entity who did not hold a beneficial interest at the time the original ~~permit~~ license was issued, shall require written notification to the board within 30 days.
- (c) A license issued by the board shall not be transferred from one owner to another. The following shall constitute a transfer of ~~permit~~ license and require application for a change of ownership: any transfer of a of the beneficial interest in a business entity licensed by the board, in a single transaction or in a series of transactions, to any person or entity, which transfer results in the transferee's holding 50% or more of the beneficial interest in that license. A change of ownership application shall be filed with the board in advance of the proposed transaction taking place.
- (d) The board may issue, or renew, a license to an entity that is controlled by a revocable or irrevocable trust that meets the requirements of this subsection.
- (1) In addition to the requirements in (a), as part of its application and during its annual renewal, the entity shall also report the name of any other person in any position with management or control of the pharmacy.

- (2) An applicant shall disclose the full name of the trust, and shall provide to the board a complete copy of, and any amendments to the trust document. A trust document and any related amendments shall be considered confidential financial documents by the board.
- (3) An applicant shall disclose as part of its application and during its annual renewal the name, address and contact information for each grantor, settlor, trustee, trust protector, as applicable. In addition, the applicant shall disclose the name, address and contact information for each beneficiary named in the trust that is age 18 or greater.
- (4) The licensee, or any person with management or control of the pharmacy, shall notify the board in writing within 30 days of all the following:
- (A) A change in the trustee, protector or any other person with management or control of the pharmacy.
 - (B) Any change in the beneficiaries of the trust, where the beneficiary is age 18 or older.
 - (C) The revocation of the trust.
 - (D) The dissolution of the trust.
 - (E) Any amendment(s) to the trust since the original application.
- (e) An applicant or licensee may be denied, suspended or revoked based on the failure of any individual required to be disclosed to the board to qualify pursuant to the provisions of sections 4302, 4307 and 4308 of the Business and Professions Code.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4058, 4110, 4111, 4112, 4113, 4120, 4124, 4130, 4133, 4144, 4149, 4160, 4161, 4196, 4201, 4302, 4304, 4305, 4307, 4308, and 4330, Business and Professions Code.

Attachment 6

1. Proposed Regulations to Add Title 16 CCR section 1717.5 Related to Automatic Refill Programs

Timeline:

Approved by Board: May 3, 2017

Summary of Regulation:

This regulation establishes regulatory requirements for automated refill programs. Board staff is currently compiling the initial rulemaking file to submit to DCA for pre-notice review.

2. Proposed Regulations to Amend Title 16 CCR sections 1735.1, 1735.2, 1735.6, 1751.1, and 1751.4 Related to Compounding

Timeline:

Approved by Board: July 25, 2017

Summary of Regulation:

This regulation formally amends the board's regulations regarding the establishment of compounding beyond use dates as it relates to sterile and non-sterile compounded drug preparations. Additionally, this regulation allows for the use of a double filtration system. Board staff is currently compiling the initial rulemaking file to submit to DCA for pre-notice review.

Automatic Refill Programs

16 CCR § 1717.5

**Title 16. Board of Pharmacy
Proposed Text**

Add section 1717.5 in Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1717.5 Automatic Refill Programs

- a) A pharmacy may offer a program to automatically refill prescription medications provided the pharmacy complies with this section.
- 1) Written notice regarding the program shall be given to the patient or patient's agent. Such notice shall include instructions about how to withdraw a prescription medication from the program.
 - 2) The patient or patient's agent shall enroll by written, online or electronic consent to participate in the program.
 - 3) The pharmacy shall keep a copy of the written consent to enroll on file for one year from date of dispensing.
 - 4) The pharmacy shall have written policies and procedures in place that outline specifics of the program. The policies and procedures shall specify the medications that may be refilled through the program.
 - 5) The patient or patient's agent shall have the option to withdraw from the program at any time.
 - 6) The pharmacy shall complete a drug regimen review for each prescription refilled through the program.
 - 7) Each time a prescription is refilled through the program, the pharmacy shall provide a written notification to the patient or patient's agent confirming that the prescription medication is enrolled in the program.
 - 8) The pharmacy shall provide a full refund to the patient, patient's agent, or payer for any prescription medication in the program reported as unneeded or unnecessary, if the pharmacy had been notified of withdrawal or disenrollment from the program.
 - 9) A pharmacy shall make available any written notification required by this section in alternate languages as required by state or federal law.
- b) A health care facility licensed pursuant to Health and Safety Code section 1250 that automatically refills prescription medications for its patients need not comply with the provisions of this section.

Authority cited: Section 4001.1 and 4005, Business and Professions Code. Reference: Sections 4063 and 4076.6 Business and Professions Code and 1250, Health and Safety Code.

Compounding

**16 CCR §§ 1735.1,
1735.2, 1735.6, 1751.1,
and 1751.4**

Title 16. Board of Pharmacy

Changes made to the current regulation language are shown by strikethrough for deleted language and underline for added language. Additionally, [Brackets] indicate language that is not being amended.

Amend section 1735.1(c) and (f) in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1735.1. Compounding Definitions.

[.....]

- (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~~ exhausting. This external ~~venting~~ exhaust 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~~ exhaust. This external ~~venting~~ exhaust should be dedicated to one BSC or CACI. Air within the CACI shall not be recirculated nor turbulent.

[.....]

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

Amend section 1735.2(i) in Article 4.5 of Division 17 of Title 16 California Code of Regulations to read as follows:

1735.2. Compounding Limitations and Requirements; Self-Assessment.

[.....]

- (i) Every compounded drug preparation shall be given 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.
 - (1) For non-sterile compounded drug preparation(s), 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 compounded drug 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, 180 days or an extended date established by the pharmacist's research, analysis, and documentation,
 - (E) ~~14 days~~ for water-containing oral formulations, 14 days or an extended date established by the pharmacist's research, analysis, and documentation, and
 - (F) ~~30 days~~ for water-containing topical/dermal and mucosal liquid and semisolid formulations, 30 days or an extended date established by the pharmacist's research, analysis, and documentation.
 - (G) A pharmacist, using his or her professional judgment may establish an extended date as provided in (D), (E), and (F), if the pharmacist researches by consulting and applying drug-specific and general stability documentation and literature; analyzes such documentation and literature as well as the other factors set forth in this subdivision, and maintains documentation of the research, analysis and conclusion. The factors the pharmacist must analyze include:
 - (i) the nature of the drug and its degradation mechanism,
 - (ii) the dosage form and its components,
 - (iii) the potential for microbial proliferation in the preparation,
 - (iv) the container in which it is packaged,
 - (v) the expected storage conditions, and
 - (vi) the intended duration of therapy.
 - Documentation of the pharmacist's research and analysis supporting an extension must be maintained in a readily retrievable format as part of the master formula.
- (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) For sterile compounded drug preparations, Eextension 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
- (4) In addition to the requirements of paragraph three (3), the drugs or compounded drug preparations tested and studied shall be identical 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.

[.....]

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

Amend section 1735.6(e) 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.

[.....]

- (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 ~~PEG~~ BSC in the room shall also be externally vented except that a BSC used only for nonsterile compounding may also use a redundant-HEPA filter in series; 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.

Amend section 1751.1(a)(5) in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1751.1. Sterile Compounding Recordkeeping Requirements.

- (a) In addition to the records required by section 1735.3, any pharmacy engaged in any compounding of sterile drug preparations shall maintain the following records, which must be readily retrievable, within the pharmacy:
- (1) Documents evidencing training and competency evaluations of employees in sterile 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) ~~Biannual~~ ~~video~~ of smoke studies in all ISO Class 5 certified spaces.
 - (6) Documents indicating daily documentation of room, 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.

[.....]

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

Amend section 1751.4(k) 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 Compounding.

[.....]

- (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.