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LEGISLATION REPORT

The legislative session started in December 2016, and the deadline for bills to be passed out of the house of origin was June 2, 2017.

a. Board Sponsored Legislation

Attachment 1

The board is sponsoring five measures this year. Details on each measure are below, and Attachment 1 includes a copy of the language for each proposal.

1. Omnibus Provisions: SB 800 (Committee on Business, Professions and Economic Development) Professions and Vocations, Including Changes to Pharmacy Law

   Version: As amended June 5, 2017
   Status: Refer Assembly Business and Professions Committee
   Summary: SB 800 contains omnibus provisions for various programs within the Department of Consumer Affairs (DCA). Board specific provisions include:

   - 4013, to amend (d)(1) to add designated representative to the list of individuals who need to join the email subscriber list.
   - 4316, to 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 is not board sponsored but rather was included by the Senate Business, Professions, and Economic Development Committee.

2. SB 351 (Roth) Hospital Satellite Compounding Pharmacy: License: Requirements

   Version: As amended April 4, 2017
   Status: Referred to Assembly Business and Professions Committee
   Summary: SB 351 creates options for hospitals that wish to obtain additional licenses from the board for purposes of providing pharmaceutical care. Specifically, this

measure will allow the board to issue hospital satellite compounding pharmacy licenses that will not need to be located in the acute care hospital building. This measure will also allow the board to issue a hospital pharmacy license that can be located outside of the general acute care hospital.

3. SB 443 (Hernandez) Pharmacy: Emergency Medical Services Automated Drug Delivery System

   Version: As introduced Feb. 15, 2017
   Status: Referred to the Assembly Business and Professions Committee
   Summary: SB 443 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 would issue a license for the use of the EMADDS and specify the conditions under which it may be used.

   As part of the Senate Business, Professions and Economic Development Committee hearing, the committee requested that the board consider amendments to allow the proposed provisions to also apply to city fire departments and special districts. Board staff has also received requests to allow a nurse or paramedic to stock the device. If such amendments are included, registration of nurse or paramedic with the board should be required.

4. SB 510 (Stone) Pharmacies: Compounding

   Version: As introduced February 16, 2017
   Status: Assembly Business and Professions Committee hearing June 20, 2017
   Summary: SB 510 repeals an outdated statutory requirement specifying the environments in which a pharmacy must compound sterile products.

5. SB 752 (Stone) Designated Representative-Reverse Distributor

   Version: As amended March 28, 2017
   Status: Assembly Business and Professions Committee hearing June 20, 2017
   Summary: SB 752 establishes the creation of a designated representative license reverse distributor.

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

Attachment 2

The below measures were previously discussed either by the board or committee and impact either board operations or the board's jurisdiction where the board has an established position. Bills that failed to meet the house of origin deadline have been removed. Unless otherwise noted, details on each measure are below. **Attachment 2** includes a copy of the language for each proposal and a bill analysis.

1. AB 40 (Santiago) CURES Database: Health Information Technology System

   Version: As amended May 26, 2017
   Status: Senate Business, Professions and Economic Development Committee hearing June 26, 2017
   Board Position: Support
   Summary: AB 40 would require the Department of Justice to make the electronic history of controlled substances dispensed to an individual under a health care practitioner's care, based on data contained in the CURES database, available to the practitioner through either an online internet web portal or an authorized health information technology system, as defined.

   Recent Updates: Amendments to the measure do not indicate change in policy but rather provide clarification.

2. AB 182 (Waldron) Heroin and Opioid Public Education (HOPE) Act

   Version: As amended May 26, 2017
   Status: Senate Health Committee hearing June 28, 2017
   Board Position: Support
   Summary: As amended requires the Department of Health Care Services (department) to develop and implement an education campaign (HOPE) to combat the growing heroin and opioid medication epidemic in California in consultation with stakeholders. The measure includes some of the information that must be used as part of the campaign as well as targeted audiences. The department would also be required to submit a report on at least an annual basis summarizing its activities and assessment of the effectiveness of the program.

   Recent Update: Amendments to the measure clarify the intent of the measure and establish a sunset date of Jan. 2, 2023.

3. AB 208 (Eggman) Deferred Entry of Judgment: Pretrial Diversion

   Version: As amended March 8, 2017
   Status: Senate Public Safety Committee hearing July 11, 2017
   Committee Recommendation: Oppose Unless Amended
   Summary: Changes the deferred entry of judgment program to a pretrial program. Expands the conditions under which someone would be 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.

4. AB 315 (Wood) Pharmacy Benefits Management

   Version: As amended May 30, 2017
   Status: Senate Health Committee Meeting hearing June 28, 2017
   Board Position: Support (prior version)

Summary: Establishes regulatory framework for PBMs.

Recent Update: As amended the board is no longer involved in the regulation of PBMs.

5. AB 401 (Aguiar-Curry) Pharmacy: Remote Dispensing Site Pharmacy: Telepharmacy

Version: As amended May 10, 2017
Status: Senate Business, Professions and Economic Development Committee hearing July 10, 2017
Board Position: Support If Amended
Summary: Establishes regulatory framework for telepharmacy.

Recent Update: As amended, the remote dispensing site pharmacy must be owned and operated by a pharmacist(s) and must be supervised by a pharmacy also owned by a pharmacist. Further, a pharmacy may only supervise one telepharmacy location under the current version. Under the prior version of the bill a supervising pharmacy could supervise two locations.

6. AB 602 (Bonta) Pharmacy: Nonprescription Diabetes Devices

Version: As amended June 13, 2017
Status: Referred to Senate Appropriations Committee
Board Position: Support If Amended
Summary: Would require pharmacies that dispense nonprescription diabetes test devices pursuant to a prescription to retain records, require the board to post the names of authorized distributors of such test strips, and make it unprofessional conduct for a licensee to seek reimbursement for such devices under specified conditions.

Recent Update: As amended the measure now includes an urgency provision. Further, amendments were incorporated to provide the board with the authority to address the board's concerns including the ability to embargo devices under specified conditions and amending the board's unprofessional conduct statute to include purchasing of such products from an unauthorized source. Staff recommends that the committee consider a recommendation to change the board's position to support.

7. AB 845 (Wood) Cannabidiol

Version: As amended June 7, 2017
Status: Senate Public Safety Committee hearing June 20, 2017
Board Position: Oppose Unless Amended
Summary: Would, if consistent with federal law, authorize prescribing and dispensing a controlled substances prescription that contains cannabidiol.

Recent Update: The author accepted the board's amendments as reflected in the current version of the bill. Staff recommends that the committee consider a recommendation to change the board's position to neutral.

8. SB 17 (Hernandez) Prescription Drugs: Pricing: Notification

Version: As amended April 25, 2017
Status: Assembly Health Committee hearing June 27, 2017
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.

9. SB 528 (Stone) Pharmacy

Version: As amended June 12, 2017
Status: Assembly Business and Professions Committee hearing June 20,2 017
Board Position: Support if Amended
Summary: Would allow a pharmacy to provide pharmacy services to outpatients in an entity covered under Section 340B through the use of an automated drug dispensing system (ADDS) under specified conditions.

Recent Update: The recent amendments included in the bill address concerns identified by the board including licensure of the ADDS and establishing a fee. Staff recommends that the committee consider a recommendation to change the board's position to support.

10. SB 641 (Lara) Controlled Substance Utilization Review and Evaluation System: Privacy

Version: As amended April 20, 2017
Status: Referred to the Assembly Public Safety Committee
Board Position: Oppose Unless Amended
Summary: Would limit the conditions under which a law enforcement or regulatory board may access CURES and would establish a multidisciplinary advisory committee to assist, advise and make recommendations for the establishment of rules and regulations necessary to insure the proper administration and enforcement of the CURES database.

11. SB 716 (Hernandez) California State Board of Pharmacy

Version: As Amended April 26, 2017
Status: Referred to the Assembly
Board Position: Oppose Unless Amended
Summary: Would increase the number of members of the board to 15 by adding one pharmacy technician appointed by the governor and one additional public member appointed by the governor. The bill would require the pharmacy technician board member to have at least five years of experience and to continue to work in California as a pharmacy technician.

c. Legislation Impacting the Practice of Pharmacy or the Board's Jurisdiction Currently Being Watched.

Attachment 3

The below measures were discussed by the board that impact either board operations or the board's jurisdiction and are currently being watched. Bills that failed to meet the house of origin deadline have been removed. Unless otherwise noted, details on each measure are below. **Attachment 3** includes a copy of the language for each proposal.

1. AB 265 (Wood) Prescription Drugs: Prohibition on Price Discount

   Version: As amended May 30, 2017
   Status: Senate Health Committee hearing June 28, 2017
   Summary: Would prohibit a manufacturer from providing a discount, rebate or other price inducement if a lower cost brand name or non-brand name prescription drug is therapeutically equivalent. Specifies that this prohibition does not apply to drugs required under an FDA REMS.

   Recent Update: As amended, the measure specifies that the Department of Public Health is responsible for enforcement of the provisions. The prior version of the bill did not specify which department was responsible for enforcement.

2. AB 444 (Ting) Medical Waste: Home-Generated Sharps Waste

   Version: As amended April 18, 2017
   Status: Referred to Senate Environmental Quality Committee
   Summary: As amended this measure would establish definitions for "home-generated medical waste," "home-generated pharmaceutical waste" and "home-generated sharps waste"; and would require the California Environmental Protection Agency to develop a statewide program for disposal of such items.

3. AB 710 (Wood) Department of Consumer Affairs

   Version: As amended April 27, 2017
   Status: Senate Business, Professions and Economic Development Committee hearing June 26, 2017
   Summary: Would require a board to meet at least once every other calendar year in rural northern California.

4. AB 827 (Rubio) Department of Consumer Affairs: Task Force: Foreign-Trained Professionals Information

   Version: As amended April 3, 2017
   Status: Senate Business, Professions and Economic Development Committee hearing June 26, 2017
   Summary: Would require DCA to establish a task force to study and issue a report regarding licensing of foreign trained professionals into the state's workforce.

5. AB 1048 (Arambula) Health Facilities: Pain Management

Version: As amended June 15, 2017
Status: Senate Business, Professions and Economic Development committee hearing June 26, 2017
Summary: Would authorize a pharmacist to dispense a partial fill of a Schedule II drug if requested by the patient or the prescribing physician.

Recent Update: As amended, the measure will allow a pharmacist to charge a dispensing fee to cover the actual supply and labor costs associate with dispensing each partial fill associated with the original prescription. The prior version of the bill prohibited such action.

6. SB 70 (Bates) Health Care Professionals [former title]

   This measure was amended outside of the board's jurisdiction and subsequently failed to meet the legislative deadline. As such neither a copy of the measure nor a bill analysis is provided.

7. SB 212 (Jackson) Medical Waste

   Version: As introduced Feb. 1, 2017
   Status: Referred to Assembly Environmental Safety and Toxic Materials Committee
   Summary: Would amend the existing definition of "home generated pharmaceutical waste" to include prescription and over-the-counter human or veterinary home-generated pharmaceutical waste.

7. SB 715 (Newman) Department of Consumer Affairs: Removal of Board Members
   Version: As Amended April 25, 2017
   Status: Senate Business and Professions Committee hearing June 20, 2017
   Summary: Would specifically include that failure to attend meetings of the board is one example of continued neglect of duties required by law that the governor can use as a reason to remove a member from a board.

Part 2: Regulations for Discussion and Consideration

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

1. Proposed Regulations to Amend Title 16 CCR section 1703 Related to Delegation of Certain Functions

   Timeline:
   Approved by Board: Feb. 24, 2016
   Rulemaking Initiated: April 22, 2016
   Adopted by Board: July 27, 2016
   Submitted to DCA: Oct. 27, 2016
   Submitted to OAL: April 17, 2017
   Approved by OAL: May 30, 2017

Effective Date: July 1, 2017

Summary of Regulation:
This regulation updates the functions delegated to the executive officer, including the authority to adopt regulation changes that are deemed to be "without regulatory effect" in accordance with Title 1 CCR section 100 and the authority to approve prescription label waivers in accordance with Business and Professions Code section 4076.5(d).

A copy of the adopted regulation text is provided in **Attachment 4**.

2. Proposed Regulations to Add Title 16 CCR sections 1776 et seq. Related to Prescription Drug Take-Back

Timeline:
Approved by Board: Jan. 19, 2016
Rulemaking Initiated: Feb. 12, 2016
Adopted by Board: Oct. 26, 2016
Submitted to DCA: Dec. 12, 2016
Submitted to OAL: April 24, 2017
Approved by OAL: June 6, 2017
Effective Date: June 6, 2017

Summary of Regulation:
This regulation establishes the regulatory requirements for prescription drug take-back programs offered by pharmacies, hospitals/clinics with onsite pharmacies, distributors and reverse distributors licensed by the board.

A copy of the adopted text is provided in **Attachment 5**.

3. Proposed Regulations to Add Title 16 CCR section 1746.5 Related to Travel Medications

Timeline:
Approved by Board: June 3, 2015
Rulemaking Initiated: Sept. 25, 2015
Adopted by Board: April 27, 2016
Submitted to DCA: May 29, 2016
Submitted to OAL: Nov. 10, 2016
Disapproved by OAL: Dec. 30, 2016
Modified Text Approved by Board: Feb. 17, 2017
Re-Submitted to DCA: March 6, 2017
Re-Submitted to OAL: April 26, 2017
Approved by OAL: June 8, 2017
Effective Date: June 8, 2017

Summary of Regulation:
This regulation establishes the requirements and training for pharmacists to furnish travel medications not requiring a diagnosis.

A copy of the adopted regulation text is provided in **Attachment 6**.

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

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

   Timeline:
   Approved by Board: July 30, 2013
   Rulemaking Initiated: Aug. 12, 2016
   Adopted by Board: Dec. 14, 2016
   Submitted to DCA: Feb. 7, 2017

   Summary of Regulation:
   This regulation establishes standardized reporting of convictions and discipline at the time of renewal for pharmacists, pharmacy technicians and designated representatives. It also requires nonresident wholesalers and nonresident pharmacies to report disciplinary actions by other entities at the time of renewal.

   A copy of the adopted text is provided in **Attachment 7.**

2. 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: Sept. 4, 2015
   Adopted by Board: April 27, 2016
   Submitted to DCA: Aug. 4, 2016
   Submitted to OAL: Nov. 30, 2016
   Disapproved by OAL: Jan. 13, 2017
   Modified Text Approved by Board: Feb. 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).

   A copy of the final adopted text is provided in **Attachment 8.** Additionally, the revised disciplinary guidelines can be found on the board's website: http://www.pharmacy.ca.gov/laws_regs/1760_mdg.pdf

c. Board Approved to Initiate Rulemaking – Comment Period Closed; Awaiting Further Action by Board

1. Proposed Regulations to Amend Title 16 CCR section 1749 Related to the Board's Fee Schedule

   Timeline:
   Approved by Board: Oct. 26, 2016
   Submitted to DCA for Pre-Notice Review: Nov. 4, 2016
   Rulemaking Initiated: April 14, 2017
   45-Day Comment Period Ended: May 30, 2017

   Summary of Regulation:
   This regulation updates the board's fee schedule in regulation to be consistent with updates made to the board's fees in Business and Professions Code section 4400 as a result of SB 1039 (Hill, Chapter 799, Statutes of 2016).

   A copy of the approved regulation language is provided in **Attachment 9**.

2. Proposed Regulation to Add Title 16 CCR Section 1715.65 Related to Inventory Reconciliation of Controlled Substances

   Timeline:
   Approved by Board: July 28, 2016
   Submitted to DCA for Pre-Notice Review: N/A
   Rulemaking Initiated: Sept. 16, 2016
   Second 15-Day Comment Period Ended: May 31, 2017

   Summary of Regulation:
   This regulation establishes the regulatory requirements for inventory reconciliation reporting of controlled substances as part of the board's efforts to combat drug loss and diversion within pharmacies and prescription drug abuse within California.

   A copy of the approved regulation language is provided in **Attachment 10**.

d. 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

1. 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: Oct. 26, 2016
   Submitted to DCA for Pre-Notice Review: Feb. 9, 2017

Summary of Regulation:
This regulation establishes the regulatory framework for third-party logistics providers.

A copy of the approved regulation language is provided in **Attachment 11**.

2. 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: Oct. 26, 2016
Submitted to DCA for Pre-Notice Review: Jan. 23, 2017

Summary of Regulation:
This regulation establishes the training requirements and certification programs and updates the application for licensure for pharmacy technicians.

A copy of the approved regulation language is provided in **Attachment 12.**

3. Proposed Regulations to Amend Title 16 CCR Section 1735.2 Related to the Compounding Self-Assessment Form 17M-39

Timeline:
Approved by Board: Dec. 14, 2016
Submitted to DCA for Pre-Notice Review: Feb. 3, 2017

Summary of Regulation:
This regulation updates the Self-Assessment form 17M-39 (rev. 10/16) as incorporated by reference in Title 16 CCR section 1735.2.

A copy of the approved regulation language and the Self-Assessment form is provided in **Attachment 13.**

4. Proposed Regulations to Amend Title 16 CCR sections 1715 and 1784 to Update Self-Assessment Forms 17M-13, 17M-14 and 17M-26

Timeline:
Approved by Board: Oct. 27, 2016
Submitted to DCA for Pre-Notice Review: Jan. 20, 2017

Summary of Regulation:
This regulation updates the Self-Assessment forms 17M-13 (rev. 10/16), 17M-14 (rev. 10/16), and 17M-26 (rev. 10/16) as incorporated by reference in Title 16 CCR sections 1715 and 1784.

A copy of the approved regulation language and the Self-Assessment forms are

provided in **Attachment 14.**

5. Proposed Regulations to Amend Title 16 CCR Section 1709 Related to Pharmacy Ownership, Management and Control, Including through Trusts

   Timeline:
   Approved by Board: Oct. 27, 2016
   Submitted to DCA for Pre-Notice Review: Jan. 26, 2017

   Summary of Regulation:
   This regulation amends the board's regulations regarding ownership to include provisions relating to trust ownership of pharmacies.

   Board staff is working to review the scope of the changes to determine the next course of action for this regulation package.

   A copy of the approved regulation language is provided in **Attachment 15.**

6. Proposed Regulations to Amend Title 16 CCR Section 1707 Related to Offsite Storage

   Timeline:
   Approved by Board: Jan. 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. Board staff is currently compiling the initial rulemaking file to submit to DCA for pre-notice review.

   A copy of the approved regulation language is provided in **Attachment 16.**

7. 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.

   A copy of the approved regulation language is provided in **Attachment 17.**

e. 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

1. Proposed Regulations to Amend Title 16 CCR section 1735.1 and 1735.6 Related to Compounding

   Timeline:
   Approved by Board: Jan. 24, 2017

   Summary of Regulation:
   This regulation amends the board's regulations regarding compounding to allow the use of a double filtration system. Board staff is currently compiling the initial rulemaking file to submit to DCA for pre-notice review.

   A copy of the approved regulation language is provided in **Attachment 18.**

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:

4980.09. (a) *(1)* The title "marriage and family therapist intern" or "marriage and family therapist registered intern" is hereby renamed "associate marriage and family therapist" or "registered associate marriage and family therapist," respectively. Any reference in statute or regulation to a "marriage and family therapist intern" or "marriage and family therapist registered intern" shall be deemed a reference to an "associate marriage and family therapist" or "registered associate marriage and family therapist."

(2) Any reference in this chapter to the term "intern" means "associate." Any reference in statute or regulation to the abbreviation "MFTI" means an "AMFT."

(b) ~~Nothing in this~~ *This* section shall *not* be construed to expand or constrict the scope of practice of a person licensed or registered pursuant to this chapter.

~~(c) This section shall become operative January 1, 2018.~~

SEC. 5. Section 4980.44 of the Business and Professions Code is amended to read:

4980.44. An unlicensed *associate* marriage and family therapist ~~intern~~ employed under this chapter shall comply with the following requirements:

(a) Possess, at a minimum, a master's degree as specified in Section 4980.36 or 4980.37, as applicable.

(b) Register with the board prior to performing any duties, except as otherwise provided in subdivision (h) of Section 4980.43.

(c) Prior to performing any professional services, inform each client or patient that he or she is an unlicensed *registered associate* marriage and family ~~therapist registered intern,~~ *therapist,* provide his or her registration number and the name of his or her employer, and indicate whether he or she is under the supervision of a licensed marriage and family therapist, licensed clinical social worker, licensed professional clinical counselor, licensed psychologist, or a licensed physician and surgeon certified in psychiatry by the American Board of Psychiatry and Neurology.

(d) (1) Any advertisement by or on behalf of a *registered associate* marriage and family therapist ~~registered intern~~ shall include, at a minimum, all of the following information:

(A) That he or she is a *registered associate* marriage and family ~~therapist registered intern.~~ *therapist.*

(B) The ~~intern's~~ *associate's* registration number.

(C) The name of his or her employer.

(D) That he or she is supervised by a licensed person.

(2) The abbreviation ~~"MFTI"~~ *"AMFT"* shall not be used in an advertisement unless the title ~~"marriage~~ *"registered associate marriage* and family ~~therapist registered intern"~~ *therapist"* appears in the advertisement.

SEC. 6. Section 4980.72 of the Business and Professions Code is amended to read:

4980.72. (a) This section applies to ~~persons~~ *a person* who ~~are~~ *is* licensed outside of California and ~~apply~~ *applies* for licensure on or after January 1, 2016.

(b) The board may issue a license to a person who, at the time of submitting an application for a license pursuant to this chapter, holds a valid license in good standing issued by a board of marriage counselor examiners, board of marriage and family therapists, or corresponding authority, of any state or country, if all of the following conditions are satisfied:

(1) The applicant's education is substantially equivalent, as defined in Section 4980.79. The applicant's degree title need not be identical to that required by Section 4980.36 or 4980.37.

(2) The applicant complies with Section 4980.76, if applicable.

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 a pharmacy that may be located outside of the hospital in another physical plant that is regulated ~~under a hospital's consolidated license issued pursuant to Section 1250.8~~ *as 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.

(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).

(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.

SEC. 4. 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.

SB 443

SECTION 1. 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).*

(c) (1) Notwithstanding any other law, a pharmacy or wholesaler may furnish dangerous drugs or dangerous devices into an emergency medical services automated drug delivery system (EMSADDS) located within a county operated fire department. 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). The EMSADDS may be used only if all of the following conditions are met:

(A) The county fire department obtains a license from the board to operate the EMSADDS on the premise of a fire station. A separate license shall be required for each location. As part of its license application, the county shall provide the address of the fire station, the name of the county medical director responsible for overseeing the emergency medical services system, the name of the designated pharmacist, the policies and procedures detailing the provisions under which the EMSADDS will operate, and the name and license number of the pharmacy or wholesaler that will furnish the dangerous drugs and dangerous devices.

(B) 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.

(C) The county medical director and designated pharmacist 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 (i) inventory controls, (ii) training, (iii) storage and security of the dangerous drugs

and dangerous devices, and (iv) safeguards to limit access to the EMSADDS to only authorized staff.

(D) A pharmacist shall stock and inventory the dangerous drugs and dangerous devices in EMSADDS.

(E) The designated pharmacist shall review, on a monthly basis, the operation of the EMSADDS for compliance with inventory controls specified in the policies and procedures.

(F) The county medical director and designated pharmacist shall be jointly responsible for monthly review of the county fire department's training, storage, and security of dangerous drugs and dangerous devices and the restocking procedures, including, but not limited to, a review of the use of EMSADDS records to verify that only authorized staff, as provided for in this section, access and remove dangerous drugs and dangerous devices from the EMSADDS.

(G) The county fire department shall limit access to the EMSADDS to only employees of the county that are licensed by the state as paramedics or pharmacists or to the fire department's medical director.

(H) A record of each access to the EMSADDS shall be maintained for at least three years in a readily retrievable form. The records shall include the identity of the licensed paramedic or pharmacist or the fire department's medical director who accessed the system as well as the drug, dosage, form, and quantity removed.

(2) A violation of any of the provisions of this subdivision shall constitute unprofessional conduct and provides the board the authority to take action against the county fire department's license for the EMSADDS.

SEC. 2. *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. 3. *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.*

SB 510

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.

(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.

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. 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 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 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 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. 9. *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).

(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 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. 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

CALIFORNIA STATE BOARD OF PHARMACY

BILL ANALYSIS

Bill Number:	**AB 40**
Current Version:	**As Amended May 26, 2017**
Author:	**Santiago**
Topic:	**CURES database: Health Information Technology System**
Board Position:	**Support**

AFFECTED SECTIONS: Amend HSC sections 11165.1 and 11165.2

STATUS: Referred to Senate Business, Professions and Economic Development Committee

THIS BILL WOULD:
Require the Department of Justice to make the electronic history of controlled substances dispensed to an individual under a health care practitioner's care, based on data contained in the CURES database, available to the practitioner through either an online internet web portal or an authorized health information technology system, as defined.

The measure includes the specific criteria that the health information technology system must satisfy to access CURES; authorizes the DOJ to approve such systems as appropriate for the interface; requires an MOU between the entity that operates the system and the DOJ; and requires the entity to pay the DOJ for costs incurred to establish and maintain the integration with the CURES database.

STAFF COMMENTS:
The board has a long history of supporting CURES and its use. This measure appears to remove a possible impediment to the use of CURES by allowing access through an authorized health information technology system.

SUPPORT / OPPOSITION:

SUPPORT:
California American College of Emergency Physicians
California Access Coalition
County Health Executives Association of California
California Medical Board
Tenet Healthcare

OPPOSITION:
None on file.

AB 40

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 access information ~~online~~ regarding the controlled substance history of a patient ~~that is stored on the Internet and maintained within the Department of Justice,~~ *through an online Internet Web portal that is maintained by the department, or through an authorized health information technology system,* and, upon approval, the department shall release to that ~~practitioner~~ *practitioner, through an online Internet Web portal or an authorized health information technology system,* 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 access information online regarding the controlled substance history of a patient that is stored on the Internet and maintained within the ~~Department of Justice,~~ *department,* and, upon approval, the department shall release to that pharmacist the electronic history of controlled substances dispensed to an individual under his or her care based on data contained in the CURES PDMP.

(B) An application may be denied, or a subscriber may be suspended, for reasons which include, but are not limited to, the following:

(i) Materially falsifying an application for a subscriber.

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

(iii) Suspended or revoked federal DEA registration.

(iv) Any subscriber who is arrested for a violation of law governing controlled substances or any other law for which the possession or use of a controlled substance is an element of the crime.

(v) Any subscriber accessing information for any other reason than caring for his or her patients.

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

(D) An entity that operates a health information technology system may establish an integration with and submit queries to the CURES database on either a user-initiated basis or an automated basis if the entity can certify all of the following:

(i) The health information technology system is authorized to query the CURES database on behalf of an authorized health care practitioner on either a user-initiated basis, an automated basis, or both, for purposes of delivering patient data from the CURES database to assist an authorized health care practitioner with evaluating the need for medical or pharmaceutical treatment or providing medical or pharmaceutical treatment to a patient for whom a health care practitioner is providing or has provided care.

(ii) The entity will not use or disclose data received from the CURES database for any purpose other than delivering the data to an authorized health care practitioner or performing data processing activities that may be necessary to enable this delivery.

(iii) The health information technology system will authenticate the identity of any authorized health care practitioner initiating queries to the CURES database on either a user-initiated basis or an automated basis 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.

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

(E) The department may, in its discretion, determine whether to establish a direct system integration between one or more health information technology systems and the CURES database, or whether to develop a gateway system to which multiple health information technology systems can establish an integration for purposes of accessing the CURES database.

(F) The department may require an entity that operates a health information technology system that is requesting to establish an integration with the CURES database to enter into a memorandum of understanding or other agreement that sets forth terms and conditions with which the entity shall comply, including, but not limited to, all of the following:

(i) Paying a reasonable fee to cover the cost of establishing and maintaining integration with the CURES database.

(ii) Enforcement mechanisms for failure to comply with oversight or audit activities by the department, up to and including termination of access to the CURES database.

(iii) Any other term or condition that the department may determine in its reasonable discretion is necessary to carry out the intent of this section.

(2) A health care practitioner authorized to prescribe, order, administer, furnish, or dispense Schedule II, Schedule III, or Schedule IV controlled substances pursuant to Section 11150 or a pharmacist shall be deemed to have complied with paragraph (1) if the licensed health care practitioner or pharmacist has been approved to access the CURES database through the process developed pursuant to subdivision (a) of Section 209 of the Business and Professions Code.

(b) Any request for, or release of, a controlled substance history pursuant to this section shall be made in accordance with guidelines developed by the ~~Department of Justice.~~ *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. *An authorized health care practitioner may use a health information technology system, either on a user-initiated basis or an automated basis, to initiate the referral of the history of controlled substances dispensed to an individual based on data contained in CURES to other licensed health care practitioners, pharmacists, or both.*

(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 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 established or approved by a health care practitioner to trigger an automated query to the CURES database, which can be attributed to a specific health care practitioner by an audit trail in the health information technology system.

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

(3) "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.

(4) "User-initiated basis" means an authorized health care practitioner 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 by an audit trail in the health information technology system.

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 ensure that information in the CURES database is available to prescribing physicians 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.

CALIFORNIA STATE BOARD OF PHARMACY

BILL ANALYSIS

Bill Number:	**AB 182**
Current Version:	**As Amended May 26, 2017**
Author:	**Waldron**
Topic:	**Heroin and Opioid Public Education (HOPE) Act**
Board Position:	**Support**

AFFECTED SECTIONS: Add Chapter 1 of Part 2 of Division 10.5 of the Health and Safety Code

STATUS: Referred to Senate Health Committee

THIS BILL WOULD:
Require the Department of Health Care Services (department) to develop and implement an education campaign (HOPE) to combat the growing heroin and opioid medication epidemic in California in consultation with stakeholders. The measure includes some of the information that must be used as part of the campaign as well as targeted audiences. The department would also be required to submit a report on at least an annual basis summarizing its activities and an assessment of the effectiveness of the program. The provisions will be in effect only until January 1, 2023, unless a later enacted statute extends or deletes the date.

STAFF COMMENTS:
The board has routinely supported and focused efforts on combatting prescription drug abuse. This education campaign appears in line with these efforts, including the education campaign under development by the Communication and Public Education Committee.

SUPPORT / OPPOSITION:

SUPPORT:
American Academy of Pediatrics, California
Biocom
California Police Chiefs Association
California State Teacher Association
California Special Districts Association
Gatekeeper Innovation

OPPOSITION:
None on file

AB 182

SECTION 1. *This act shall be known, and may be cited, as the "HOPE Act."*

SEC. 2. *Article 5 (commencing with Section 11774) is added to Chapter 1 of Part 2 of Division 10.5 of the Health and Safety Code, to read:*

Article 5. Heroin and Opioid Public Education (HOPE)

11774. The Legislature finds and declares all of the following:

(a) There is an epidemic in this state stemming from the use of heroin and the abuse of opioid medications.

(b) Prescription drug overdoses now kill more people than car accidents.

(c) Every day, 2,500 children 12 to 17, inclusive, years of age abuse a prescription painkiller for the first time, and more people are becoming addicted to prescription drugs.

(d) Data from the federal Centers for Disease Control and Prevention suggests that the nonmedical use of prescription painkillers costs public and private health insurers seventy-two billion eight hundred million dollars ($72,800,000,000) annually.

(e) In order for the state to combat this epidemic, citizens in all walks of life shall be alerted to the problem, and shall be armed with information that will allow them to recognize, and undertake appropriate actions, when they or their loved ones are at risk of, or are succumbing to, a heroin or opioid medication addiction.

(f) The widespread dissemination of information necessary to combat the state's heroin and opioid medication epidemic could be successfully achieved through the institution and maintenance of a multicultural statewide public awareness campaign, which would be carefully coordinated through all available multimedia channels to reach a wide variety of audiences, including drug users, their family members and friends, medical practitioners and nurses, emergency personnel, and employers.

11774.1. (a) The State Department of Public Health, upon appropriation by the Legislature or receipt of adequate state or federal grant funding, and in consultation with stakeholders, as appropriate, shall develop, coordinate, implement, and oversee a comprehensive multicultural public awareness campaign, to be known as "Heroin and Opioid Public Education (HOPE)," which shall allow for the coordinated and widespread dissemination of information designed to combat the growing heroin and opioid medication epidemic in the state.

(b) Using the means described in subdivision (c), HOPE shall provide for the coordinated and widespread public dissemination of individual case stories and other generalized information that focuses on any of the following:

(1) Identifying the pathways that can lead to opioid medication abuse and heroin use, and the reasons why opioid medication abuse may evolve into heroin use.

(2) Showing the many faces of heroin and opioid medication addiction, and rebutting the commonly accepted myths and stereotypes about heroin users and opioid medication abusers.

(3) Educating the public on the negative impact of abuse and diversion of opioid medication, while recognizing the legitimate use of those same opioid drugs as medications.

(4) Describing the effects and warning signs of heroin use and opioid medication abuse, so as to better enable members of the public to determine when help is needed.

(5) Showing the link that exists between heroin and opioid medication addiction and suicidal behavior.

(6) Identifying the pathways that are available for individuals to seek help in association with their own, or another person's, heroin or opioid medication addiction, and indicating the various telephone hotline systems that exist in the state for persons who wish to report a case of drug abuse or engage in substance abuse treatment.

(7) Highlighting the availability of naloxone hydrochloride as a means to avert death from a heroin or opioid medication overdose, identifying pathways for members of the public to obtain a prescription for naloxone hydrochloride and training in the emergency administration of naloxone hydrochloride, and promoting the proper use of naloxone hydrochloride in crisis situations.

(8) Highlighting the benefits of substance abuse treatment and the potential for treatment to allow for the reclaiming of lives that have been upset by addiction, and underscoring the fact that relapses occur not because treatment is ineffective, but because of the nature of addiction, which is a recurring and relapsing disorder.

(9) Highlighting the benefits of medication-assisted therapy using medications approved by the federal Food and Drug Administration, such as methadone, buprenorphine, extended-release injectable naltrexone, or other similar drugs, and destigmatizing the use of that medication-assisted therapy.

(10) Identifying the methods that can be used by an individual to help finance the costs of substance abuse treatment.

(11) Identifying the steps that individuals can take to prevent and deter family members, friends, students, patients, coworkers, and others from first experimenting with inappropriately obtained opioid medications, and from misusing or mismanaging lawful opioid medications.

(12) Identifying the proper methods for safeguarding, and for safely disposing of, legitimate opioid medications.

(13) Addressing any other issues that the department may deem appropriate and necessary to proactively educate the public about the state's heroin and opioid medication epidemic and the actions that can be taken by members of the public to reduce the likelihood of heroin or opioid medication addiction, or to otherwise respond to, or mitigate the effects of, heroin or opioid medication addiction in cases in which it is present.

(c) (1) The HOPE program shall effectuate the dissemination of information described in subdivision (b) by using appropriate types of media to achieve the goal efficiently and effectively, including new technologies in media, print media, television and radio, and Internet and social media.

(2) In disseminating the information described in subdivision (b), the HOPE program shall employ a variety of complementary educational themes and messages that shall be tailored to appeal to different target audiences in the state. At a minimum, the HOPE program shall incorporate all of the following:

(A) At least one message that is directed at, and is tailored to influence and resonate with, individuals who are personally at risk of heroin use or opioid medication abuse or who have already started down a pathway to addiction.

(B) At least one message that is directed at, and is tailored to influence and resonate with, the family members and friends of addicted persons, teachers, school nurses, medical practitioners, and employers.

(C) At least one message that is directed at the dangers of teen drug pilfering from the household medicine cabinet and how this could be avoided through the use of safe storage products.

(3) Information under the HOPE program shall be disseminated using culturally and linguistically appropriate means, in a manner that demonstrates respect for individual dignity and cultural differences. Where feasible and appropriate, the information shall be made available in a variety of languages.

(4) The department may enter into public-private partnerships with pharmaceutical or health care insurance companies, nonprofit social services organizations, mental health services providers and clinics, law enforcement, health care agencies, and school districts, that provide services in the state in order to facilitate the dissemination of information under the HOPE program.

11774.2. *(a) The department shall submit to the Governor and the Legislature on at least an annual basis, a report that summarizes the actions that have been undertaken by the department to implement this article and includes an assessment of the effectiveness of the program, including, but not limited to, effects on the rate of new opioid and heroin addictions by populations, mitigation of the effects of opioid or heroin addiction, crime rates, hospitalization rates, death rates, and other calculable results as determined by the department. The report shall provide any recommendations for legislative or executive action that may be necessary to facilitate the ongoing success of the program.*

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

11774.3. The department may adopt regulations in accordance with 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) as necessary to implement this article.

11774.4. This article shall remain in effect only until January 1, 2023, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2023, deletes or extends that date.

CALIFORNIA STATE BOARD OF PHARMACY

BILL ANALYSIS

Bill Number:	**AB 208**
Current Version:	**As Amended March 8, 2017**
Author:	**Eggman**
Topic:	**Deferred Entry of Judgment: Pretrial Diversion**
Board Position:	**Oppose Unless Amended**

AFFECTED SECTIONS: Add Chapter 1 to Part 2 of Division 10.5 of the Health and Safety Code

STATUS: Referred to Senate Public Safety Committee

THIS BILL WOULD:
Change the existing "deferred entry of judgment program" into a pretrial diversion program. Under the pretrial diversion program created by this bill, a defendant may qualify if he or she has no prior conviction for any offense involving controlled substances (other than the offenses that qualify for the diversion program); the charged offense did not involve violence; there is no evidence of a violation relating to narcotics or restricted dangerous drugs (other than a violation that qualifies for the program); and the defendant has not suffered a conviction within the prior five years to the alleged commission or had a prior conviction for a serious or violent felony.

EXISTING LAW:
Allows individuals convicted of specified crimes to qualify for deferred entry of judgment if they had no conviction for any offense involving controlled substances; the charged offense did not involve violence; there was no evidence of a violation relating to narcotics or restricted dangerous drugs (other than a violation that qualified the individual for the program); the defendant's record did not indicate that probation or parole has ever been revoked without being completed; and the defendant's record did not indicate that he or she has been granted diversion or deferred entry of judgment, or was convicted of a felony.

Further, under the existing "deferred entry of judgment program," defendants plead guilty and have entry of judgment deferred in return for entering a drug treatment program for 18 months to 3 years. If the defendant doesn't perform satisfactorily in the program, doesn't benefit from the program, gets convicted of specified crimes, or engages in criminal activity rendering him or her unsuitable for deferred entry of judgment, the defendant's guilty plea gets entered and the court proceeds to schedule a sentencing hearing. In the alternative, if the defendant completes the program, the criminal charges are dismissed. Under existing law the presiding judge of the Superior Court, with the district attorney and public defender, <u>may</u> establish a pretrial diversion drug program.

Pursuant to the provisions of Business and Professions Code (BPC) section 144, an applicant for licensure is required to submit fingerprints to the board for purposes of conducting criminal history record checks. BPC section 144.5 provides the explicit authority for the board to receive certified records of all arrests and convictions or other related documentation needed to complete an applicant or licensee investigation.

BPC 480(a)(1) provides the authority for the board to deny a license under specified conditions, including being convicted of a crime. The definition of conviction includes a plea or verdict of guilty.

BPC 4301(l) provides that a conviction of a crime substantially related to the qualifications, functions and duties of a licensee is unprofessional conduct. This section also includes that 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 the provision.

THIS BILL WOULD:

1. This bill would change the existing statewide "deferred entry of judgment program" into a pretrial diversion program. Under this pretrial diversion program, a defendant qualifies if he or she has no prior conviction for any offense involving controlled substances (other than offenses that qualify for pretrial diversion diversion); the charged offense did not involve violence; there is no evidence of a violation relating to narcotics or restricted dangerous drugs (other than a violation that qualifies them for the diversion); and the defendant has no prior felony conviction for a serious or violent felony in the five years prior to the alleged commission of the charged offense.

2. In this pretrial diversion program, a qualifying defendant doesn't enter a guilty plea; instead, the court suspends the proceedings and places the defendant in a drug treatment program for six months to one year. If the defendant does not perform satisfactorily in the program or is convicted of specified crimes, the court terminates the program and the criminal proceedings are reinstated. In the alternative, if the defendant completes the program, the criminal charges are dismissed.

The bill allows a defendant to request and mandate that the court shall grant, for good cause shown, an extension of time to complete a pretrial diversion program.

STAFF COMMENTS:
This bill amends the Penal Code in a way that will negatively impact the board's ability to prove in disciplinary proceedings that a licensee or applicant is engaged in illicit drug activities. The bill is likely to increase the board's costs of prosecution or lead to the dismissal of certain disciplinary charges, to the detriment of public safety. This is because the changes proposed will allow defendants to not plead guilty. This means the board won't be able to use a guilty plea as an admission of guilt, and when a defendant participates in a pretrial diversion program, the board can't consider that to be an admission of guilt.

The policy being put forth in this measure runs contrary to the board's consumer protection mandate as well as efforts by the Legislature to strengthen the ability of programs within the DCA to more robustly protect consumers. As part of the DCA's Consumer Protection Enforcement Initiative (CPEI), it was noted that any delay in an investigation of a licensee may

result in a potentially dangerous licensee continuing to practice. Creating barriers to the board's investigative efforts such are the one proposed in the measure will undo some of the gains the board has made in this area.

In 2015 a similar measure was proposed (AB 1351, Eggman). The board initially established an OUA position and offered amendments. Although this measure provides some discretion to the court to enroll someone in such a program, many of the same challenges still exist.

An analysis of administrative cases closed in the past three years that involved an arrest or conviction revealed that 119 of these cases would have been eligible for the pretrial program being proposed under this bill. In each of those cases the board would need to prove the arrest and underlying conduct. It is worth noting the breakdown:

- 106 pharmacy technicians: 87 revocations, 8 surrenders, 1 suspension and probation, 10 probations
- 1 designated representative: probation
- 1 intern: suspension and probation
- 5 pharmacists: 2 revocations, 1 surrender, 1 suspension and probation, 1 probation
- 6 application denials. These are very troubling, because it would not need to be reported to the board.

In addition, the board used the authority granted under Penal Code 23 to seek, as part of the criminal process, immediate restrictions on a license until the administrative case was completed. Such restrictions, which generally result in suspension, provide for immediate public protection while the administrative process is pending. This measure will limit the board's ability to use this process.

SUPPORT / OPPOSITION:

SUPPORT:
America Civil Liberties Union (Co-Sponsor)
Coalition for Humane Immigrant Rights (Co-Sponsor)
Drug Policy Alliance (Co-Sponsor)
Immigrant Legal Resource Center (Co-Sponsor)
Mexican American Legal Defense and Education Fund (Co-Sponsor)
California Attorneys for Criminal Justice
California Public Defenders Association
Ella Baker Center for Human Rights
Human Impact Partners
National Association of Social Workers, California Chapter

OPPOSITION:
None on file

AB 208

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)~~ *(4)* ~~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.~~ *Within five years prior to the alleged commission of the charged offense, the defendant has no prior conviction for a serious felony, as defined in subdivision (c) of Section 1192.7, or a violent felony, as defined in subdivision (c) of Section 667.5.*

~~(6) 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. 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 and to a speedy preliminary hearing, 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~~ *six* months and no later than ~~three years~~ *one year* 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~~ *and* a speedy preliminary hearing, *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 and to a speedy preliminary hearing, 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.*

(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~~ *six* months nor longer than ~~three years.~~ *one year. 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). 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.

(b) 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. 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 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:*

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

CALIFORNIA STATE BOARD OF PHARMACY

BILL ANALYSIS

Bill Number:	**AB 315**
Current Version:	**As Amended May 30, 2017**
Author:	**Wood**
Topic:	**Pharmacy Benefits Management**
Board Position:	**Support (Prior Version)**

Affected Sections: Add Division 121 to the Health and Safety Code

Status: Referred to the Senate Health Committee

THIS BILL WOULD:
Establish the regulatory framework for pharmacy benefits manager including licensure by the Department of Managed Health Care.

STAFF COMMENTS:
The board discussed this measure during its March 2017 board meeting and established a support position. As part of its discussion, the board highlighted its consumer protection mandate and how such a mandate and focus make regulation by the board appropriate. The board's requirement to perform its policy making in public provides transparency in its decision making. Comments from the board noted that under current contractual requirements, pharmacists are sometimes prohibited from acting in the best interest of their consumers.

As amended, the board will no longer have a role in the regulation of pharmacy benefits managers.

FISCAL IMPACT:

In its current form, there will no longer be a fiscal impact.

AB 315

SECTION 1. *Division 121 (commencing with Section 152000) is added to the Health and Safety Code, to read:*

DIVISION 121. Pharmacy Benefit Management

PART 1. General Provisions

152000. *For the purposes of this division, the following definitions shall apply:*

(a) "Dangerous drug" or "dangerous device" means any drug or device unsafe for self-use in humans or animals, and includes the following:

(1) Any drug that bears the legend: "Caution: federal law prohibits dispensing without prescription," "Rx only," or words of similar import.

(2) Any device that bears the statement: "Caution: federal law restricts this device to sale by or on the order of a ____," "Rx only," or words of similar import, the blank to be filled in with the designation of the practitioner licensed to use or order use of the device.

(3) Any other drug or device that by federal or state law can be lawfully dispensed only on prescription or furnished pursuant to Section 4006 of the Business and Professions Code.

(b) "Department" means the Department of Managed Health Care.

(c) "Director" means the Director of the Department of Managed Health Care.

(d) "Labeler" means a person or entity that receives prescription drugs from a manufacturer or wholesaler and repackages those drugs for later retail sale and who has a labeler code from the federal Food and Drug Administration under Section 207.20 of Title 21 of the Code of Federal Regulations.

(e) "Person beneficially interested" with respect to an applicant for a pharmacy benefit manager license means and includes:

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

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

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

(f) "Pharmacy benefit manager" means a person, business, or other entity that, pursuant to a contract or under an employment relationship with a carrier, health benefit plan sponsor, or other third-party payer, either directly or through an intermediary, manages the prescription drug coverage provided by the carrier, plan sponsor, or other third-party payer, including, but not limited to, the processing and payment of claims for prescription drugs, the performance of drug utilization review, the processing of drug prior authorization requests, the adjudication of appeals or grievances related to prescription drug coverage, contracting with network pharmacies, and controlling the cost of covered prescription drugs.

(g) "Proprietary information" means information on pricing, costs, revenue, taxes, market share, negotiating strategies, customers, and personnel that is held by a pharmacy benefit manager and used for its business purposes.

(h) "Purchaser" means health benefit plan sponsor or other third-party payer with whom a pharmacy benefit manager contracts to provide the administration and management of prescription drug benefits.

152002. *This division shall not apply to the following:*

(a) A health care service plan or health insurer, if the health care service plan or health insurer offers or provides pharmacy benefit management services and if those services are offered or provided only to enrollees, subscribers, policyholders, or insureds who are also covered by health benefits offered or provided by that health care service plan or health insurer.

(b) An affiliate, subsidiary, related entity, or contracted medical groups of a health care service plan or health insurer that would otherwise qualify as a pharmacy benefit manager but offers or provides services only to enrollees, subscribers, policyholders, or insureds who are also covered by health benefits offered or provided by the health care service plan or health insurer.

152004. *The department has the authority to enforce the provisions of this division, including the authority to adopt, amend, or repeal any rules and regulations, not inconsistent with the laws of this state, as may be necessary for the protection of the public and to implement this division.*

PART 2. Pharmacy Benefit Manager Licensing

152100. *A pharmacy benefit manager shall obtain a license from the department before conducting business, including, but not limited to, acting as a pharmacy benefit manager for any dangerous drug or dangerous device, in the state.*

152102. *(a) A pharmacy benefit manager shall obtain a license by completing and submitting an application for a license and paying a license fee to the department.*

(b) A pharmacy benefit manager shall renew its license on an annual basis by completing and submitting an application for a renewed license and paying a renewed license fee to the department.

152104. *(a) Upon receipt of a completed application and license fee for a new pharmacy benefit manager license from a pharmacy benefit manager, the department shall issue a new pharmacy benefit manager license to the applicant.*

(b) Upon receipt of a completed application and license fee for a renewed license from a pharmacy benefit manager, the department shall issue a renewed license to the applicant.

(c) A new or renewed pharmacy benefit manager license shall be effective for a period of one year from the date of issuance of the license.

(d) A pharmacy benefit manager license issued pursuant to this section is not transferable.

152106. *(a) The department shall develop application forms for new and renewed pharmacy benefit manager licenses.*

(b) The application form for a new pharmacy benefit manager license shall require the pharmacy benefit manager to submit the following information to the department:

(1) The name of the pharmacy benefit manager.

(2) The address and contact telephone number for the pharmacy benefit manager.

(3) The name and address of the pharmacy benefit manager's agent for service of process in the state.

(4) The name and address of each person beneficially interested in the pharmacy benefit manager.

(5) The name and address of each person with management or control over the license.

(6) The location, name, and title of all pharmacists of the pharmacy benefit manager who are dispensing controlled substances, dangerous drugs, or dangerous devices to residents of the state.

(c) If the applicant is a partnership or other unincorporated association, a limited liability company, or a corporation, and the number of partners, members, or stockholders, as the case may be, exceeds five, the application shall so state, and shall further state the name, address, usual occupation, and professional qualifications of each of the five partners, members, or stockholders who own the five largest interests in the applicant entity. Upon request by the department, the

applicant shall furnish the department with the name, address, usual occupation, and professional qualifications of partners, members, or stockholders not named in the application, or shall refer the department to an appropriate source of that information.

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

152108. *The department may set a fee for a new or renewed license required by this part. The license fee shall not exceed the actual costs incurred by the department in carrying out its duties under this division.*

152110. *Within 30 days of a change in any of the information disclosed to the department on an application for a new or renewed license, the pharmacy benefit manager shall notify the department of that change in writing.*

152112. *The director may assess a civil penalty of ____ dollars ($____) against a pharmacy benefit manager who conducts business, including, but not limited to, acting as a pharmacy benefit manager for a dangerous drug or dangerous device, in the state, without a current license.*

152114. *(a) The director may suspend, revoke, or place on probational status a pharmacy benefit manager's license under the following circumstances:*

(1) The pharmacy benefit manager has engaged in fraudulent activity that constitutes a violation of state or federal law.

(2) The department has received consumer complaints that justify an action under this subdivision in order to protect the safety and interests of consumers.

(3) The pharmacy benefit manager fails to pay a civil penalty assessed pursuant to Section 152112.

(4) The pharmacy benefit manager fails to pay an application fee for a new or renewed license.

(5) The pharmacy benefit manager fails to comply with a requirement set forth in Part 3 (commencing with Section 152200).

(b) The department shall develop procedures that provide a pharmacy benefit manager subject to an action described in subdivision (a) with reasonable notice of and an opportunity to respond to the department prior to taking that action.

PART 3. Duties of Pharmacy Benefit Managers

152200. *This part shall apply to a contract or a contractual relationship between a pharmacy benefit manager and a purchaser or a pharmacy benefit manager and a pharmacy network provider that is entered into, issued, amended, renewed, or delivered on or after January 1, 2018.*

152202. *A pharmacy benefit manager shall exercise good faith and fair dealing in the performance of its contractual duties to a purchaser.*

152204. *A pharmacy benefit manager shall notify a purchaser in writing of any activity, policy, or practice of the pharmacy benefit manager that directly or indirectly presents a conflict of interest that interferes with the discharge of the pharmacy benefit manager's duty to the purchaser to exercise good faith and fair dealing in the performance of its contractual duties pursuant to Section 152202.*

152206. *(a) Beginning in the second fiscal quarter after the effective date of a contract between a pharmacy benefit manager and a purchaser, the pharmacy benefit manager shall, on a quarterly basis, disclose, upon the request of the purchaser, the following information with respect to prescription product benefits specific to the purchaser:*

(1) The aggregate acquisition cost from a pharmaceutical manufacturer or labeler for each therapeutic class of drugs.

(2) The aggregate amount of rebates received by the pharmacy benefit manager for each therapeutic class of drugs. The aggregate amount of rebates shall include any utilization discounts the pharmacy benefit manager receives from a pharmaceutical manufacturer or labeler.

(3) Any administrative fees received from a pharmaceutical manufacturer or labeler.

(4) The aggregate of rates negotiated by the pharmacy benefit manager with pharmacies with respect to each therapeutic class of drugs.

(5) Prescription drug utilization information for the purchaser's enrollees or insureds that is not specific to any individual enrollee or insured.

(6) Whether the pharmacy benefit manager has a contract, agreement, or other arrangement with a pharmaceutical manufacturer to exclusively dispense or provide a drug to a purchaser's employees or enrollees, and the application of all consideration or economic benefits collected or received pursuant to that arrangement.

(b) The information disclosed pursuant to subdivision (a) shall include all retail, mail order, specialty, and compounded prescription products.

(c) For the purposes of subdivision (a), a therapeutic class shall include at least three drugs. If there are fewer than three drugs in a therapeutic class, the information required by subdivision (a) shall be reported by therapeutic category.

(d) A pharmacy benefit manager shall not impose a penalty or offer an inducement to a purchaser for the purpose of deterring the purchaser from requesting the information set forth in subdivision (a).

152208. *Except for utilization information, a pharmacy benefit manager does not need to make the disclosures required by Section 152206 unless and until the purchaser agrees, in writing, to maintain as confidential any proprietary information as defined in this division.*

152210. *A pharmacy benefit manager shall disclose to a pharmacy network provider contracting with the pharmacy benefit manager of any material change to a contract provision that affects the terms of reimbursement, the process for verifying benefits and eligibility, dispute resolution, procedures for verifying drugs included on the formulary, and contract termination at least 30 days before the date of the change to the provision.*

152212. *A pharmacy benefit manager shall not include in a contract with a pharmacy network provider any of the following provisions:*

(a) A provision that prohibits the provider from informing a patient of a less costly alternative to a prescribed medication.

(b) A provision that prohibits the provider from dispensing a particular amount of a prescribed medication, if the pharmacy benefit manager allows that amount to be dispensed through a pharmacy owned or controlled by the pharmacy benefit manager.

(c) This section shall not be construed to prohibit differential cost sharing designed to encourage or discourage the use of mail-order pharmacy services.

152214. *A pharmacy network provider may report to the department, through the toll-free provider line (877-525-1295) or by submitting a complaint to the department's provider complaint unit, instances in which the pharmacy network provider believes a pharmacy benefit manager is engaging in a violation of Section 152210 or 152212.*

CALIFORNIA STATE BOARD OF PHARMACY

BILL ANALYSIS

Bill Number:	**AB 401**
Current Version:	**As Amended May 10, 2017**
Author:	**Aguiar-Curry**
Topic:	**Remote Dispensing Site Pharmacy: Telepharmacy**
Board Position:	**Support if Amended**

AFFECTED SECTIONS: Amend BPC section 4059.5 and add sections 4044.3, 4044.6 and 4044.7 and add Article 8 to Chapter 9 of Division 2 of the Business and Professions Code

STATUS: Referred to Assembly Appropriations Committee

EXISTING LAW:
Pharmacy law provides for the licensure and regulation of the drug distribution channel, including pharmacies that dispense medications as well as the pharmacists, pharmacist interns and pharmacy technicians.

THIS BILL WOULD:
Allow for dispensing of medications in a remote dispensing site pharmacy via a telepharmacy system. As proposed, a pharmacist would not be present in the remote dispensing site but would supervise the pharmacy dispensing and management using a telepharmacy system. Specifically, this bill:

1. Makes legislative findings and declarations about the benefits of greater access to health care professionals and the role pharmacists play, given their accessibility, improvements in health care delivery and technology that can be used to connect patients to pharmacists in rural areas, and an identified reduction in pharmacies in rural communities.
2. States it is the intent of the Legislature to enact legislation that will promote policies to allow Californians to have access to a pharmacist, thereby increasing medication adherence.
3. Defines “remote dispensing site pharmacy” (RDSP) as a pharmacy licensed in California that is operated by a supervising pharmacy, staffed by licensed pharmacy technicians and remotely monitored by a licensed pharmacist through the use of telepharmacy technology.
4. Defines “supervising pharmacy” as a pharmacy located in California that oversees the activities of the RDSP. As amended the definition now includes that the pharmacy must be owned by a pharmacist or more than one pharmacist.

5. Defines “telepharmacy” as a system used by a supervising pharmacy for purposes of monitoring the dispensing of medications and providing drug regimen review and patient consultation via an electronic method.
6. Would allow for the ordering of dangerous drugs and controlled substances at the RDSP and allow pharmacy technicians to sign for and receive shipments. Would require controlled substances deliveries to be stored separately until the order is reviewed and countersigned by a pharmacy.
7. Would establish the regulatory framework for an RDSP, including licensure of the site if the following conditions are met:
    a. It can only be located in a medically underserved area, as defined, unless otherwise approved by the board.
    b. Can only be staffed with licensed pharmacists and pharmacy technicians.
    c. The supervising pharmacy must be within 150 road miles of the RDSP unless otherwise approved by the board, and the supervising pharmacy must be under common ownership. (The prior version allowed for a contractual relationship between the remote site and the supervising pharmacy. The provision was amended out.)
    d. A pharmacist supervising operations through audio and visual technology.
    e. The pharmacist-in-charge (PIC) of the RDSP and the supervising pharmacist on duty at the supervising pharmacy shall be responsible for ensuring both locations are sufficiently staffed to allow for appropriate supervision.
    f. Cannot be located in a state facility. (This is a new requirement.)
8. Would establish additional requirements for pharmacy technicians working in an RDSP and would not expand the functions a pharmacy technician could perform in the RDSP.
9. Would allow a supervising pharmacy to supervise two RDSPs including up to two pharmacy technicians as each site. (This would be in addition to the technicians the pharmacist may also be supervising at the pharmacy.)
10. Would require patient consultation for all prescriptions dispensed from an RDSP.
11. Would require the telepharmacy system to:
    a. Collect the identity and record of the pharmacy technician preparing each prescription and the supervising pharmacist who reviewed and authorized the dispensing.
    b. Require a pharmacist’s review and comparison of the electronic image of a new prescription with the data entry performed.
    c. Require the technician to use barcode technology to verify the accuracy of the drug to be dispensed as well as remote visual confirmation by a pharmacist of the drug stock bottle and drug to be dispensed.
    d. Ensure that a prescription is not sold or delivered prior to final verification and releasing the prescription for sale and delivery.
    e. Require HIPPA compliance.
    f. Maintain records for three years.
12. Would require a pharmacist from the supervising pharmacy to complete an in-person monthly self-inspection and require a perpetual inventory for all controlled substances.

13. Would require controlled substances to be stored in a secure cabinet or safe that is locked and require a pharmacist from the supervising pharmacy to perform inventory reconciliation functions to detect and prevent drug losses.
14. Would require the board to establish written policies and procedures for performing inventory reconciliation reports.
15. Would establish inventory control and reconciliation consistent with the board's pending regulations.
16. Would require use of an alarm or other monitoring system while the RDSP is closed and prohibit access at all times when the supervising pharmacy is closed unless a pharmacist is present at the RDSP.

STAFF COMMENTS:
Board staff has not had an opportunity to work with the sponsor to secure the necessary amendments to address the board's concerns. An update will be provided during the meeting if available.

SUPPORT / OPPOSITION:

SUPPORT:
California Pharmacists Association
Cardinal Health

OPPOSITION:
None on file

FISCAL IMPACT:

According to the author's office, it is estimated that there are approximately 115 underserved communities. There is no current fee established in this measure. Board staff estimates the need for ½ analyst to establish and manage the new licensing program. Further, the DCA has estimated $196,000 costs. Board staff suggests identification of a fee to offset these additional expenses.

AB 401

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. *"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 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.*

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

4044.6. *"Supervising pharmacy" means a licensed pharmacy located in this state that is owned and operated by a pharmacist or more than one pharmacist, as defined in Section 4036, that exclusively oversees the operations of a remote dispensing site pharmacy.*

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

4044.7. *"Telepharmacy" means a system that is used by a supervising pharmacy for the purpose of monitoring the dispensing of prescription drugs 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. The receipt and storage of a controlled substance by a pharmacy technician under this section shall be maintained on video that is accessible to the supervising pharmacy and shall be maintained for 90 days.

SEC. 6. *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 may 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.

(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.

4131. (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) (1) Except as otherwise provided in paragraph (2), a supervising pharmacy and remote dispensing site pharmacy shall be under common ownership.

(2) If a supervising pharmacy and a remote dispensing site pharmacy are not under common ownership, the supervising pharmacy and remote dispensing site pharmacy shall enter into a written contract or agreement that specifies the services to be provided and the responsibilities and accountabilities of each party in fulfilling the terms of the contract or agreement, consistent with all federal and state laws.

(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 law, a pharmacist may serve as the pharmacist-in-charge for no more than two remote dispensing site pharmacies in addition to serving as pharmacist-in-charge of a supervising pharmacy.

(f) Notwithstanding any 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 have both of the following:

(1) At least one year of experience in the past three years working in retail pharmacy practice.

(2) Completed a documented training program on proper use of the telepharmacy system at the remote dispensing site pharmacy.

(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.

(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.

(c) Patient counseling shall be provided using audio-visual communication for all prescriptions 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 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.

(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.

(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.

(c) The remote dispensing site pharmacy shall retain a recording of facility surveillance, excluding patient communications, for a minimum of 90 days.

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.

CALIFORNIA STATE BOARD OF PHARMACY

BILL ANALYSIS

Bill Number:	**AB 602**
Current Version:	**As Amended June 13, 2017**
Author:	**Bonta**
Topic:	**Nonprescription Diabetes Test Devices**
Board Position:	**Support if Amended**

AFFECTED SECTIONS: Amends BPC sections 4057, 4081 and 4301, and adds BPC sections 4025.2, 4084.1 and 4160.5

Status: Referred to Assembly Appropriations Committee

EXISTING LAW:
Provides for the licensing and regulation of the practice of pharmacy. As part of this, the board has the authority to take action against a licensee for unprofessional conduct. Pharmacy law also establishes recordkeeping requirements.

THIS BILL WOULD:

1. Define "nonprescription diabetes test device" as a glucose meter or test strip used for treatment of diabetic or prediabetic individuals that may be sold without a prescription.
2. Require a pharmacy that dispenses nonprescription diabetes test devices pursuant to a prescription to retain records of acquisition and sale for at least three years.
3. Require the board to post the names of authorized distributors of nonprescription diabetes test devices as provided by manufacturers within 30 days.
4. Specify that it is unprofessional conduct to seek reimbursement for a nonprescription diabetes test device if the licensee knew or reasonably should have known that the device was not purchased either from a manufacturer or authorized distributor.
5. Authorize the board to embargo any nonprescription diabetes test device where the inspector finds or has reasonable cause to believe the devices were not purchased from an authorized source.
6. Declare that acquiring from an unauthorized source is unprofessional conduct.
7. Include an urgency provision.

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 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. 5.**~~***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.

(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.

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.

CALIFORNIA STATE BOARD OF PHARMACY

BILL ANALYSIS

Bill Number:	**AB 845**
Current Version:	**As Amended June 7, 2017**
Author:	**Wood**
Topic:	**Cannabidiol: Prescriptions in Accordance with Federal Law**
Board Position:	**Oppose Unless Amended**

AFFECTED SECTIONS: Add HSC section 11150.2

STATUS: Assembly Appropriations Committee hearing April 26, 2017

THIS BILL WOULD:
Specify that if the federal government removes cannabidiol from Schedule I of the federal Controlled Substances Act, or if a product composed of cannabidiol is placed on a schedule other than Schedule I, a prescriber or pharmacist that prescribes or dispenses the product shall be deemed to be in compliance with state law.

The measure includes an urgency provision and as such would take effect immediately.

STAFF COMMENT:
According to the sponsor, the intent of the legislation is to allow for the immediate prescribing and dispensing of such products upon action by the federal government. However, in its current form the drafting appears to go beyond the stated intent.

Amendments were secured to address the board's concern relating to corresponding responsibility.

FISCAL IMPACT:
In its current form, the impact would be minor and absorbable.

AB 845

SECTION 1. The Legislature finds and declares that both children and adults with epilepsy are in desperate need of new treatment options and that cannabidiol is showing potential as one of these treatments. If federal laws prohibiting the prescription of medications composed of cannabidiol are repealed or if an exception from the general prohibition is enacted permitting the prescription of drugs composed of cannabidiol, patients should have rapid access to this treatment option. The availability of this new prescription medication is intended to augment, not to restrict or otherwise amend, other cannabinoid treatment modalities currently available under state law.

SEC. 2. *Section 11150.2 is added to the Health and Safety Code, to read:*

11150.2. (a) Notwithstanding any other law, if cannabidiol is removed from Schedule I of the federal Controlled Substances Act and placed on a schedule of the act other than Schedule I, or if a product composed of cannabidiol is approved by the federal Food and Drug Administration and either placed on a schedule of the act other than Schedule I, or exempted from one or more provisions of the act, so as to permit a physician, pharmacist, or other authorized healing arts licensee acting within his or her scope of practice, to prescribe, furnish, or dispense that product, the physician, pharmacist, or other authorized healing arts licensee who prescribes, furnishes, or dispenses that product in accordance with federal law shall be deemed to be in compliance with state law governing those acts.

(b) For purposes of this chapter, upon the effective date of one of the changes in federal law described in subdivision (a), notwithstanding any other state law, a product composed of cannabidiol may be prescribed, furnished, dispensed, transferred, possessed, or used in accordance with federal law and is authorized pursuant to state law.

SEC. 3. 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 ensure that patients are able to obtain access to a new treatment modality as soon as federal law makes it available, it is necessary that this act take effect immediately.

CALIFORNIA STATE BOARD OF PHARMACY

BILL ANALYSIS

Bill Number:	**SB 17**
Current Version:	**As Amended April 25, 2017**
Author:	**Hernandez**
Topic:	**Prescription Drugs: Pricing Notification**
Board Position:	**Support**

AFFECTED SECTIONS: Amend HSC section 1385.045 and add HSC section 1367.245, amend Insurance Code section 10181.45, and add section 10123.04 to the Insurance Code

STATUS: Assembly Health Committee hearing June 27, 2017.

THIS BILL WOULD:
Establish a reporting requirement for health care services plans relating to prescription drug coverage as specified in the measure.

Require notification to state purchasers (e.g., CalPERS, Department of Health Care Services, etc.) of increases in drug prices as specified at least 90 days prior to the effective date of the increase as well as a basis for the increase.

Require drug manufacturers to include specific financial and nonfinancial factors used to make a decision to increase the cost of the drug, including justification for the increase, historical cost information, patent information and sales volume.

Require drug manufacturers to provide in writing notification of a new prescription drug to market and cost information as specified. As part of the notification the manufacturer must describe marketing and pricing plans, estimated volume of patients that may be prescribed the drug, documentation of efficacy when compared to existing treatments, and specified financial information.

STAFF COMMENTS:
This measure is intended to improve understanding and transparency in the cost determinations of prescription drugs. Although the board does not have a role in this measure, the board's vision reflects the need for quality pharmaceutical care. A patient cannot receive the benefits of a prescription if he or she cannot afford it.

SB 17

SECTION 1. *Section 1367.245 is added to the Health and Safety Code, to read:*

1367.245. (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 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.

(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.

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

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.

127677. *(a) A manufacturer of a prescription drug shall notify each purchaser described in Section 127675 that it is increasing the wholesale acquisition cost of a prescription drug if any of the following circumstances apply:*

(1) The wholesale acquisition cost for the prescription drug is under 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)) and if the cumulative increase is more than 25 percent over the three calendar years prior to the current year.

(2) The wholesale acquisition cost for the prescription drug is over 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)), and if the cumulative increase is more than 10 percent over the three calendar years prior to the current year.

(b) The notice required by subdivision (a) shall be provided in writing at least 90 days prior to the planned effective date of the increase.

(c) The notice required by subdivision (a) shall include a statement of any changes or improvements to the clinical efficacy of the drug that explain the increase in wholesale acquisition cost. The manufacturer shall state if there are no changes or improvements made to the clinical efficacy of the drug subject to the notice.

(d) The notice required by subdivision (a) shall not be required for a prescription drug that is not already purchased or reimbursed by a purchaser described in subdivision (a), except for prescription drugs described in Section 127681.

(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) At the time that the increase in wholesale acquisition cost described in subdivision (a) of Section 127677 takes effect, a manufacturer shall report all of the following information to the office:*

(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 justify the increase in the wholesale acquisition cost of the drug.

(2) The previous year's marketing budget for the drug, including the budget for patient assistance programs specific to the drug.

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

(4) 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.

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

(6) 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.

(7) Documentation of increased clinical efficacy of the drug, if any. The manufacturer shall state if the drug subject to the notice does not exceed the clinical efficacy of existing treatments.

(8) Volume of sales of the drug in the United States for the previous year.

(b) 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.

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 approval by the federal Food and Drug Administration. 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.*

(b) No later than 30 days after notification pursuant to this section, a manufacturer shall report all of the following information to 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) Any documentation showing increased efficacy of the drug compared to existing treatments. The manufacturer shall state if there are no changes or improvements made to the clinical efficacy of the drug subject to the notice.

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

(5) The expected marketing budget for the drug, including the budget for patient assistance programs.

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

(c) The office shall publish the information provided to it pursuant to this section on its Internet Web site on no less than a monthly 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.

127683. *(a) A manufacturer of a prescription drug subject to the requirements of this chapter shall comply with this chapter. The office shall be responsible for the enforcement of these provisions.*

(b) (1) A manufacturer of a prescription drug subject to this chapter that does not report the information required pursuant to this chapter to state purchasers, health care service plans, health insurers, or pharmacy benefit managers is liable for a civil penalty of one thousand dollars ($1,000) per day for every day after the applicable notification period that the required information is not reported.

(2) 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 chapter, be reviewed on appeal, and the penalty may be reduced or waived for good cause.

(c) Any money that is received by the office pursuant to this section shall be paid into the General Fund.

127685. *(a) The office may adopt regulations or issue guidance for the implementation of this chapter.*

(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.

SEC. 4. *Section 10123.204 is added to the Insurance Code, to read:*

10123.204. *(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 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, 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. 5. 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 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 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.

(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 total 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)).

SEC. 6. *The Legislature finds and declares that Sections 1 and 4 of this act, which add Section 1367.245 to the Health and Safety Code and Section 10123.204 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. 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.

CALIFORNIA STATE BOARD OF PHARMACY

BILL ANALYSIS

Bill Number:	**SB 528**
Current Version:	**As Amended April 20, 2017**
Author:	**Stone**
Topic:	**Automated Drug Dispensing Systems**
Board Position:	**Support if Amended**

AFFECTED SECTIONS: Add BPC section 4119.11

STATUS: Referred to Senate Appropriations

EXISTING LAW:
Allows for the use of automated drug delivery systems (ADDS) in both the clinic setting and in a skilled nursing facility.

THIS BILL WOULD:
Allow a pharmacy to provide pharmacy services to outpatients in an entity covered under Section 340B through the use of an automated drug delivery system (ADDS) if all of the following conditions are met:

1. The ADDS is stocked with drugs purchased under the 340B Drug Pricing Program, and the pharmacy is providing services to the entity under a contract.
2. Drugs stored and dispensed are considered to have been dispensed by the pharmacy.
3. The pharmacy maintains records of acquisition and disposition separate from other pharmacy records.
4. The pharmacy is solely responsible for the ADDS.
5. The pharmacy provides training to staff (both pharmacy and entity staff).
6. The operation of the ADDS shall be under the supervision of a pharmacist and may be done electronically.
7. Transaction information must be readily retrievable and maintained by the pharmacy for three years.
8. Drugs removed from the ADDS must be provided to the patient by a health care professional.
9. The pharmacy must have policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality and appropriate maintenance of the drugs.
10. The pharmacy must have policies and procedures to define access to the ADDS and limits to access to equipment and drugs.
11. Labeling must be consistent with BPC 4076.
12. Drugs are only released to a patient upon authorization by a pharmacist after the pharmacist has reviewed the prescription and the patient's profile for contraindications and adverse drug reactions.

13. Access to the ADDS shall be tracked using identification, password or biosensor
14. Records of transactions including all transactions, stocking and removal must be maintained.
15. Stocking of the machine must be done by a pharmacist unless specified conditions are met. (Such conditions are similar to the conditions a pharmacy must meet in using an ADDS in a skilled nursing facility.)
16. Patient consultation, as required in CCR 1707.2, must be provided via telecommunication link that has two-way audio and video.
17. Establishes licensure of the device, including an application and annual renewal fee of between $200 and $350.

STAFF COMMENTS:

The measure now includes many of the safeguards in place under current law for ADDS used as an extension of a pharmacy in a skilled nursing facility, and recent amendments incorporate additional board concerns.

SUPPORT/OPPOSITION:

Support

IMGRX (Sponsor)
United Health Centers of San Joaquin Valley
Western Sierra Medical Clinic

Opposition
None on file.

SB 528

SECTION 1. *Section 4119.11 is added to the Business and Professions Code, immediately following Section 4119.1, to read:*

4119.11. (a) A pharmacy may provide pharmacy services to a clinic, as defined in Sections 1200 and 1200.1 of the Health and Safety Code, that qualifies as a "covered entity" under Section 340B of the federal Public Health Service Act to purchase and dispense or arrange for the dispensing of drugs purchased at reduced costs under the 340B Drug Pricing Program to its outpatients, through the use of an automated drug delivery system, located on the premises of the covered entity, which need not be the same location as the pharmacy, if all of the following conditions are met:

(1) The pharmacy obtains a license from the board to operate the automated drug delivery system within the covered entity. As part of the application, the pharmacy shall provide the address of the covered entity. A separate license shall be required for each location and shall be renewed annually concurrent with the pharmacy license. The application and renewal fee shall be two hundred dollars ($200) and may be increased to three hundred fifty dollars ($350).

(2) The pharmacy providing the pharmacy services to the covered entity shall be under contract with that covered entity to facilitate its 340B drug program through the use of the automated drug delivery system to dispense drugs purchased under the federal 340B drug pricing program to its eligible outpatients.

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

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

(5) The pharmacy shall be solely responsible for the security, operation, and maintenance of the automated drug delivery system.

(6) The pharmacy shall provide training regarding the operation and use of the automated drug delivery system to both pharmacy and covered entity personnel using the system.

(7) The operation of the automated drug delivery system shall be under the supervision of a licensed pharmacist acting on behalf of the pharmacy providing services to the health center. The pharmacist need not be physically present at the site of the automated drug delivery system and may supervise the system electronically.

(8) Notwithstanding Section 4107, the board may issue a license for the operation of an automated drug delivery system at the address of a clinic licensed under Section 4180.

(b) For purposes of this section, an "automated drug delivery system" has the same meaning as in subdivision (a) of Section 4105.5.

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

(d) Drugs removed from the automated drug delivery system shall be provided to the patient by a health professional licensed pursuant to this division.

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

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

(f) Drugs removed from the automated drug delivery system for a patient shall be labeled pursuant to Section 4076.

(g) A pharmacist shall review and approve all orders prior to a drug being removed from the automated drug delivery system for a patient. The pharmacist shall review the prescriber's order and the patient's profile for potential contraindications and adverse drug reactions. Drugs shall be released from the system only upon

completion of that review.

(h) Access to the automated drug delivery system shall be controlled and tracked using an identification or password system or biosensor. A system that is accessed via a password system shall include a camera that records a picture of the individual accessing the machine. The record shall be maintained for a minimum of 180 days.

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

(j) The stocking of an automated drug delivery system shall be performed by a pharmacist. If the automated drug delivery system utilizes removable pockets, cards, drawers, similar technology, or unit of use or single dose containers as defined by the United States Pharmacopoeia, the stocking system may be done outside of the facility and be delivered to the facility if all of the following conditions are met:

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

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

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

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

(l) The automated drug delivery system used at the clinic shall provide for patient consultation pursuant to Section 1707.2 of Title 16 of the California Code of Regulations with a pharmacist via a telecommunications link that has two-way audio and video.

SEC. 2. *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.*

CALIFORNIA STATE BOARD OF PHARMACY

BILL ANALYSIS

Bill Number:	**SB 641**
Current Version:	**As Amended April 20, 2017**
Author:	**Lara**
Topic:	**Controlled Substance Utilization Review and Evaluation System: Privacy**
Board Position:	**Oppose Unless Amended**

AFFECTED SECTIONS: Amend HSC Code section 11165

STATUS: Referred to Assembly Public Safety Committee

THIS BILL WOULD:
Prohibit the release of data obtained from CURES to a law enforcement agency except pursuant to a warrant. Also it would allow DOJ to convene stakeholder meetings to assist and make recommendations on the establishment of rules and regulations necessary to ensure the proper administration and enforcement of the CURES database.

STAFF COMMENTS:
It appears to be problematic to allow stakeholders to make recommendations on the rules and regulations necessary to ensure appropriate administration and enforcement of the CURES database. The board's consumer protection mandate is clear and indicates that whenever protection of the public is inconsistent with other interests sought, the protection of the public shall be paramount. Allowing unspecified stakeholders to participate in a process to make such recommendations could create problems and undermine the board's authority. Board staff suggests that amendments be offered to specifically identify that at a minimum the board be part of any stakeholder meeting.

Further, board staff has been advised by the DCA that the measure may require the board to secure a subpoena every time it requires information from the CURES system. Staff notes that, if true, this would create a significant barrier to board investigations and would further create a significant fiscal impact to the board. Staff notes that the board does not use the information in CURES to investigate individual patients and questions the policy behind requiring the board to obtain a subpoena to access information in the CURES system that is reported by its licensees.

SB 641

SECTION 1. Section 11165 of the Health and Safety Code is amended to read:

11165. (a) To assist health care practitioners in their efforts to ensure appropriate prescribing, ordering, administering, furnishing, and dispensing of controlled substances, law enforcement and regulatory agencies in their efforts to control the diversion and resultant abuse of Schedule II, Schedule III, and Schedule IV controlled substances, and for statistical analysis, education, and research, the Department of Justice shall, contingent upon the availability of adequate funds in the CURES Fund, maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of, and Internet access to information regarding, the prescribing and dispensing of Schedule II, Schedule III, and Schedule IV controlled substances by all practitioners authorized to prescribe, order, administer, furnish, or dispense these controlled substances.

(b) The Department of Justice may seek and use grant funds to pay the costs incurred by the operation and maintenance of CURES. The department shall annually report to the Legislature and make available to the public the amount and source of funds it receives for support of CURES.

(c) (1) The operation of CURES shall comply with all applicable federal and state privacy and security laws and regulations.

(2) (A) CURES shall operate under existing provisions of law to safeguard the privacy and confidentiality of patients. Data obtained from CURES shall only be provided to appropriate state, local, and federal public agencies for disciplinary, civil, or criminal purposes and to other agencies or entities, as determined by the Department of Justice, for the purpose of educating practitioners and others in lieu of disciplinary, civil, or criminal actions. Data may be provided to public or private entities, as approved by the Department of Justice, for educational, peer review, statistical, or research purposes, provided that patient information, including any information that may identify the patient, is not compromised. Further, data disclosed to any individual or agency as described in this subdivision shall not be disclosed, sold, or transferred to any third party, unless authorized by, or pursuant to, state and federal privacy and security laws and regulations. ~~The Department of Justice shall establish policies, procedures, and regulations regarding the use, access, evaluation, management, implementation, operation, storage, disclosure, and security of the information within CURES, consistent with this subdivision.~~

(B) The Department of Justice shall only provide data obtained from CURES to a federal, state, or local law enforcement agency pursuant to a warrant based on probable cause and issued at the request of a federal, state, or local law enforcement agency engaged in an open and active criminal investigation regarding prescription drug abuse or diversion of prescription of controlled substances involving the individual to whom the requested information pertains.

(C) The Department of Justice shall establish policies, procedures, and regulations regarding the use, access, evaluation, management, implementation, operation, storage, disclosure, and security of the information within CURES, consistent with Section 11165.1.

~~(B)~~ *(D)* Notwithstanding subparagraph (A), a regulatory board whose licensees do not prescribe, order, administer, furnish, or dispense controlled substances shall not be provided data obtained from CURES.

(3) In accordance with federal and state privacy laws and regulations, a health care practitioner may provide a patient with a copy of the patient's CURES patient activity report as long as no additional CURES data is provided and keep a copy of the report in the patient's medical record in compliance with subdivision (d) of Section 11165.1.

(d) For each prescription for a Schedule II, Schedule III, or Schedule IV controlled substance, as defined in the controlled substances schedules in federal law and regulations, specifically Sections 1308.12, 1308.13, and 1308.14, respectively, of Title 21 of the Code of Federal Regulations, the dispensing pharmacy, clinic, or other dispenser shall report the following information to the Department of Justice as soon as reasonably possible, but not more than seven days after the date a controlled substance is dispensed, in a format specified by the Department of Justice:

(1) Full name, address, and, if available, telephone number of the ultimate user or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services, and the gender, and date of birth of the ultimate user.

(2) The prescriber's category of licensure, license number, national provider identifier (NPI) number, if applicable, the federal controlled substance registration number, and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility.

(3) Pharmacy prescription number, license number, NPI number, and federal controlled substance registration number.

(4) National Drug Code (NDC) number of the controlled substance dispensed.

(5) Quantity of the controlled substance dispensed.

(6) International Statistical Classification of Diseases, ~~9th revision (ICD-9) or~~ 10th revision (ICD-10) Code, if available.

(7) Number of refills ordered.

(8) Whether the drug was dispensed as a refill of a prescription or as a first-time request.

(9) Date of origin of the prescription.

(10) Date of dispensing of the prescription.

(e) The Department of Justice may invite stakeholders to assist, advise, and make recommendations on the establishment of rules and regulations necessary to ensure the proper administration and enforcement of the CURES database. All prescriber and dispenser invitees shall be licensed by one of the boards or committees identified in subdivision (d) of Section 208 of the Business and Professions Code, in active practice in California, and a regular user of CURES.

(f) The Department of Justice shall, prior to upgrading CURES, consult with prescribers licensed by one of the boards or committees identified in subdivision (d) of Section 208 of the Business and Professions Code, one or more of the boards or committees identified in subdivision (d) of Section 208 of the Business and Professions Code, and any other stakeholder identified by the department, for the purpose of identifying desirable capabilities and upgrades to the CURES Prescription Drug Monitoring Program (PDMP).

(g) The Department of Justice may establish a process to educate authorized subscribers of the CURES PDMP on how to access and use the CURES PDMP.

CALIFORNIA STATE BOARD OF PHARMACY

BILL ANALYSIS

Bill Number:	**SB 716**
Current Version:	**As Amended April 26, 2017**
Author:	**Hernandez**
Topic:	**California Board of Pharmacy**
Board Position:	**Oppose Unless Amended**

AFFECTED SECTIONS: Amend BPC section 106

STATUS: Referred to Senate Appropriations Committee

THIS BILL WOULD:
Add two governor appointed board members to the current composition of the board, including a pharmacy technician and a public member.

FISCAL IMPACT:

The board estimates the annual cost would be approximately $15,000 annually. This could be absorbed within existing resources.

SUPPORT / OPPOSITION:

SUPPORT:
California Society of Health Systems Pharmacists

SB 716

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

4001. (a) There is in the Department of Consumer Affairs a California State Board of Pharmacy in which the administration and enforcement of this chapter is vested. The board consists of ~~13~~ *15* members.

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

(c) *(1)* At least five of the seven pharmacist appointees to the board shall be pharmacists who are actively engaged in the practice of pharmacy. Additionally, the membership of the board shall include at least one pharmacist representative from each of the following practice settings: an acute care hospital, an independent community pharmacy, a chain community pharmacy, and a long-term health care or skilled nursing facility. The pharmacist appointees shall also include a pharmacist who is a member of a labor union that represents pharmacists. For the purposes of this subdivision, a “chain community pharmacy” means a chain of 75 or more stores in California under the same ownership, and an “independent community pharmacy” means a pharmacy owned by a person or entity who owns no more than four pharmacies in California.

(2) (A) The pharmacy technician board member shall have at least five years of experience and shall continue to work in California as a pharmacy technician.

(B) The pharmacy technician board member shall have work experience as a pharmacy technician in at least two of the following health care settings:

(i) Acute care hospital.

(ii) Outpatient pharmacy.

(iii) Long-term care pharmacy.

(iv) Community pharmacy.

(C) The pharmacy technician board member shall have documented work experience in a variety of pharmacy procedures and practices, including, but not limited to, procedures and practices related to sterile compounding, medication reconciliation, medication history, and automated drug delivery devices.

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

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

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

Attachment 3

AB 265

SECTION 1. *Article 7 (commencing with Section 111657) is added to Chapter 6 of Part 5 of Division 104 of the Health and Safety Code, to read:*

Article 7. Prescription Drug Discount Prohibition

111657. *Except as provided in Section 111657.5, a person who manufactures a prescription drug shall not offer in the state a discount, repayment, product voucher, or other reduction in an individual's out-of-pocket expenses associated with his or her insurance coverage, including, but not limited to, a copayment, coinsurance, or deductible, for a prescription drug if a lower cost generic drug is covered under the individual's health plan on a lower cost-sharing tier that is designated to be therapeutically equivalent as indicated by the United States Food and Drug Administration's "Approved Drug and Products with Therapeutic Equivalence Evaluations."*

111657.1. *Except as provided in Section 111657.5, a person who manufactures a prescription drug shall not offer in the state a discount, repayment, product voucher, or other reduction in the individual's out-of-pocket expenses associated with his or her insurance coverage, including, but not limited to, a copayment, coinsurance, or deductible, for a prescription drug if the active ingredients of the drug are available without prescription at a lower cost and are not otherwise contraindicated for treatment of the condition for which the prescription drug is approved.*

111657.5. *The prohibitions in Sections 111657 and 111657.1 shall not apply to any of the following:*

(a) A discount, repayment, product voucher, or other payment to a patient or another person on the patient's behalf for a prescription drug required under a United States Food and Drug Administration Risk Evaluation and Mitigation Strategy for the purpose of monitoring or facilitating the use of that prescription drug in a manner consistent with the approved labeling of the prescription drug.

(b) A single-tablet drug regimen for treatment or prevention of human immunodeficiency virus (HIV) or acquired immune deficiency syndrome (AIDS) that is as effective as a multitablet regimen, unless, consistent with clinical guidelines and peer-reviewed scientific and medical literature, the multitablet regimen is clinically equally effective or more effective and is more likely to result in adherence to the drug regimen.

(c) Rebates received by a state agency.

111657.7. *This article does not prohibit an entity, including an entity that manufactures prescription drugs, from offering pharmaceutical products free of any cost to both patients and insurers.*

111657.10. *(a) This article shall not be deemed to affect a pharmacist's ability to substitute a prescription drug pursuant to Section 4073 of the Business and Professions Code.*

(b) (1) This article shall not prohibit or limit assistance to a patient provided by an independent charity patient assistance program.

(2) For purposes of this section, "independent charity patient assistance program" means a program that meets all of the following requirements:

(A) The program does not allow a pharmaceutical manufacturer or an affiliate of the manufacturer, including, but not limited to, an employee, agent, officer, shareholder, contractor, wholesaler, distributor, or pharmacy benefits manager, to exert any direct or indirect influence or control over the charity or subsidy program.

(B) Assistance is awarded in a truly independent manner that severs any link between a pharmaceutical manufacturer's funding and the beneficiary.

(C) Assistance is awarded without regard to the pharmaceutical manufacturer's interest and without regard to the beneficiary's choice of product, provider, practitioner, supplier, or insurance plan.

(D) Assistance is awarded based upon a reasonable, verifiable, and uniform measure of financial need that is applied in a consistent manner.

(E) The pharmaceutical manufacturer does not solicit or receive data from the program that would facilitate the manufacturer in correlating the amount or frequency of its donations with the number of subsidized prescriptions for its products.

111657.12. *The department shall enforce a violation of this article only upon receipt of a complaint that alleges that violation.*

SEC. 2. *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 444

SECTION 1. *Section 117906 is added to the Health and Safety Code, to read:*

117906. (a) For purposes of this section, the following definitions apply:

(1) "Home-generated medical waste" includes home-generated pharmaceutical waste and home-generated sharps waste.

(2) "Home-generated pharmaceutical waste" means a prescription or over-the-counter human or veterinary home-generated pharmaceutical, as defined in Section 109925 or in the Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. Sec. 321(g)(1)), that is a waste, as defined by Section 25124, derived from a household, including, but not limited to, a multifamily residence or household.

(3) "Home-generated sharps waste" means hypodermic needles, pen needles, intravenous needles, lancets, and other devices that are used to penetrate the skin for the delivery of medications, that are wastes, as defined pursuant to Section 25124, derived from a household, including, but not limited to, a multifamily residence or household.

(4) "Stakeholder" means a person, including, but not limited to, a consumer, retailer, distributor, or healthcare provider or facility, who will be participating in a program developed pursuant to subdivision (b).

(b) (1) The California Environmental Protection Agency, in consultation with stakeholders, may develop a statewide program for the collection, transportation, and disposal of home-generated medical waste that complies with federal and state laws regulating the collection, transportation, and disposal of medical waste.

(2) The program developed pursuant to paragraph (1) shall not be implemented without appropriation by the Legislature in the annual Budget Act.

AB 710

SECTION 1. Section 101.7 of the Business and Professions Code is amended to read:

101.7. (a) Notwithstanding any other provision of law, boards shall meet at least three times each calendar year. Boards shall meet at least once each calendar year in northern ~~California~~ *California, once every other calendar year in rural California,* and once each calendar year in southern California in order to facilitate participation by the public and its licensees.

(b) The director at his or her discretion may exempt any board from the requirement in subdivision (a) upon a showing of good cause that the board is not able to meet at least three times in a calendar year.

(c) The director may call for a special meeting of the board when a board is not fulfilling its duties.

(d) An agency within the department that is required to provide a written notice pursuant to subdivision (a) of Section 11125 of the Government Code, may provide that notice by regular mail, email, or by both regular mail and email. An agency shall give a person who requests a notice the option of receiving the notice by regular mail, email, or by both regular mail and email. The agency shall comply with the requester's chosen form or forms of notice.

(e) An agency that plans to Web cast a meeting shall include in the meeting notice required pursuant to subdivision (a) of Section 11125 of the Government Code a statement of the board's intent to Web cast the meeting. An agency may Web cast a meeting even if the agency fails to include that statement of intent in the notice.

AB 827

SECTION 1. This act shall be known as the California Opportunity Act of 2017.

SEC. 2. *Section 110.5 is added to the Business and Professions Code, to read:*

110.5. (a) The Department of Consumer Affairs shall create a task force to study and write the report described in subdivision (c) regarding the licensing of foreign-trained professionals with the goal of integrating foreign-trained professionals into the state's workforce.

(b) The task force shall consist of the following 15 members:

(1) The Director of Consumer Affairs, or his or her designee, who shall serve as the chair of the task force.

(2) One member appointed by the Governor.

(3) One member appointed by the President pro Tempore of the Senate.

(4) One member appointed by the Speaker of the Assembly.

(5) One member of the Regents of the University of California.

(6) One member of the Trustees of the California State University.

(7) One member of the Board of Governors of the California Community Colleges.

(8) Four members appointed by the Governor who are representatives of the private sector from diverse regions in the state.

(9) Four members appointed by the Governor who are representatives of nonprofit organizations that serve the immigrant community from diverse regions in the state.

(c) (1) The task force shall write a report of its findings and recommendations regarding the licensing of foreign-trained professionals, that include, but are not limited to, the following:

(A) Strategies to integrate foreign-trained professionals and methods of implementing those strategies, including those recommended by the Little Hoover Commission in its October 2016 report entitled Jobs for Californians: Strategies to Ease Occupational Licensing Barriers (Report #234).

(B) Identification of state and national licensing regulations that potentially pose unnecessary barriers to practice for foreign-trained professionals, corresponding changes to state licensing requirements, and opportunities to advocate for corresponding changes to national licensing requirements.

(C) Identification of best practices learned from similar efforts to integrate foreign-trained professionals into the workforce in other states.

(2) The task force may include in the report guidelines for full licensure and conditional licensing of foreign-trained professionals.

(3) The task force may hold hearings and invite testimony from experts and the public to gather information.

(d) The task force shall submit the report described in subdivision (c) to the Legislature no later than January 1, 2019, and in compliance with Section 9795 of the Government Code.

(e) The following shall also apply:

(1) The task force shall meet at least once each calendar quarter. The task force shall meet at least once in northern California, once in central California, and once in southern California to facilitate participation by the public.

(2) A majority of the appointed task force shall constitute a quorum. Task force meetings shall be held in accordance with the Bagley-Keene Open Meeting Act (Article 9 (commencing with Section 11120) of Chapter 1 of Part 1 of Division 3 of Title 2 of the Government Code).

(3) (A) Each member shall receive a per diem of one hundred dollars ($100) for each day actually spent in the discharge of official duties, and shall be reimbursed for traveling and other expenses necessarily incurred in the performance of official duties.

(B) Notwithstanding any other law, a public officer or employee shall not receive per diem salary compensation for serving on the task force on any day when the officer or employee also received compensation for his or her regular public employment.

(4) The task force shall solicit input from a variety of government agencies, stakeholders, and the public, including, but not limited to, the following:

(A) The Little Hoover Commission.

(B) The California Workforce Development Board.

(C) The Department of Industrial Relations.

(D) In- and out-of-state licensing entities.

(E) Professional associations.

(F) Labor and workforce organizations.

AB 1048

SECTION 1. *Section 4052.10 is added to the Business and Professions Code, to read:*

4052.10. (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 first partial fill. Thirty-one days after the initial partial fill on a prescription, 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 dispensing fee to cover the actual supply and labor costs associated with dispensing each partial fill associated with the original prescription.

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

(h) 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.

SEC. 2. Section 1254.7 of the Health and Safety Code is amended to read:

1254.7. (a) It is the intent of the Legislature that pain be assessed and treated promptly, effectively, and for as long as pain persists.

(b) ~~Every~~ *A* health facility licensed pursuant to this chapter shall, as a condition of licensure, include pain as an item to be ~~assessed at the same time as vital signs are taken.~~ *assessed.* The health facility shall ensure that pain assessment is performed in a consistent manner that is appropriate to the patient. The pain assessment shall be noted in the patient's ~~chart in a manner consistent with other vital signs.~~ *chart.*

SEC. 3. *Section 1367.43 is added to the Health and Safety Code, to read:*

1367.43. A health care service plan contract that is issued, amended, or renewed on or after January 1, 2018, shall not allow the health care service plan or the entity with which it contracts to administer prescription drug benefits for enrollees, to consider a copayment or any portion thereof, or the payment for the ingredient costs of the drug, paid to a pharmacy for a partial fill of a prescription pursuant to Section 4052.10 of the Business and Professions Code, to be an excess payment recoverable by the plan or its contracting entity or a basis for denial of the pharmacy's claim for reimbursement for the medication.

SEC. 4. *Section 10123.203 is added to the Insurance Code, to read:*

10123.203. A health insurance policy that is issued, amended, or renewed on or after January 1, 2018, shall not allow the insurer or the entity with which it contracts to administer prescription drug benefits for the insured, to consider a copayment or any portion thereof, or the payment for the ingredient costs of the drug, paid to a pharmacy for a partial fill of a prescription pursuant to Section 4052.10 of the Business and Professions Code, to be an excess payment recoverable by the insurer or its contracting entity or a basis for denial of the pharmacy's claim for reimbursement for the medication.

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.

SB 212

SECTION 1. *Section 117670.1 is added to the Health and Safety Code, to read:*

117670.1. "Home-generated pharmaceutical waste" means a prescription or over-the-counter human or veterinary home-generated pharmaceutical, as defined in Section 109925 of the Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C.A. Sec. 321(g)(1)), that is a waste, as defined in Section 25124, derived from a household, including, but not limited to, a multifamily residence or household.

SB 715

SECTION 1. *Section 106 of the Business and Professions Code is amended to read:*

106. The Governor has power to remove from office at any time, any member of any board appointed by him *or her* for continued neglect of duties required by law, *which may include the failure to attend board meetings,* or for incompetence, or unprofessional or dishonorable conduct. Nothing in this section shall be construed as a limitation or restriction on the power of the Governor, conferred on him *or her* by any other ~~provision of~~ law, to remove any member of any board.

Attachment 4

Delegation of Certain Functions

§ 1703

Title 16. Board of Pharmacy

ORDER OF ADOPTION

Amend Section 1703 of Article 1 of Division 17 of Title 16 of the California Code of Regulations to read:

§ 1703. Delegation of Certain Functions.

The power and discretion conferred by law upon the board to receive and file accusations; issue notices of hearing, statements to respondent and statements of issues; receive and file notices of defense; determine the time and place of hearings under Section 11508 of the Government Code; set and calendar cases for hearing and perform other functions necessary to the business-like dispatch of the business of the board in connection with proceedings under the provisions of Sections 11500 through 11528 of the Government Code, prior to the hearing of such proceedings; the certification and delivery or mailing of copies of decisions under Section 11518 of said code; ~~and~~ issue summary suspension orders or notices of suspension under Section 4311 of the Business and Professions Code; make changes to its regulations without regulatory effect pursuant to Title 1, California Code of Regulations Section 100; and approve waivers pursuant to Section 4076.5(e) of the Business and Professions Code are hereby delegated to and conferred upon the executive officer, or, in his or her absence from the office of the board, the acting executive officer.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4003, 4076.5 and 4311, Business and Professions Code.

Attachment 5

Prescription Drug Take-Back

§§ 1776-1776.6

Title 16. Board of Pharmacy
Order of Adoption

Proposal to add new Article 9.1 of Division 17 of Title 16 of the California Code of Regulations and a new Article title as follows:

Article 9.1. Prescription Drug Take-Back Services

Proposal to add § 1776 of Article 9.1 of Division 17 of Title 16 of the California Code of Regulations as follows:

Section 1776 Prescription Drug Take-Back Services: Authorization

Pharmacies, hospitals/clinics with onsite pharmacies, distributors and reverse distributors licensed by the board may offer, under the requirements in this article, specified prescription drug take-back services through collection receptacles and/or mail back envelopes or packages to provide options for the public to discard unwanted, unused or outdated prescription drugs. Each entity must comply with regulations of the federal Drug Enforcement Administration (DEA) and this article.

Only California-licensed pharmacies, hospitals/clinics with onsite pharmacies, and drug distributors (licensed wholesalers and third-party logistics providers) who are registered with the DEA as collectors and licensed in good standing with the board may host a pharmaceutical take-back receptacle as authorized under this article.

Note: Authority cited: Section 4005, Business and Professions Code.
Reference: Sections 4005, 4026.5, and 4301, Business and Professions Code and Section 1317.40, Title 21 Code of Federal Regulations.

Proposal to add § 1776.1 of Article 9.1 of Division 17 of Title 16 of the California Code of Regulations as follows:

Section 1776.1 Pharmacies

(a) Pharmacies may provide take-back services to the public. Retail pharmacies and hospital/clinics with onsite pharmacies may maintain collection receptacles in their facilities. Pharmacies may offer drug take-back services as specified in section 1776.4 in skilled nursing facilities licensed under Health and Safety Code section 1250(c).
(b) There are multiple federal, state and local requirements governing the collection and destruction of dangerous drugs. Pharmacies are expected to know and adhere to these requirements when operating a prescription drug take-back program.
(c) For purposes of this article, prescription drugs means dangerous drugs as defined by Business and Professions Code section 4022, which includes controlled substances. Controlled substances may be commingled in collection receptacles or mail back envelopes or packages with other dangerous drugs.
(d) Once drugs are deposited into a collection receptacle or mail back envelopes or packages by a consumer, they are not to be removed, counted, sorted or otherwise individually handled.

(e) The collection receptacle shall contain signage that includes:
   (1) The name and phone number of the responsible pharmacy;
   (2) Medical sharps and needles (e.g., insulin syringes) shall not be deposited; and
   (3) Consumers may deposit prescription drugs including Schedule II-V controlled substances.

(f) Prescription drugs that are eligible for collection as part of drug take-back services maintained by pharmacies are only those prescription drugs that have been dispensed by any pharmacy or practitioner to a consumer. Dangerous drugs that have not been dispensed to consumers for use (such as outdated drug stock in a pharmacy, drug samples provided to a medical practitioner or medical waste) may not be collected as part of a pharmacy's drug take-back service.

(g) As part of its drug take-back services, a pharmacy shall not:
   (1) Review, accept, count, sort, or otherwise individually handle any prescription drugs from consumers.
   (2) Accept or possess prescription drugs from skilled nursing facilities, residential care homes, health care practitioners or any other entity.
   (3) Dispose of quarantined, recalled or outdated prescription drugs from pharmacy stock.

(h) A pharmacy must be registered with the federal DEA as a collector for purposes of maintaining a prescription drug take-back collection receptacle. Such pharmacies cannot employ anyone convicted of a felony related to controlled substances, or anyone who has had a DEA permit denied, surrendered or revoked.

(i) Any pharmacy that maintains a drug take-back collection receptacle as authorized in this article shall notify the board in writing within 30 days of establishing the collection program. Additionally:
   (1) Any pharmacy that ceases to maintain a drug take-back collection receptacle shall notify the board in writing within 30 days.
   (2) Any pharmacy maintaining a collection receptacle shall disclose to the board that it provides such services annually at the time of renewal of the pharmacy license, and shall identify all locations where its collection receptacles are located.
   (3) Any tampering with a collection receptacle or theft of deposited drugs shall be reported to the board in writing within 14 days.
   (4) Any tampering, damage or theft of a removed liner shall be reported to the board in writing within 14 days.

(j) If the pharmacy ceases to maintain a registered collection receptacle, the pharmacy must notify the DEA within 30 days.

(k) A pharmacy shall not provide take-back services to consumers if, in the professional judgment of the pharmacist-in-charge, the pharmacy cannot comply with the provisions of this article or the DEA rules.

(l) A pharmacy shall not provide take-back services to consumers if the pharmacy or the pharmacist-in-charge is on probation with the board, and, if the pharmacy had previously provided take-back services, the pharmacist-in-charge shall notify the board and the DEA as required in subsections (i) and (j), above.

Note: Authority cited: Section 4005, Business and Professions Code.
Reference: Section 4005 and 4022, Business and Professions Code and Sections 1301.71, 1317.30, 1317.40, Title 21 Code of Federal Regulations.

Proposal to add § 1776.2 of Article 9.1 of Division 17 of Title 16 of the California Code of Regulations as follows:

1776.2 Pharmacies Offering Mail Back Envelope or Package Services

(a) Pharmacies that provide prescription drug take-back services may do so by providing preaddressed mailing envelopes or packages to allow a consumer to return prescription drugs to an authorized DEA destruction location.

(b) All envelopes and packages must be preaddressed to a location registered with the DEA as a collector. The pharmacy is responsible for ensuring that all preaddressed envelopes and packages it makes available to the public are preaddressed for delivery to facilities that comply with this section.

(c) The preaddressed envelopes and packages must be water and spill proof, tamper evident, tear resistant and sealable. The exterior shall be nondescript and not include markings that indicate the envelope or package contains prescription drugs. Postage shall be prepaid on each envelope or package.

(d) The preaddressed envelope and package shall contain a unique identification number for each envelope and package, and instructions for users that indicate the process to mail back drugs.

(e) A pharmacy shall not accept any mail back packages or envelopes that contain drugs unless they are registered as a collector and have an onsite method of destruction that complies with the DEA requirements. Instead, consumers shall be directed to mail the envelopes or packages.

Note: Authority cited: Section 4005, Business and Professions Code.
Reference: Section 4005, Business and Professions Code and Section 1317.70, Title 21 Code of Federal Regulations.

Proposal to add § 1776.3 of Article 9.1 of Division 17 of Title 16 of the California Code of Regulations as follows:

1776.3 Collection Receptacles in Pharmacies

(a) A pharmacy may maintain a collection receptacle for the public to deposit their unwanted prescription drugs for destruction. The pharmacy is responsible for the management and maintenance of the receptacle. The receptacle shall be substantially constructed, with a permanent outer container and a removable inner liner. The collection receptacle shall be locked at all times to prevent access to the inner liner.

(b) A pharmacy maintaining a collection receptacle must securely fasten the receptacle to a permanent structure so it cannot be removed. The receptacle shall be installed in an inside location. Except as provided in subsection (c), the receptacle is visible to pharmacy or DEA registrant employees, but not located in or near emergency areas, nor behind the pharmacy's counter.

(c) In hospitals/clinics with a pharmacy on the premises, the collection receptacle must be located in an area that is regularly monitored by pharmacy or DEA registrant employees and not in the proximity of any emergency or urgent care areas. When no pharmacy or DEA registrant employees are present, the collection receptacle shall be locked so that

drugs may not be deposited into the collection receptacle.

(d) The receptacle shall include a small opening that allows deposit of drugs into the inside of the receptacle directly into the inner liner, but does not allow for an individual to reach into the receptacle's contents. During hours when the pharmacy is closed, the collection receptacle shall not be accessible to the public for deposit of drugs. The pharmacy shall lock the deposit opening on the collection receptacle.

(e) A pharmacy shall direct consumers to directly deposit drugs into the collection receptacle. A pharmacy shall not accept, count, sort or otherwise handle prescription drugs from consumers.

(f) A liner as used in this article shall be made of material that is certified by the manufacturer to meet the American Society for Testing Materials (ASTM) D1709 standard test for impact resistance of 165 grams (drop dart test), and the ASTM D1922 standards for tear resistance of 480 grams in both parallel and perpendicular planes.

(1) The liner shall be waterproof, tamper evident and tear resistant.

(2) The liner shall be opaque to prevent viewing or removal of any contents once the liner has been removed from a collection receptacle. The liner shall be clearly marked to display the maximum contents (for example, in gallons). The liner shall bear a permanent, unique identification number established by the pharmacy or pre-entered onto the liner by the liner's manufacturer or distributor.

(g) The liner shall be removable as specified in this section. The receptacle shall allow the public to deposit prescription drugs into the receptacle for containment into the inner liner, without permitting access to or removal of prescription drugs already deposited into the collection receptacle and liner. Once a prescription drug or any other item is placed in the collection receptacle, the prescription drug or item cannot be removed, counted, sorted or otherwise individually handled.

(h) If the liner is not already itself rigid or already inside of a rigid container when it is removed from the collection receptacle, the liner must be immediately, without interruption, placed in a rigid container for storage, handling and transport. A rigid container may be disposable, reusable, or recyclable. Rigid containers shall be leak resistant, have sealable tight-fitting covers, and be kept clean and in good repair.

(i) The liner may be removed from a locked collection receptacle only by or under the supervision of two employees of the pharmacy. Upon removal, the liner shall be immediately, without interruption, sealed and the pharmacy employees shall record, in a log, their participation in the removal of each liner from a collection receptacle. Liners and their rigid containers shall not be opened, x-rayed, analyzed or penetrated at any time by the pharmacy or pharmacy personnel.

(j) Liners and their rigid containers that have been filled and removed from a collection receptacle must be stored in a secured, locked location in the pharmacy no longer than 14 days.

(k) The pharmacy shall make and keep the records specified in 1776.6.

(l) The pharmacy shall ensure the sealed inner liners and their contents are shipped to a reverse distributor's registered location by common or contract carrier (such as UPS, FEDEX or USPS) or by licensed reverse distributor pick-up at the licensed pharmacy's premises.

(m) The collection receptacle shall contain signage that includes:

(1) The name and phone number of the responsible pharmacy;

(2) Medical sharps and needles (e.g., insulin syringes) shall not be deposited; and
(3) Consumers may deposit prescription drugs including Schedule II-V controlled substances.

Note: Authority cited: Section 4005, Business and Professions Code.

Reference: Section 4005, Business and Professions Code and Sections 1304.22, 1317.05, 1317.60, and 1317.75, Title 21 Code of Federal Regulations.

Proposal to add § 1776.4 of Article 9.1 of Division 17 of Title 16 of the California Code of Regulations as follows:

1776.4 Drug Take-Back Services in Skilled Nursing Facilities

A pharmacy may offer drug take-back services in skilled nursing facilities licensed under Health and Safety Code section 1250(c) as authorized by this article.

(a) Skilled nursing facility employees or person lawfully entitled to dispose of the resident decedent's property may dispose of unwanted or unused prescription drugs by using mail back envelopes or packages. The pharmacy shall require skilled nursing facility employees to keep records noting the specific quantity of each prescription drug mailed back, the unique identification number of the mail back package and the preaddressed location to which the mail back envelope is sent.

(b) Only pharmacies and hospitals/clinics with onsite pharmacies may establish collection receptacles in skilled nursing facilities for the collection and ultimate disposal of unwanted prescription drugs. A pharmacy and hospital/clinic with an onsite pharmacy maintaining a collection receptacle in a skilled nursing facility shall:
(1) Be registered and maintain registration with the DEA as a collector.
(2) Notify the board in writing within 30 days of establishing a collection receptacle.
(3) Notify the board in writing within 30 days when they cease to maintain the collection receptacle.
(4) Notify the board in writing within 14 days of any tampering of the collection receptacle or theft of deposited drugs.
(5) Notify the board in writing within 14 days of any tampering, damage or theft of a removed liner.
(6) List all collection receptacles it maintains annually at the time of renewal of the pharmacy license.

(d) Within three business days after the permanent discontinuation of use of a medication by a prescriber, as a result of the resident's transfer to another facility or as a result of death, the skilled nursing facility may place the patient's unneeded prescription drugs into a collection receptacle. Records of such deposit shall be made in the patient's records, with the name and signature of the employee discarding the drugs.

(e) A collection receptacle must be located in a secured area regularly monitored by skilled nursing facility employees.

(f) The collection receptacle shall be securely fastened to a permanent structure so that it cannot be removed. The collection receptacle shall have a small opening that allows deposit of drugs into the inside of the collection receptacle and directly into the inner liner, but does not allow for an individual to reach into the receptacle's contents.

(g) The receptacle shall be securely locked and substantially constructed, with a permanent outer container and a removable inner liner.

(1) The liner shall comply with provisions in this article. The receptacle shall allow deposit of prescription drugs into the receptacle for containment into the inner liner, without permitting access to or removal of prescription drugs already deposited into the collection receptacle and liner. Once a prescription drug or any other item is placed in the collection receptacle, the prescription drug or item cannot be removed, sorted, counted, or otherwise individually handled.

(2) If the liner is not already itself rigid or already inside of a rigid container when it is removed from the collection receptacle, the liner must be immediately placed in a rigid container for storage, handling and transport. A rigid container may be disposable, reusable, or recyclable. Rigid containers shall be leak resistant, have sealable tight-fitting covers, and be kept clean and in good repair.

(h) A liner as used in this article shall be made of material that is certified by the manufacturer to meet American Society for Testing Materials (ASTM) D1709 standard test for impact resistance of 165 grams (drop dart test), and the ASTM D1922 standards for tear resistance of 480 grams in both parallel and perpendicular planes.

(1) The liner shall be waterproof, tamper evident and tear resistant.

(2) The liner shall be opaque to prevent viewing and discourage removal of any contents once the liner has been removed from a collection receptacle. The liner shall be clearly marked to display the maximum contents (for example, in gallons). The liner shall bear a permanent, unique identification number.

(i) The collection receptacle shall contain signage that includes:

(1) The name and phone number of the responsible pharmacy;

(2) Medical sharps and needles (e.g., insulin syringes) shall not be deposited; and

(3) Consumers may deposit prescription drugs including Schedule II-V controlled substances.

(j) Once deposited, the prescription drugs shall not be counted, sorted or otherwise individually handled.

(k) The installation, removal, transfer and storage of inner liners shall be performed only by:

(1) One employee of the authorized collector pharmacy and one supervisory level employee of the long-term care facility (e.g., a charge nurse or supervisor) designated by the authorized collector, or

(2) By or under the supervision of two employees of the authorized collector pharmacy.

(l) Sealed inner liners that are placed in a container may be stored at the skilled nursing facility for up to three business days in a securely locked, substantially constructed cabinet or a securely locked room with controlled access until transfer to a reverse distributor for destruction.

(m) Liners still housed in a rigid container may be delivered to a reverse distributor for destruction by common or contract carrier or by reverse distributor pickup at the skilled nursing facility.

(n) A pharmacy maintaining a collection receptacle in a skilled nursing facility shall make and keep the records as specified in 1776.6.

Note: Authority cited: Section 4005, Business and Professions Code.
Reference: Sections 4005, Business and Professions Code and Sections 1304.22, 1317.05, 1317.40, 1317.60, 1317.75, 1317.80, and 1317.95, Title 21 Code of Federal Regulations

Proposal to add § 1776.5 of Article 9.1 of Division 17 of Title 16 of the California Code of Regulations as follows:

1776.5 Reverse Distributors

(a) A licensed reverse distributor (either a reverse wholesaler or a reverse third-party logistics provider) registered with the DEA may accept the sealed inner liners of collection receptacles at the reverse distributor's registered location by common or contract carrier pick-up, or by reverse distributor pick-up at the collector's authorized collection location. Once received, the reverse distributor shall establish records required by this section.

(b) A licensed reverse distributor may not open, survey, or otherwise analyze the contents of inner liners. All liners shall be destroyed by an appropriately licensed and registered DEA reverse distributor in a manner that makes the drugs irretrievable.

(c) If a reverse distributor picks up the sealed inner liners from the collector's authorized location, at least two employees of the reverse distributor shall be present. If the sealed inner liners are delivered to the reverse distributor via common or contract carrier, at least one employee of the reverse distributor shall accept the receipt of the inner liners at the reverse distributor's registered location.

(d) A reverse distributor shall not employ as an agent or employee anyone who has access to or influence over controlled substances, any person who has been convicted of any felony offense related to controlled substances or who at any time had a DEA registration revoked or suspended, or has surrendered a DEA registration for cause.

(e) For each sealed liner or mail back envelopes or packages received pursuant to federal Title 21 CFR section 1317.55, the reverse distributor shall maintain records of the number of sealed inner liners or mail back envelopes or packages, including the:

(1) Date of acquisition;
(2) Number and the size (e.g., five 10-gallon liners, etc.);
(3) Unique Identification number of each liner or envelope/package;
(4) The method of delivery to the reverse distributor, the signature of the individuals delivering the liners to the reverse distributor, and the reverse distributor's employees who received the sealed liner;
(5) The date, place and method of destruction;
(6) Number of packages and inner liners received;
(7) Number of packages and inner liners destroyed;
(8) The name and signature of the two employees of the registrant that witnessed the destruction.

(e) For liners only, the information specified in subsection (e)(1)-(8) above shall be created at the time of receipt and at the time of destruction.

Note: Authority cited: Section 4005, Business and Professions Code.
Reference: Sections 4005, Business and Professions Code and Section 1301.71, 1304.21, 1304.22, 1317.15, 1317.55, and 1317.95, Title 21 Code of Federal Regulations.

Proposal to add § 1776.6 of Article 9.1 of Division 17 of Title 16 of the California Code of Regulations as follows:

1776.6 Record Keeping Requirements for Board Licensees Providing Drug Take-Back Services

Each entity authorized by this article to collect unwanted prescription drugs from consumers shall maintain the records required by this article for three years.

(a) For pharmacies maintaining collection receptacles, the pharmacy shall make and keep the following records for each liner:

(1) Date each unused liner is acquired, its unique identification number and size (e.g., 5 gallon, 10 gallon). The pharmacy shall assign the unique identification number if the liner does not already contain one.

(2) Date each liner is installed in a collection receptacle, the address of the location where each liner is installed, the unique identification number and size (e.g., 5 gallon, 10 gallon), the registration number of the collector pharmacy, and the names and signatures of the two employees that witnessed each installation.

(3) Date each inner liner is removed and sealed, the address of the location from which each inner liner is removed, the unique identification number and size (e.g., 5 gallon, 10 gallon) of each inner liner removed, the registration number of the collector pharmacy, and the names and signatures of the two employees that witnessed the removal and sealing.

(4) Date each sealed inner liner is transferred to storage, the unique identification number and size (e.g., 5 gallon, 10 gallon) of each inner liner stored, and the names and signatures of the two employees that transferred each sealed inner liner to storage.

(5) Date each sealed inner liner is transferred for destruction, the address and registration number of the reverse distributor or distributor to whom each sealed inner liner was transferred, the unique Identification number and the size (e.g., 5 gallon, 10 gallon) of each liner transferred, and the names and signatures of the two employees who transferred each sealed inner liner to the reverse distributor or distributor, or the common carrier who delivered it, the company used, and any related paperwork (invoice, bill of lading).

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005, Business and Professions Code and Section 1304.22, Title 21 Code of Federal Regulations

Attachment 6

Travel Medications

§ 1746.5

BOARD OF PHARMACY
Order of Adoption

Add §1746.5 to Article 5 of Division 17 of Title 16 of the California Code of Regulations as follows:

§1746.5 Pharmacists Furnishing Travel Medications.

(a) A pharmacist furnishing prescription medications not requiring a diagnosis that are recommended by the federal Center for Disease Control and Prevention (CDC) for individuals traveling outside the 50 states and the District of Columbia pursuant to section 4052(a)(10)(A)(3) of the Business and Professions Code (hereafter, "travel medications") shall follow the requirements of this section.

(b) For purposes of Business and Professions Code section 4052(a)(10)(A)(3), a prescription medication "not requiring a diagnosis" means a prescription medication that is either:

(1) For treatment of a condition that is recognized as both self-diagnosable and self-treatable by the CDC's Health Information for International Travel (commonly called the Yellow Book), or

(2) For prophylaxis of a condition.

(c) Training: A pharmacist who furnishes travel medications shall keep documentation of the following on site and available for inspection by the Board:

(1) Completion of an immunization training program that meets the requirements of Business and Professions Code section 4052.8(b)(1),

(2) Completion of a travel medicine training program, which must consist of at least 10 hours of training and cover each element of the International Society of Travel Medicine's Body of Knowledge for the Practice of Travel Medicine (2012), hereby incorporated by reference,

(3) Completion of the CDC Yellow Fever Vaccine Course, and

(4) Current basic life support certification.

(d) Continuing Education: Pharmacists must complete two hours of ongoing continuing education focused on travel medicine, separate from continuing education in immunizations and vaccines, from an approved provider once every two years.

(e) Prior to furnishing travel medications, a pharmacist shall perform a good faith evaluation of the patient, including evaluation of the patient's travel history using destination-specific travel criteria. The travel history must include all the information necessary for a risk assessment during pre-travel consultation, as identified in the CDC Yellow Book. An example of an appropriate and comprehensive travel history is available on the Board's website.

(f) Notifications: The pharmacist shall notify the patient's primary care provider of any drugs or devices furnished to the patient within 14 days of the date of furnishing, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by the primary care provider. If the patient does not have a primary care provider, or is unable to provide contact information for his or her primary care provider, the pharmacist shall provide the patient with a written record of the drugs or devices furnished and advise the patient to consult a physician of the patient's choice.

(g) Documentation: For each travel medication furnished by a pharmacist, a patient medication record shall be maintained and securely stored in physical or electronic manner such that the information required under section 300aa-25 of title 42 of the United States Code is readily retrievable during the pharmacy or facility's normal operating hours. A pharmacist shall provide the patient with a written document that reflects the clinical assessment and travel medication plan.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4052 and 4052.8, Business and Professions Code.

Attachment 7

Renewal Requirements 16 CCR §§ 1702, 1702.1, 1702.2, and 1702.5

Board of Pharmacy
Modified Text

Changes made to the originally proposed language are shown by ~~double strikethrough~~ for deleted language and double underline for added language. Additionally, the changes are shown in red for color printing.

Amend Section 1702 of Article 5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1702. Pharmacist Renewal Requirements

(a) A pharmacist applicant for renewal who has not previously submitted fingerprints as a condition of licensure or for whom an electronic record of the licensee's fingerprints does not exist in the Department of Justice's criminal offender record identification database shall successfully complete a state and federal level criminal offender record information search conducted through the Department of Justice by the licensee's or registrant's renewal date ~~that occurs on or after December 7, 2010~~.

(1) A pharmacist shall retain for at least three years as evidence of having complied with subdivision (a) either a receipt showing that he or she has electronically transmitted his or her fingerprint images to the Department of Justice or, for those who did not use an electronic fingerprinting system, a receipt evidencing that his or her fingerprints were recorded and submitted to the Board.

(2) A pharmacist applicant for renewal shall pay the actual cost of compliance with subdivision (a).

(3) As a condition of petitioning the board for reinstatement of a revoked or surrendered license, or for restoration of a retired license, an applicant shall comply with subdivision (a).

(4) The board may waive the requirements of this section for licensees who are actively serving in the United States military. The board may not return a license to active status until the licensee has complied with subdivision (a).

(b) As a condition of renewal, a pharmacist applicant shall disclose on the renewal form whether he or she has been convicted, as defined in Section 490 of the Business and Professions Code, of any violation of the law in this or any other state, the United States, or other country, since his or her last renewal . ~~omitting t~~Traffic infractions ~~under~~ ~~$300~~ ~~$500~~ not involving alcohol, dangerous drugs, or controlled substances do not need to be disclosed.

(c) As a condition of renewal, a pharmacist applicant shall disclose on the renewal form any disciplinary action against any license issued to the applicant by a government agency. For the purposes of this section, "disciplinary action" means an adverse licensure or certification action that resulted in a restriction or penalty being placed on the license, such as revocation, suspension, probation or public reprimand or reproval.

(d) Failure to provide all of the information required by this section renders an application for renewal incomplete and the board shall not renew the license and shall issue the applicant an inactive pharmacist license. An inactive pharmacist license issued pursuant to this section may only be reactivated after compliance is confirmed for all licensure renewal requirements.

Authority: Sections 4001.1 and 4005, Business and Professions Code.
Reference: Sections 490, 4036, 4200.5, 4207, 4301, 4301.5 and 4400, Business and Professions Code; and Sections 11105(b)(10) and 11105(e), Penal Code.

Adopt Section 1702.1 of Article 5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1702. 1 Pharmacy Technician Renewal Requirements

(a) A pharmacy technician applicant for renewal who has not previously submitted fingerprints as a condition of licensure or for whom an electronic record of the licensee's fingerprints does not exist in the Department of Justice's criminal offender record identification database shall successfully complete a state and federal level criminal offender record information search conducted through the Department of Justice by the licensee's or registrant's renewal date that occurs on or after July 1, 2017~~4~~.

(1) A pharmacy technician shall retain for at least three years as evidence of having complied with subdivision (a) either a receipt showing that he or she has electronically transmitted his or her fingerprint images to the Department of Justice or, for those who did not use an electronic fingerprinting system, a receipt evidencing that his or her fingerprints were recorded and submitted to the Board.

(2) A pharmacy technician applicant for renewal shall pay the actual cost of compliance with subdivision (a).

(3) As a condition of petitioning the board for reinstatement of a revoked or surrendered license an applicant shall comply with subdivision (a).

(4) The board may waive the requirements of this section for licensees who are actively serving in the United States military. The board may not return a license to active status until the licensee has complied with subdivision (a).

(b) As a condition of renewal, a pharmacy technician applicant shall disclose on the renewal form whether he or she has been convicted, as defined in Section 490 of the Business and Professions Code, of any violation of the law in this or any other state, the United States, or other country, since his or her last renewal . Traffic infractions ~~under $500~~ not involving alcohol, dangerous drugs, or controlled substances do not need to be disclosed.

(c) As a condition of renewal, a pharmacy technician applicant shall disclose on the renewal form any disciplinary action against any license issued to the applicant by a government agency. For the purposes of this section, "disciplinary action" means an adverse licensure or certification action that resulted in a restriction or penalty against the license or certification such as revocation, suspension, probation or public reprimand or reproval.

(d) Failure to provide all of the information required by this section renders an application for renewal incomplete and the board shall not renew the license until the licensee demonstrates compliance with all requirements.

Authority: Sections 4001.1 and 4005, Business and Professions Code.
Reference: Sections 490, 4038, 4115, 4202, 4207, 4301, 4301.5 and 4400, Business and Professions Code; and Sections 11105(b)(10) and 11105(e), Penal Code.

Adopt Section 1702.2 of Article 5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1702. 2 Designated Representative Renewal Requirements

(a) A designated representative applicant for renewal who has not previously submitted fingerprints as a condition of licensure or for whom an electronic record of the licensee's fingerprints does not exist in the Department of Justice's criminal offender record identification database shall successfully complete a state and federal level criminal offender record information search conducted through the Department of Justice by the licensee's or registrant's renewal date that occurs on or after July 1, 2017~~4~~.

(1) A designated representative shall retain for at least three years as evidence of having complied with subdivision (a) either a receipt showing that he or she has electronically transmitted his or her fingerprint images to the Department of Justice or, for those who did not use an electronic fingerprinting system, a receipt evidencing that his or her fingerprints were recorded and submitted to the Board.

(2) A designated representative applicant for renewal shall pay the actual cost of compliance with subdivision (a).

(3) As a condition of petitioning the board for reinstatement of a revoked or surrendered license an applicant shall comply with subdivision (a).

(4) The board may waive the requirements of this section for licensees who are actively serving in the United States military. The board may not return a license to active status until the licensee has complied with subdivision (a).

(b) As a condition of renewal, a designated representative applicant shall disclose on the renewal form whether he or she has been convicted, as defined in Section 490 of the Business and Professions Code, of any violation of the law in this or any other state, the United States, or other country, since his or her last renewal. Traffic infractions ~~under $500~~ not involving alcohol, dangerous drugs, or controlled substances do not need to be disclosed.

(c) As a condition of renewal, a designated representative applicant shall disclose on the renewal form any disciplinary action against any license issued to the applicant by a government agency. For the purposes of this section, "disciplinary action" means an adverse licensure or certification action that resulted in a restriction or penalty against the license or certification such as revocation, suspension, probation or public reprimand or reproval.

(d) Failure to provide all of the information required by this section renders an application for renewal incomplete and the board shall not renew the license until the licensee demonstrates compliance with all requirements.

Authority : Sections 4001.1 and 4005, Business and Professions Code.
Reference: Sections 490, 4022.5, 4053, 4207, 4301, 4301.5 and 4400, Business and Professions Code; and Sections 11105(b)(10) and 11105(e), Penal Code.

Adopt Section 1702.5 of Article 5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1702.5. Disclosure of Discipline, Renewal, Nonresident Wholesaler or Nonresident Pharmacy.

(a) As a condition of renewal, an applicant seeking renewal of a license as a nonresident wholesaler or as a nonresident pharmacy shall report to the board any disciplinary action taken by any government agency since the last renewal of the license. An applicant seeking the first renewal of a license as a nonresident wholesaler or a nonresident pharmacy shall report to the board any disciplinary action taken by any government agency since issuance of the license. Failure to provide information required by this section shall render an application for renewal incomplete, and the board shall not renew the license until such time as the information is provided.

(b) For purposes of this section, "disciplinary action" means any adverse licensure or certification action that resulted in a restriction or penalty against the license or certification. Such actions include revocation, suspension, probation or public reprimand or reproval.

Authority: Section 4005, Business and Professions Code.
Reference: Sections 4112, 4161, 4300, and 4301, Business and Professions Code

Attachment 8

Disciplinary Guidelines

§ 1760

California State Board of Pharmacy
Specific Language to Amend 16 CCR § 1760

Initial proposed changes indicated with single ~~strikethrough~~ for deletions and single underline for additions.

Modified changes indicated with ~~double strikethrough~~ for deletions and double underline for additions

Changes made to the second modified language are shown by ~~bold double strikethrough in red ink~~ for deletion and by bold double underline in red ink for additions.

Amend Section 1760 to Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1760. Disciplinary Guidelines.
In reaching a decision on a disciplinary action under the Administrative Procedure Act (Government Code section 11400 et seq.) the board shall consider the disciplinary guidelines entitled "Disciplinary Guidelines" (Rev. ~~10/2007~~ ~~7/2015~~ ~~10/2015~~ 2/2017), which are hereby incorporated by reference.

Deviation from these guidelines and orders, including the standard terms of probation, is appropriate where the board, in its sole discretion, determines that the facts of the particular case warrant such a deviation-the presence of mitigating factors; the age of the case; evidentiary problems.

Note: Authority cited: Sections 315, 315.2, 315.4 and 4005, Business and Professions Code; and Section 11400.20, Government Code. Reference: Sections 315, 315.2, 315.4, 4300 - 4313 ~~and 4301~~, Business and Professions Code; and Sections 11400.20 and 11425.50(e), Government Code.

Attachment 9

Fee Schedule

§ 1749

Title 16. Board of Pharmacy

Amend section 1749 in Article 6 of Division 17 of Title 16 California Code of Regulations to read as follows:

1749. Fee Schedule

The fees for the issuance and renewal of licenses, certificates, and permits, and the penalties to be assessed for failure to renew in accordance with section~~s~~ 163.5~~, 4110, 4127.5, 4128.2, 4196, and 4400~~ of the Business and Professions Code and Pharmacy Law are hereby fixed as follows:

(a) The fee for the issuance of any pharmacy license is five hundred twenty dollars ($520). The fee for the annual renewal of pharmacy license is ~~three hundred twenty-five dollars ($325)~~ six hundred sixty five dollars ($665). The penalty for failure to renew is one hundred fifty dollars ($150).
(b) The fee for the issuance of a temporary license is three hundred twenty-five dollars ($325).
(c) The fee for the issuance of a pharmacy technician license shall be ~~one hundred five dollars ($105)~~ one hundred and forty dollars ($140). The fee for the biennial renewal of a pharmacy technician license shall be ~~one hundred thirty dollars ($130)~~ one hundred forty dollars ($140). The penalty for failure to renew a pharmacy technician license is ~~sixty-five dollars ($65)~~ seventy dollars ($70).
(d) The fee for application and examination as a pharmacist is two hundred sixty dollars ($260).
(e) The fee for regrading an examination is one hundred fifteen dollars ($115).
(f)(1) The fee for the issuance of an original pharmacist license is one hundred ninety-five dollars ($195).
(2) The fee for application of an advanced practice pharmacist license is three hundred dollars ($300). If granted, there is no fee for the initial license issued, which will expire at the same time the pharmacist's license expires. *(***This language is added pursuant to the advanced practice pharmacist rulemaking currently being reviewed by OAL.)*
(g)(1) The fee for the biennial renewal of a pharmacist's license is ~~one hundred ninety-five dollars ($195)~~ three hundred sixty dollars ($360). The penalty fee for failure to renew is ~~ninety-seven dollars fifty cents ($97.50)~~ one hundred fifty dollars ($150).
(2) The fee for the biennial renewal of an advanced practice pharmacist license is three hundred dollars ($300). The penalty fee for failure to renew is one hundred fifty dollars ($150). The fees in this paragraph are in addition to the fees required to renew the pharmacist's license as specified in paragraph 1.
(h) The fee for the issuance or renewal of a wholesaler's license or third-party logistics provider is seven hundred eighty dollars ($780). The penalty for failure to renew is one hundred fifty dollars ($150).
(i) The fee for the issuance ~~or renewal~~ of a hypodermic license is ~~one hundred sixty five dollars ($165)~~ one hundred seventy dollars ($170). The fee for the annual renewal of

a hypodermic needle license is two hundred dollars ($200). The penalty for failure to renew is ~~eighty two dollars fifty cents ($82.50)~~ one hundred dollars ($100).

(j) The fee for the issuance of a license as a designated representative pursuant to Section 4053 of the Business and Professions Code or designated representative-3PL pursuant to Section 4053.1 ~~shall be three hundred thirty dollars ($330)~~ is one hundred fifty dollars ($150). The fee for the annual renewal of a license as a designated representative or designated representative-3PL shall be ~~one hundred ninety-five dollars ($195)~~ two hundred and fifteen dollars ($215). The penalty for failure to renew is ~~ninety seven dollars and fifty cents ($97.50)~~ one hundred seven dollars and fifty cents ($107.50).

(k) The fee for the ~~issuance~~ application or renewal of a license as a nonresident wholesaler or nonresident third-party logistics provider is seven hundred eighty dollars ($780). The penalty for failure to renew is one hundred fifty dollars ($150). The fee for a temporary license is seven hundred fifteen dollars ($715).

(l) The fee for an intern pharmacist license is ~~one hundred fifteen dollars ($115)~~ one hundred sixty-five dollars ($165). The fee for transfer of intern hours or verification of licensure to another state is thirty dollars ($30).

(m) The fee for the reissuance of any permit, license, or certificate, or renewal thereof, which must be reissued because of change in the information, other than name change, is one hundred dollars ($100).

(n) The fee for the reissuance of any license that has been lost or destroyed or reissued due to a name change is forty-five dollars ($45).

~~(n)~~ (o) The fee for evaluation of continuing education courses for accreditation is forty dollars ($40) for each hour of accreditation requested.

~~(o)~~ (p) The fee for the issuance of a clinic license is five hundred twenty dollars ($520). The fee for the annual renewal of a clinic license is three hundred twenty-five dollars ($325). The penalty for failure to renew is one hundred fifty dollars ($150).

~~(p)~~ (q) The fee for the issuance of a nongovernmental license, ~~or renewal of a license,~~ to compound sterile drug products is ~~seven hundred eighty dollars ($780)~~ one thousand six hundred forty-five dollars ($1,645). The fee for the annual renewal of a nongovernmental license to compound sterile drug products is one thousand three hundred twenty-five dollars ($1,325). The penalty for failure to renew is one hundred fifty dollars ($150). The fee for a temporary license is five hundred fifty dollars ($550).

(r) The fee for the issuance of a nonresident sterile compounding pharmacy is two thousand three hundred eighty dollars ($2,380). The fee for the annual renewal of nonresident sterile compounding pharmacy license is two thousand two hundred seventy dollars ($2,270). The penalty for failure to renew is one hundred fifty dollars ($150). The fee for a temporary license is five hundred fifty dollars ($550).

~~(q)~~ (s) The fee for the issuance of a license as a designated representative for a veterinary food-animal drug retailer ~~shall be three hundred thirty dollars ($330)~~ is one hundred fifty dollars ($150). The fee for the annual renewal of a license as a designated representative ~~shall be one hundred and ninety-five dollars ($195)~~ is two hundred fifteen dollars ($215). The penalty for failure to renew is ~~ninety-seven dollars and fifty cents ($97.50)~~ is one hundred seven dollars and fifty cents ($107.50).

~~(r)~~ (t)The fee for a veterinary food-animal drug retailer license is ~~four hundred twenty-five dollars ($425)~~ four hundred and thirty-five dollars ($435). The annual renewal fee for a veterinary food-animal drug retailer is ~~three hundred twenty-five dollars ($325)~~ three hundred thirty dollars ($330). The fee for the issuance of a temporary license is two hundred and fifty dollars ($250). The penalty for failure to renew is ~~one hundred twenty-five dollars ($125)~~ one hundred fifty dollars ($150).

~~(s)~~ (u) The fee for the issuance of a retired pharmacist license shall be forty-five dollars ($45).

~~(t)~~ (v) The fee for the issuance of a centralized hospital packaging pharmacy license ~~shall be $800~~ is eight hundred twenty dollars ($820). The annual renewal fee for a centralized hospital packaging pharmacy license ~~shall be $800~~ is eight hundred five dollars ($805). The penalty for failure to renew is one hundred fifty dollars ($150).

(w) The fee for the issuance of an outsourcing facility license is two thousand two hundred seventy dollars ($2,270). The annual renewal fee for an outsourcing facility is one thousand three hundred twenty-five dollars ($1,325). The penalty for failure to renew is one hundred fifty dollars ($150). The fee for a temporary outsourcing facility license is seven hundred fifteen dollars ($715).

(x) The fee for the issuance of a nonresident outsourcing facility license is two thousand three hundred eighty dollars ($2,380). The annual renewal fee for a nonresident outsourcing facility is two thousand two hundred seventy dollars ($2,270). The penalty for failure to renew is one hundred fifty dollars ($150).

Note: Authority cited: Sections ~~163.5 and~~ 4005 and 4400, Business and Professions Code. Reference: Sections 163.5, 4005, 4053, 4053.1, 4110, 4112~~(h),~~ 4120, 4127.1, 4127.2, 4128.2, 4129.1, 4129.2, 4160, 4161, 4180, 4190, 4196, 4200, 4202, 4203, 4208, 4210, 4304, 4400, 4401 and 4403, Business and Professions Code.

Attachment 10

Inventory Reconciliation Report of Controlled Substances

§ 1715.65

Title 16. Board of Pharmacy
Second Modified Text

Changes made to the originally proposed language are shown by ~~strikethrough~~ for deleted language and underline for added language.

Changes made to the first modified language are shown by ~~double strikethrough~~ for deleted language and double underline for added language.

Adopt section 1715.65 in Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1715.65. Inventory Reconciliation Report of Controlled Substances

a) Every pharmacy, and every clinic licensed under sections 4180 or 4190, shall perform periodic inventory and inventory reconciliation functions to detect and prevent the loss of controlled substances.
b) The pharmacist-in-charge of a pharmacy or consultant pharmacist for a clinic shall review all inventory and inventory reconciliation reports taken, and establish and maintain secure methods to prevent losses of controlled drugs. Written policies and procedures shall be developed for performing the inventory reconciliation reports required by this section.
c) A pharmacy or clinic shall compile an ~~I~~inventory ~~R~~reconciliation ~~R~~report of all federal Schedule II controlled substances at least every three months. This compilation shall require:
   1) A physical count, not an estimate, of all quantities of federal Schedule II controlled substances. The biennial inventory of controlled substances required by federal law may serve as one of the mandated inventories under this section in the year where the federal biennial inventory is performed, provided 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 federal Schedule II controlled substances since the last ~~I~~inventory ~~R~~reconciliation ~~R~~report;
   3) A comparison of (1) and (2) to determine if there are any variances; ~~and~~
   4) All records used to compile each Inventory Reconciliation Report shall be maintained in the pharmacy or clinic for at least three years in a readily retrievable form~~.~~; and
   5) Possible causes of overages shall be identified in writing and incorporated into the inventory reconciliation report.
d) A pharmacy or clinic shall report in writing identified ~~L~~ losses and known ~~possible~~ causes~~, shall be identified in writing and reported~~ to the board ~~and, when appropriate, to the Drug Enforcement Administration~~ within 30 days unless the cause of the loss is theft, diversion, or self-use in which case the report shall be made within 14 days. If the pharmacy or clinic is unable to identify the cause of the loss, further investigation shall be undertaken to identify the cause and actions ~~security improvements~~ necessary to prevent additional losses of controlled substances.

~~e) Likely Possible causes of overages shall be identified in writing and incorporated into the Inventory Reconciliation Report.~~

e) ~~f)~~ The Inventory Reconciliation Report shall be dated and signed by the individual(s) performing the inventory, and countersigned by the pharmacist-in-charge or professional director~~,~~ (if a clinic~~,~~) and be readily retrievable in the pharmacy or clinic for three years. A countersignature is not required if the pharmacist-in-charge or professional director personally completed the inventory reconciliation report.

f) ~~g)~~ A new pharmacist-in-charge of a pharmacy shall complete an inventory reconciliation report ~~within 30 days of becoming pharmacist-in-charge~~ as identified in subdivision (c) within 30 days of becoming pharmacist-in-charge. Whenever possible an outgoing pharmacist-in-charge should also complete an inventory reconciliation report as required in subdivision (c).

g) ~~h)~~ For inpatient hospital pharmacies, a separate quarterly ~~L~~inventory ~~R~~ reconciliation ~~R~~ report shall be required for federal Schedule II controlled substances stored within the pharmacy and for each pharmacy satellite location.

h) ~~i)~~ The pharmacist-in-charge of an inpatient hospital pharmacy or of a pharmacy servicing onsite or offsite automated drug delivery systems shall ensure that:

1) All controlled substances added to an automated drug delivery system are accounted for;
2) Access to automated drug delivery systems is limited to authorized facility personnel;
3) An ongoing evaluation of discrepancies or unusual access associated with controlled substances is performed; and
4) Confirmed losses of controlled substances are reported to the board.~~; and~~
5) ~~A pharmacy or clinic identifying losses of controlled drugs but unable to identify the cause within 30 days shall take additional steps to identify the origin of the losses and improve security of controlled substance access to prevent losses.~~

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4081, 4104, 4105.5, 4119.1, and 4332, Business and Professions Code and 1261.6, Health and Safety Code.

Attachment 11

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 Wholesalers.~~

The following minimum standards shall apply to all wholesale and third-party logistics provider establishments for which permits have been issued by the Board:

(a) A wholesaler and a third-party logistics provider shall store dangerous drugs in a secured and lockable area.

(b) All wholesaler and third-party logistics provider premises, fixtures and equipment therein shall be maintained in a clean and orderly condition. Wholesale and third-party logistics provider premises shall be well ventilated, free from rodents and insects, and adequately lighted. Plumbing shall be in good repair. Temperature and humidity monitoring shall be conducted to assure compliance with the ~~United States Pharmacopeia Standards (1990, 22nd Revision)~~ official compendium.

(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 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, Business and Professions Code; Section 321 of Title 21, U.S. Code; and Section 205.05 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 manufacturer~~s~~, ~~and~~ wholesaler~~s~~ 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.

Attachment 12

Pharmacy Technician

§ 1793.5, 1793.6, 1793.65

Proposal to Amend Title 16 CCR § 1793.5

§ 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 163.5, 4005, 4007, 4038, 4115, 4202, 4207 and 4400, Business and Professions Code. Reference: Sections 163.5, 4005, 4007, 4038, 4115, 4202, 4207, 4402 and 4400, Business and Professions Code; and Section 11105, Penal Code.

California State Board of Pharmacy
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www.pharmacy.ca.gov

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

PHARMACY TECHNICIAN APPLICATION

All items of information requested in this application are mandatory. Failure to provide any of the requested information will result in the application being considered incomplete ~~an incomplete application and a deficiency letter being mailed to you~~. An applicant for a pharmacy technician license, who fails to complete all the application requirements within 60 days after being notified by the board of deficiencies, may be deemed to have abandoned the application and may be required to file a new application, fee, and meet all the requirements which are in effect at the time of reapplication. ~~Please~~ Read all the application instructions before you complete the application.~~prior to completing this application.~~ ~~**Page 1, 2, and 3 of the application must be completed and signed by the applicant.**~~ All questions on this application must be answered. If not applicable indicate N/A. Attach additional sheets of paper if necessary.

Military Expedite ☐ **MILITARY** (Are you serving in the United States military?)
☐ **VETERAN** (Have you ever served in the United States military?)
☐ **ACTIVE DUTY MILITARY-Spouse or Partner (**~~Check here if you meet the requirements for expediting your application.)~~

Applicant Information - Please Type or Print

Applicant Information - Please Type or Print

Full Legal Name: Last Name: First Name: Middle Name:

Previous Names (AKA, Maiden Name, Alias, etc):

*Official Mailing/Public Address of Record (Street Address, PO Box #, etc):

City: State: Zip Code:

Residence Address (if different from above):

City: State: Zip Code:

Home#: ( ) Cell#: ( ) Work#: ( ) Email Address:

Date of Birth (Month/Day/Year): **Social Security # or Individual Tax ID #: Driver's License No: State:

Mandatory Education (check one box)

Please indicate how you satisfy the mandatory education requirement in Business and Professions Code Section 4202(a).

☐ High school graduate or foreign equivalent.
Attach an official embossed transcript or notarized copy of your high school transcript, or certificate of proficiency, or foreign secondary school diploma along with a certified translation of the diploma.

☐ Completed a general education development certificate equivalent.
Attach an official transcript of your test results or certificate of proficiency.

TAPE A COLOR PASSPORT STYLE PHOTOGRAPH (2"X2") TAKEN WITHIN 60 DAYS OF THE FILING OF THIS APPLICATION
NO POLAROID OR SCANNED IMAGES
PHOTO MUST BE ON PHOTO QUALITY PAPER

Pharmacy Technician Qualifying Method (check one box)

Please check one of the boxes below indicating how you qualify in order to apply for a pharmacy technician license pursuant to Section 4202(a)(1)(2)(3)(4) of the Business and Professions Code.

☐ Attached Affidavit of Completed Coursework or Graduation for: Associate degree in Pharmacy Technology, Training Course, or Graduate of a school of pharmacy

☐ Attached is a certified copy of PTCB certificate or ExCPT certificate – Date certified: _____

☐ Attached is a certified copy of your military training DD214

List all state(s) where you hold or held a license as a pharmacist, intern pharmacist and/or pharmacy technician and or another health care profession license, including California. Attach an additional sheet if necessary.

State	Registration Number	Active or Inactive	Issued Date	Expiration Date

Self-Query Report by the National Practitioner Data Bank (NPDB)

☐ Attached is the original sealed envelope containing my Self-Query Report from NPDB. (This must be submitted with your application.)

Photo ☐ Enf 1st Check ☐ Enf 2nd Check ☐ Qualify Code _____ Self-Query ☐	FP Cards/Live Scan ☐ FP Cards Sent _____ FP Fees ☐ DOJ Clear Date: _____ FBI Clear Date: _____	**FOR BOARD USE ONLY** License no. _____ Date issued _____ Date expires _____	App fee no. _____ Amount _____ Date cashiered _____

~~**You must provide a written explanation for all affirmative answers indicated below.**~~ **Please answer the following questions.**
Failure to do so may result in this application being deemed incomplete and being withdrawn.

1. Do you have a mental illness or physical illness that in any way impairs or limits your ability to practice your profession with reasonable skill and safety without exposing others to significant health or safety risks? **If "yes," attach a statement of explanation. If "no," proceed to #2.** Are the limitations caused by your mental illness or physical illness reduced or improved because you receive ongoing treatment or participate in a monitoring program? Yes ☐ No ☐ **If "yes," attach a statement of explanation.** If you do receive ongoing treatment or participate in a monitoring program, the board will make an individualized assessment of the nature, the severity and the duration of the risks associated with an ongoing mental illness or physical illness to determine whether an unrestricted license should be issued, whether conditions should be imposed, or whether you are not eligible for license.	Yes ☐ No ☐
2. Have you previously engaged in the illegal use of controlled substances? If "yes," are you currently participating in a supervised substance abuse program or professional assistance program which monitors you in order to assure that you are not engaging in the illegal use of controlled dangerous substances? Yes ☐ No ☐ **Attach a statement of explanation.**	Yes ☐ No ☐
3. Do you currently participate in a substance abuse program or have previously participated in a substance abuse program in the past five years? If "yes," are you currently participating in a supervised substance abuse program or professional assistance program which monitors you to ensure you are maintaining sobriety? Yes ☐ No ☐ **Attach a statement of explanation.**	Yes ☐ No ☐
4. Has disciplinary action ever been taken against your designated representative, pharmacist, intern pharmacist and/or pharmacy technician license in this state or any other state? **If "yes," attach a statement of explanation to include circumstances, type of action, date of action and type of license, registration or permit involved.**	Yes ☐ No ☐
5. Have you ever had an application for a designated representative, pharmacist, intern pharmacist and/or pharmacy technician license denied in this state or any other state? **If "yes," attach a statement of explanation to include circumstances, type of action, date of action and type of license, registration or permit involved.**	Yes ☐ No ☐
6. Have you ever had a pharmacy license, or any professional or vocational license or registration denied, suspended, revoked, placed on probation or had other disciplinary action taken by this or any other government authority in California or any other state? **If "yes," provide the name of company, type of permit, type of action, year of action and state.** _____	Yes ☐ No ☐

7. Are you currently or have you previously been listed as a corporate officer, partner, owner, manager, member, administrator or medical director on a permit to conduct a pharmacy, wholesaler, medical device retailer or any other entity licensed in this state or any other state? **If "yes," provide company name, type of permit, permit number and state where licensed.**	Yes ☐ No ☐
8. Have you ever been convicted of, or pleaded guilty or nolo contender/no contest to, any crime, in any state, the United States or its territories, a military court, or any foreign country? Include any felony or misdemeanor offense, and any infraction involving drugs or alcohol ~~with a fine of $500 or more~~. You must disclose a conviction even if it was: (1) later dismissed or expunged pursuant to Penal Code section 1203.4 et seq., or an equivalent release from penalties and disabilities provision from a non-California jurisdiction, or (2) later dismissed or expunged pursuant to Penal Code section 1210 et seq., or an equivalent post-conviction drug treatment diversion dismissal provision from a non-California jurisdiction. Failure to answer truthfully and completely may result in the denial of your application. NOTE: You may answer "NO" regarding, and need not disclose, any of the following: (1) criminal matters adjudicated in juvenile court; (2) criminal charges dismissed or expunged pursuant to Penal Code section 1000.4 or an equivalent deferred entry of judgment provision from a non-California jurisdiction; (3) convictions more than two years old on the date you submit your application for violations of California Health and Safety Code section 11357, subdivisions (b), (c), (d), or (e), or California Health and Safety Code section 11360, subdivision (b); and (4) infractions or traffic violations ~~with a fine of less than $500~~ that do not involve drugs or alcohol. ~~You may wish to provide the following information in order to assist in the processing of your application: descriptive explanation of the circumstances surrounding the conviction (i.e. dates and location of incident and all circumstances surrounding the incident). If documents were purged by the arresting agency and/or court, a letter of explanation from these agencies is required.~~ You may wish to provide the following information in order to assist in the processing of your application: 1) certified copies of the arresting agency report; 2) certified copies of the court documents; 3) and a descriptive explanation of the circumstances surrounding the conviction (i.e. dates and location of incident and all circumstances surrounding the incident.) If documents were purged by the arresting agency and/or court, a letter of explanation from these agencies is required. **Failure to disclose a disciplinary action or conviction may result in the license being denied or revoked for falsifying the application. Attach additional sheets if necessary.**	Yes ☐ No ☐

Arrest Date	Conviction Date	Violation(s)	Case #	Court of Jurisdiction (Full Name and Address)

APPLICANT AFFIDAVIT

~~You must provide a written explanation for all affirmative answers. Failure to do so will result in this application being deemed incomplete.~~ Falsification of the information on this application may constitute ground for denial or revocation of the license.

All items of information requested in this application are mandatory. Failure to provide any of the requested information may result in the application being rejected as incomplete.

Collection and Use of Personal Information. The California State Board of Pharmacy of the Department of Consumer Affairs collects the personal information requested on this form as authorized by Business and Professions Code sections 4200 and 4202 and Title 16 California Code of Regulations section 1793.5 and 1793.6. The California State Board of Pharmacy uses this information principally to identify and evaluate applicants for licensure, issue and renew licenses, and enforce licensing standards set by law and regulation.

Mandatory Submission. Submission of the requested information is mandatory. The California State Board of Pharmacy cannot consider your application for licensure or renewal unless you provide all of the requested information.

Access to Personal Information. You may review the records maintained by the California State Board of Pharmacy that contain your personal information, as permitted by the Information Practices Act. The official responsible for maintaining records is the Executive Officer at the board's address listed on the application. Each individual has the right to review the files or records maintained by the board, unless confidential and exempt by law ~~Civil Code Section 1798.40~~.

Possible Disclosure of Personal Information. We make every effort to protect the personal information you provide us. The information you provide, however, may be disclosed in the following circumstances:

- In response to a Public Act request (Government Code section 6250 and following), as allowed by the Information Practices Act (Civil Code section 1798 and following);
- To another government agency as required or permitted by state or federal law; or
- In response to a court or administrative order, a subpoena, or a search warrant.

*Once you are licensed with the board, the address of record you enter on this application is considered public information pursuant to the Information Practices Act (Civil Code section 1798 et seq.) and the Public Records Act (Government Code section 6250 et seq.) and will be ~~placed~~ available on the Internet. This is where the board will mail all official correspondence. If you do not wish your residence address to be available to the public, you may provide a post office box number or a personal mail box (PMB). However, if your address of record is not your residence address, you must also provide your residence address to the board, in which case your residence will not be available to the public.

**Disclosure of your U.S. social security account number or individual taxpayer identification number is mandatory. Section 30 of the Business and Professions Code, Section 17520 of the Family Code, and Public Law 94-455 (42 USC § 405(c)(2)(C)) authorize collection of your social security account number. Your social security account number will be used exclusively for tax enforcement purposes, for purposes of compliance with any judgment or order for child or family support in accordance with section 17520 of the Family Law Code, or for verification of license or examination status by a licensing or examination entity which utilizes a national examination and where licensure is reciprocal with the requesting state. If you fail to disclose your social security account number, your application will not be processed and you may be reported to the Franchise Tax Board, which may assess a $100 penalty against you.

MANDATORY REPORTER

Under California law, each person licensed by the California State Board of Pharmacy is a "mandated reporter" for both child and elder abuse or neglect ~~purposes~~ laws.

California Penal Code Section 11166 and Welfare and Institutions Code Section 15630 require that all mandated reporters make a report to an agency specified in Penal Code Section 11165.9 and Welfare and Institutions Code Section 15630(b)(1) [generally law enforcement, state and/or county adult protective services agencies, etc.] whenever the mandated reporter, in his or her professional capacity or within the scope of his or her employment, has knowledge of or observes a child, elder and/or dependent adult whom the mandated reporter knows or reasonably suspects has been the victim of child abuse or elder abuse or neglect. The mandated reporter must contact by telephone immediately or as soon as possible, to make a report to the appropriate agency(ies) or as soon as practicably possible. The mandated reporter must prepare and send a written report thereof within two working days or 36 hours of receiving the information concerning the incident.

Failure to comply with the requirements of ~~Section 11166 and Section 15630~~ the laws above is a misdemeanor, punishable by up to six months in a county jail, by a fine of one thousand dollars ($1,000), or by both that imprisonment and fine. For further details about these requirements, ~~consult~~ refer to Penal code section 11164 and Welfare and Institutions Code section 15630, and ~~subsequent~~ following sections.

APPLICANT AFFIDAVIT

(must be signed and dated by the applicant)

I, _____ , hereby attest to the fact that I am the applicant whose signature appears
(Print full Legal Name)

below. I hereby certify under penalty of perjury under the laws of the State of California to the truth and accuracy of all statements, answers and representations made in this application, including all supplementary statements. I understand that my application may be denied, or any license disciplined, for fraud or misrepresentation.

_____ _____

Original Signature of Applicant (signed and dated by the applicant within 60 days of filing the application) Date

California State Board of Pharmacy
1625 N. Market Blvd, Suite N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

AFFIDAVIT OF COMPLETED COURSEWORK OR GRADUATION FOR PHARMACY TECHNICIAN

Instructions: This form must be completed by the university, college, school, or pharmacist (The person who must complete this form will depend on how the applicant is qualifying). All dates must include the month, day, and year in order for the form to be accepted.

This is to certify that _____ has
Print Name of Applicant

☐ Completed a pharmacy technician training program accredited by the American Society of Health-System Pharmacists as specified in Title 16 California Code of Regulations Section 1793.6(a) on _____/_____/_____
(completion date must be included)

☐ Completed 240 hours of instruction as specified in Title 16 California Code of Regulations Section 1793.6(c) on _____/_____/_____
(completion date must be included)

☐ Completed an Associate Degree in Pharmacy Technology and was conferred on her/him on _____/_____/_____
(graduation date must be included)

☐ Graduated from a school of pharmacy accredited by the American Council on Pharmaceutical Education (ACPE). The degree of Bachelor of Science in Pharmacy or the degree of PharmD was conferred on her/him on _____/_____/_____
(graduation date must be included)

I hereby certify under penalty of perjury under the laws of the State of California to the truth and accuracy of the above:

Signed: _____ Title: _____ Date: _____/_____/_____

Affix school seal here. **OR** **Attach a business card of the pharmacist who provided the training pursuant to Section 1793.6(c) of the California Code of Regulation here. The pharmacist's license number shall be listed.**	University, College, or School of Pharmacy Name: _____ Address: _____ _____ Print Name of Director, Registrar, or Pharmacist: _____ Phone Number: _____ Email: _____

Draft Proposal to Amend Title 16 California Code of Regulations Section 1793.6

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:

(~~1~~ 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 Section 1793.65

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.

Attachment 13

Compounding Self-Assessment § 1735.2

1735.2. Compounding Limitations and Requirements; Self-Assessment.

(k) Prior to allowing any drug product preparation to be compounded in a pharmacy, the pharmacist-in-charge shall complete a self-assessment for compounding pharmacies developed by the board (Incorporated by reference is "Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment" Form 17M-39 Rev. ~~02/12~~ 12/2016.) as required by Section 1715 of Title 16, Division 17, of the California Code of Regulations. That form contains a first section applicable to all compounding, and a second section applicable to sterile injectable compounding. The first section must be completed by the pharmacist-in-charge before any compounding is performed in the pharmacy. The second section must be completed by the pharmacist-in-charge before any sterile compounding is performed in the pharmacy. The applicable sections of the self-assessment shall subsequently be completed before July 1 of each odd-numbered year, within 30 days of the start date of a new pharmacist-in-charge or change of location, and within 30 days of the issuance of a new pharmacy license. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

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Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment

The California Code of Regulations section 1735.2 requires the pharmacist-in-charge of each pharmacy licensed under section 4037 or 4029 of the Business and Professions Code that compounds drug preparations to complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. **The assessment shall be performed before July 1 of every odd-numbered year. The pharmacist-in-charge must also complete a self-assessment within 30 days whenever; (1) a new pharmacy permit has been issued, or (2) there is a change in the pharmacist-in-charge; or (3) there is a change in the licensed location of the pharmacy. The primary purpose of the self-assessment is to promote compliance through self-examination and education.**

The self-assessment must be completed in its entirety and may be completed online, printed, readily retrievable and retained in the pharmacy. Do not copy a previous assessment.

Each self-assessment must be kept on file in the pharmacy for three years after it is performed.

Pharmacy Name: _____

Address: _____ Phone: _____

Fax: _____

Ownership: Sole Owner ☐ Partnership ☐ Corporation ☐ LLC ☐ Trust☐
Non-Licensed Owner ☐ Other (please specify) ☐ _____

License #: _____ Exp. Date: _____ Other License #: _____ Exp. Date: _____

Licensed Sterile Compounding License # _____ Expiration: _____

Accredited by: _____ From: _____ To: _____

Centralized Hospital Packaging License #: _____ Exp. Date: _____

Hours: Weekdays_ _____ Sat _____ Sun. _____ 24 Hours _____

PIC: _____ RPH # _____ Exp. Date: _____

Website address (optional): _____

DRAFT

_____
PIC Initials

Pharmacy Staff (pharmacists, intern pharmacists, pharmacy technicians assigned to compounding duties):
(Please use an additional sheet if necessary)

1. _____ RPH # _____ Exp. Date: _____
   APH # _____ Exp. Date: _____

2. _____ RPH # _____ Exp. Date: _____
   APP # _____ Exp. Date: _____

3. _____ RPH # _____ Exp. Date: _____
   APH # _____ Exp. Date: _____

4. _____ RPH # _____ Exp. Date: _____
   APH # _____ Exp. Date: _____

5. _____ RPH # _____ Exp. Date: _____
   APH # _____ Exp. Date: _____

6. _____ RPH # _____ Exp. Date: _____
   APH # _____ Exp. Date: _____

7. _____ RPH # _____ Exp. Date: _____
   APH # _____ Exp. Date: _____

8. _____ INT # _____ Exp. Date: _____

9. _____ INT # _____ Exp. Date: _____

10. _____ INT # _____ Exp. Date: _____

11. _____ TCH # _____ Exp. Date: _____

12. _____ TCH # _____ Exp. Date: _____

13. _____ TCH # _____ Exp. Date: _____

14. _____ TCH # _____ Exp. Date: _____

15. _____ TCH # _____ Exp. Date: _____

DRAFT

_____
PIC Initials

COMPOUNDING SELF-ASSESSMENT

All references to the California Code of Regulations (CCR) are to Title 16 unless otherwise noted. Please mark the appropriate box for each question. If "NO", enter an explanation on "CORRECTIVE ACTION OR ACTION PLAN" lines at the end of the section. If more space is needed, you may add additional sheets.

ALL COMPOUNDING Complete Sections 1 through 8.

1. Definitions (CCR 1735 and 1735.1)

Yes No N/A

☐☐☐ 1.1 The pharmacy compounds as defined in CCR 1735(a).

☐☐☐ 1.2 Each pharmacist involved with compounding understands the definitions in CCR 1735.1.

2. Compounded Limitations and Requirements (CCR 1735.2)

Yes No N/A

☐☐☐ 2.1 The pharmacy does not compounded drug preparations prior to receipt of a valid prescription unless under the following conditions as allowed in CCR 1735.2 (b-c) (CCR 1735.2(a)). See sections 2.2 and 2.3

☐☐☐ 2.2 The pharmacy prepares and stores a limited quantity of a compounded drug preparation in advance of receipt of a patient specific prescription solely in such quantity as is necessary to ensure continuity of care of an identified population as defined in CCR 1735.2(b).

☐☐☐ 2.3 The pharmacy compounds a reasonable quantity of drug preparation which is furnished to a prescriber for office use upon prescriber order as allowed in CCR 1735.2(c) and under all of the following requirements:

- 2.3.1 Is ordered by the prescriber or the prescribers' agent on a purchase order or other documentation received by the pharmacy prior to furnishing that lists the number of patients seen or to be seen in the prescriber's office for whom the drug is needed or anticipated, and the quantity for each patient sufficient for office administration; (CCR 1735.2[c][1]) **AND**
- 2.3.2 Is delivered to the prescriber's office and signed for by the prescriber or the prescriber's agent; (CCR 1735.2[c][2]) **AND**
- 2.3.3 Is sufficient for administration or application to patients in the prescriber's office or for distribution of not more than a 120-hour supply for veterinary medical practices; (CCR 1735.2[c][3]) **AND**
- 2.3.4 The pharmacist has a credible basis for concluding it is a reasonable quantity for office use considering the intended use of the compounded preparation and the nature of the prescriber's practice; (CCR 1735.2[c][4]) **AND**
- 2.3.5 Is an amount which the pharmacy is capable of compounding in compliance with pharmaceutical standards for integrity, potency, quality and strength of the compounded drug preparation; (CCR 1735.2[c][5]) **AND**
- 2.3.6 Does not exceed an amount the pharmacy can reasonably and safely compound. (CCR 1735.2[c][6])

☐☐☐ 2.4. The pharmacy does NOT compound drug preparations that: (CCR 1735.2[d])

- 2.4.1 Are classified by the FDA as demonstrably difficult to compound; (CCR 1735.2[d][1])

DRAFT

_____
PIC Initials

2.4.2 Appear on an FDA list of drugs that have been withdrawn or removed from the market; (CCR 1735.2[d][2]) or

2.4.3 Are copies or essentially copies of one or more commercially available drug products. (CCR 1735.2[d][3])

Yes No N/A

☐☐☐ 2.5 The pharmacy does not compound drug preparations until it has prepared a written master formula document that includes the following elements: (CCR 1735.2[e][1-8])

- 2.5.1 Active ingredients used.
- 2.5.2 Equipment to be used.
- 2.5.3 Beyond use date (BUD).
- 2.5.4 Inactive ingredients used.
- 2.5.5 Specific and essential compounding steps.
- 2.5.6 Quality reviews required at each step.
- 2.5.7 Post-compounding process or procedures, if required.
- 2.5.8 Instructions for storage and handling.

☐☐☐ 2.6 The master formula for a drug preparation not routinely compounded by the pharmacy may be recorded on the prescription document itself. (CCR 1735.2[f])

☐☐☐ 2.7 The pharmacists performing or supervising compounding understand they are responsible for the integrity, potency, quality, and labeled strength of a compounded drug preparation until the beyond use date indicated on the label, so long as label instructions for storage and handling are followed after the preparation is dispensed. (CCR 1735.2[g])

☐☐☐ 2.8 All chemicals, bulk drug substances, drug preparations and other components used for drug compounding are stored and used according to compendia and other applicable requirements to maintain their integrity, potency, quality and labeled strength. (CCR 1735.2[h])

☐☐☐ 2.9 Every compounded drug preparation is given a 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 is determined based on the professional judgment of the pharmacist performing or supervising the compounding. (CCR 1735.2[i])

- 2.9.1 For non-sterile compounded drug preparations, the beyond use date does not exceed any of the following: (CCR 1735.2[i][1][A-F])
  - 2.9.1.1 The shortest expiration date or beyond use date of any ingredient in the compounded drug preparation,
  - 2.9.1.2 The chemical stability of any one ingredient in the compounded drug preparation;
  - 2.9.1.3 The chemical stability of the combination of all ingredients in the compounded drug preparation,
  - 2.9.1.4 180 days for non-aqueous formulations,
  - 2.9.1.5 14 days for water-containing oral formulations, and
  - 2.9.1.6 30 days for water-containing topical/dermal and mucosal liquid and semisolid formulations.
- 2.9.2 For sterile compounded drug preparations, the beyond use date does not exceed any of the following: (CCR 1735.2[i][2][A-D])
  - 2.9.2.1 The shortest expiration date or beyond use date of any ingredient in the sterile compounded drug preparation,
  - 2.9.2.2 The chemical stability of any one ingredient in the sterile compounded drug preparation,
  - 2.9.2.3 The chemical stability of the combination of all ingredients in the sterile compounded drug preparation, and
  - 2.9.2.4 The beyond use date assigned for sterility in CCR 1751.8.
- 2.9.3 Extension of a beyond use date is supported by the following: (CCR 1735.2[i][3][A-C])
  - 2.9.3.1 Method Suitability Test,
  - 2.9.3.2 Container Closure Integrity Test, and

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2.9.3.3 Stability Studies.

2.9.4 The finished drugs or compounded drug preparations tested and studied are compounded using the same identical components or ingredients, specific and essential compounding steps, quality reviews, and packaging as the finished drug or compounded drug preparation. (CCR 1735.2[i][4])

2.9.5 Shorter dating is used if it is deemed appropriate in the professional judgment of the responsible pharmacist. (CCR 1735.2[i][5])

☐☐☐ 2.10 Self-assessment is completed, as required, prior to compounding a drug preparation. (CCR 1735.2[k])

☐☐☐ 2.11 Packages of ingredients, both active and inactive, which lack a supplier's expiration date are subject to the following limitations: (CCR 1735.2[l])

2.11.1 Ingredients are not used for any non-sterile compounded drug preparation more than three (3) years after the date of receipt by the pharmacy.

2.11.2 Ingredients are not used for any sterile compounded drug preparation more than one (1) year after the date of receipt by the pharmacy.

CORRECTIVE ACTION OR ACTION PLAN: _____

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3. Recordkeeping for Compounded Drug Preparation (CCR 1735.3)

Yes No N/A

☐☐☐ 3.1 The pharmacy makes and retains a record for each compounded drug preparation which includes, at least, the following: (CCR 1735.3[a][1-2])

3.1.1 The master formula document.

3.1.2 A compounding log consisting of a single document containing all of the following:

3.1.2.1 The name and strength of the compounded drug preparation.

3.1.2.2 The date the drug preparation was compounded.

3.1.2.3 The identity of the pharmacy personnel who compounded the drug preparation.

3.1.2.4 The identity of the pharmacist reviewing the final drug preparation.

3.1.2.5 The quantity of each component used in compounding the drug preparation.

3.1.2.6 The manufacturer or supplier, expiration date and lot number of each component.

3.1.2.7 The pharmacy assigned reference or lot number for the compounded drug preparation.

3.1.2.8 The beyond use date or beyond use date and time of the final compounded drug preparation.

3.1.2.9 The final quantity or amount of drug preparation compounded.

3.1.2.10 Documentation of quality reviews and required post-compounding process and procedures.

☐☐☐ 3.2 The pharmacy maintains records of the proper acquisition, storage, and destruction of chemicals, bulk drug substances, components and drug preparations used in compounding. (CCR 1735.3[b])

☐☐☐ 3.3 Active ingredients are obtained from a supplier registered with the Food and Drug Administration (FDA). All other chemicals, bulk drug substances, and drug components used to compound drug preparations are to be obtained, whenever possible, from FDA-registered suppliers. The pharmacy acquires and retains certificates of purity or analysis, either written in English or translated into English, for chemicals, bulk drug substances, and drug products used in compounding. (CCR 1735.3[c])

☐☐☐ 3.5 The pharmacy maintains and retains all records required in the pharmacy in a readily retrievable form for at least three years (CCR 1735.3[d]).

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4. Labeling of Compounded Drug Preparation (CCR 1735.4)

Yes No N/A

☐☐☐ 4.1 Each compounded drug preparation has at least the following affixed to the container on a label prior to dispensing: (CCR 1735.4[a][1-6])

- 4.1.1 Name of the compounding pharmacy and dispensing pharmacy (if different);
- 4.1.2 Name (brand or generic) and strength, volume, or weight of each active ingredient. For admixed intravenous (IV) solutions, the IV solution utilized shall be included;
- 4.1.3 Instructions for storage, handling, and administration. For admixed IV solutions, the rate of infusion shall be included;
- 4.1.4 The beyond use date for the drug preparation;
- 4.1.5 The date compounded; and
- 4.1.6 The lot number or pharmacy reference number.

☐☐☐ 4.2 Any compounded drug preparation dispensed to a patient or readied for dispensing to a patient is labeled with the information required under Business and Professions Code section 4076 and California Code of Regulations, title 16, section 1707.5. (CCR 1735.4[b])

☐☐☐ 4.3 Any compounded drug preparation dispensed to a patient or readied for dispensing to a patient also includes, on the container label or on a receipt provided to the patient, a statement the drug preparation has been compounded by the pharmacy. (CCR 1735.4[c])

☐☐☐ 4.4 Drug preparations compounded into unit-dose containers that are too small or otherwise impractical for full compliance with the requirements of CCR 1735.4(a), (b), and (c) are labeled with at least the name(s) of the active ingredient(s), concentration of strength, volume or weight, pharmacy reference or lot number, and beyond use date. (CCR 1735.4[d])

☐☐☐ 4.5 All hazardous agents bear a special label which states "Chemotherapy - Dispose of Properly" or "Hazardous – Dispose of Properly. (CCR 1735.4[e])

CORRECTIVE ACTION OR ACTION PLAN: _____

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5. Compounding Policies and Procedures (CCR 1735.5)

Yes No N/A

☐☐☐ 5.1 The pharmacy maintains written policies and procedure for compounding which establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding. (CCR 1735.5[a])

☐☐☐ 5.2 The policy and procedures are reviewed on an annual basis by the pharmacist-in-charge and are updated whenever changes are implemented. (CCR 1735.5[b])

☐☐☐ 5.3 The policies and procedures include at least the following: (CCR 1735.5[c][1-11])

- 5.3.1 Procedures for notifying staff assigned to compounding duties of any changes in policies or procedures.
- 5.3.2 A written plan for recall of a dispensed compounded drug preparation where subsequent information demonstrates the potential for adverse effects with continued use. The plan ensures

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all affected doses can be accounted for during the recall and shall provide steps to identify which patients received the affected lot or compounded drug preparation(s).

5.3.3 Procedures for maintaining, storing, calibrating, cleaning, and disinfecting equipment used in compounding, and for training on these procedures as part of the staff training and competency evaluation process.

5.3.4 Procedures for evaluating, maintaining, certifying, cleaning, and disinfecting the facility (physical plant) used for compounding, and for training on these procedures as part of the staff training and competency evaluation process.

5.3.5 Documentation of the methodology used to validate integrity, potency, quality, and labeled strength of compounded drug preparations. The methodology must be appropriate to compounded drug preparations.

5.3.6 Documentation of the methodology and rationale or reference source used to determine appropriate beyond use dates for compounded drug preparations.

5.3.7 Dates and signatures reflecting all annual reviews of the policies and procedures by the pharmacist-in-charge.

5.3.8 Dates and signatures accompanying any revisions to the policies and procedures approved by the pharmacist-in-charge.

5.3.9 Policies and procedures for storage of compounded drug preparations in the pharmacy and daily documentation of all room, refrigerator, and freezer temperatures within the pharmacy.

5.3.10 Policies and procedures for ensuring appropriate functioning of refrigeration devices, monitoring refrigeration device temperatures, and actions to take regarding any out of range temperature variations within the pharmacy.

5.3.11 Policies and procedures for proper garbing when compounding with hazardous products; including when to utilize double shoe covers.

CORRECTIVE ACTION OR ACTION PLAN: _____

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6. Compounding Facilities and Equipment (CCR 1735.6)

Yes No N/A

☐☐☐ 6.1 The pharmacy maintains written documentation regarding the facilities and equipment necessary for safe and accurate compounding of compounded drug preparations which includes records of certification of facilities or equipment, if applicable. (CCR 1735.6[a])

☐☐☐ 6.2 All equipment used to compound a drug preparation is stored, used and maintained in accordance with manufacturers' specifications. (CCR 1735.6[b])

☐☐☐ 6.3 All equipment used to compound a drug preparation is calibrated prior to use to ensure accuracy. (CCR 1735.6[c])

6.3.1 Documentation of each calibration is recorded in a form which is not alterable and is maintained and retained in the pharmacy.

☐☐☐ 6.4 When engaged in hazardous drug compounding, the pharmacy maintains written documentation regarding appropriate cleaning of facilities and equipment to prevent cross-contamination with non-hazardous drugs. (CCR 1735.6[d])

☐☐☐ 6.5 Hazardous drug compounding is completed in an externally vented physically separate room with the following requirements: (CCR 1735.6[e])

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6.5.1 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 preparations are assigned a BUD of 12 hrs or less or when nonsterile products are compounded; and

6.5.2 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

6.5.3 Each PEC in the room is externally vented; and

6.5.4 All surfaces within the room are smooth, seamless, impervious, and non-shedding.

☐☐☐ 6.6 This pharmacy has applied and was granted a waiver by the board for the following physical construction or alteration to a facility or physical environment. (CCR 1735.6[f])

☐☐☐ 6.6.1 Waiver approved the Board. Please see attached.

CORRECTIVE ACTION OR ACTION PLAN:

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7. Training of Compounding Staff (CCR 1735.7)

Yes No N/A

☐☐☐ 7.1 The pharmacy maintains documentation demonstrating personnel involved in compounding have the skills and training required to properly and accurately perform their assigned responsibilities and documentation demonstrating all personnel involved in compounding are trained in all aspects of policies and procedures. This training includes, but is not limited to, support personnel (e.g. institutional environmental services, housekeeping), maintenance staff, supervising pharmacists and all others whose jobs are related to the compounding process. (CCR 1735.7[a])

☐☐☐ 7.2 The pharmacy has developed and maintains an ongoing competency evaluation process for pharmacy personnel involved in compounding and shall maintain documentation of any and all training related to compounding undertaken by pharmacy personnel. (CCR 1735.7[b])

☐☐☐ 7.3 Pharmacy personnel assigned to compounding duties demonstrate knowledge about processes and procedures used in compounding prior to compounding any drug preparation. (CCR 1735.7[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

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8. Compounding Quality Assurance (CCR 1735.8)

Yes No N/A

☐☐☐ 8.1 The pharmacy maintains, as part of its written policies and procedures, a written quality assurance plan to monitor and ensure the integrity, potency, quality and labeled strength of compounded drug preparation. (CCR 1735.8[a])

☐☐☐ 8.2 The pharmacy's quality assurance plan includes the written procedures and standards for at least the following:

8.2.1 Verification, monitoring and review of the adequacy of the compounding processes as well as documentation of review of those processes by qualified pharmacy personnel. (CCR 1735.8[b])

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8.2.2 Qualitative and quantitative analysis of compounded drug preparations to ensure integrity, potency, quality and labeled strength, including the frequency of testing. Frequency of routine testing and analysis is done on an annual basis. (CCR 1735.8[c])

8.2.3 Such reports are retained by the pharmacy and collated with the compounding record and master formula document. (CCR 1735.8[c])

8.2.4 Scheduled action in the event any compounded drug preparation is ever discovered to be below minimum standards for integrity, potency, quality or labeled strength. (CCR 1735.8[d])

8.2.5 Response to out-of-range temperature variations within the pharmacy and within patient care areas of a hospital where furnished drug is returned for redispensing. (CCR 1735.8[e])

9. Duties of a Pharmacy Issuing a Compounded Drug Recall (B&PC 4126.9)

Yes No N/A

☐☐☐ 9.1 When the pharmacy issues a recall notice regarding a nonsterile compounded drug product, in addition to any other duties all of the following take place, contact the recipient pharmacy, prescriber, or patient of the recalled drug and the board within 12 hours of the recall notice if both of the following apply: (B&PC 4126.9[a][1-2])

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

9.1.2 The recalled drug was dispensed, or is intended for use, in this state.

☐☐☐ 9.2 A recall notice issued pursuant to subdivision (a) is made as follows: (B&PC 4126.9[b][1-3])

9.2.1 If the recalled drug was dispensed directly to the patient, the notice is be made to the patient.

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

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

☐☐☐ 9.3 If the pharmacy has been advised that a patient has been harmed by using a nonsterile compounded product potentially attributable to the pharmacy reports the event to MedWatch within 72 hours of the pharmacy being advised. (B&PC 4126.9[c])

COMPOUNDING STERILE DRUGS

Does the pharmacy compound sterile drug preparation? (B&PC 4127)

☐ **Yes** ☐ **No**

If yes, complete Sections 9 through 25.

FOR PHARMACIES THAT COMPOUND STERILE DRUG preparation:

10. Compounding Drug for Other Pharmacy for Parenteral Therapy

Yes No N/A

☐☐☐ 10.1 Any pharmacy that contracts to compound a drug for parenteral therapy, pursuant to a prescription, for delivery to another pharmacy shall report that contractual arrangement to the board. (B&PC 4123)

10.1.1 The contractual arrangement is reported to the board within 30 days of commencing that compounding.

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11. Compounding Sterile from Nonsterile Ingredients; Requirements

Yes No N/A

☐☐☐ 11.1 The pharmacy compounds sterile preparations from one or more nonsterile ingredients in one of the following environments: (B&PC 4127.7)

- 11.1.1 An ISO Class 5 laminar airflow hood within an ISO Class 7 cleanroom. (B&PC 4127.7[a])
- 11.1.2 An ISO Class 5 cleanroom. (B&PC 4127.7[b])
- 11.1.3 A barrier isolator that provides an ISO Class 5 environment for compounding. (B&PC 4127.7[c])

12. Sterile Compounding; Compounding Area (CCR 1751)

Yes No N/A

☐☐☐ 12.1 The pharmacy conforms to the parameters and requirements stated by Article 4.5 (Section 1735 et seq.), applicable to all compounding, and shall also conform to the parameters and requirements stated by this Article 7 (Section 1751 et seq.), applicable solely to sterile compounding. (CCR 1751[a])

Yes No N/A

☐☐☐ 12.2 The pharmacy has a compounding area designated for the preparation of sterile drug preparations in a restricted location where traffic has no impact on the performance of the Primary Engineering Control(s) (PEC). (CCR 1751[b])

- 12.2.1 The cleanroom, including the walls, ceilings, and floors, are constructed in accordance with Section 1250.4 of Title 24, Part 2, Chapter 12, of the California Code of Regulations.
- 12.2.2 The pharmacy is ventilated in a manner in accordance with Section 505.5 of Title 24, Part 4, Chapter 5 of the California Code of Regulations.
- 12.2.3 The environments within the pharmacy meet at least the following standards: (CCR 1751[b])
  - 12.2.3.1 Each ISO environment is certified at least every six months by a qualified technician in accordance with Section 1751.4.
    - 12.2.3.1.1 Certification records must be retained in the pharmacy.
  - 12.2.3.2 Items related to the compounding of sterile drug preparations within the compounding area are stored in such a way as to maintain the integrity of an aseptic environment.
  - 12.2.3.3 A sink is included in accordance with Section 1250.4 of Title 24, Part 2, Chapter 12, of the California Code of Regulations. Sinks and drains are not present in any ISO Class 7 or better cleanroom, nor in a segregated sterile compounding area within three feet of an ISO Class 5 or better PEC, with the exception of emergency eye-rinsing stations. A sink may be located in an ante-area.
  - 12.3.3.4 There is a refrigerator and where appropriate, a freezer, of sufficient capacity to meet the storage requirements for all material requiring refrigeration or freezing, and a backup plan is in place to ensure continuity of available compounded drug preparations in the event of a power outage.

13. Sterile Compounding; Compounding Area (CCR 1250.4, 505.5 and 505.5.1)

TITLE 24, PART 2, CHAPTER 12, REGULATIONS

Yes No N/A

☐☐☐ 13.1 The pharmacy has designated area for the preparation of sterile products for dispensing which meets at least the following: (24 CCR 1250.4)

- 13.1.1 In accordance with Federal Standard 209(b), Clean Room and Work Station Requirements, Controlled Environment, as approved by the Commission, Federal Supply Service, General Services Administration meet standards for class 100 HEPA (high efficiency particulate air) filtered air such as laminar air flow hood or clean room. (24 CCR 1250.4[1])

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PIC Initials

13.1.2 Has non-porous and cleanable surfaces, walls, floors, ceilings and floor coverings. (24 CCR 1250.4[2])

13.1.3 The pharmacy is arranged in such a manner that the laminar-flow hood (PEC) is located in an area which is exposed to minimal traffic flow, and is separate from any area used for bulk storage of items not related to the compounding of parenteral preparations. There is sufficient space, well separated from the laminar-flow hood area, for the storage of bulk materials, equipment and waste materials. (24 CCR 1250.4[3])

13.1.4 A sink with hot and cold running water is within the parenteral preparation compounding area or adjacent to it. (24 CCR 1250.4[4])

13.1.5 The pharmacy compounding sterile injectable preparations from one or more nonsterile ingredients, compounds the preparations in one of the following environments: (24 CCR 1250.4[5])

13.1.5.1 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.

13.1.5.2 An ISO Class 5 cleanroom.

13.1.5.3 A barrier isolator that provides an ISO Class 5 environment for compounding.

Yes No N/A

☐☐☐ 13.2 The pharmacy has a designated area for the compounding of sterile preparations for dispensing which shall: (24 CCR 505.5)

13.2.1 Be ventilated in a manner not interfering with laminar air flow.

Yes No N/A

☐☐☐ 13.3 Pharmacies preparing parenteral cytotoxic agents, all compounding is conducted within a certified Class II Type A or Class II Type B vertical laminar air flow hood with bag in-bag out design. The pharmacy ensures that contaminated air plenums under positive air pressure are leak tight. (24 CCR 505.5.1)

CORRECTIVE ACTION OR ACTION PLAN: _____

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14. Sterile Compounding Recordkeeping Requirements. (CCR 1751.1)

Yes No N/A

☐☐☐ 14.1 In addition to the records required by section 1735.3 the pharmacy maintains at least the following records, which are in a readily retrievable, within the pharmacy: (CCR 1751.1[a][1-11])

14.1.1 Documents evidencing training and competency evaluations of employees in sterile drug preparation policies and procedures.

14.1.2 Results of hand hygiene and garbing assessments with integrated gloved fingertip testing.

14.1.3 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.

14.1.4 Results of viable air and surface sampling.

14.1.5 Video of smoke studies in all ISO certified spaces.

14.1.6 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:

14.1.6.1 Controlled room temperature.

14.1.6.2 Controlled cold temperature.

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14.1.6.3 Controlled freezer temperature.

14.1.7 Certification(s) of the sterile compounding environment(s).

14.1.8 Documents indicating daily documentation of air pressure differentials or air velocity measurements between all adjoining ISO rooms or areas, including those associated with compounding aseptic (containment) isolators, and air pressure differentials or air velocity measurements between all rooms or spaces with an immediate entry or opening to ISO rooms or areas.

14.1.9 Other facility quality control records specific to the pharmacy's policies and procedures (e.g., cleaning logs for facilities and equipment, incubator temperatures).

14.1.10 Logs or other documentation of inspections for expired or recalled chemicals, bulk drug substances, drug products, or other ingredients.

14.1.11 Preparation records including the master formula document, the preparation compounding log, and records of end-product evaluation testing and results.

☐☐☐ 14.2 The pharmacy compounds for future use pursuant to section 1735.2, and in addition to those records required by section 1735.3, the pharmacy makes and keeps records indicating the name, lot number, and amount of any drug preparation compounded for future use, the date on which any preparation was provided to a prescriber, and the name, address, license type and number of the prescriber. (CCR 1751.1[b])

☐☐☐ 14.3 The pharmacy maintains and retains all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was created. If only recorded and stored electronically, on magnetic media, or in any other computerized form, the records are maintained as specified by Business and Professions Code section 4070 subsection (c). (CCR 1751.1[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

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15. Sterile Labeling Requirements (CCR 1751.2)

Yes No N/A

☐☐☐ 15.1 In addition to the labeling information required under Business and Professions Code section 4076 and California Code of Regulations, title 16, sections 1707.5 and 1735.4, the pharmacy labels each compounded sterile drug preparations with at least the following information: (CCR 1751.2[a-c])

15.1.1 The telephone number of the pharmacy.

15.1.2 Instructions for storage, handling, and administration.

15.1.3 All hazardous agents shall bear a special label which states "Chemotherapy - Dispose of Properly" or "Hazardous – Dispose of Properly.":

CORRECTIVE ACTION OR ACTION PLAN: _____

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16. Sterile Policies and Procedures (CCR 1751.3)

Yes No N/A

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☐☐☐ 16.1 The pharmacy maintains written policies and procedures for compounding and understands any material failure to follow the pharmacy's written policies and procedures shall constitute a basis for disciplinary action. CCR 1751.3[a])

16.2 In addition to the elements required by section 1735.5, there are written policies and procedures regarding at least the following: (CCR 1751.3[a][1-24])

- 16.2.1 Action levels for colony-forming units (CFUs) detected during viable surface sampling, glove fingertip, and viable air sampling and actions to be taken when the levels are exceeded.
- 16.2.2 Airflow considerations and pressure differential monitoring.
- 16.2.3 An environmental sampling plan and procedures specific to viable air, surface and gloved fingertip sampling as well as nonviable particle sampling.
- 16.2.4 Cleaning and maintenance of ISO environments and segregated compounding areas.
- 16.2.5 Compounded sterile drug preparation stability and beyond use dating.
- 16.2.6 Compounding, filling, and labeling of sterile drug preparations.
- 16.2.7 Daily and monthly cleaning and disinfection schedule for the controlled areas and any equipment in the controlled area as specified in section 1751.4.
- 16.2.8 Depyrogenation of glassware (if applicable)
- 16.2.9 Facility management including certification and maintenance of controlled environments and related equipment.
- 16.2.10 For compounding aseptic isolators and compounding aseptic containment isolators, documentation of the manufacturer's recommended purge time.
- 16.2.11 Hand hygiene and garbing.
- 16.2.12 Labeling of the sterile compounded drug preparations based on the intended route of administration and recommended rate of administration.
- 16.2.13 Methods by which the supervising pharmacist will fulfill his or her responsibility to ensure the quality of compounded drug preparations.
- 16.2.14 Orientation, training, and competency evaluation of staff in all aspects of the preparation of sterile drug preparations including didactic training and knowledge/competency assessments which include at minimum: hand hygiene and garbing; decontamination (where applicable); cleaning and disinfection of controlled compounding areas; and proper aseptic technique demonstrated through the use of a media-fill test performed by applicable personnel; and aseptic area practices.
- 16.2.15 Preparing sterile compounded drug preparations from non-sterile components (if applicable). This shall include sterilization method suitability testing for each master formula document.
- 16.2.16 Procedures for handling, compounding and disposal of hazardous agents. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.
- 16.2.17 Procedures for handling, compounding and disposal of infectious materials. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.
- 16.2.18 Proper use of equipment and supplies.
- 16.2.19 Quality assurance program compliant with sections 1711, 1735.8, and 1751.7.
- 16.2.20 Record keeping requirements.
- 16.2.21 Temperature monitoring in compounding and controlled storage areas.
- 16.2.22 The determination and approval by a pharmacist of ingredients and the compounding process for each preparation before compounding begins.
- 16.2.23 Use of automated compounding devices (if applicable).
- 16.2.24 Visual inspection and other final quality checks of sterile drug preparations.

☐☐☐ 16.3 For lot compounding, the pharmacy maintains ~~a~~ written policies and procedures which include~~s~~ at least the following: (CCR 1751.3[b][1-3])

- 16.3.1 Use of master formula documents and compounding logs.
- 16.3.2 Appropriate documentation.
- 16.3.3 Appropriate sterility and potency testing.

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☐☐☐ 16.4 For non-sterile-to-sterile batch compounding, the pharmacy maintains a written policies and procedures for compounding which included at least the following. (CCR 1751.2[c][1-2])

16.4.1 Process validation for chosen sterilization methods.

16.4.2 End-product evaluation, quantitative, and qualitative testing.

☐☐☐ 16.5 All personnel involved have read the policies and procedures before compounding sterile drug preparations. All personnel involved have read all additions, revisions, and deletions to the written policies and procedures. Each review is documented by a signature and date. (CCR 1751.3[e])

CORRECTIVE ACTION OR ACTION PLAN: _____

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17. Facility & Equipment Standards for Sterile Compounding (CCR 1751.4)

Yes No N/A

☐☐☐ 17.1 No sterile drug preparation is compounded if it is known, or reasonably should be known, that the compounding environment fails to meet criteria specified in the pharmacy's written policies and procedures for the safe compounding of sterile drug preparations (CCR 1751.4[a])

☐☐☐ 17.2 During the compounding of sterile drug preparations, access to the areas designated for compounding is limited to those individuals who are properly attired (CCR 1751.4[b])

☐☐☐ 17.3 All equipment used in the areas designated for compounding is made of a material that can be easily cleaned and disinfected. (CCR 1751.4[c])

☐☐☐ 17.4 Cleaning is done using a germicidal detergent and sterile water. A sporicidal agent is used at least monthly (CCR 1751.4[d][1-4])

17.4.1 All ISO Class 5 surfaces, work table surfaces, carts, counters, and the cleanroom floor are cleaned at least daily. After each cleaning, disinfection using a suitable sterile agent occurs on all ISO Class 5 surfaces, work table surfaces, carts, and counters.

17.4.2 Walls, ceilings, storage shelving, tables, stools, and all other items in the ISO Class 7 or ISO Class 8 environment are cleaned at least monthly.

17.4.3 Cleaning shall also occur after any unanticipated event that could increase the risk of contamination.

17.4.4 All cleaning materials, such as wipers, sponges, and mops, shall be non-shedding and dedicated to use in the cleanroom, or ante-area, and segregated sterile compounding areas and shall not be removed from these areas except for disposal.

☐☐☐ 17.5 Disinfection, using a suitable sterile agent, occurs on all surfaces in the ISO Class 5 PEC frequently, including: (CCR 1751.4[e])

17.5.1 At the beginning of each shift;

17.5.2 At least every 30 minutes when compounding involving human staff is occurring or before each lot;

17.5.3 After each spill; and

17.5.4 When surface contamination is known or suspected.

☐☐☐ 17.6 Pharmacies preparing sterile compounded preparations are using a PEC that provides ISO Class 5 air or better air quality (CCR 1751.4[f])

17.6.1 Certification and testing of primary and secondary engineering controls are performed no less than every six months and whenever the device or area designated for compounding is relocated, altered or a service to the facility is performed which would impact the device or area.

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17.6.2 Certification is completed by a qualified technician who is familiar with certification methods and procedures in accordance with CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006-13, Revised May 20, 2015).

17.6.2.1 Certification records are retained for at least 3 years.

17.6.3 Unidirectional compounding aseptic isolators or compounding aseptic containment isolators used outside of an ISO Class 7 cleanroom if the isolators are certified to meet the following criteria: (CCR 1751.4[f][1-3])

17.6.3.1 Particle counts sampled approximately 6-12 inches upstream of the critical exposure site shall maintain ISO Class 5 levels during compounding operations.

17.6.3.2 Not more than 3520 particles (0.5 um and larger) per cubic meter shall be counted during material transfer, with the particle counter probe located as near to the transfer door as possible without obstructing transfer.

17.6.3.3 Recovery time to achieve ISO Class 5 air quality shall be documented and internal procedures developed to ensure that adequate recovery time is allowed after material transfer before and during compounding operations.

17.6.4 Compounding aseptic isolators that do not meet the requirements as outlined in this subdivision or are not located within an ISO Class 7 cleanroom are only be used to compound preparations that meet the criteria specified in accordance with subdivision (d) of Section 1751.8 of Title 16, Division 17, of the California Code of Regulations.

☐☐☐ 17.7 Pharmacies preparing sterile hazardous agents shall do so in accordance with Section 505.5.1 of Title 24, Chapter 5, of the California Code of Regulations, requiring a negative pressure PEC.

17.7.1 Additionally, each PEC used to compound hazardous agents shall be externally vented.

17.7.2 The negative pressure PEC is certified every six months by a qualified technician who is familiar with CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006-13, Revised May 20, 2015).

17.7.3 Any drug preparation compounded in a PEC where hazardous drugs are prepared are labeled as hazardous, regardless of whether the drug ingredients are considered hazardous. (CCR 1751.4[g])

17.7.4 During hazardous drug compounding performed in a compounding aseptic containment isolator, full hand hygiene and garbing occurs. Garbing shall include hair cover, facemask, beard cover (if applicable), polypropylene or low shedding gown that closes in the back, shoe covers, and two pairs of sterile ASTM D6978-05 standard gloves. (CCR 1751.4[g][1])

☐☐☐ 17.8 If a compounding aseptic isolator is certified by the manufacturer to maintain ISO Class 5 air quality during dynamic operation conditions during compounding as well as during the transfer of ingredients into and out of the compounding aseptic isolator, then it may be placed into a non-ISO classified room. Individuals who use compounding aseptic isolators in this manner must ensure appropriate garbing, which consists of donning sterile gloves over the isolator gloves immediately before non-hazardous compounding. These sterile gloves must be changed by each individual whenever continuous compounding is ceased and before compounding starts again. (CCR 1751.4[h])

☐☐☐ 17.9 Compounding aseptic isolators and compounding aseptic containment isolators used in the compounding of sterile drug preparations shall use non-turbulent unidirectional air flow patterns. A smoke patterned test shall be used to determine air flow patterns. (CCR 1751.4[i])

☐☐☐ 17.10 Viable surface sampling is done at least every six months for all sterile-to-sterile compounding and quarterly for all non-sterile-to-sterile compounding. Viable air sampling is be done by volumetric air sampling procedures which test a sufficient volume of air (400 to 1,000 liters) at each location and shall be done at least once every six months. Viable surface and viable air sampling are performed by a qualified individual who is familiar with the methods and procedures for surface testing and air sampling. Viable air sampling is performed under dynamic conditions which simulate actual production. Viable surface

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sampling is performed under dynamic conditions of actual compounding. When the environmental monitoring action levels are exceeded, the pharmacy identifies the CFUs at least to the genus level in addition to conducting an investigation pursuant to its policies and procedures. Remediation shall include, at minimum, an immediate investigation of cleaning and compounding operations and facility management. (CCR 1751.4[j])

☐☐☐ 17.11 The sterile compounding area in the pharmacy has 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. (CCR 1751.4[k])

CORRECTIVE ACTION OR ACTION PLAN: _____

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18. Sterile Compounding Attire (CCR 1751.5)

Yes No N/A

☐☐☐ 18.1. When compounding sterile drug preparations the following standards are met: (CCR 1751.5[a][1-6])

18.1.1 Personal protective equipment consisting of a low non-shedding coverall gown, head cover, face mask, facial hair covers (if applicable), and shoe covers are worn inside the designated area at all times. For hazardous compounding, double shoe covers are worn.

18.1.2 Personal protective equipment is donned and removed in an ante-area or immediately outside the segregated compounding area.

18.1.3 Personnel dons personal protective equipment in an order that proceeds from those activities considered the dirtiest to those considered the cleanest. The following order is to be followed unless the pharmacy has a procedure in place which documents a method equivalent to or superior to the method described here: The donning of shoe covers or dedicated shoes, head and facial hair covers and face masks shall be followed by the washing of hands and forearms up to the elbows for 30 seconds with soap and water, drying hands, and then the donning of a non-shedding gown.

18.1.4 Compounding personnel does not wear any wrist, hand, finger, or other visible jewelry, piercing, headphones, earbuds, or personal electronic device.

18.1.5 Sterile gloves that have been tested for compatibility with disinfection by isopropyl alcohol are worn. Hand cleansing with a persistently active alcohol-based product followed by the donning of sterile gloves may occur within the ante or cleanroom. Gloves are routinely disinfected with sterile 70 percent isopropyl alcohol before entering or re-entering the PEC and after contact with non-sterile objects. Gloves are routinely inspected for holes, punctures, or tears and replaced immediately if such are detected.

18.1.6 Individuals experiencing exposed rashes, sunburn, weeping sores, conjunctivitis, active respiratory infections or other communicable disease, or those wearing cosmetics, nail polish, or artificial nails are excluded from the ISO Class 5 and ISO Class 7 compounding areas until their conditions are remedied.

☐☐☐ 18.2. When preparing hazardous agents, appropriate gowns and personal protective equipment are worn regardless of the PECs used (e.g., biological safety cabinet and compounding aseptic containment isolator). (CCR 1751.5[b])

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19. Sterile Compounding Consultation; Training of Sterile Compounding Staff. (CCR 1751.6)

Yes No N/A

☐☐☐ 19.1 Consultation is available to the patient and/or primary caregiver concerning proper use, storage, handling, and disposal of sterile drug preparations and related supplies furnished by the pharmacy. (CCR 1751.6[a])

☐☐☐ 19.2 The pharmacist-in-charge ensures all pharmacy personnel engaging in compounding sterile drug preparations have training and demonstrated competence in the safe handling and compounding of sterile drug preparations, including hazardous agents if the pharmacy compounds products with hazardous agents. (CCR 1751.6[b])

☐☐☐ 19.3 Records of training and demonstrated competence are available for each individual and shall be retained for three years beyond the period of employment (CCR 1751.6[c])

☐☐☐ 19.4 The pharmacist-in-charge is responsible to ensure the continuing competence of pharmacy personnel engaged in compounding sterile drug preparations (CCR 1751.6[d])

☐☐☐ 19.5 The pharmacy complies with at least the following training requirements: (CCR 1751.6[e])

19.5.1 The pharmacy establishes and follows a written program of training and performance evaluation designed to ensure each person working in the designated area has the knowledge and skills necessary to perform their assigned tasks properly. This program of training and performance evaluation must address at least the following: (CCR 1751.6[e][1][A-J])

19.5.1.1 Aseptic technique.
19.5.1.2 Pharmaceutical calculations and terminology.
19.5.1.3 Sterile preparation compounding documentation.
19.5.1.4 Quality assurance procedures.
19.5.1.5 Aseptic preparation procedures.
19.5.1.6 Proper hand hygiene, gowning and gloving technique.
19.5.1.7 General conduct in the controlled area (aseptic area practices).
19.5.1.8 Cleaning, sanitizing, and maintaining of the equipment and the controlled area.
19.5.1.9 Sterilization techniques for compounding sterile drug preparations from one or more non-sterile ingredients.
19.5.1.10 Container, equipment, and closure system selection.

19.5.2 Each person engaged in sterile compounding has successfully completed practical skills training in aseptic technique and aseptic area practices using models that are comparable to the most complex manipulations to be performed by the individual. Each pharmacist responsible for, or directly supervising and controlling, aseptic techniques or practices, must demonstrate the skills needed to ensure the sterility of compounded drug preparations. Evaluation must include written testing and a written protocol of periodic routine performance checks involving adherence to aseptic area policies and procedures. Each person's proficiency and continuing training needs must be reassessed at least every 12 months. Results of these assessments must be documented and retained in the pharmacy for three years. (CCR 1751.6[e][2])

CORRECTIVE ACTION OR ACTION PLAN: _____

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20. Sterile Compounding Quality Assurance and Process Validation (CCR 1751.7)

Yes No N/A

☐☐☐ 20.1 There is a written, documented, ongoing quality assurance program maintained by the pharmacy that monitors personnel performance, equipment, and facilities, and the pharmacist-in-charge assures the end-product meets the required specifications by periodic sampling. (CCR 1751.7[a])

20.1.1 The quality assurance program shall include at least the following (CCR 1751.7[a][1-3])

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20.1.1.1 Procedures for cleaning and sanitization of the sterile preparation area.
20.1.1.2 Actions to be taken in the event of a drug recall.
20.1.1.3 Documentation justifying the chosen beyond use dates for compounded sterile drug preparations.

☐☐☐ 20.2.1 The pharmacy and each individual involved in the compounding of sterile drug preparations successfully demonstrate competency on aseptic technique and aseptic area practices before being allowed to prepare sterile drug preparations. (CCR 1751.7[b][1])

20.2.2 Each individual's competency is revalidated at least every twelve months for sterile to sterile compounding and at least every six months for individuals compounding sterile preparations from non-sterile ingredients. (CCR 1751.7[b][2])

20.2.3 The pharmacy's validation process on aseptic technique and aseptic area practices is to be revalidated whenever: (CCR 1751.7[b][3][A-B])

20.2.3.1 The quality assurance program yields an unacceptable result.

20.2.3.2 There is any change in the compounding process, the Primary Engineering Control (PEC), or the compounding environment. For purposes of this subsection, a change includes, but is not limited to, when the PEC is moved, repaired or replaced, when the facility is modified in a manner affecting airflow or traffic patterns, or when improper aseptic techniques are observed.

20.2.4 The pharmacy must document the validation and revalidation process (CCR 1751.7[b][4]).

☐☐☐ 20.3 All sterile compounding personnel have successfully completed an initial competency evaluation. In addition, immediately following the initial hand hygiene and garbing procedure, each individual who may be required to do so in practice has successfully completed a gloved fingertip (all fingers on both hands) sampling procedure (zero colony forming units for both hands) at least three times before initially being allowed to compound sterile drug preparations. (CCR 1751.7[c])

☐☐☐ 20.4 Re-evaluation of garbing and gloving competency occurs at least every 12 months for personnel compounding products made from sterile ingredients and at least every six months for personnel compounding products from non-sterile ingredients. (CCR 1751.7[d])

☐☐☐ 20.5 Batch-produced sterile drug preparations compounded from one or more non-sterile ingredients, except as provided in paragraph (2), are subject to documented end product testing for sterility and pyrogens and are quarantined until the end product testing confirms sterility and acceptable levels of pyrogens. Sterility testing is performed per USP chapter 71 and pyrogen testing confirms acceptable levels of pyrogen per USP chapter 85 limits before dispensing. This requirement of end product testing confirming sterility and acceptable levels of pyrogens prior to dispensing applies regardless of any sterility or pyrogen testing that may have been conducted on any ingredient or combination of ingredients which were previously non-sterile. Exempt from pyrogen testing are topical ophthalmic and inhalation preparation. (CCR 1751.7[e][1])

20.5.1 The following non-sterile-to-sterile batch drug preparations do not require end product testing for sterility and pyrogens: (CCR 1751.7[e][2][A-B])

20.5.1.1 Preparations for self-administered ophthalmic drops in a quantity sufficient for administration to a single patient for 30 days or less pursuant to a prescription.

20.5.1.2 Preparations for self-administered inhalation in a quantity sufficient for administration to a single patient for 5 days or less pursuant to a prescription.

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21. Beyond Use Dating for Sterile Compounded Drug Preparations (CCR 1751.8)

Yes No N/A

☐☐☐ 21.1 Every sterile compounded drug preparation is given and labeled with a beyond use date incompliance with 1735.2 and does not exceed the shortest expiration date or beyond use date of any ingredient in sterile the compounded drug preparation, nor the chemical stability of any one ingredient in the sterile compounded drug preparation, nor the chemical stability of the combination of all ingredients in the sterile compounded drug preparation, and , in the absence of passing a sterility test in accordance with standards for sterility testing found in Chapter 797 of the United States Pharmacopeia would justify an extended beyond use date, conforms to the following limitations:

☐☐☐ 21.2 The beyond use date states storage and exposure periods cannot exceed 48 hours at controlled room temperature, 14 days at controlled cold temperature, and 45 days in solid frozen state, where the sterile compounded drug preparation is compounded solely with aseptic manipulations and all of the following apply: (CCR 1751.8[a])

- 21.2.1 The preparation is compounded entirely within an ISO Class 5 PEC located in an ISO Class 7 cleanroom with an ante-area or compounded entirely within a CAI which meets the requirements in 1751.4(f)(1)-(3), using only sterile ingredients, products, components, and devices; **and**
- 21.2.2 The compounding process involves transferring, measuring, and mixing manipulations using not more than three commercially manufactured packages of sterile preparations and not more than two entries into any one sterile container or package of sterile preparations or administration containers/devices to prepare the drug preparation; **and**
- 21.2.3 Compounding manipulations are limited to aseptically opening ampules, penetrating disinfected stoppers on vials with sterile needles and syringes or spiked transfer devices, and transferring sterile liquids in sterile syringes to sterile administration devices, package containers of other sterile preparations, and containers for storage dispensing.

☐☐☐ 21.3 The beyond use date states storage and exposure periods cannot exceed 30 hours at controlled room temperature, 9 days at controlled cold temperature, and 45 days in solid frozen state, where the sterile compounded drug preparation is compounded solely with aseptic manipulations and all of the following apply: (CCR 1751.8[b])

- 21.3.1 The preparation is compounded entirely within an ISO Class 5 PEC located in an ISO Class 7 cleanroom with an ante-area or compounded entirely within a CAI which meets the requirements in 1751.4(f)(1)-(3), using multiple individual or small doses of sterile preparations combined or pooled to prepare a compounded sterile preparation that will be administered either to multiple patients or to one patient on multiple occasions; and
- 21.3.2 The compounding process involves complex aseptic manipulations other than the single-volume transfer; and
- 21.3.3 The compounding process requires unusually long duration such as that required to complete dissolution or homogenous mixing.

☐☐☐ 21.4 The beyond use date states storage and exposure periods cannot exceed 24 hours at controlled room temperature, 3 days at controlled cold temperature, and 45 days in solid frozen state, where the sterile compounded drug preparation is compounded solely with aseptic manipulations using non-sterile ingredients, regardless of intervening sterilization of that ingredient and the following applies: (CCR 1751.8[c])

- 21.4.1 The preparation is compounded entirely within an ISO Class 5 PEC located in an ISO Class 7 cleanroom with an ante-area or compounded entirely within a CAI which meets the requirements in 1751.4(f)(1)-(3).

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☐☐☐ 21.5 The beyond use date states storage and exposure periods cannot exceed 12 hours where the sterile compounded drug preparation is compounded solely with aseptic manipulations and all of the following apply: (CCR 1751.8[d])

21.5.1 The preparation was compounded entirely within an ISO Class 5 PEC that is located in a segregated sterile compounding area and restricted to sterile compounding activities, using only sterile ingredients, components, and devices, by personnel properly cleansed and garbed; and

21.5.2 The compounding process involves simple transfer of not more than three commercially manufactured packages of sterile nonhazardous preparations or diagnostic radiopharmaceutical preparations from the manufacturer's original containers; and

21.5.3 The compounding process involves not more than two entries into any one container or package (e.g., bag, vial) of sterile infusion solution or administration container/device.

☐☐☐ 21.6 Any sterile compounded drug preparation which was compounded either outside of an ISO class 5 PEC or under conditions that do not meet all of the requirements for any of subdivisions (a) through (e), the sterile compounded drug preparation is be labeled "for immediate use only" and administration shall begin no later than one hour following the start of the compounding process.

21.6.1 Unless the "immediate use" preparation is immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, the preparation shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the compounded sterile preparation, and the exact one-hour beyond use date and time.

21.6.2 If administration has not begun within one hour following the start of the compounding process, the compounded sterile preparation shall be promptly, properly, entirely, and safely discarded.

21.6.3 "Immediate use" preparations are only compounded in those limited situations where there is a need for immediate administration of a sterile preparation compounded outside of an ISO Class 5 environment and where failure to administer could result in loss of life or intense suffering.

21.6.4 Any such compounding shall be only in such quantity as is necessary to meet the immediate need and the circumstance causing the immediate need shall be documented in accordance with policies and procedures. (CCR 1751.8[e])

☐☐☐ 21.7 The beyond use date for any compounded allergen extracts is the earliest manufacturer expiration date of the individual allergen extracts. (CCR 1751.8[f])

CORRECTIVE ACTION OR ACTION PLAN: _____

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22. Single-Dose and Multi-Dose Containers; Limitations on Use (CCR 1751.9)

Yes No N/A

☐☐☐ 22.1 Single-dose ampules are for immediate use only, and once opened are not stored for any time period. (CCR 1751.9[a])

☐☐☐ 22.2 Unless otherwise specified by the manufacturer, any single-dose container of a compounded sterile drug preparation other than an ampule, such as a bag, bottle, syringe or vial, is used in its entirety or its remaining contents are be labeled with a beyond use date and discarded within the following time limit, depending on the environment: (CCR 1751.9[b])

22.2.1 When needle-punctured in an environment with air quality worse than ISO Class 5, within one (1) hour.

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22.2.2 When needle-punctured in an environment with ISO Class 5 or better air quality, within six (6) hours. A container remains within the ISO Class 5 or better air quality to be used for the full six hours, unless otherwise specified by the manufacturer.

22.2.3 If the puncture time is not noted on the container, the container is immediately discarded.

☐☐☐ 22.3 Unless otherwise specified by the manufacturer, a multi-dose container stored according to the manufacturer's specifications is used in its entirety or its remaining contents are be labeled with a beyond use date and discarded within twenty eight (28) days from initial opening or puncture. Any multi-dose container not stored according to the manufacturer's specifications is discarded immediately upon identification of such storage circumstance. If any open container is not labeled with a beyond use date or the beyond use date is not correct, the container is immediately be discarded. (CCR 1751.9[c])

23. Sterile Compounding Reference Materials (CCR 1751.10)

☐☐☐ 23.1 The pharmacy has current and appropriate reference materials regarding the compounding of sterile drug preparations located in or immediately available to the pharmacy. (CCR 1751.10)

24. Sterile Compounding License Renewal (B&PC 4127.1, 4127.2)

A license to compound sterile drug preparation will not be renewed until the following is met: (B&PC 4127.1, 4127.2)

Yes No N/A

☐☐☐ 24.1 The pharmacy has been inspected by the board and is in compliance with applicable laws and regulations.

☐☐☐ 24.2 The board reviews a current copy of the pharmacy's policies and procedures for sterile compounding.

☐☐☐ 24.3 The board is provided with copies of all inspection reports conducted of the pharmacy's premises in the prior 12 months documenting the pharmacy's operation.

☐☐☐ 24.4 The board is provided with copies of any reports from a private accrediting agency conducted in the prior 12 months documenting the pharmacy's operation.

☐☐☐ 24.5 The board receives a list of all sterile medications compounded by the pharmacy since the last license renewal.

☐☐☐ 24.6 A nonresident pharmacy has reimbursed the board for all actual and necessary costs incurred by the board in conducting an inspection of the pharmacy at least once annually. (B&PC 4127.2[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

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25. Duties of a Pharmacy Issuing a Sterile Compounded Drug Recall (B&PC 4127.9)

Yes No N/A

☐☐☐ 25.1 The pharmacy contacts 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 (1) the use of or exposure to the recalled drug preparations may cause serious adverse health consequences or death; and (2) the recalled drug was dispensed or is intended for use in California. (B&PC 4127.9[a] B&PC 4127.1 and 4127.2)

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☐☐☐ 25.2 A recall notice is made to the patient if the recalled drug was dispensed directly to the patient. (B&PC 4127.9[b][1])

Yes No N/A

☐☐☐ 25.3 A recall notice is made to the prescriber if the recalled drug was dispensed directly to the prescriber. (B&PC 4127.9[b][2])

☐☐☐ 25.4 A recall notice is made to the recipient pharmacy who shall notify the prescriber or patient if the recalled drug was dispensed thereafter. (B&PC 4127.9[b][3])

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PHARMACIST-IN-CHARGE CERTIFICATION:

I, (Please print) _____, RPH # _____ hereby certify that I have completed the self-assessment of this pharmacy of which I am the pharmacist-in-charge. Any deficiency identified herein will be corrected. I understand that all responses are subject to verification by the Board of Pharmacy. I further state under penalty of perjury of the laws of the State of California that the information I have provided in this self-assessment form is true and correct.

Signature _____ Date _____
(Pharmacist-in-Charge)

ACKNOWLEDGEMENT BY OWNER OR HOSPITAL ADMINISTRATOR:

I, (please print) _____, hereby certify under penalty of perjury of the laws of the State of California that I have read and reviewed this completed self-assessment. I understand that failure to correct any deficiency identified in this self-assessment could result in the revocation of the pharmacy's license issued by the California State Board of Pharmacy.

Signature _____ Date _____

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Attachment 14

Self-Assessment Forms

§ 1715 and 1784

17M – 13

17M – 14

17M – 26

Amend Section 1715 in Article 2 of Division 17 of Title 16 to read:

§ 1715. Self-Assessment of a Pharmacy by the Pharmacist-in-Charge.

(a) The pharmacist-in-charge of each pharmacy as defined under section 4029 or section 4037 of the Business and Professions Code shall complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. The assessment shall be performed before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

(b) In addition to the self-assessment required in subdivision (a) of this section, the pharmacist-in-charge shall complete a self-assessment within 30 days whenever:

(1) A new pharmacy permit has been issued, or

(2) There is a change in the pharmacist-in-charge, and he or she becomes the new pharmacist-in-charge of a pharmacy.

(3) There is a change in the licensed location of a pharmacy to a new address.

(c) The components of this assessment shall be on Form 17M-13 ~~(Rev. 10/14)~~ (Rev. 10/16) entitled "Community Pharmacy Self-Assessment Hospital Outpatient Pharmacy Self-Assessment" and on Form 17M-14 ~~(Rev. 10/14)~~ (Rev. 10/16) entitled "Hospital Pharmacy Self-Assessment" which are hereby incorporated by reference to evaluate compliance with federal and state laws and regulations.

(d) Each self-assessment shall be kept on file in the pharmacy for three years after it is performed.

Authority: Business and Professions Code §4005 and §4127. Reference: Business and Professions Code §4021, §4022, §4029, §4030, §4037, §4038, §4040, §4050, §4052, §4070, §4081, §4101, §4105, §4113, §4115, §4119, §4127, §4305, §4330, §4332 and §4333.

Amend Section 1784 in Article 10 of Division 17 of Title 16 to read:

§ 1784. Self-Assessment of a Wholesaler by the Designated Representative-In-Charge.

(a) The designated representative-in-charge of each wholesaler as defined under section 4160 of the Business and Professions Code shall complete a self-assessment of the wholesaler's compliance with federal and state pharmacy law. The assessment shall be performed before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

(b) In addition to the self-assessment required in subdivision (a) of this section, the designated representative-in-charge shall complete a self-assessment within 30 days whenever:

(1) A new wholesaler permit is issued, or

(2) There is a change in the designated representative-in-charge. The new designated representative-in-charge of a wholesaler is responsible for compliance with this subdivision.

(3) There is a change in the licensed location of a wholesaler to a new address.

(c) The components of this assessment shall be on Form 17M-26 ~~(Rev. 10/14)~~ (Rev. 10/16) entitled "Wholesaler Dangerous Drugs & Dangerous Devices Self-Assessment" which is hereby incorporated by reference to evaluate compliance with federal and state laws and regulations.

(d) Each self-assessment shall be kept on file in the licensed wholesale premises for three years after it is completed.

(e) The wholesaler is jointly responsible with the designated representative-in-charge for compliance with this section.

Authority: Business and Professions Code §4005. Reference: Business and Professions Code §4022.5, §4043, §4053, §4059, §4120, §4160, §4161, §4201, §4301 and §4305.5.

California State Board of Pharmacy
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Phone: (916) 574-7900 Fax: (916) 574-8618
www.pharmacy.ca.gov

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

COMMUNITY PHARMACY SELF-ASSESSMENT
HOSPITAL OUTPATIENT PHARMACY SELF-ASSESSMENT

Title 16 of the California Code of Regulations section 1715 requires the pharmacist-in-charge of each pharmacy licensed under section 4037 or 4029 of the Business and Professions Code to complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. **The assessment shall be performed before July 1 of every odd-numbered year. The pharmacist-in-charge must also complete a self-assessment within 30 days whenever: (1) a new pharmacy permit has been issued; (2) there is a change in the pharmacist-in-charge; or (3) there is a change in the licensed location of the pharmacy. The primary purpose of the self-assessment is to promote compliance through self-examination and education.**

The self-assessment must be completed in its entirety and may be completed online, printed, readily available ~~and retained~~ in the pharmacy. Do not copy a previous assessment.

Notes: If a hospital pharmacy dispenses prescriptions for outpatient use, this Hospital Outpatient Pharmacy Self-Assessment must be completed in addition to the Hospital Pharmacy Self-Assessment (17M-14 Rev. ~~10/14~~ 10/16).
Any pharmacy that compounds drug products must also complete the Compounding Self-Assessment (17M-39 Rev. ~~02/12~~ 10/16).

Each self-assessment must be kept on file in the pharmacy for three years after it is performed.

Pharmacy Name: _____

Address: _____ Phone: _____

Ownership: Sole Owner ☐ Partnership ☐ Corporation ☐ LLC ☐ Trust ☐
Non-Licensed Owner ☐ Other (please specify) ☐

~~Permit~~ License #: _____ Exp. Date: _____ Other Permit #: _____ Exp. Date: _____

Licensed Sterile Compounding ~~Permit~~ License# _____ Expiration: _____

Accredited by (optional): _____ From: _____ To: _____

DEA Registration #: _____ Exp. Date: _____ Date of DEA Inventory: _____

Hours: *Weekdays* _____ *Sat* _____ *Sun.* _____ *24 Hours* _____

PIC: _____ RPH # _____ Exp. Date: _____

Website address (optional): _____

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PIC Initials

Pharmacy Staff (pharmacists, intern pharmacists, pharmacy technicians):
Please use an additional sheet if necessary. ~~APP~~ APH=Advanced Practice Pharmacist, DEA =Drug Enforcement Administration.

1. _____ RPH # _____ Exp. Date: _____
   ~~APP~~ APH# _____ Exp. Date: _____
   DEA # _____ Exp. Date: _____

2. _____ RPH # _____ Exp. Date: _____
   ~~APP~~ APH # _____ Exp. Date: _____
   DEA # _____ Exp. Date: _____

3. _____ RPH # _____ Exp. Date: _____
   ~~APP~~ APH # _____ Exp. Date: _____
   DEA # _____ Exp. Date: _____

4. _____ RPH # _____ Exp. Date: _____
   ~~APP~~ APH # _____ Exp. Date: _____
   DEA # _____ Exp. Date: _____

5. _____ RPH # _____ Exp. Date: _____
   ~~APP~~ APH # _____ Exp. Date: _____
   DEA # _____ Exp. Date: _____

6. _____ INT # _____ Exp. Date: _____

7. _____ INT # _____ Exp. Date: _____

8. _____ INT # _____ Exp. Date: _____

9. _____ TCH # _____ Exp. Date: _____

10. _____ TCH # _____ Exp. Date: _____

11. _____ TCH # _____ Exp. Date: _____

_____
PIC Initials

COMMUNITY PHARMACY SELF-ASSESSMENT

HOSPITAL OUTPATIENT PHARMACY SELF-ASSESSMENT

All references to the California Code of Regulations (CCR) are to Title 16 unless otherwise noted.

Please mark the appropriate box for each item. If "NO", enter an explanation on "CORRECTIVE ACTION OR ACTION PLAN" lines at the end of the section. If more space is needed, you may add additional sheets.

1. Facility

Yes No N/A

☐☐☐ 1.1. The pharmacy has an area suitable for confidential patient consultation. (CCR 1764, 1714)

☐☐☐ 1.2. The pharmacy is secure and only a pharmacist possesses a key. The pharmacy has provisions for effective control against the theft of dangerous drugs and devices. (B&PC 4116, CCR 1714)

☐☐☐ 1.3. The pharmacy is of sufficient size and has an unobstructed area to accommodate the safe practice of pharmacy. (CCR 1714)

☐☐☐ 1.4. The pharmacy premises, fixtures, and equipment are maintained in a clean and orderly condition, properly lighted and free from rodents and insects. (CCR 1714)

☐☐☐ 1.5. The pharmacy sink has hot and cold running water. (CCR 1714)

☐☐☐ 1.6. The pharmacy has a readily accessible restroom. (CCR 1714)

☐☐☐ 1.7. Current board-issued "Notice to Consumers" is posted in public view where it can be read by the consumer, or written receipts containing the required information are provided to the consumers. A written receipt that contains the required information on the notice may be provided to consumers as an alternative to posting the notice in the pharmacy. A pharmacy may also provide this information in a video in lieu of the poster. Additional "Notice to Consumers" in languages other than English may also be posted. (B&PC 4122, CCR ~~1707.2~~ 1707.6)

☐☐☐ 1.8. ~~Pharmacists, interns, pharmacy technicians, and pharmacy technician trainees wear nametags, in 18-point type, that contain their name and license status. (B&PC 680, B&PC 4115.5[e], CCR 1793.7[d])~~ "Point to Your Language" poster is posted in a place conspicuous to and readable by a prescription drug consumer or adjacent to each counter in a pharmacy where drugs are dispensed. (CCR 1707.6(c))

☐☐☐ ~~1.8~~ 1.9. Pharmacists, interns, pharmacy technicians, and pharmacy technician trainees wear nametags, in 18-point type, that contain their name and license status. (B&PC 680, B&PC 4115.5[e], CCR 1793.7[d])

☐☐☐ ~~1.9~~ 1.10. The original board-issued pharmacy license and the current renewal are posted where they may be clearly read by the purchasing public. (B&PC 4032, 4058)

PIC Initials

☐☐☐ ~~1.10~~ 1.11. Does the pharmacy compound sterile drugs? (If yes, complete section 27 – "Compounding.")

Yes No N/A

☐☐☐ ~~1.11~~ 1.12. The pharmacy has procedures in place to take action to protect the public when a licensed individual employed by or with the pharmacy is discovered or known to be chemically, mentally, or physically impaired to the extent it affects his or her ability to practice the profession or occupation authorized by his or her license, or is discovered or known to have engaged in the theft, diversion, or self-use of dangerous drugs. (B&PC 4104[a])

☐☐☐ ~~1.12~~ 1.13. The pharmacy has written policies and procedures for addressing chemical, mental, or physical impairment, as well as theft, diversion, or self-use of dangerous drugs, among licensed individual employed by or with the pharmacy. (B&PC 4104[b])

☐☐☐ ~~1.13~~ 1.14. The pharmacy reports to the board within 14 days of the receipt or development of the following information with regard to any licensed individual employed by or with the pharmacy: (1) any admission by a licensed individual of chemical, mental, or physical impairment affecting his or her ability to practice; (2) Any admission by a licensed individual of theft, diversion, or self-use of dangerous drugs; (3) Any video or documentary evidence demonstrating chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice; (4) Any video or documentary evidence demonstrating theft, diversion, or self-use of dangerous drugs by a licensed individual; (5) Any termination based on chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice; (6) Any termination of a licensed individual based on theft, diversion, or self-use of dangerous drugs. (B&PC 4104[c])

☐☐☐ ~~1.14~~ 1.15. The pharmacy is subscribed to the board's e-mail notifications. (B&PC 4013)

Date Last Notification Received: _____

E-mail address registered with the board:_____ _____

☐☐☐ ~~1.15~~ 1.16. For a pharmacy whose owner owns two or more pharmacies, the pharmacy receives the board's e-mail notifications through the owner's electronic notice system. (B&PC 4013[c])

Date Last Notification Received: _____

E-mail address registered with the board:_____ _____

CORRECTIVE ACTION OR ACTION PLAN: _____

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PIC Initials

2. Delivery of Drugs

Yes No N/A

☐☐☐ 2.1. Dangerous drugs and dangerous devices are only delivered to the licensed premises, and signed for and received by a pharmacist. (B&PC 4059.5[a], H&SC 11209(a))

☐☐☐ 2.2. 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: (B&PC 4059.5[f]):

- ☐ 2.2.1. The drugs are placed in a secure storage facility in the same building as the pharmacy (B&PC 4059.5[f][1]);
- ☐ 2.2.2. 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 (B&PC 4059.5[f][2]);
- ☐ 2.2.3. The secure storage facility has a means of indicating whether it has been entered after dangerous drugs or dangerous devices have been delivered (B&PC 4059.5[f][3]);
- ☐ 2.2.4. The pharmacy maintains written policies and procedures for the delivery of dangerous drugs and dangerous devices to a secure storage facility (B&PC 4059.5[f][4]); and
- ☐ 2.2.5. 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. B&PC 4059.5[f][5])

☐☐☐ 2.3 Prior to, or at the time of, accepting ownership of a product included in the Drug Supply Chain Security Act from an authorized trading partner, the pharmacy is provided transaction history, transaction information, and a transaction statement. (Title II of the DQSA Section 582[d])

☐☐☐ 2.4 Prior to, or at the time of, each transaction in which the pharmacy transfers ownership of a product included in the Drug Supply Chain Security Act to an authorized trading partner, the subsequent owner is provided transaction history, transaction information, and a transaction statement for the product. This requirement does not apply to sales by a pharmacy to another pharmacy to fulfill a specific patient need. (Title II of the DQSA Section[d][ii])

☐☐☐ 2.5 The pharmacy captures transaction information (including lot level information, if provided), transaction history, and transaction statements, as necessary to investigate a suspect product, and maintains such information, history, and statements for not less than 6 years after the transaction. (Title II of the DQSA Section 582[d][iii])

PIC Initials

CORRECTIVE ACTION OR ACTION PLAN: _____

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3. Drug Stock

Yes No N/A

☐☐☐ 3.1. The drug stock is clean, orderly, properly stored, properly labeled and in-date. (B&PC 4342, H&SC 111255, 22 CCR 70263[q], CCR 1714[b])

☐☐☐ 3.2. Dangerous drugs or dangerous devices are purchased, traded, sold or transferred with an entity licensed with the board as a wholesaler or pharmacy, or a manufacturer, and provided the dangerous drugs and devices: (B&PC 4169)

- ☐ 3.2.1. Are known or reasonably are known to the pharmacy as not being adulterated.
- ☐ 3.2.2. Are known or reasonably are known to the pharmacy as not being misbranded.
- ☐ 3.2.3. Are not expired.

CORRECTIVE ACTION OR ACTION PLAN: _____

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4. Voluntary Drug Repository and Distribution Program (H&SC 150200)

Yes No N/A

☐☐☐ 4.1. Does the pharmacy donate to or operate a county-approved Voluntary Drug Repository and Distribution Program?

(If yes, complete Section 29 [donate drugs] or Section 30 [operate program] of this Self-Assessment.)

5. Pharmacist-in-Charge (PIC)

Yes No N/A

☐☐☐ 5.1. The pharmacy has a PIC that is responsible for the daily operation of the pharmacy. (B&PC 4101, 4113, 4305, 4330, CCR 1709, 1709.1)

☐☐☐ 5.2. The PIC has adequate authority to assure the pharmacy's compliance with laws governing the operation of a pharmacy. (B&PC 4113(c), CCR 1709.1[b])

☐☐☐ 5.3. The PIC has completed a biennial pharmacy self-assessment before July 1 of each odd numbered year. An additional self-assessment will be completed within 30 days if a new permit is issued or a new PIC employed. Each self-assessment will be maintained in the pharmacy for three years. (CCR 1715)

☐☐☐ 5.4. Is the PIC in charge of another pharmacy?

☐☐☐ 5.5. If yes, are the pharmacies within 50 driving miles of each other? (CCR 1709.1[c])

Name of the other pharmacy _____

☐☐☐ 5.6. Any change of PIC is reported by the pharmacy and the departing PIC to the board in writing within 30 days. (B&PC 4101, 4113)

~~☐☐☐ 5.7. Is the PIC serving concurrently as the designated representative-in-charge for a wholesaler or veterinary food-animal retailer? (CCR 1709.1[d])~~

~~If yes, name the wholesaler or veterinary food-animal retailer. _____~~

☐☐☐ ~~5.8~~ 5.7. The PIC is responsible for directing and overseeing the performance of waived clinical laboratory tests, if the pharmacy holds a registration from CDPH to conduct such tests. (H&SC 1206, 1265)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

PIC Initials

6. Duties of a Pharmacist

Yes No N/A

☐☐☐ 6.1. ~~The pharmacist furnishes a reasonable quantity of compounded drug products to a prescriber office for office use by the prescriber; transmits a valid prescription to another pharmacist; administers drugs and biological products ordered by the prescriber; manufactures, measures, fits to the patient or sells and repairs dangerous devices or furnishes instructions to the patient or patient representative concerning the use of the dangerous devices; provides consultation, training and education to patients about drug therapy disease management and disease prevention; provides professional information and participates in multidiscipline review of patient progress; furnishes medication including emergency contraception drug therapy and self-administered hormonal contraceptives, nicotine replacement products, prescription medication not requiring a diagnosis recommended by the Centers for Disease Control when traveling outside of the US; administers immunizations pursuant to a protocol; orders and interprets tests for monitoring and managing efficacy and toxicity of drug therapies. (B&PC 4052)~~

Only a pharmacist:

- ☐ transmits a valid prescription to another pharmacist (B&PC 4052)
- ☐ administers drugs and biological products ordered by the prescriber; (B&PC 4052)
- ☐ provides consultation, training and education to patients about drug therapy disease management and disease prevention; (B&PC 4052)
- ☐ provides professional information and participates in multidiscipline review of patient progress; (B&PC 4052)
- ☐ furnishes medication including emergency contraception drug therapy, self-administered hormonal contraceptives, nicotine replacement products, naloxone, prescription medication not requiring a diagnosis recommended by the Centers for Disease Control when traveling outside of the US; administers immunizations pursuant to a protocol; (B&PC 4052 (a)(10), B&PC 4052(a)(11), 4052.01, B&PC 4052.3, B&PC 4052.8, 4052.9)
- ☐ responds to end of life option drugs (Health and Safety Code section 443.59 (b)(2))
- ☐ orders and interprets tests for monitoring and managing efficacy and toxicity of drug therapies. (B&PC 4052 (a)(12)

☐☐☐ 6.2. ~~The pharmacist receives a new prescription order from the prescriber, consults with the patient, identifies, evaluates and interprets a prescription, interprets the clinical data in a patient medication record, consults with any prescriber, nurse, health professional or agent thereof, supervises the packaging of drugs, checks the packaging procedure and product upon completion, is responsible for all activities of pharmacy technicians to ensure that all such activities are performed completely, safely and without risk of harm to patients, performs any other duty which federal or state law or regulation authorizes only a registered pharmacist to perform and performs all functions which require professional judgment. (CCR 1707.2, 1793.1, B&PC 4052, 4052.1, 4052.2, 4052.3, 4052.4, 4070(a))~~

Only a pharmacist:

- ☐ receives a new prescription order from the prescriber
- ☐ consults with the patient
- ☐ identifies, evaluates and interprets a prescription,
- ☐ interprets the clinical data in a patient medication record,
- ☐ consults with any prescriber, nurse, health professional or agent thereof,
- ☐ supervises the packaging of drugs,
- ☐ checks the packaging procedure and product upon completion,
- ☐ is responsible for all activities of pharmacy technicians to ensure that all such activities are performed completely, safely and without risk of harm to patients,
- ☐ performs any other duty which federal or state law or regulation authorizes only a registered pharmacist to perform and performs all functions which require professional judgment. (CCR 1707.2, 1793.1, B&PC 4052, 4052.1, 4052.2, 4052.3, 4052.4, 4070(a))

☐☐☐ 6.3. The pharmacist as part of the care provided by a health care facility, a licensed clinic and a licensed home health agency in which there is physician oversight, or a provider who contracts with a licensed health care service plan with regard to the care or services provided to the enrollees of that health care service plan, is performing the following functions, in accordance with policies, procedures~~,~~ or protocols of that facility, licensed clinic, or health care service plan that were developed by health professionals, including physicians and surgeons, pharmacists and registered nurses. The functions are: ordering or performing routine drug therapy related patient assessment procedures; ordering drug therapy related laboratory tests; administering drugs or biologicals by injection; initiating and adjusting the drug regimen of a patient; and performing moderate or waived laboratory tests. (B&PC 4052, 4052.1, 4052.2, 4052.3, 4052.4)

☐☐☐ 6.4. Pharmacists are ~~able to~~ provided access to ~~information on the Internet that is maintained by the California Department of Justice regarding controlled substance history of a patient who is under the care of the pharmacy based on data obtained through~~ the CURES Prescription Drug Monitoring Program (PDMP). (H&SC 11165.1)

☐☐☐ 6.5. The pharmacist dispenses emergency contraceptive pursuant to the statewide protocol found in 16 CCR 1746.

☐☐☐ 6.6. Only a pharmacist performs blood glucose, hemoglobin A1c, or cholesterol tests that are waived under CLIA. (No CDPH registration required.) (B&PC 1206.6)

Yes No N/A

☐☐☐ 6.7. Only a pharmacist performs CLIA waived clinical laboratory tests, where the pharmacy is registered with CDPH to perform such services. (B&PC 1206.6)

CDPH (CLIA) Registration #:_____ Expiration: _____

☐☐☐ 6.8. The pharmacist who is authorized to issue an order to initiate or adjust a controlled substance therapy is personally registered with the federal Drug Enforcement Administration. (B&PC 4052[b])

CORRECTIVE ACTION OR ACTION PLAN: _____

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PIC Initials

7. Duties of an Advance Practice Pharmacist

Yes No N/A

☐☐☐ ~~7.1. The pharmacist who is authorized to issue an order to initiate or adjust a controlled substance therapy is personally registered with the federal Drug Enforcement Administration. (B&PC 4052[b])~~

☐☐☐ ~~7.2~~ 7.1. The advance practice pharmacist has received an advance practice pharmacist ~~recognition~~ license ~~by~~ from the board and may do the following: (B&PC 4016.5, 4210)

- ☐ ~~7.2.1~~ 7.1.1Perform patient assessments, order and interpret drug therapy-related tests, and refer patients to other health care providers; (B&PC 4052.6[a])
- ☐ ~~7.2.2~~ 7.1.2 Participate in the evaluation and management of diseases and health conditions in collaboration with other health care providers; (B&PC 4052.6[a])
- ☐ ~~7.2.2~~ 7.1.3 Initiate drug therapy and promptly transmit written notification to, or enter the appropriate information in to a patient record system shared with the patient's primary care provider or diagnosing provider; (B&PC 4052.6[b])
- ☐ ~~7.2.2~~ 7.1.4 Adjust or discontinue drug therapy and promptly transmit written notification to the patient's diagnosing prescriber or enters the appropriate information in a patient's record system shared with the prescriber; (B&PC 4052.6[b])
- ☐ ~~7.2.2~~ 7.1.5 Prior to initiating or adjusting a controlled substance therapy, the advance practice pharmacist is personally registered with the federal Drug Enforcement Administration; (B&PC 4052.6[d])
- ☐ ~~7.2.2~~ 7.1.6 Ordering of tests is done in coordination with the patient's primary care provider or diagnosing prescriber, including promptly transmitting written notification to the prescriber or entering information in a patient record system shared with the prescriber. (B&PC 4052.6[e])

8. Duties of an Intern Pharmacist

Yes No N/A

☐☐☐ 8.1. The intern pharmacist may perform all the functions of a pharmacist only under the direct supervision of a pharmacist. A pharmacist may supervise **two interns** at any one time. (B&PC 4114, 4023.5, CCR 1726)

Yes No N/A

☐☐☐ 8.2. All prescriptions filled or refilled by an intern are, prior to dispensing, checked for accuracy by a licensed pharmacist and the prescription label initialed by the checking pharmacist. (CCR 1717[b][1], CCR 1712)

☐☐☐ 8.3. The intern hours affidavits are signed by the pharmacist under whom the experience was earned, when applicable. (B&PC 4209, CCR 1726)

☐☐☐ 8.4. During a temporary absence of a pharmacist or duty free breaks or meal periods, an intern pharmacist may not perform any discretionary duties nor act as a pharmacist. (CCR 1714.1[d])

PIC Initials

CORRECTIVE ACTION OR ACTION PLAN: _____

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9. Duties of a Pharmacy Technician

Yes No N/A

☐☐☐ 9.1. ~~Registered~~ ~~p~~Pharmacy technicians ~~are performing~~ only perform packaging, manipulative, repetitive, or other nondiscretionary tasks, while assisting and under the direct supervision and control of a pharmacist. (B&PC 4023.5, 4038, 4115, CCR 1793, 1793.2, 1793.7)

☐☐☐ 9.2. Pharmacy technician ratio when only one pharmacist is present, is no more than one technician. For each additional pharmacist present, the ratio may not exceed 2 technicians for each additional pharmacist. (B&PC 4038, 4115, CCR 1793.7[f])

☐☐☐ 9.3. A pharmacy technician or pharmacy technician trainee wears identification, in 18-point type, that identifies him or ~~her self~~ herself as a pharmacy technician or pharmacy technician trainee. (B&PC 680, B&PC 4115.5[e], CCR 1793.7[d])

☐☐☐ 9.4. The pharmacy has a job description for the pharmacy technician and written policies and procedures to ensure compliance with technician requirements. (CCR 1793.7[e])

☐☐☐ 9.5. A pharmacy technician trainee participating in an externship may perform packaging, manipulative, repetitive or other nondiscretionary tasks only under the direct supervision and control of a pharmacist; a pharmacist may only supervise one technician trainee and only for a period of no more than 120 hours. (B&PC 4115.5)

CORRECTIVE ACTION OR ACTION PLAN: _____

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10. Duties of Non-Licensed Personnel

Yes No N/A

☐☐☐ 10.1. A non-licensed person (clerk/typist) is permitted to type a prescription label or otherwise enter prescription information into a computer record system, and—at the direction of a pharmacist—may request and receive refill authorization. (CCR 1793.3)

☐☐☐ 10.2. The number of non-licensed personnel supervised by each pharmacist does not interfere with the effective performance of the pharmacist's responsibilities under the Pharmacy Law. (CCR 1793.3[b])

CORRECTIVE ACTION OR ACTION PLAN: _____

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PHARMACY PRACTICE

11. Consultation/Patient Profile/Review of Drug Therapy

Yes No N/A

☐☐☐ 11.1. Pharmacists provide oral consultation: (~~B&PC 4052[a][7],~~ B&P 4052[a][8], CCR 1707.2)~~:~~

- ☐ 11.1.1. whenever the prescription drug has not been previously dispensed to the patient;
- ☐ 11.1.2. whenever a refill prescription drug is dispensed in a different dosage form, strength, or with new written directions;
- ☐ 11.1.3. upon request; and
- ☐ 11.1.4. whenever the pharmacist deems it is warranted in the exercise of his or her professional judgment.
- ☐ 11.1.5. unless a patient declines the consultation directly to the pharmacist.

☐☐☐ 11.2. The pharmacy maintains patient profile information including allergies, date of birth or age, gender and other prescription and nonprescription drugs that the patient takes. (CCR 1707.1)

☐☐☐ 11.3. The pharmacist reviews a patient's drug therapy and medication record prior to consultation. (CCR 1707.3)

☐☐☐ 11.4. Consultation is performed in a manner that protects the patient's protected health care information and in an area suitable for confidential patient consultation. (Civil Code 56.10, CCR 1714[a])

☐☐☐ 11.5. Appropriate drug warnings are provided orally or in writing. (B&PC 4074, CCR 1744)

☐☐☐ 11.6. If prescription medication is mailed or delivered, written notice about the availability of consultation is provided. (CCR 1707.2[b][2])

CORRECTIVE ACTION OR ACTION PLAN: _____

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12. Prescription Requirements

Yes No N/A

☐☐☐ 12.1. Prescriptions are complete with all the required information. (B&PC 4040, 4070)

☐☐☐ 12.2. Orally transmitted prescriptions are received and reduced to writing only by a pharmacist or intern pharmacist working under the direct supervision of a pharmacist. (B&PC 4070, CCR 1717)

☐☐☐ 12.3. If a prescription is orally or electronically transmitted by the prescriber's agent, the pharmacist makes a reasonable attempt to verify that the prescriber's agent is authorized to do so, and the agent's name is recorded. (B&PC 4071)

☐☐☐ 12.4. If orally transmitted, the pharmacist who received the prescription is identified by initialing the prescription, and if dispensed by another pharmacist, the dispensing pharmacist also initials the prescription. (CCR 1717, 1712)

PIC Initials

☐☐☐ 12.5. The security and confidentiality of electronically transmitted prescriptions are maintained. (B&PC 4070[c], CCR 1717.4[h])

☐☐☐ 12.6. Facsimile prescriptions are received only from a prescriber's office. (B&PC 4040[c])

☐☐☐ 12.7. Internet prescriptions for patients (human or animal) in this state are only dispensed or furnished pursuant to a prior good faith examination. (B&PC 4067[a])

☐☐☐ 12.8. With the exception of those prescriptions written under H&SC 11159.2 and H&SC 11167.5, all written controlled substances prescriptions (Schedules II – V) are on California Security Prescription forms. (H&SC 11164[a], H&SC 11167.5)

☐☐☐ 12.9. All controlled substance prescriptions are valid for six months and are signed and dated by the prescriber. (H&SC 11164[a][1], 11120[e])

☐☐☐ 12.10. All controlled substance prescriptions that are e-prescribed conform to provisions of federal law. (21 CFR 1306.08, 1311.100, 1306.11)

CORRECTIVE ACTION OR ACTION PLAN: _____

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13. Prescription Labeling, Furnishing and Dispensing

Yes No N/A

☐☐☐ 13.1. The prescription label contains all the required information. (B&PC 4076)

☐☐☐ 13.2. The prescription label is formatted in accordance with CCR 1707.5.

~~☐☐☐ 13.3. If requested by the consumer, the pharmacy provides the consumer with a prescription label that is printed in 12-point typeface. (CCR 1707.5[a])~~

~~**Yes No N/A**~~

~~☐☐☐ 13.4. The label on a drug container dispensed to a patient in California conforms to the following format: (CCR 1707.5[a])~~

~~☐ 13.4.1 The name of the patient, name of the drug and strength of the drug, the directions for use of the drug, the condition or purpose for which the drug was prescribed, if indicated on the prescription, are clustered into one area of the label and comprise at least 50 percent of the label.~~

~~☐ 13.4.2 The label is highlighted in bold typeface or color or uses blank space to set off the items in 13.4.1; (CCR 1707.5[a][2])~~

~~☐ 13.4.3 When applicable, standardized directions for use are utilized. (CCR 1707.5[a][4])~~

☐☐☐ ~~13.5. The pharmacy is exempt from the prescription label requirements in CCR 1707.5.~~

~~Exemption approved by board from: _____ to _____~~

☐☐☐ 13.6. The ~~E~~expiration date~~s~~ of a ~~drugs'~~ drug's effectiveness ~~are~~ is consistent with those of the manufacturer ~~if the information is required on the original manufacturer's label~~. (B&PC 4076)

☐☐☐ 13.7. The trade name or generic name and manufacturer of the prescription drug is accurately identified on the label and prescription record. (B&PC 4076, CCR 1717[b][2])

☐☐☐ 13.8. Generic substitution is communicated to the patient. (B&PC 4073)

☐☐☐ 13.9. If the prescription is filled by a pharmacy technician, before dispensing the prescription is checked for accuracy by a licensed pharmacist and that pharmacist initials the prescription label or as otherwise allowed. (B&PC 4115, CCR 1793.7, CCR 1712)

☐☐☐ 13.10. The federal warning label prohibiting transfer of controlled substances is on the prescription container. (21 CFR 290.5)

☐☐☐ 13.11. Prescriptions are dispensed in a new and child-resistant container, or senior-adult ease-of-opening tested container, or in a non-complying package only pursuant to the prescriber or when requested by the purchaser. (15 USC 1473[b], 16 CFR 1700.15, CCR 1717)

☐☐☐ 13.12. Patient package inserts are dispensed with all estrogen medications. (21 CFR 310.515)

☐☐☐ 13.13. The pharmacy provides patients with Black Box Warning Information in conformance with 21 CFR 201.57[c].

☐☐☐ 13.14. Medication guides are provided on required medications. (21 CFR 208.1)

☐☐☐ 13.~~14~~15. The pharmacy furnishes dangerous drugs in compliance with B&PC 4126.5 only to a patient pursuant to a prescription, a wholesaler from whom the dangerous drugs were purchased, a manufacturer from whom the drugs were purchased, a licensed wholesaler acting as a reverse distributor, another pharmacy to alleviate a temporary shortage with a quantity sufficient to alleviate the temporary shortage, a health care provider authorized to received drugs, or to another pharmacy of common ownership.

☐☐☐ 13.~~15~~16. The label includes a physical description of the dispensed medication, including its color, shape, and any identification code that appears on the tablets or capsules. (B&PC 4076)

Yes No N/A

☐☐☐ 13.~~16~~17. Controlled substance prescriptions are not filled or refilled more than six months from the date written. (H&SC 11200)

☐☐☐ 13.18. Refills for Schedule III and IV controlled substance prescriptions are limited to a maximum of 5 times within 6 months, and all refills taken together do not exceed a 120 day supply. (H&SC 11200)

☐☐☐ 13.~~17~~ 19. The pharmacy dispenses not more than a 90-day supply of a dangerous drug with the following exceptions medications~~(other than controlled substances, or psychotropic medication or drugs)~~: (B&PC 4064.5)

- Controlled substances

PIC Initials

- Psychotropic medications
- Self-administered hormonal contraception

☐ 13.~~17~~ 20.1 Where the prescription specifies an initial quantity of less than a 90-day supply followed by periodic refills; **and where:** (B&PC 4064.5[a])

☐ 13.~~17~~20.1.1 The prescriber has not indicated "no change to quantity" or words of similar meaning; (B&PC 4064.5[d])

☐ 13.~~17~~20.1.2. The patient has completed an initial 30-day supply; (B&PC 4064.5[a][1]) (This is not required where the prescription continues the same medication as previously dispensed in a 90-day supply. B&PC 4064.5[b])

☐ 13.~~17~~20.1.3. The total quantity dispensed does not exceed the total quantity authorized on the prescription, including refills; (B&PC 4064.5[a][2])

☐ 13.~~17~~20.1.4. The prescriber has not specified on the prescription that dispensing the prescription in an initial amount, followed by periodic refills, is medically necessary; and (B&PC 4064.5[a][3])

☐ 13.~~17~~20.1.5. The pharmacist is exercising his or her professional judgment. (B&PC 4064.5[a][4])

☐ 13.~~17~~20.2. The pharmacist notifies the prescriber of the increase in quantity dispensed. (B&PC 4064.5[c])

☐☐☐ 13.~~18~~21. The pharmacist includes a written label on the drug container indicating that the drug may impair a person's ability to operate a vehicle or vessel. The label may be printed on an auxiliary label affixed to the prescription container. (B&PC 4074[b], CCR 1744)

CORRECTIVE ACTION OR ACTION PLAN: _____

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14. Refill Authorization

Yes No N/A

☐☐☐ 14.1. Refill authorization from the prescriber is obtained before refilling a prescription. (B&PC 4063, 4064)

☐☐☐ 14.2. Refills are documented. (CCR 1717)

☐☐☐ 14.3. Prescriptions for dangerous drugs or devices are filled without the prescriber's authorization if the prescriber is unavailable to authorize the refill and if, in the pharmacist's professional judgment, failure to refill the prescription might interrupt the patient's ongoing care and have a significant adverse effect on the patient's well-being. (B&PC 4064)

☐☐☐ 14.4. Refills for Schedule II controlled substances are prohibited. (H&SC 11200)

Yes No N/A

☐☐☐ ~~14.5. Refills for Schedule III and IV controlled substance prescriptions are limited to a maximum of 5 times within 6 months, and all refills taken together do not exceed a 120 day supply. (H&SC 11200)~~

CORRECTIVE ACTION OR ACTION PLAN: _____

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15. Quality Assurance and Medication Errors

Yes No N/A

☐☐☐ 15.1. Pharmacy has established quality assurance program that documents medication errors attributable, in whole or in part, to the pharmacy or its personnel. (B&PC 4125, CCR 1711)

☐☐☐ 15.2. Pharmacy quality assurance policies and procedures are maintained in the pharmacy and are immediately retrievable. (CCR 1711[c])

☐☐☐ 15.3. The pharmacist communicates with the patient or patient's agent that a medication error has occurred and the steps required to avoid injury or mitigate the error. (CCR 1711[c][2][A], 1711[c][3])

☐☐☐ 15.4. When a medication error has occurred (drug was administered to or by the patient, or resulted in a clinically significant delay in therapy) the pharmacist communicates to the prescriber that a medication error has occurred. (CCR 1711[c][2][B], 1711[c][3])

☐☐☐ 15.5. Investigation of pharmacy medication errors is initiated within two business days from the date the medication error is discovered. (CCR 1711[d])

☐☐☐ 15.6. The record for quality assurance review for a medication error contains: (CCR 1711[e])

- ☐ 15.6.1. Date, location, and participants in the quality assurance review;
- ☐ 15.6.2. Pertinent data and other information related to the medication error(s) reviewed;
- ☐ 15.6.3. Findings and determinations; and
- ☐ 15.6.4. Recommended changes to pharmacy policy, procedure, systems or processes, if any.

☐☐☐ 15.7. The record of the quality assurance review is immediately retrievable in the pharmacy and is maintained in the pharmacy for at least one year from the date it was created. (CCR 1711[f])

☐☐☐ 15.8. Pharmacists are not deviating from the requirements of a prescription except upon the prior consent of the prescriber, and selection of the drug product is in accordance with B&PC 4073 (generic substitution). (CCR 1716)

CORRECTIVE ACTION OR ACTION PLAN: _____

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16. Erroneous or Uncertain Prescriptions / Corresponding Responsibility for Filling Controlled Substance Prescriptions

Yes No N/A

☐☐☐ 16.1. Before dispensing a prescription that contains any significant error, omission, irregularity, uncertainty, ambiguity or alteration, the pharmacist contacts the prescriber to obtain information needed to validate the prescription. (CCR 1761[a])

☐☐☐ 16.2. Pharmacists are aware of their corresponding responsibility to determine that a prescription written for a controlled substance was issued for legitimate medical purposes only. (H&SC 11153)

☐☐☐ 16.3. Even after conferring with the prescriber, the pharmacist does not dispense a controlled substance prescription if he or she knows or has objective reason to know that the prescription was not issued for a legitimate medical purpose. (CCR 1761[b], HSC 11153)

~~☐☐☐ 16.4. Internet prescriptions are only dispensed on a prescription issued pursuant to a good faith prior examination. (B&PC 4067[a])~~

☐☐☐ 16.~~5~~ 4. Internet prescriptions for controlled substances are only dispensed if in compliance with the Ryan Haight Online Pharmacy Consumer Protection Act of 2008. (21 USC 829, 21 USC 802.)

~~☐☐☐ 16.6. All pharmacists have obtained approval to access information online regarding the controlled substance history of a patient that is stored on the Internet and maintained by the California Department of Justice (HSC 11165.1[a][1][A][i])~~

CORRECTIVE ACTION OR ACTION PLAN: _____

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17. Prescription Transfer

Yes No N/A

☐☐☐ 17.1. Only pharmacists may transfer prescriptions from pharmacy to pharmacy, and records of prescription transfers are kept as required. (CCR 1717 [e][1-6])

☐☐☐ 17.2. Complete and accurate transfer records are kept on each prescription and refill when dispensed by pharmacies sharing a common electronic file. (CCR 1717.1)

a. Schedule III, IV and V Controlled Substance Prescription Transfers

☐☐☐ 17.3. For the **transferring pharmacy**: the prescription hard copy is pulled and "void" is written on its face. The name of the pharmacy to which the prescription is transferred is written on the back of the voided prescription and all other information is recorded as required. The prescription can be transferred only once unless the pharmacies electronically share a real-time, on-line database, in which case the prescription is transferred up to the maximum refills permitted by law and the prescriber's authorization. (CFR 1306.25, CCR 1717[f])

PIC Initials

Yes No N/A

☐☐☐ 17.4. For the **receiving pharmacy**: the prescription is reduced to writing by the pharmacist and "transfer" is written on the face of the transferred prescription and all other information is recorded as required. (CCR 1717[e], CFR 1306.25)

CORRECTIVE ACTION OR ACTION PLAN: _____

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18. Confidentiality of Prescriptions

Yes No N/A

☐☐☐ 18.1. Patient information is maintained to safeguard confidentiality. (Civil Code 56.10 et seq.)

☐☐☐ 18.2. All prescriptions are kept confidential and only disclosed as authorized by law. (CCR 1764)

☐☐☐ 18.3. The pharmacy ensures electronically transmitted prescriptions are received, maintained and transmitted in a secure and confidential manner. (CCR 1717.4[h])

☐☐☐ 18.4. If electronically transmitted prescriptions are received by an interim storage device (to allow for retrieval at a later time), the pharmacy maintains the interim storage device in a manner to prevent unauthorized access. (CCR 1717.4[d])

☐☐☐ 18.5. If pharmacy has established and utilizes common electronic prescription files to maintain required dispensing information, the system shall not permit disclosure of confidential medical information except as authorized by law. (CCR 1717.1)

☐☐☐ 18.6. Destruction or disposal of patient records preserves the confidentiality of the information contained therein. (Civil Code 56.101)

CORRECTIVE ACTION OR ACTION PLAN: _____

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19. Record Keeping Requirements

Yes No N/A

☐☐☐ 19.1. ~~A~~ All completed ~~biennial~~ pharmacy self -assessments ~~is~~ are on file in the pharmacy and maintained for three years. (CCR 1715)

☐☐☐ 19.2. All drug acquisition and disposition records (complete accountability) are maintained for at least three years. These records include (B&PC 4081, 4105, 4333):

- ☐ 19.2.1. Prescription records (B&PC 4081[a])
- ☐ 19.2.2. Purchase Invoices for all prescription drugs (B&PC 4081[b])
- ☐ 19.2.3. Biennial controlled substances inventory (21 CFR 1304.11, CCR 1718)
- ☐ 19.2.4. U.S. Official Order Forms (DEA Form 222) (21 CFR 1305.13)

☐ 19.2.5. Power of Attorney for completion of DEA 222 forms (21 CFR 1305.07)

☐ 19.2.6. Theft and Loss Reports (DEA Form 106) (21 CFR 1301.74[c])

☐ 19.2.7. Record documenting return of drugs to wholesaler or manufacturer (B&PC 4081)

☐ 19.2.8. Record documenting transfers or sales to other pharmacies, licensees and prescribers (B&PC 4081, 4105, CCR 1718)

Yes No N/A

☐☐☐ 19.3. Hypodermic needle and syringe sales by a pharmacist to a person without a prescription are limited to: (B&PC 4145.5)

☐ 19.3.1. Persons known to the pharmacist and when the pharmacist has previously been provided with a prescription or other proof of legitimate medical need;

☐ 19.3.2. Use on animals, provided the person is known to the pharmacist or the person's identity can be properly established.

☐ 19.3.3. The sale of hypodermic needles or syringes at any one time to a person 18 or older **only** if the pharmacy is registered in their local county or city with the Disease Prevention Demonstration Project, and complies with the requirements of that project. (H&S 11364, B&PC 4145.5)

☐ 19.3.4. For industrial use, as determined by the board. (B&PC 4144.5)

☐ 19.3.5. As a public health measure intended to prevent the transmission of HIV, viral hepatitis, and other bloodborne diseases, furnishing of ~~30 or fewer~~ hypodermic needles and syringes for human use to a person 18 years of age or older for personal use. (B&PC 4145.5)

☐☐☐ 19.4. When hypodermic needles and syringes are furnished by a pharmacy ~~or hypodermic needle and exchange program~~ without a prescription, the pharmacy provides the consumer with written information or verbal counseling on how to access drug treatment, testing and treatment for HIV and hepatitis C and safe disposal of sharps waste; and provide one or more of the following disposal options: (B&PC 4145.5[e][f])

☐ 19.4.1. Onsite, safe, hypodermic needle and syringe collection and disposal program.

☐ 19.4.2. Furnish or make available mail-back sharps containers.

☐ 19.4.3. Furnish or make available sharps containers.

☐☐☐ 19.5. Records stored off-site (only for pharmacies who have obtained a waiver from the Board of Pharmacy to store records off-site) are secure and retrievable within two business days. Records for non-controlled substances are maintained on the licensed premises for at least one year from the date of dispensing. Controlled substances are maintained on the licensed premises for at least two years from the date of dispensing. (CCR 1707, B&PC 4105)

Date Waiver Approved _____ Waiver Number _____

Address of offsite storage location: _____

☐☐☐ 19.6. The pharmacy ~~dispenses~~ furnish epinephrine auto-injector to an authorized entity ~~a prehospital emergency medical care person or lay rescuer~~ for the purpose of rendering emergency care in accordance with H&SC 1797.197a (B&PC 4119.3, 4119.4)

PIC Initials

☐ 19.6.1.A ~~physician/surgeon~~ authorized healthcare provider provides a written order that specifies the quantity of epinephrine auto-injectors to be dispensed (B&PC 4119.3[a][1], 4119.4)

☐ 19.6.2. The pharmacy labels each epinephrine auto-injector with the name of the person to whom the prescription was issued, the designation "Section 1797.197a responder" and "First Aid Purposes Only", the dosage, use and expiration date. (B&PC 4119.3[a][1], 4119.4)

☐ 19.6.3. Each dispensed prescription includes the manufacturer's product information sheet for epinephrine auto-injectors. (B&PC 4119.3[a][2], 4119.4)

CORRECTIVE ACTION OR ACTION PLAN: _____

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20. DEA Controlled Substances Inventory

Inventory:

Yes	No	N/A	
☐	☐	☐	20.1. Is completed biennially (every two years). Date completed: _____ (21 CFR 1304.11[b])
☐	☐	☐	20.2. Schedule II inventory is separate from Schedule III, IV and V. (21 CFR 1304.04[h][1], 1304.04[h][2])
☐	☐	☐	20.3. All completed inventories are ~~Is~~ available for inspection for three years. (CCR 1718)
☐	☐	☐	20.4. Indicates on the inventory record whether the inventory was taken at the "open of business" or at the "close of business." (21 CFR 1304.11[a])
☐	☐	☐	20.5. Separate Schedule II records are maintained. This includes Schedule II prescriptions, invoices, US official order forms, and inventory records. (21 CFR 1304.04[h])
☐	☐	☐	20.6. Schedule III-V prescriptions are filed separately from all prescription records or are designated with a red "C." However, the red C requirement is waived if the pharmacy uses an automated data processing or other record keeping system for identification of controlled substances by prescription number and the original prescription documents can be retrieved promptly. (21 CFR 1304.04[h][2])
☐	☐	☐	20.7. Inventories and records for Schedule III-V controlled substances are filed separately or are designated in some manner that makes the required information readily retrievable from ordinary business records. (21 CFR 1304.04)
☐	☐	☐	20.8. U.S. Official Order Form (DEA Form222) or electronic equivalent (CSOS) is utilized when ordering all schedule II controlled substances. When schedule II controlled substance orders are received by the pharmacy, for each item received, the date and quantity received is indicated on the DEA Form222. (21 CFR 1305.03, 1305.12)
☐	☐	☐	20.9. When a pharmacy distributes schedule II controlled substances to a DEA registrant (pharmacies, wholesales, manufacturers, prescribers) a DEA Form222 is prepared by the purchasing

registrant and provided to the pharmacy selling the schedule II controlled substances. (21 CFR 1305.12)

Yes No N/A

☐☐☐ 20.10. When the pharmacy distributes Schedule II controlled substances to other DEA registrants, such as those listed above, Copy 2 of the DEA Form222, is properly completed by the pharmacy selling the controlled substances and that copy is submitted at the end of each month to the DEA regional office. (21 CFR 1305.13)

☐☐☐ 20.11. Sales of controlled substances to other pharmacies or prescribers do not exceed five percent of the total number of controlled substances dosage units dispensed per calendar year; otherwise a wholesaler registration is obtained from DEA and from the board. (21 CFR 1307.11[b], Prescription Drug Marketing Act of 1987 [Pub. L. 100-293, Apr. 22, 1988] 503. B&PC 4160)

☐☐☐ 20.12. When dispensed upon an "oral" order for a true emergency, a Schedule II prescription is provided by the prescriber by the 7th day following the transmission of the oral order. If not received, the pharmacy reports failure to provide prescription document to the California Bureau of Narcotic Enforcement within 144 hours of the failure to provide prescription. (H&SC 11167[d])

☐☐☐ 20.13. The pharmacy generates a controlled substance printout for refills of Schedule III-V prescriptions at least every three days (72 hours) which contains the signature of the dispensing pharmacist, or the pharmacy maintains an alternate system to document the refilling of controlled substance prescriptions that complies with 21 CFR 1306.22.

☐☐☐ 20.14. Any controlled substances drug loss is reported upon discovery to the DEA and within 30 days of discovery to the Board of Pharmacy. (21 CFR 1301.74[c], CCR 1715.6)

☐☐☐ 20.15. Do pharmacy staff hand initial prescription records or prescription labels, or

☐☐☐ 20.16. Does the pharmacy comply with the requirement for a pharmacist to initial or sign a prescription record or prescription label by recording the identity of the reviewing pharmacist in a computer system by a secure means. This computer does not permit the record to be altered after made and the record of the pharmacist's identity made in the computer system is immediately retrievable in the pharmacy. (CCR 1712, 1717[b][1])

☐☐☐ 20.17. All Schedule II through IV controlled substance dispensing data is successfully transmitted to CURES weekly. (H&SC 11165[d])

☐☐☐ 20.18. When furnishing controlled substances for physician office use, a prescription is not issued in order for an individual practitioner to obtain controlled substances for supplying the practitioner's general dispensing to patients. (21 CFR 1306.04[b])

CORRECTIVE ACTION OR ACTION PLAN: _____

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PIC Initials

21. Oral/Electronic Transmission and Fractionation of Schedule II Controlled Substance Prescriptions

Yes No N/A

☐☐☐ 21.1. A faxed prescription for a Schedule II controlled substance is dispensed only **after** the original written prescription is received from the prescriber. (21 CFR 1306.11[a], H&SC 11164)

☐☐☐ 21.2. An oral or electronically transmitted prescription for a Schedule II controlled substance for a patient in a licensed skilled nursing facility, licensed intermediate care facility, licensed home health agency or a licensed hospice care is dispensed only **after** the pharmacist has reduced the prescription to writing on a pharmacy-generated prescription form, and: (21 CFR 1306.11, 21 CFR 1306.11[f], H&SC 11167.5)

- ☐ 21.2.1. The licensed facility provides the pharmacy with a copy of the prescriber's signed order, when available.
- ☐ 21.2.2. The prescription is endorsed by the pharmacist with the pharmacy's name, license, and address.
- ☐ 21.2.3. The physician has signed the original prescription or provides a facsimile signature on the prescription.
- ☐ 21.2.4. The signature of the person who received the controlled substance for the licensed skilled nursing facility, licensed intermediate care facility, licensed home health agency or licensed hospice. (21 CFR 1306.11[f], H&SC 11167.5)

☐☐☐ 21.3. If unable to supply the full quantity, the pharmacist partially fills a Schedule II prescription and is aware that if the remaining portion of the prescription is to be filled, it must be filled within 72 hours. (21 CFR 1306.13[a])

☐☐☐ 21.4. The pharmacist maintains records of each partial filling (filled within 60 days from the date of prescription issuance) of an original prescription for a Schedule II controlled substance written for a patient of a skilled nursing facility or a patient diagnosed as "terminally ill." (21 CFR 1306.13[b], CCR 1745)

☐☐☐ 21.5 The pharmacist maintains records of each partial filling (filled within 30 days from the date of prescription issuance) of an original prescription for a Schedule II controlled substance written when requested by the patient or practitioner. (21 USC 829[f])

☐☐☐ 21.~~5~~6. The pharmacist, in a true emergency dispenses a Schedule II controlled substance from a prescription transmitted orally or electronically by a prescriber. If the order is written by the prescriber, the prescription is in ink, signed and dated by the prescriber. If the prescription is orally or electronically transmitted, it must be reduced to hard copy. The prescriber provides a written prescription on a controlled substance form that meets the requirements of H&SC 11162.1 by the seventh day following the transmission of the initial order. (21 CFR 1306.11[d], H&SC 11167)

☐☐☐ 21.~~6~~7. All prescriptions received, maintained or transmitted by the pharmacy, whether new or refill, received orally, in writing or electronically, are handled to ensure their security, integrity, authenticity and confidentiality. (CCR 1717.4)

PIC Initials

☐☐☐ 21.~~7~~8. Electronic image transmission prescriptions are either received in hard copy or the pharmacy has the capacity to retrieve a hard copy facsimile of the prescription from the pharmacy's computer memory. (CCR 1717.4[e])

☐☐☐ 21.~~8~~9. All electronically transmitted prescriptions include the name & address of the prescriber, a telephone number for oral confirmation, date of transmission and the name of identity of the recipient. (CCR 1717.4[c])

Yes No N/A

☐☐☐ 21.~~9~~10. Prescriptions received into an interim storage device, in addition to the prescription information, record and maintain the date the prescription is entered into the device, the date the prescription is transmitted out of the device and the recipient of the outgoing transmission. (CCR 1717.4[d])

☐☐☐ 21.~~10~~11. A computer generated prescription that is not an e-script and is printed out or faxed by the practitioner to the pharmacy must be manually signed. (21 CFR 1306.05)

☐☐☐ 21.~~11~~12. Controlled substances written with the "11159.2 exemption" for the terminally ill are only dispensed when the original prescription is received, is tendered and partially filled within 60 days and no portion is dispensed more than 60 days from the date issued. (H&SC 11159.2, 21 CFR 1306.11[a], CCR 1745)

☐☐☐ 21.~~12~~13. Electronic prescriptions (e-scripts) for controlled substances that are received from the prescriber meet federal requirements. (21 CFR 1306.08, 21 CFR 1311)

CORRECTIVE ACTION OR ACTION PLAN: _____

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22. Automated Dispensing/Delivery Devices

Yes No N/A

☐☐☐ 22.1. Does the pharmacy use an automated dispensing/delivery device and/or prescription drop box? (CCR 1713)

☐☐☐ 22.2. The pharmacy has registered with the board all automated drug delivery systems that it operates in any location within 30 days of installation, removal, and at the time of renewal. (B&PC 4105.5(b))

☐☐☐ 22.3. The pharmacy has policies and procedures for security measures and monitoring of the inventory to prevent theft and diversion. (B&PC 4105.5(c))

☐☐☐ 22.4. The pharmacy reports drugs losses as required by law. (B&PC 4105.5(c))

☐☐☐ 22.~~2~~5. The drugs in an automated dispensing unit are properly labeled and identified with at least the following information: name of drug, strength and dosage form, manufacturer and manufacturer's lot number, and expiration date. (21 CFR Part 210, 211, B&PC 4342, 21 CFR Part 201.17, H&SC 111355)

PIC Initials

☐☐☐ 22.~~3~~4. For an "automated drug delivery system" located in a skilled or intermediate care facility licensed by the Department of Public Health, the following is required:

☐ 22.3.1. Pharmacy and facility have developed policies and procedures to insure safety, accuracy, accountability, security, access, patient confidentiality, and maintenance of the quality, potency, and purity of stored drugs. (H&SC 1261.6[d][1])

☐ 22.3.2. A pharmacist reviews the order and patient's profile prior to the drug being removed. (H&SC 1261.6[e][2])

☐ 22.3.3. Stocking of the automated drug delivery system is done by a pharmacist. (H&SC 1261.6[f])

☐☐☐ 22.4. If the automated drug delivery system utilizes removable pockets, drawers, or similar technology, the stocking system is done outside the facility in a pharmacy and delivered to the facility:

☐ 22.4.1. Drugs are restocked by a pharmacist or by an intern or technician working under the supervision of a pharmacist. (H&SC 1261.6[f][1])

☐ 22.4.2. Removable pockets or drawers are transported between the pharmacy and the facility in a secure tamper-evident container. (H&SC 1261.1[f][2])

CORRECTIVE ACTION OR ACTION PLAN: _____

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23. Repackaging by the Pharmacy

Yes No N/A

☐☐☐ 23.1. Drugs are repackaged (precounted or poured) in quantities suitable for dispensing to patients of the pharmacy. Such repackaging is performed according to the Current Good Manufacturing Practice (CGMP), and the drugs are properly labeled with at least the following information: name of drug, strength, dosage form, manufacturer's name and lot number, expiration date, and quantity per repackaged unit. (21 CFR Part 210, 211 [CGMP], B&PC 4342, H&SC 110105, 111430, CCR 1707.5)

☐☐☐ 23.2. A log is maintained for drugs pre-packed for future dispensing. (CCR 1751.1, 21 CFR Parts 210, 211)

☐☐☐ 23.3. Drugs previously dispensed are re-packaged at the patient's request in compliance with B&PC 4052.7.

CORRECTIVE ACTION OR ACTION PLAN: _____

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24. Refill Pharmacy

Yes No N/A

☐☐☐ 24.1. Pharmacy processes refills for another California licensed pharmacy (CCR 1707.4[a])

If the answer is "yes", name the pharmacy or pharmacies _____

☐☐☐ 24.2. Does the pharmacy employ the use of a common electronic file? If yes, are there policies and procedures in place to prevent unauthorized disclosures? (CCR 1717.1)

☐☐☐ 24.3. Some or all pharmacy refill orders are processed by another California licensed pharmacy. (CCR 1707.4[a])

If the answer is "yes," name of refilling pharmacy(s) _____

If the answer to both questions above is “no” or “not applicable” go to section 23.

☐☐☐ 24.4. Originating pharmacy and refill pharmacy have a contract outlining the refill arrangement, or the pharmacies have the same owner. (CCR 1707.4[a][1])

☐☐☐ 24.5. Refill prescription label meets requirements of B&PC 4076 and CCR 1707.5 and shows the name and address of the refilling and or originating pharmacy. (CCR 1707.4[a][2])

☐☐☐ 24.6. Patient is provided with written information, either on the prescription label or prescription container that describes which pharmacy to contact for questions. (CCR 1707.4[a][3])

Yes No N/A

☐☐☐ 24.7. Both pharmacies maintain complete and accurate records of refill. (CCR 1707.4[a][4])

☐☐☐ 24.8. Both pharmacies are responsible for accuracy of the refilled prescription. (CCR 1707.4[a][5])

☐☐☐ 24.9. Originating pharmacy is responsible for consultation, maintenance of a medication profile and reviewing the patient's drug therapy before delivery of each prescription. (CCR 1707.4[a][6])

CORRECTIVE ACTION OR ACTION PLAN: _____

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Standards of Service for Providers of Blood Clotting Products for Home Use (HSC 125286.10)

Yes No N/A

☐☐☐ 25.1. The pharmacy is a provider of blood clotting products for home use. (HSC 125286.20)

☐ 25.1.1. Health system pharmacy. (HSC 125286.20[j][1][B])

☐ 25.1.2. Pharmacy affiliated with hemophilia treatment centers. (HSC 125286.20[j][1][C])

☐ 25.1.3. Specialty home care pharmacy. (HSC 125286.20[j][1][D])

☐ 25.1.4. Retail pharmacy. (HSC 125286.20[j][1][E])

☐☐☐ 25.2. The pharmacy meets the following requirements:

☐ 25.2.1. Has sufficient knowledge and understanding of bleeding disorders to accurately follow the instructions of the prescribing physician and ensure high-quality service for the patient. (HSC 125286.25[a])

☐ 25.2.2. Has access to a provider with sufficient clinical experience that enables the provider to know when patients have an appropriate supply of clotting factor on hand and about proper storage and refrigeration of clotting factors. (HSC 125286.25[b])

☐ 25.2.3. Maintains 24-hour on-call service 7 days a week, screens telephone calls for emergencies, acknowledges all telephone calls within one hour or less, and has access to knowledgeable pharmacy staffing on call 24 hours a day. (HSC 125286.25[c])

☐ 25.2.4. Has the ability to obtain all brands of blood clotting products approved by the FDA in multiple assay ranges and vial sizes, including products manufactured from human plasma and those manufactured with recombinant biotechnology techniques, provided manufacturer supply exists and payer authorization is obtained. (HSC 125286.25[d])

☐ 25.2.5. Supplies all necessary ancillary infusion equipment and supplies with each prescription, as needed. (HSC 125286.25[e])

☐ 25.2.6. Stores and ships, or otherwise delivers, all blood clotting products in conformity with all state and federally mandated standards, including those set forth in the product's approved package insert. (HSC 125286.25[f])

☐ 25.2.7. Upon authorization for a nonemergency prescription, ships the prescribed blood clotting products and ancillary infusion equipment and supplies to the patient within two business days or less. (HSC 125286.25[g])

☐ 25.2.8. Upon approved authorization to dispense a prescription for an emergency situation, provided manufacturer supply exists, delivers prescribed blood products, ancillary infusion equipment and supplies, and medications to the patient within 12 hours for patients living within 100 miles of a major metropolitan airport, and within one day for patients living more than 100 miles from a major metropolitan airport. (HSC 125286.25[h])

☐ 25.2.9. Provides patients who have ordered their products with a designated contact telephone number for reporting problems with a delivery, and responds to calls within a reasonable time period. (HSC 125286.25[i])

☐ 25.2.10. Notifies patients of Class 1 and Class 2 recalls and withdrawals of blood clotting products and ancillary infusion equipment within 24 hours of receiving such notice, and participates in the National Patient Notification System for blood clotting recalls. (HSC 125286.25[j])

☐ 25.2.11. Provides language interpretive services over the telephone or in person, as needed by the patient. (HSC 125286.25[k])

☐ 25.2.12. Has a detailed plan for meeting the requirements of the Standards of Service for Providers of Blood Clotting Products for Home Use Act in the event of a natural or manmade disaster or other disruption of normal business operations. (HSC 125286.25[l])

PIC Initials

26. Policies and Procedures

Yes No N/A

☐☐☐ 26.1. There are written policies and procedures in place for:

☐ ~~26.1.1. The pharmacist's administration of immunizations by injection pursuant to a prescriber's order or state protocol for immunizations; (B&PC 4052.1[a][3])~~

☐ 26.1.2. Action to be taken to protect the public when a licensed individual employed by or with the pharmacy is known to be chemically, mentally, or physically impaired to the extent that it affects his or her ability to practice the profession or occupation authorized by his or her license, including the reporting to the board within 14 days of receipt or development; (B&PC 4104[a],[c])

☐ 26.1.3. Action to be taken to protect the public when a licensed individual employed by or with the pharmacy is known to have engaged in the theft or diversion or self-use of prescription drugs belonging to the pharmacy, including the reporting to the board within 14 days of receipt or development; (B&PC 4104[b],[c])

☐ 26.1.4. Oral consultation for discharge medications to an inpatient of a health care facility licensed pursuant to H&SC 1250, or to an inmate of an adult correctional facility or juvenile detention facility; (B&PC 4074, CCR 1707.2[b][3])

☐ 26.1.5. Operation of the pharmacy during the temporary absence of the pharmacist for breaks and meal periods including authorized duties of personnel, pharmacist's responsibilities for checking all work performed by ancillary staff, and pharmacist's responsibility for maintaining the security of the pharmacy; (CCR 1714.1[f])

☐ 26.1.6. Assuring confidentiality of medical information if your pharmacy maintains the required dispensing information for prescriptions, other than controlled substances, in a shared common electronic file; (CCR 1717.1[e])

☐ 26.1.7. The delivery of dangerous drugs and dangerous devices to a secure storage facility, if the pharmacy accepts deliveries when the pharmacy is closed and there is no pharmacist present; (B&PC 4059.5[f][1])

☐ 26.1.8. Compliance with Title VII of Public Law 109-177 – Combat Methamphetamine Epidemic Act of 2005;

☐ 26.1.9. Reporting requirements to protect the public; (B&PC 4104)

☐ 26.1.10. ~~Preventing the dispensing of a prescription drug that is contrary to the law;~~ A policy to establish how a patient will receive a medication when a pharmacist has a conscientious objection. (B&PC 733)

☐ 26.1.11. Preventing the dispensing of a prescription when the pharmacist determines that the prescribed drug or device would cause a harmful drug interaction or would otherwise adversely affect the patient's medical condition; and (B&PC 733)

☐ 26.1.12. Helping patients with limited or no English proficiency understand the information on the prescription container label in the patient's language, including the selected means to identify the patient's language and providing interpretive services in the patient's language. (CCR 1707.5)

PIC Initials

Yes No N/A

☐☐☐ 26.2. Does your pharmacy employ the use of a common electronic file?

☐ 26.2.1. If yes, are there policies and procedures in place to prevent unauthorized disclosures? (CCR 1717.1)

☐☐☐ 26.3. Does your pharmacy furnish emergency contraceptives pursuant to B&PC 4052.3[a][1]? (B&PC 4052, CCR 1746) If yes, does the pharmacy

☐ 26.3.1. Follow the protocol for pharmacists furnishing Emergency Contraception (EC) approved by the California State Board of Pharmacy and the Medical Board of California? (CCR 1746)

☐ 26.3.2. Provide the patient with a copy of the current EC Fact Sheet approved by the Board of Pharmacy? (CCR 1746)

☐ 26.3.3. Maintain in the pharmacy EC medications and adjunctive medications (for nausea and vomiting when taken with EC containing estrogens) as listed in the protocol? (CCR 1746)

☐ 26.3.4. Prior to furnishing EC, the pharmacist has completed a minimum of one hour of continuing education specific to emergency contraception. (CCR 1746)

☐ 26.3.5. If no, EC services are not immediately available or any pharmacist declines to furnish pursuant to a conscience clause, does the pharmacist refer the patient to another emergency contraception provider? (CCR 1746)

☐ 26.3.6. Does the pharmacy have a protocol that ensures a patient has timely access to a prescribed drug or device despite a pharmacist's refusal to dispense a prescription or order? (B&PC 733[b])

☐ 26.3.7. If a pharmacist declines to dispense a prescription drug or device pursuant to an order or prescription, the pharmacist has previously notified his or her employer in writing? (B&PC 733[b], B&PC 4052.3)

☐ 26.3.8. If no, EC services are not immediately available or any pharmacist declines to furnish pursuant to a conscience clause, does the pharmacist refer the patient to another emergency contraception provider? (CCR 1746)

☐☐☐ 26.4. Furnishes naloxone hydrochloride in accordance with standardized procedures or protocols developed and approved by both the Board of Pharmacy and the Medical Board of California. (B&PC 4052.01[a], CCR 1746.3)

☐ 26.4.1. Procedures to ensure education of the person to whom the drug is furnished, not limited to opioid prevention, recognition and response, safe administration, potential side effects, or adverse events and the imperative to seek emergency medical care for the patient.

☐ 26.4.2. Procedures for the notification of the patient's primary care provider with patient consent of any drug or device furnished to the patient or entry of appropriate information in a patient record system.

☐☐☐ 26.5. Furnishes nicotine replacement products in accordance with standardized procedures or protocols developed and approved by both the Board of Pharmacy and the Medical Board of California. (B&PC 4052.9, CCR 1746.2)

PIC Initials

☐☐☐ 26.6. Furnishes hormonal contraception products in accordance with standardized procedures or protocols developed and approved by both the Board of Pharmacy and the Medical Board of California. (B&PC 4052.3, CCR 1746.1)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

27. Compounding

Yes No N/A

☐☐☐ 27.1. Prior to allowing any drug product to be compounded in a pharmacy, the pharmacist-in-charge must complete the "Compounding Self-Assessment" Form 17M-39 (Rev. ~~02/12~~ 10/16) (CCR 1735.2~~[j])~~

28. Nuclear Pharmacy

Yes No N/A

☐☐☐ 28.1. All pharmacists handling radioactive drugs are competent in the preparation, handling, storage, receiving, dispensing, disposition and pharmacology of radioactive drugs. (CCR 1708.4)

☐☐☐ 28.2. A pharmacist qualified under CCR 1708.4 to furnish radioactive drugs is in the pharmacy whenever the furnishing of radioactive drugs occurs. All personnel involved in the furnishing of radioactive drugs are under the immediate and direct supervision of such a qualified pharmacist. (CCR 1708.5)

☐☐☐ 28.3. The pharmacy possesses a current Sterile Compounding Permit (B&PC 4127) and is compliant with CCR 1751. (Must also complete Compounding Self-Assessment, 17M-39 Rev. ~~02/12~~ 10/16.) (CCR 1735.2 et al.)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

29. Pharmacies That Donate Drugs to a Voluntary County-Approved Drug Repository and Distribution Program

Yes No N/A

☐☐☐ 29.1. The pharmacy donates medications to a county-approved drug repository and distribution program, and meets the following requirements: (H&SC 150202.5, 150204, B&PC 4169.5)

☐ 29.1.1. The pharmacy is licensed by and is not on probation with the California State Board of Pharmacy, **and** (H&SC 150202.5)

☐ 29.1.2. The pharmacy's primary or sole type of pharmacy practice is limited to skilled nursing facility, home health care, board and care, or mail order. (H&SC 150202.5)

☐☐☐ 29.2. If the pharmacy utilizes a surplus medication collection and distribution intermediary, the pharmacy ensures that the intermediary is licensed by the California State Board of Pharmacy. (B&PC 4169.5)

☐☐☐ 29.3. No controlled substances shall be donated. (H&SC 150204[c][1])

☐☐☐ 29.4. Drugs that are donated are unused, unexpired and meet the following requirements: (H&SC 150202.5, 150204[c])

☐ 29.4.1. Have not been adulterated, misbranded, or stored under conditions contrary to standards set by the USP or the product manufacturer. (H&SC 150204[c][2])

☐ 29.4.2. Were received directly from a manufacturer or wholesaler. (H&SC 150202.5[a])

☐ 29.4.3. Were returned from a health facility to which the drugs were originally issued, in a manner consistent with state and federal law, and where the drugs were centrally stored; were under the control of a health facility staff member; and that were never in the possession of a patient or individual member of the public. (H&C 150202.5[b], 150204[c][3])

☐ 29.4.4. Are in unopened, tamper-evident packaging or modified unit dose containers with lot numbers and expiration dates affixed. (H&SC 105204[d])

☐ 29.4.5. For donated medications that require refrigeration, are medications that are stored, packaged and transported at appropriate temperatures and in accordance with USP standards and pharmacy law. (H&SC 150204[m])

30. Pharmacies That Operate a Voluntary County-Approved Drug Repository and Distribution Program

Yes No N/A

☐☐☐ 30.1. The pharmacy conducts a county-approved drug repository and distribution program. (H&SC 150201, 150204)

☐ 30.1.1. The pharmacy is licensed by and is not on probation with the California State Board of Pharmacy, **and:** (H&SC 150201[a][1])

☐ 30.1.1.1 Is county owned (H&SC 150201[b][1]) or

☐ 30.1.1.2 Contracts with the county to establish a voluntary drug repository and distribution program. (H&SC 150201[b][1], 150200)

☐ 30.1.2. The pharmacy is owned and operated by a primary care clinic licensed by the California Department of Public Health, and is not on probation with the California State Board of Pharmacy. (H&SC 150201[a][2])

Yes No N/A

☐☐☐ 30.2. The pharmacy has been prohibited by the county board of supervisors, the county public health officer, or the California State Board of Pharmacy from participating in the program because it does not comply with the provisions of the program. (H&SC 150204[a][5])

Issued By: _____ Date: _____

PIC Initials

☐☐☐ 30.3. Date that the county health department confirmed receipt of the pharmacy's "notice of intent" to participate in the program: _____ (H&SC 150204[a][3])

☐☐☐ 30.4. The pharmacy provides the county health department on a quarterly basis the name and location of all sources of donated medication it receives. (H&SC 150204[a][4][A])

Date last quarterly report was submitted: _____

☐☐☐ 30.5. The pharmacy complies with the county's established written procedures. (H&SC 150204[b])

Drugs and Maintenance of Drug Stock

☐☐☐ 30.6. Donated medications are segregated from the participating entity's other drug stock by physical means, for purposes that include inventory, accounting and inspection. (H&SC 150204[j])

☐☐☐ 30.7. Records of acquisition and disposition of donated medications are kept separate from the participating entity's other drug acquisition and disposition records. (H&SC 150204[k])

☐☐☐ 30.8. The participating entity follows the same procedural drug pedigree requirements for donated drugs as it does for drugs purchased from a wholesaler or directly from a drug manufacturer. (H&SC 150204[n])

☐☐☐ 30.9. Donated medications received are unused, unexpired and meet the following requirements: (H&SC 150202, 150202.5, 150204[c])

☐ 30.9.1. Are received from authorized sources. (H&SC 150202, 150203)

☐ 30.9.2. No controlled substances are received. (H&SC 150204[c][1])

☐ 30.9.3. Are not adulterated, misbranded, or stored under conditions contrary to USP standards or the product manufacturer. (H&SC 150204[c][2])

☐ 30.9.4. Medications received from a health care facility were centrally stored and under the control of a licensed health care professional or trained staff member of facility, and were never in the possession of a patient or member of the public. (H&SC 150204[c][3])

☐ 30.9.5. Are received in unopened, tamper-evident packaging or modified unit dose containers with lot numbers and expiration dates affixed. (H&SC 150204[d])

☐ 30.9.6. Are maintained in the donated packaging until dispensed to an eligible patient under the program, who presents a valid prescription. (H&SC 150204[i])

☐ 30.9.7. For donated medications that require refrigeration, there are specific procedures to ensure that the medications are packaged, transported, stored, and dispensed at appropriate temperatures and in accordance with USP standards and pharmacy law. (H&SC 150204[m])

Yes No N/A

☐☐☐ 30.10. Donated medication received in open containers is not dispensed under the program or transferred to another participating entity; and once identified, is quarantined immediately and disposed of in accordance with the Medical Waste Management Act. (H&SC 150204[d], 150204[h])

PIC Initials

Transferring Donated Drugs From One Participating Entity to Another

☐☐☐ 30.11. The pharmacy transfers donated medications to another participating county-owned pharmacy within an adjacent county. (H&SC 150204[g][4])

☐☐☐ 30.12. The pharmacy has a written agreement outlining the protocols and procedures for the transfer of donated medications. (H&SC 150204[g][4][A])

Adjacent counties to which donated medications are transferred:

_____

☐☐☐ 30.13. Donated medication is not transferred by any participating entity more than once. (H&SC 150204[g][4][B])

☐☐☐ 30.14. When transferring donated medications, documentation accompanies the medication that identifies the drug name, strength, quantity of medication, and the donating facility from where the medication originated. (H&SC 150204[g][4][C])

☐☐☐ 30.15. When transferring donated medication, documentation includes a statement that the medication may not be transferred to another participating entity. (H&SC 150204[g][4][C])

Dispensing to Eligible Patients

☐☐☐ 30.16. Donated medications that are dispensed to an eligible patient that presents a valid prescription are dispensed in a new and properly labeled container, specific to the eligible patient. (H&SC 150204[i])

☐☐☐ 30.17. The pharmacist adheres to standard pharmacy practices, as required by state and federal law, when dispensing donated medications under this program. (H&SC 150204[f])

PHARMACIST-IN-CHARGE CERTIFICATION:

I, (please print) _____, RPH # _____ hereby certify that I have completed the self-assessment of this pharmacy of which I am the pharmacist-in-charge. Any deficiency identified herein will be corrected. I understand that all responses are subject to verification by the Board of Pharmacy. I further state under penalty of perjury of the laws of the State of California that the information that I have provided in this self-assessment form is true and correct.

Signature _____ Date _____
(Pharmacist-in-Charge)

ACKNOWLEDGEMENT BY PHARMACY OWNER OR HOSPITAL ADMINISTRATOR:

I, (please print) _____, hereby certify under penalty of perjury of the laws of the State of California that I have read and reviewed this completed self-assessment. I understand that failure to correct any deficiency identified in this self-assessment could result in the revocation of the pharmacy's license issued by the California State Board of Pharmacy.

Signature _____ Date _____

PIC Initials

The following **Legal References** are used in the self-assessment form. Many of these references can be viewed on the Board of Pharmacy Web site at www.pharmacy.ca.gov (see *Laws and Regulations*), at the California State Law Library, or at other libraries or Internet web sites.

California Code of Regulations (CCR), Title 16 and Title 24
Business and Professions Code (B&PC), Chapter 9, Division 2
Health and Safety Code (H&SC), Division 10, Uniform Controlled Substances Act
California Code of Regulations (CCR), Chapter 1, Division 5, Title 22
Code of Federal Regulations (CFR), Title 21, Chapter II, Drug Enforcement Administration (www.dea.gov)

California State Board of Pharmacy
1625 N. Market Blvd, N219, Sacramento, CA 95834
Phone: (916) 574-7900
Fax: (916) 574-8618
www.pharmacy.ca.gov

HOSPITAL PHARMACY SELF-ASSESSMENT

Title 16 of the California Code of Regulations section 1715 requires the pharmacist-in-charge of each pharmacy licensed under section 4037 or 4029 of the Business and Professions Code to complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. **The assessment shall be performed before July 1 of every odd-numbered year. The pharmacist-in-charge must also complete a self-assessment within 30 days whenever (1) a new pharmacy permit has been issued, or (2) there is a change in the pharmacist-in-charge. The primary purpose of the self-assessment is to promote compliance through self-examination and education.**

The self-assessment must be completed in its entirety and may be completed online, printed and retained in the pharmacy. Do not copy a previous assessment.

Notes: If dispensing prescriptions for outpatient use, a Hospital Outpatient Pharmacy Self-Assessment (17M-13, Rev. ~~10/14~~ 10/16 must be completed also. A hospital that compounds drug products must also complete the Compounding Self-Assessment (17M-39 Rev. ~~02/12~~ 10/16).)

Each self-assessment must be kept on file in the pharmacy for three years after it is performed.

Pharmacy Name: _____

Address: _____ Phone: _____

Ownership: Sole Owner ☐ Partnership ☐ Corporation ☐ LLC ☐
Non-Licensed Owner ☐ Other (please specify) ☐ _____

Permit #: _____ Exp. Date: _____ Other Permit #: _____ Exp. Date: _____

Licensed Sterile Compounding Permit # _____ Expiration: _____

Accredited by (optional): _____ From: _____ To: _____

Centralized Hospital Packaging Permit #: _____ Exp. Date: _____

DEA Registration #: _____ Exp. Date: _____ Date of DEA Inventory: _____

Hours: *Weekdays* _____ *Sat* _____ *Sun.* _____ *24 Hours* _____

PIC: _____ RPH # _____ Exp. Date: _____

_____
PIC
Initials

Pharmacy staff (pharmacists, interns, technicians):
APP=Advanced Practice Pharmacist, DEA =Drug Enforcement Administration.

1. _____ RPH # _____ Exp. Date:_____
~~APP~~ APH# _____ Exp. Date: _____
DEA # _____ Exp. Date: _____

2. _____ RPH # _____ Exp. Date: _____
~~APP~~ APH # _____ Exp. Date: _____
DEA # _____ Exp. Date: _____

3. _____ RPH # _____ Exp. Date: _____
~~APP~~ APH # _____ Exp. Date: _____
DEA # _____ Exp. Date: _____

4. _____ RPH # _____ Exp. Date: _____
~~APP~~ APH # _____ Exp. Date: _____
DEA # _____ Exp. Date: _____

5. _____ RPH # _____ Exp. Date: _____
~~APP~~ APH # _____ Exp. Date: _____
DEA # _____ Exp. Date: _____

6. _____ RPH # _____ Exp. Date: _____
~~APP~~ APH # _____ Exp. Date: _____
DEA # _____ Exp. Date: _____

7. _____ RPH # _____ Exp. Date: _____
~~APP~~ APH # _____ Exp. Date: _____
DEA # _____ Exp. Date: _____

8. _____ RPH # _____ Exp. Date: _____
~~APP~~ APH # _____ Exp. Date: _____
DEA # _____ Exp. Date: _____

9. _____ INT # _____ Exp. Date: _____

10. _____ INT # _____ Exp. Date: _____

11. _____ INT # _____ Exp. Date: _____

12. _____ INT # _____ Exp. Date: _____

13. _____ TCH # _____ Exp. Date: _____

14. _____ TCH # _____ Exp. Date: _____

15. _____ TCH # _____ Exp. Date: _____

16. _____ TCH # _____ Exp. Date: _____

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PIC
Initials

HOSPITAL PHARMACY SELF-ASSESSMENT

All references to the California Code of Regulations (CCR) are Title 16 unless otherwise noted.

Please mark the appropriate box for each question. If "NO," enter an explanation on "CORRECTIVE ACTION or ACTION PLAN" lines below. If more space is needed, you may add additional sheets.

1. Pharmacy

Yes No N/A

☐☐☐ 1.1. The pharmacy is secure and has provisions for effective control against the theft of dangerous drugs and devices. (B&PC 4116, 4117, CCR 1714)

☐☐☐ 1.2. The pharmacy has procedures in place to take action to protect the public when a licensed individual employed by or with the pharmacy is discovered or known to be chemically, mentally, or physically impaired to the extent it affects his or her ability to practice the profession or occupation authorized by his or her license, or is discovered or known to have engaged in the theft, diversion, or self-use of dangerous drugs. (B&PC 4104[a])

☐☐☐ 1.3. The pharmacy has written policies and procedures for addressing chemical, mental, or physical impairment, as well as theft, diversion, or self-use of dangerous drugs, among licensed individual employed by or with the pharmacy. (B&PC 4104[b])

☐☐☐ 1.4. The pharmacy reports to the board within 14 days of the receipt or development of the following information with regard to any licensed individual employed by or with the pharmacy: (1) any admission by a licensed individual of chemical, mental, or physical impairment affecting his or her ability to practice; (2) Any admission by a licensed individual of theft, diversion, or self-use of dangerous drugs; (3) Any video or documentary evidence demonstrating chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice; (4) Any video or documentary evidence demonstrating theft, diversion, or self-use of dangerous drugs by a licensed individual; (5) Any termination based on chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice; (6) Any termination of a licensed individual based on theft, diversion, or self-use of dangerous drugs. (B&PC 4104[c])

☐☐☐ 1.5. The pharmacy maintains "night stock" medications which are accessible without entering the pharmacy during hours when the pharmacy is closed, and the pharmacist is not available. Access is limited to designated registered nurses. (22 CCR 70263[n])

☐☐☐ 1.6. The pharmacy is of sufficient size and has an unobstructed area to accommodate the safe practice of pharmacy. (CCR 1714)

☐☐☐ 1.7. The pharmacy premises, fixtures, and equipment are maintained in a clean and orderly condition. (CCR 1714)

☐☐☐ 1.8. The pharmacy sink has hot and cold running water. (CCR 1714)

☐☐☐ 1.9. The pharmacy has a readily accessible restroom. (CCR 1714)

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PIC
Initials

Yes No N/A

☐☐☐ 1.10. The original board-issued pharmacy license and the current renewal are posted where they may be clearly read by the purchasing public. (B&PC 4032, 4058)

☐☐☐ 1.11. Pharmacists, interns, pharmacy technicians, and pharmacy technician trainees wear nametags, in 18-point type, that contain their name and license status. (B&PC 680, B&PC 4115.5[e], CCR 1793.7[c])

☐☐☐ 1.12. Does the pharmacy compound sterile drugs?
(~~If yes, complete section 27 – "Compounding"~~) (If yes, complete Compounding Self-Assessment Form 17M-39 10/16)

☐☐☐ 1.13. The pharmacy is subscribed to the board's e-mail notifications. (B&PC 4013)

Date Last Notification Received: _____

E-mail address registered with the board:_____

☐☐☐ 1.14. For a pharmacy whose owner owns two or more pharmacies, the pharmacy receives the board's e-mail notifications through the owner's electronic notice system. (B&PC 4013[c])

Date Last Notification Received: _____

E-mail address registered with the board:_____

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

2. Nursing Stations

Yes No N/A

☐☐☐ 2.1. Adequate space is available at ward or nursing station for the storage of drugs and preparation of medication doses. All such spaces and areas can be locked and are accessible to authorized personnel only. (22 CCR 70269)

☐☐☐ 2.2. The pharmacist, intern, or pharmacy technician completes the monthly inspections of all floor stock and drugs maintained in nursing stations. Any irregularities are reported to the director of nursing services, and as required by hospital policy. (B&PC 4119.7[c], 4115[j], 22 CCR 70263[q][10])

☐ 2.2.1. An intern shall report any irregularities to the pharmacist. (B&PC 4119.7[c]);

☐ 2.2.2. A pharmacy technician shall report any irregularities to the pharmacist-in-charge and to the director of the health care facility within 24 hours. (B&PC 4115[i][3]);

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

_____
PIC Initials

3. Delivery of Drugs

Yes No N/A

☐☐☐ 3.1. Delivery to the pharmacy of dangerous drugs and dangerous devices are only delivered to the licensed premise and signed for and received by a pharmacist. (B&PC 4059.5[a])

☐☐☐ 3.2. 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 premise within one working day following receipt by the hospital, and the pharmacist on duty at that time shall immediately inventory the drugs or devices. (B&PC 4059.5[c])

☐☐☐ 3.3. 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 (B&PC 4059.5[f]):

- ☐ 3.3.1. The drugs are placed in a secure storage facility in the same building as the pharmacy (B&PC 4059.5[f][1]);
- ☐ 3.3.2. 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 (B&PC 4059.5[f][2]);
- ☐ 3.3.3. The secure storage facility has a means of indicating whether it has been entered after dangerous drugs or dangerous devices have been delivered (B&PC 4059.5[f][3]);
- ☐ 3.3.4. The pharmacy maintains written policies and procedures for the delivery of dangerous drugs and dangerous devices to a secure storage facility (B&PC 4059.5[f][4]); and
- ☐ 3.3.5. 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. (B&PC 4059.5[f][5])

☐☐☐ 3.4. Prior to, or at the time of, accepting ownership of a product included in the Drug Supply Chain Security Act from an authorized trading partner, the pharmacy is provided transaction history, transaction information, and a transaction statement. (Title II of the DQSA Section 582[d][i])

☐☐☐ 3.5. Prior to, or at the time of, each transaction in which the pharmacy transfers ownership of a product included in the Drug Supply Chain Security Act to an authorized trading partner, the subsequent owner is provided transaction history, transaction information, and a transaction statement for the product. Note: This requirement does not apply to sales by a pharmacy to another pharmacy to fulfill a specific patient need. (Title II of the DQSA Section 582[d][ii])

☐☐☐ 3.6. The pharmacy captures transaction information (including lot level information, if provided), transaction history, and transaction statements, as necessary to investigate a suspect product, and maintains such information, history, and statements for not less than 6 years after the transaction. (Title II of DQSA Section 582[d][iii])

CORRECTIVE ACTION OR ACTION PLAN: _____

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PIC Initials

4. Drug Stock

Yes No N/A

☐☐☐ 4.1. The drug stock is clean, orderly, properly stored, properly labeled and in-date. (B&PC 4342, H&SC 111255, CCR 1714 (b), 22 CCR 70263[q])

☐☐☐ 4.2. All ward/floor drug stock and drug supplies that are maintained for access when the pharmacist is not available are properly labeled and stored. (22 CCR 70263[n])

☐☐☐ 4.3. Preferentially priced drugs are furnished solely or predominately to inpatients in accordance with provisions of the Nonprofit Institutions Act (15 USC 13c). Such drugs also may be dispensed pursuant to prescriptions for inpatients at the time of discharge, for employees of the hospital, or on an emergency basis for a walk-in customer (provided that sales to walk-ins do not exceed one percent of the pharmacy's total prescription sales). (B&PC 4380, CCR 1710[a])

Yes No N/A

☐☐☐ 4.4. All unit-dose drugs received from a centralized hospital packaging pharmacy are correctly labeled, are barcoded, and the barcode is readable at the patient's bedside. (B&PC 4128.4, 4128.5)

☐☐☐ 4.5. All drugs are maintained in accordance with national standards regarding the storage area and refrigerator or freezer temperature and manufacturer's guidelines. (B&PC 4119.7[b]

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

5. Pharmacies That Donate Drugs to a Voluntary County-Approved Drug Repository and Distribution Program

Yes No N/A

☐☐☐ 5.1. The hospital pharmacy donates medications to a county-approved drug repository and distribution program, and meets the following requirements: (H&SC 150202, 150202.5, 150204)

- ☐ 5.1.1. The hospital pharmacy is licensed by and is not on probation with the California State Board of Pharmacy, **and** (H&SC 150202.5)
- ☐ 5.1.2. The hospital pharmacy's primary or sole type of pharmacy practice is limited to skilled nursing facility, home health care, board and care, or mail order. (H&SC 150202.5)

☐☐☐ 5.2. No controlled substances shall be donated. (H&SC 150204[c][1])

☐☐☐ 5.3. Drugs that are donated are unused, unexpired and meet the following requirements: (H&SC 150202.5, 150204[c])

- ☐ 5.3.1. Have not been adulterated, misbranded, or stored under conditions contrary to standards set by the USP or the product manufacturer. (H&SC 150204[c][2])
- ☐ 5.3.2. Were received directly from a manufacturer or wholesaler. (H&SC 150202.5[a])

_____
PIC Initials

☐ 5.3.3. Were centrally stored and under the control of a health facility staff member, and were never in the possession of a patient or individual member of the public. (H&SC 150202.5[b], 150204[c][3])

☐ 5.3.4. Are in unopened, tamper-evident packaging or modified unit dose containers with lot numbers and expiration dates affixed. (H&SC 105204[d])

☐ 5.3.5. For donated medications that require refrigeration, are medications that are stored, packaged and transported at appropriate temperatures and in accordance with USP standards and pharmacy law. (H&SC 150204[m])

☐☐☐ 5.4. The hospital pharmacy follows the same procedural drug pedigree requirements for donated drugs as it does for drugs purchased from a wholesaler or directly from a drug manufacturer. (H&SC 150204[n])

6. Pharmacist-in-Charge (PIC)

Yes No N/A

☐☐☐ 6.1. The pharmacy has a PIC who is responsible for the daily operation of the pharmacy. (B&PC 4101, 4113, 4305, 4330, CCR 709, 1709.1)

☐☐☐ 6.2. The PIC has adequate authority to assure the pharmacy's compliance with laws governing the operation of a pharmacy (CCR 1709.1[b])

☐☐☐ 6.3. Is the PIC in charge of another pharmacy?

If yes, the pharmacies are within 50 driving distance miles of each other. (CCR 1709.1[c])

If yes, name of other pharmacy _____

☐☐☐ 6.4. Any change of PIC is reported by the pharmacy and the departing PIC to the board in writing within 30 days. (B&PC 4101, 4330)

~~☐☐☐ 6.5. Is the PIC serving concurrently as the designated representative-in-charge for a wholesaler or veterinary food-animal retailer? (CCR 1709.1 [d])~~

~~If yes, name the wholesaler or veterinary food-animal retailer. _____~~

CORRECTIVE ACTION OR ACTION PLAN: _____

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7. Duties of a Pharmacist

Yes No N/A

☐☐☐ 7.1. 7.1. ~~Within the scope of the inpatient pharmacy service, the pharmacist receives a chart order for an inpatient; identifies, evaluates and interprets the chart order; reviews patient's drug regimen and interprets the clinical data in the patient's medication record; consults with any prescriber, nurse or health care professional; calculates drug doses; supervises the packaging of drugs and checks the packaging procedures and products upon completion; is responsible for all activities of pharmacy technicians, interns and clerks related to the furnishing of drugs to ensure~~

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PIC Initials

~~that all such activities are performed completely, safely and without risk of harm to patients; performs any other duty which federal or state law or regulation authorizes only a registered pharmacist to perform; and performs all functions which require professional judgment. (B&PC 4052, 4052.2, CCR 1793.1)~~ Only a pharmacist: (BPC 4052, BPC 4052.2, CCR 1717(c), CCR 1793.1)

- ~~The pharmacist~~ ~~r~~Receives a chart order for an inpatient;
- Identifies, evaluates and interprets the chart order;
- Reviews patient's drug regimen and interprets the clinical data in the patient's medication record;
- Consults with any prescriber, nurse or health care professional;
- Calculates drug doses;
- Supervises the packaging of drugs and checks the packaging procedures and products upon completion;
- Is responsible for all activities of pharmacy technicians, interns and clerks related to the furnishing of drugs to ensure that all such activities are performed completely, safely and without risk of harm to patients;
- Performs any other duty which federal or state law or regulation authorizes only a registered pharmacist to perform; and performs all functions which require professional judgment.

☐☐☐ 7.2 7.2. ~~Pharmacists in a licensed health care facility who are performing the following functions are doing so in accordance with the hospital's policies, procedures and protocols which have been developed by health professionals including physicians, pharmacists, and registered nurses, with the concurrence of the facility administrator; ordering or performing routine drug therapy-related patient assessment procedures; ordering drug therapy-related laboratory tests; administering drugs or biologicals by injection; initiating or adjusting the drug regimen of a patient, and/or performing moderate or waived laboratory tests. Prior to performing any of these functions, the pharmacist must have either (1) successfully completed clinical residency training, or (2) demonstrated clinical experience in direct patient care delivery as specified in B&PC section 4052.2.~~ Pharmacists in a licensed health care facility who are performing the following functions are doing so in accordance with the hospital's policies, procedures and protocols which have been developed by health professionals including physicians, pharmacists, and registered nurses, with the concurrence of the facility administrator: (B&PC 4027, 4051, 4052, 4052.2)

- Ordering or performing routine drug therapy-related patient assessment procedures;
- Ordering drug therapy-related laboratory tests; administering drugs or biologicals by injection;
- Initiating or adjusting the drug regimen of a patient;
- Performing moderate or waived laboratory tests. (Prior to performing any of these functions, the pharmacist must have either (1) successfully completed

clinical residency training, or (2) demonstrated clinical experience in direct patient care delivery as specified in B&PC section 4052.2)

☐☐☐ 7.3. The pharmacist who is authorized to issue an order to initiate or adjust a controlled substance therapy is personally registered with the federal Drug Enforcement Administration. (B&PC 4052[b])

CORRECTIVE ACTION OR ACTION PLAN: _____

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8. Duties of an Advanced Practice Pharmacist

Yes No N/A

☐☐☐ ~~8.1. The pharmacist who is authorized to issue an order to initiate or adjust a controlled substance therapy is personally registered with the federal Drug Enforcement Administration. (B&PC 4052[b])~~

☐☐☐ ~~8.2~~.8.1 The advance practice pharmacist has received an advance practice pharmacist ~~recognition~~ license ~~by~~ from the board and may do the following: (B&PC 4016.5, 4210)

- ☐ ~~8.2.1~~ 8.1.1 Perform patient assessments, order and interpret drug therapy-related tests, and refer patients to other health care providers; (B&PC 4052.6[a])
- ☐ ~~8.2.1~~ 8.1.2 Participate in the evaluation and management of diseases and health conditions in collaboration with other health care providers; (B&PC 4052.6[a])
- ☐ ~~8.2.1~~ 8.1.3 Initiate drug therapy and promptly transmit written notification to, or enter the appropriate information into a patient record system shared with the patient's primary care provider or diagnosing provider; (B&PC 4052.6[b])
- ☐ ~~8.2.1~~ 8.1.4 Adjust or discontinue drug therapy and promptly transmit written notification to the patient's diagnosing prescriber or enters the appropriate information in a patient's record system shared with the prescriber; (B&PC 4052.6[b])
- ☐ ~~8.2.1~~ 8.1.5 Prior to initiating or adjusting a controlled substance therapy, the advance practice pharmacist is personally registered with the federal Drug Enforcement Administration; (B&PC 4052.6[d])
- ☐ ~~8.2.1~~ 8.1.6 Ordering of tests is done in coordination with the patient's primary care provider or diagnosing prescriber, including promptly transmitting written notification to the prescriber or entering information in a patient record system shared with the prescriber. (B&PC 4052.6[e])

9. Duties of an Intern Pharmacist

Yes No N/A

☐☐☐ 9.1. Intern pharmacists are performing all the functions of a pharmacist only under the direct supervision of a pharmacist, and the pharmacist is supervising no more than **two interns** at any one time. (B&PC 4023.5, 4030, 4114, 4119.6, 4119.7, CCR 1726)

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PIC Initials

☐ 9.1.1 Stock, replenish and inspect the emergency pharmaceutical supply container and the emergency medical system supplies. (B&PC 4119.6)

☐ 9.1.2. Inspect the drugs maintained in the health care facility at least once per month. (B&PC 4119.7[c]

Yes No N/A

☐☐☐ 9.2. All prescriptions filled or refilled by an intern are initialed or documented by secure computer entry by a pharmacist prior to dispensing. (CCR 1712[a], 1717[b][1])

☐☐☐ 9.3. During a temporary absence of a pharmacist for a meal period or duty free break, an intern pharmacist does not perform any discretionary duties or act as a pharmacist. (CCR 1714.1[d])

☐☐☐ 9.4. The intern hours affidavits are signed by the pharmacist under whom the experience was earned when applicable. (B&PC 4209, CCR 1726)

CORRECTIVE ACTION OR ACTION PLAN: _____

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10. Duties of a Pharmacy Technician

Yes No N/A

☐☐☐ 10.1. Registered pharmacy technicians are performing packaging, manipulative, repetitive, or other nondiscretionary tasks related to the furnishing of drugs, while assisting and under the direct supervision and control of a pharmacist. (B&PC 4023.5, 4038, 4115, CCR 1793.2)

☐☐☐ 10.2. The ratio is no less than one pharmacist to two technicians. (B&PC 4115[g], CCR 1793.7)

☐☐☐ ~~10.2~~ 10.3. ~~The ratio for technicians performing the tasks above, related to the furnishing of drugs to inpatients, does not exceed one pharmacist on duty for two technicians on duty. However, w~~When prescriptions are dispensed to discharge patients with only one pharmacist, there is no more than one technician performing the tasks as defined in B&PC 4115(a). The ratio of pharmacy technicians performing those tasks for additional pharmacists does not exceed 2:1. (B&PC 4038, 4115, CCR 1793.7[f])

☐☐☐ ~~10.2~~ 10.4. Any function performed by a technician in connection with the dispensing of a prescription or chart order, including repackaging from bulk and storage of pharmaceuticals is verified and documented in writing by a pharmacist or documented by a pharmacist using secure computer entry. (CCR 1712, 1793.7)

☐☐☐ ~~10.2~~ 10.5. A pharmacy technician or pharmacy technician trainee wears identification, in 18-point type that identifies him or her ~~self~~ herself as a pharmacy technician or pharmacy technician trainee. (B&PC 680, B&PC 4115.5[e], CCR 1793.7[d])

☐☐☐ ~~10.2~~ 10.6. The pharmacy has a job description for the pharmacy technician and written policies and procedures to ensure compliance with the technician requirements. (CCR 1793.7)

~~☐☐☐ 10.6. The ratio is no less than one pharmacist to two technicians. (B&PC 4115[g], CCR 1793.7)~~

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PIC Initials

☐☐☐ 10.7. During a temporary absence of a pharmacist for a meal period or duty free break, a pharmacy technician may, at the discretion of the pharmacist, remain in the pharmacy but may only perform nondiscretionary tasks. Any task performed by the pharmacy technician during the pharmacist's temporary absence is reviewed by the pharmacist. (B&PC 4115[g], CCR 1714.1[c])

Yes No N/A

☐☐☐ 10.8. The general acute-care hospital has an ongoing clinical pharmacy program and allows specially trained pharmacy technicians to check the work of other pharmacy technicians when the following conditions are met: (CCR 1793.8)

- ☐ 10.8.1. Pharmacists are deployed to the inpatient care setting to provide clinical services.
- ☐ 10.8.2. Compounded or repackaged products are previously checked by a pharmacist, then used by the technician to fill unit dose distribution and floor and ward stock.
- ☐ 10.8.3. The overall operations are the responsibility of the pharmacist-in-charge.
- ☐ 10.8.4. The pharmacy technician checking technician program is under the direct supervision of the Pharmacist as specified in the policies and procedures.
- ☐ 10.8.5. There is an ongoing evaluation of the program that uses specialized and advanced trained pharmacy technicians to check the work of other pharmacy technicians.

☐☐☐ 10.9. Pharmacy technician duties include the following:

- ☐ 10.9.1. Package emergency supplies for use in the health care facility and the hospital's emergency medical system. (B&PC 4119, 4115[i])
- ☐ 10.9.2. Seal emergency containers for use in the health care facility. (B&PC 4115[i])
- ☐ 10.9.3. Perform monthly checks of the drug supplies stored throughout the health care facility and report any irregularities within 24 hours to the pharmacist-in-charge and to the director or chief executive officer. (B&PC 4115[i])

CORRECTIVE ACTION OR ACTION PLAN: _____

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11. Duties of Non-Licensed Personnel

Yes No N/A

☐☐☐ 11.1. A non-licensed person (clerk/typist) is permitted to type a prescription label or otherwise enter prescription information into a computer record system, and at the direction of a pharmacist, may request and receive refill authorization. (B&P 4007,CCR 1793.3)

☐☐☐ 11.2. The number of non-licensed personnel supervised by each pharmacist does not interfere with the effective performance of the pharmacist's responsibilities under the Pharmacy Law. (CCR 1793.3[b])

CORRECTIVE ACTION OR ACTION PLAN: _____

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PIC Initials

PHARMACY PRACTICE

12. Pharmaceutical Service Requirements

Yes No N/A

☐☐☐ 12.1. The pharmacy complies with the requirements of 22 CCR 70263, addressing the following areas in written policies and procedures:

- ☐ 12.1.1. Basic information concerning investigational drugs and adverse drug reactions;
- ☐ 12.1.2. Repackaging and compounding records;
- ☐ 12.1.3. Physician orders;
- ☐ 12.1.4. Wards, nursing stations and night stock medications;
- ☐ 12.1.5. Drugs brought into the facility by patients for storage or use;
- ☐ 12.1.6. Bedside medications;
- ☐ 12.1.7. Emergency drug supply;
- ☐ 12.1.8. Pass medications;
- ☐ 12.1.9. Inspection of ward stock, nursing stations and night lockers no less frequently than every 30-days\\Outdated drugs;
- ☐ 12.1.10. Routine distribution of inpatient medications;
- ☐ 12.1.11. Preparation, labeling and distribution of IV admixtures and cytotoxic agents;
- ☐ 12.1.12. Handling of medication when pharmacist not on duty; and
- ☐ 12.1.13. Use of electronic image and data order transmissions.

Yes No N/A

☐☐☐ 12.2. The pharmacy complies with the requirements of 22 CCR 70263, addressing the following areas:

- ☐ 12.2.1. Destruction of controlled substances; and
- ☐ 12.2.2. Development and maintenance of the hospital's formulary. (22 CCR 70263, CCR 1751, CCR 1751.8)

CORRECTIVE ACTION OR ACTION PLAN: _____

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13. Medication/Chart Order

Yes No N/A

☐☐☐ 13.1. The pharmacy receives the original, the electronic transmission, or a copy of the medication order. Faxed copies, tele-autograph copies, or transmissions between computers are permissible. (B&PC 4019, 4040, CCR 1717.4)

☐☐☐ 13.2. The chart or medical record of the patient contains all of the information required by B&PC 4040 and the chart order is signed by the practitioner authorized by law to prescribe drugs if present or, if not present, within a specified time frame not exceeding 48 hours. (B&PC 4019, 4040, 22 CCR 70263[g])

Yes No N/A

☐☐☐ 13.3. A copy of the chart order is maintained on the premises for three years. (B&PC 4081, 4105, 4333)

☐☐☐ 13.4. The pharmacy furnishes dangerous drugs or dangerous devices pursuant to preprinted or electronic standing orders, order sets and protocols established under policies and procedures. (B&PC 4119.7)

CORRECTIVE ACTION OR ACTION PLAN: _____

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14. Labeling and Distribution

Yes No N/A

☐☐☐ 14.1. Unit dose medication and ~~parenteral admixtures~~ compounded preparations are properly labeled and include the information as required by B&PC 4076, or the information is otherwise readily available at the time of drug administration. (B&PC 4076, CCR 1735.4, CCR 1751.2)

☐☐☐ 14.2. The pharmacist is responsible for the proper labeling, storage and distribution of investigational drugs pursuant to the written order of the investigator. (22 CCR 70263[o]).

☐☐☐ 14.3. This pharmacy furnishes dangerous drugs in compliance with B&PC 4126.5 only to a patient pursuant to a prescription, a wholesaler from whom the dangerous drugs were purchased, a manufacturer from whom the drugs were purchased, a licensed wholesaler acting as a reverse distributor, another pharmacy to alleviate a temporary shortage with a quantity sufficient to alleviate the temporary shortage, a health care provider authorized to receive drugs, to another pharmacy of common ownership, or to a patient or to another pharmacy pursuant to a prescription. (B&PC 4126.5)

CORRECTIVE ACTION OR ACTION PLAN: _____

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PIC Initials

15. Duration of Drug Therapy

Yes No N/A

☐☐☐ 15.1. The hospital has policies limiting the duration of drug therapy in the absence of the prescriber's specific indication of duration of drug therapy or under other circumstances recommended by the pharmacy and therapeutics committee or its equivalent and approved by the executive committee of the medical staff. Limitations are established for classes of drugs and/or individual drug entities. (22 CCR 70263[j])

CORRECTIVE ACTION OR ACTION PLAN: _____

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16. Confidentiality of Chart Orders, Prescriptions and Patient Medical Information

Yes No N/A

☐☐☐ 16.1. Patient information is maintained to safeguard confidentiality. (Civil Code 56 et seq.)

☐☐☐ 16.2. Patient medical information, all prescriptions (chart orders, patient discharge and employee prescriptions) are confidential and are not disclosed unless authorized by law. (B&PC 4040, CCR 1764, Civil Code 56 et seq.)

☐☐☐ 16.3. Destruction or disposal of patient records preserves the confidentiality of the information contained therein. (Civil Code 56.101)

☐☐☐ 16.4. The pharmacy ensures electronically transmitted prescriptions (chart orders, discharge patient or employee prescriptions) are received, maintained and transmitted in a secure and confidential manner. (CCR 1717.4)

☐☐☐ 16.5. Records stored off-site (only for pharmacies who have obtained a waiver from the Board of Pharmacy to store records off-site) are secure and retrievable within two business days. Records for non-controlled substances are maintained on the licensed premises for at least one year from the date of dispensing. Controlled substances are maintained on the licensed premises for at least two years from the date of dispensing. (CCR 1707, B&PC 4105)

Date Waiver Approved _____ Waiver Number _____

Address of offsite storage location: _____

CORRECTIVE ACTION OR ACTION PLAN: _____

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PIC Initials

17. Quality Assurance and Medication Errors

Yes No N/A

☐☐☐ 17.1. Pharmacy has established quality assurance program that documents medication errors attributable, in whole or in part, to the pharmacy or its personnel. (B&PC 4125, CCR 1711)

☐☐☐ 17.2. Pharmacy quality assurance policies and procedures are maintained in the pharmacy and are immediately retrievable. (CCR 1711[c])

☐☐☐ 17.3. When a medication error has occurred (drug was administered to or by the patient, or resulted in a clinically significant delay in therapy) the pharmacist communicates with the patient or patient's agent that a medication error has occurred and the steps required to avoid injury or mitigate the error. (CCR 1711[c][2][A], 1711 [c][3])

Yes No N/A

☐☐☐ 17.4. When a medication error has occurred (drug was administered to or by the patient, or resulted in a clinically significant delay in therapy) the pharmacist communicates to the prescriber that a medication error has occurred. (CCR 1711[c][2][B], 1711 [c][3])

☐☐☐ 17.5. Investigation of pharmacy medication errors is initiated within two business days from the date the medication error is discovered. (CCR 1711[d])

☐☐☐ 17.6. The record for quality assurance review for a medication error contains: (CCR 1711[e]);

- ☐ 17.6.1. Date, location, and participants in the quality assurance review;
- ☐ 17.6.2. Pertinent data and other information related to the medication error(s) reviewed;
- ☐ 17.6.3. Findings and determinations;
- ☐ 17.6.4. Recommended changes to pharmacy policy, procedure, systems or processes, if any.

☐☐☐ 17.7. The record of the quality assurance review is immediately retrievable in the pharmacy and is maintained in the pharmacy for at least one year from the date it was created. (CCR 1711[f])

☐☐☐ 17.8. Pharmacists are not deviating from the requirements of a prescription except upon the prior consent of the prescriber, and selection of the drug product is in accordance with B&PC 4073 (generic substitution). (CCR 1716)

CORRECTIVE ACTION OR ACTION PLAN: _____

18. Record Keeping Requirements

Yes No N/A

☐☐☐ 18.1. ~~A~~ All completed ~~biennial~~ pharmacy self -assessments ~~is~~ are on file in the pharmacy and is maintained for three years. (CCR 1715)

☐☐☐ 18.2. All drug acquisition and disposition records (complete accountability) are maintained for at least three years. These records include:

- ☐ 18.2.1. Prescription records (B&PC 4081[a])
- ☐ 18.2.2. Purchase Invoices for all prescription drugs (B&PC 4081[b])

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PIC Initials

☐ 18.2.3. Biennial controlled substances inventory (21 CFR 1304.11)

☐ 18.2.4. U.S. Official Order Forms (DEA Form- 222) (21 CFR 1305.13)

☐ 18.2.5. Power of Attorney for completion of DEA 222 forms (21 CFR 1305.07)

☐ 18.2.6. Theft and Loss Reports (DEA Form 106) (21 CFR 1301.74[c])

☐ 18.2.7. Record documenting return of drugs to wholesaler or manufacturer (B&PC 4081)

☐ 18.2.8. Record documenting transfers or sales to other pharmacies and prescribers (B&PC 4059, 4081, 4105, 4332, CCR 1718)

☐ 18.2.9. Centrally stored unused medications donated to a drug repository and distribution program. (H&SC 150200, 150202[a][1]), 150204(k), B&PC 4105(c).

Yes No N/A

☐☐☐ 18.3. Transfers or sales to other pharmacies and prescribers do not exceed five percent of the pharmacy's total annual purchases of dangerous drugs or devices. If more than five percent, registration with the board as a wholesaler has been obtained. (21 CFR 1307.11, Prescription Drug Marketing Act [PDMA] [Pub. L. 100-293, Apr. 11, 1988] 503, B&PC 4160)

☐☐☐ 18.4. If sales or distributions of controlled substances to other hospitals, pharmacies, or prescribers exceed five percent of the total number of controlled substances dosage units (that are furnished to the inpatients or dispensed on prescriptions to discharge patients or employees) per calendar year, the following have been obtained: a separate DEA distributor registration and a wholesaler's permit from the board. (21 CFR 1307.11, PDMA 503, B&PC 4160)

☐☐☐ 18.5. A controlled substances inventory is completed biennially (every two years).

Date completed: _____ (21 CFR 1304.11)

☐☐☐ 18.6. All completed controlled substances inventories are available for inspection for three years. (CCR 1718)

☐☐☐ ~~18.6~~ 18.7. Separate Schedule II records are maintained. This includes triplicate prescriptions, invoices, US official order forms and inventory records. (21 CFR 1304.04)

☐☐☐ ~~18.6~~ 18.8. Inventories and records for Schedule III-V controlled substances are filed separately or maintained in a readily retrievable manner that distinguishes them from other ordinary business records. (21 CFR 1304.04)

☐☐☐ ~~18.6~~ 18.9. DEA Forms 222 are properly executed. (21 CFR 1305.12)

☐☐☐ ~~18.6~~ 18.10. When the pharmacy distributes Schedule II controlled substances to other DEA registrants, Copy 2 of the DEA Form 222, properly completed, are submitted at the end of each month to the DEA Regional Office. (21 CFR 1305.13)

☐☐☐ ~~18.6~~ 18.11. Any controlled substances drug loss is reported upon discovery to the DEA and to the Board of Pharmacy within 30 days. (21 CFR 1301.74[c], CCR 1715.6)

☐☐☐ ~~18.6~~ 18.12. Records stored off-site (only for pharmacies who have obtained a waiver from the Board of Pharmacy to store records off-site) are secure and retrievable within two business days. Records for non-controlled substances are maintained on the licensed premises for at least one

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PIC
Initials

year from the date of dispensing. Controlled substances are maintained on the licensed premises for at least two years from the date of dispensing. (CCR 1707)

☐☐☐ ~~18.6~~ 18.13. Do pharmacy staff hand initial prescription records and prescription labels, OR

☐☐☐ ~~18.6~~ 18.14. Does the pharmacy comply with the requirement for a pharmacist to initial or sign a prescription record or prescription label by recording the identity of the reviewing pharmacist in a computer system by a secure means. This computer does not permit the record to be altered after made and the record of the pharmacist's identity made in the computer system is immediately retrievable in the pharmacy. (CCR 1712)

CORRECTIVE ACTION OR ACTION PLAN: _____

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19. After-Hours Supply of Medication

Yes No N/A

☐☐☐ 19.1. The pharmacy maintains a record of the drugs taken from the after-hours supply of medications and the pharmacist is notified of such use. The record includes the name and strength of the drug, the amount taken, the date and time, the name of the patient to whom the drug was administered and the signature of the registered nurse. (22 CCR 70263[n])

CORRECTIVE ACTION OR ACTION PLAN: _____

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20. Drug Supplies for Use in Medical Emergencies

Yes No N/A

☐☐☐ 20.1. A supply of drugs for use in medical emergencies only is immediately available at each nursing unit or service area as required. (22 CCR 70263[f])

☐☐☐ 20.2. Written policies and procedures have been developed that establish the contents of the supply, procedures for use, restocking and sealing of the emergency drug supply. (22 CCR 70263[f][1])

☐☐☐ 20.3. The emergency drug supply is stored in a clearly marked portable container which is sealed by the pharmacist in such a manner that a seal must be broken to gain access to the drugs. The contents of the container are listed on the outside cover and include the earliest expiration date of any drugs within. (22 CCR 70263[f][2])

☐☐☐ 20.4. The pharmacist is responsible for inspection of the drug supply at periodic intervals (no less frequently than every 30 days) specified in the writ ten policies. Records of the inspection are kept for at least three years. (22 CCR 70263[f][3])

CORRECTIVE ACTION OR ACTION PLAN: _____

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PIC Initials

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21. Schedule II-V Controlled Substances Floor Stock Distribution Records

Yes No N/A

☐☐☐ 21.1. Records for the distribution of Schedule II-V controlled substances floor stock are open to inspection by authorized officers of the law and are preserved for at least three years from the date of making. (B&PC 4081)

CORRECTIVE ACTION OR ACTION PLAN: _____

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22. Emergency Room Dispensing

Yes No N/A

☐☐☐ 22.1. A prescriber may dispense a dangerous drug, including a controlled substance, to an emergency room patient if all of the following apply: (B&PC 4068[a])

- ☐ 22.1.1. The hospital pharmacy is closed and there is no pharmacist available in the hospital;
- ☐ 22.1.2. The dangerous drug is acquired by the hospital pharmacy;
- ☐ 22.1.3. The dispensing information is recorded and provided to the pharmacy when the pharmacy reopens;
- ☐ 22.1.4. The hospital pharmacy retains the dispensing information and, if the drug is a schedule II, III or IV controlled substance, reports the dispensing information to the Department of Justice pursuant to Section 11165 of the Health and Safety Code;
- ☐ 22.1.5.The prescriber determines that it is in the best interest of the patient that a particular drug regimen be immediately commenced or continued, and the prescriber reasonably believes that a pharmacy located outside the hospital is not available and accessible at the time of dispensing to the patient; and
- ☐ 22.1.6. The quantity of drugs dispensed to any patient pursuant to this section are limited to that amount necessary to maintain uninterrupted therapy during the period when pharmacy services outside the hospital are not readily available or accessible, but shall not exceed a 72-hour supply;

☐☐☐ 22.2. The prescriber shall ensure that the label on the drug contains all the information required by Section 4076. (B&PC 4068[a][7])

☐☐☐ 22.3. The prescriber shall be responsible for any error or omission related to the drugs dispensed. (B&PC 4068[b])

☐☐☐ 22.4. The brand name or generic name and manufacturer of the prescription drug is accurately identified on the label and prescription record. (B&PC 4076, CCR 1717)

☐☐☐ 22.5. Controlled substances are dispensed in prescription containers bearing a federal warning label prohibiting transfer of the drugs. (CFR 290.5)

☐☐☐ 22.6. Prescriptions are dispensed in new, senior-adult ease –of-opening tested, and child-resistant containers or in a noncomplying package, only pursuant to the prescription or when requested by the purchaser. (15 USC 1473 section 4[b], 16 CFR 1700.15., CCR 1717)

☐☐☐ 22.7. Patient package inserts are dispensed with all estrogen medications (21 CFR 310.515)

☐☐☐ 22.8. The pharmacy provides patients with Black Box Warning Information in conformance with 21 CFR 201.57[c].

☐☐☐ 22.9. Medication guides are provided on required medications. (21 CFR 208.1)

CORRECTIVE ACTION OR ACTION PLAN: _____

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23. Discharge Medication/Consultation Services

Yes No N/A

☐☐☐ 23.1. Patients receive information regarding each medication given at the time of discharge. The information includes the use and storage of each medication, the precautions and relevant warnings and the importance of compliance with directions. A written policy has been developed in collaboration with a physician and surgeon, a pharmacist, and a registered nurse and approved by the medical staff that ensures that each patient receives the medication consultation. (B&PC 4074, CCR 1707.2)

☐☐☐ 23.2. Prescriptions are transmitted to another pharmacy as required by law. (B&PC 4072, CCR 1717[f], 1717.4)

☐☐☐ 23.3. The prescription label contains all the required information and is formatted in accordance with CCR 1707.5. (B&PC 4076, CCR 1707.5)

~~☐☐☐ 23.4. If requested by the patient, the prescription label is printed in 12-point typeface. (CCR 1707.5[a])~~

~~☐☐☐ 23.5. The pharmacy is exempt from the prescription label requirements in CCR 1707.5.~~

~~Exemption approved by board from: _____ to _____~~

☐☐☐ 23.~~6~~4. Appropriate drug warnings are provided orally or in writing. (B&PC 4074, CCR 1744)

☐☐☐ 23.~~7~~5. The trade name or generic name and manufacturer of the prescription drug is accurately identified on the label and prescription record. (B&PC 4076, CCR 1717)

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PIC Initials

☐☐☐ 23.~~8~~6. Generic substitution for discharge medications is communicated to the patient, and the name of the dispensed drug product is indicated on the prescription label. (B&PC 4073)

☐☐☐ 23.~~9~~7. If the prescription is filled by a pharmacy technician, the pharmacist's initials are on the prescription label to document the pharmacist's verification of the product. (B&PC 4115[f], CCR 1793.7)

☐☐☐ 23.~~10~~8. Controlled substances are dispensed in prescription containers bearing a federal warning label prohibiting transfer of the drugs. (21 CFR 290.5)

☐☐☐ 23.~~11~~9. Prescriptions are dispensed in a new and child-resistant container, or senior-adult ease-of-opening tested container, or in a non-complying package only pursuant to the prescriber or when requested by the purchaser. (25 USC 1473 section 4[b], 16 CFR 1700.15, CCR 1717)

☐☐☐ 23.~~12~~10. Patient package inserts are dispensed with all estrogen medications. (21 CFR 310.515)

☐☐☐ 23.~~13~~11. The pharmacy provides patients with Black Box Warning Information in conformance with 21 CFR 201.57[c].

☐☐☐ 23.~~14~~12. Medication guides are provided on required medications. (21 CFR 208.1)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

24. Central Filling of Patient Cassettes For Other Hospital Pharmacies

Yes No N/A

☐☐☐ 24.1. Pharmacy processes orders for the filling of patient cassettes for another hospital or Pharmacy receives filled medication orders or patient cassettes from another hospital. (CCR 1710[b])

If the answer is "yes," name of hospital: _____

☐☐☐ 24.2. Pharmacy receives filled medication containers or cassettes from another pharmacy. (CCR 1710[b])

If the answer is "yes," name of supplying pharmacy:

If the answer to this and the previous question is "no" or "not applicable" go to Section ~~23.~~ 25.

☐☐☐ 24.3. Prescription information is electronically transferred between the two pharmacies (CCR 1710[b][6])

☐☐☐ 24.4. Pharmacy has a contract with the ordering hospital pharmacy or has the same owner. (CCR 1710[b][1])

_____
PIC Initials

☐☐☐ 24.5. Filled cassettes are delivered directly to the ordering hospital pharmacy. (CCR 1710[b][2])

☐☐☐ 24.6. Each cassette or container meets the requirements of Business and Professions Code section 4076 (CCR 1710[b][3]

☐☐☐ 24.7. Complete and accurate records are maintained of each cassette fill transaction, including the name of the pharmacist checking the cassettes at each pharmacy. (CCR 1710[b][5])

25. Centralized Hospital Packaging Pharmacy

Yes No N/A

☐☐☐ 25.1. The pharmacy prepares medications, by performing the following specialize functions, for administration only to inpatients within its own general acute care hospital and one or more general acute care hospitals under common ownership and located ~~packages unit dose medication for inpatients of one or more hospitals under common ownership~~ within a 75-mile radius: (B&PC 4128)

Hospitals to which central packaged unit dose medications are provided:

- ☐ 25.1.1. _____ Distance (miles): _____
- ☐ 25.1.2. _____ Distance (miles): _____
- ☐ 25.1.3. _____ Distance (miles): _____
- ☐ 25.1.4. _____ Distance (miles): _____
- ☐ 25.1.5 Prepares unit dose packages for single administration to inpatients from bulk containers, if each unit dose package is barcoded pursuant to Section 4128.4.
- ☐ 25.1.6 Prepares sterile compounded unit dose drugs for administration to inpatients, if each unit dose drug is barcoded pursuant to Section 4128.4.
- ☐ 25.1.7 Prepares compounded unit dose drugs for administration to inpatients, if each unit dose package is barcoded pursuant to Section 4128.4.

☐☐☐ 25.2. The pharmacy prepares and stores limited quantities of unit-dose drugs in advance of a patient-specific prescription in amounts necessary to ensure continuity of care. (B&PC 4128.3)

☐☐☐ 25.3. ~~All~~ Any unit dose medications produced by a centralized hospital packaging pharmacy are barcoded ~~and readable~~ to be machine readable at the inpatient's bedside using barcode medication administrative software. ~~The barcode information contains the required information~~: (B&PC 4128.4)

- ☐ ~~25.3.1. The date the medication was prepared.~~ The barcode medication administration software shall permit health care practitioners to ensure, before a medication is administered to an inpatient, it is the right medication, for the right inpatient, in the right dose, and via the right route of administration.
- ☐ ~~25.3.2. The components used in the drug product.~~ The software verifies that the medication satisfies the above criteria by reading the barcode on the medication and comparing the information retrieved to the electronic medical record of the patient.
- ☐ ~~25.3.3. The lot number or control number.~~

_____
PIC Initials

☐ ~~25.3.4. The expiration date.~~

☐ ~~25.3.5. The National Drug Code Directory number.~~

☐ ~~25.3.6. The name of the centralized hospital packaging pharmacy.~~

Yes No N/A

☐☐☐ 25.4. ~~The~~ Any label for each unit dose medication produced by a centralized hospital packaging pharmacy ~~contains the expiration date, the established name of the drug, the quantity of the active ingredient, and special storage or handling requirements~~ displays a human-readable label that contains the following: (B&PC 4128.5)

☐ 25.4.1 The date the medication was prepared.

☐ 25.4.2 The beyond-use date

☐ 25.4.3 The establishd name of the drug.

☐ 25.4.4 The quantity of each active ingredient.

☐ 25.4.6 The lot number or control number assigned by the centralized hospital packaging pharmacy.

☐ 25.4.5 Special storage or handling requirements.

☐ 25.4.7 The name of the centralized hospital packaging pharmacy.

☐☐☐ 25.5 The pharmacist is able to retrieve all of the following information using the lot number or control number: (B&PC 4128.5)

☐ 25.5.1 The components used in the drug product.

☐ 25.5.2 The expiration date of each of the drug's components.

☐ 25.5.3 The National Drug Code Directory number.

☐☐☐ 25.~~5~~6. The centralized hospital packaging pharmacy and the pharmacists working in the pharmacy are responsible for the integrity, potency, quality, and labeled strength of any unit dose drug product prepared by the centralized hospital packaging pharmacy. (B&PC 4128.7)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

26. Policies and Procedures

Yes No N/A

☐☐☐ 26.1. There are written policies and procedures in place for:

_____
PIC
Initials

☐ 26.1.1. The assurance that each patient received information regarding each medication given at the time of discharge.

☐ 26.1.2. Action to be taken to protect the public when a licensed individual employed by or with the pharmacy is known to be chemically, mentally, or physically impaired to the extent that it effects his or her ability to practice the profession or occupation authorized by his or her license. (B&PC 4104[a])

☐ 26.1.3. Action to be taken to protect the public when a licensed individual employed by or with the pharmacy is known to have engaged in the theft or diversion or self-use of prescription drugs belonging to the pharmacy. (B&PC 4104[b])

☐ 26.1.4. Addressing chemical, mental, or physical impairment, as well as, theft, diversion, or self-use of dangerous drugs, among licensed individual employees by or with the pharmacy. (B&PC 4104[b])

☐ 26.1.5. Reporting to the board within 14 days of the receipt or development of information as specified in B&PC 4104[c][1-6].

☐ 26.1.6. Oral consultation for discharge medications to an inpatient of a health care facility licensed pursuant to H&SC 1250, or to an inmate of an adult correctional facility or juvenile detention facility. (B&PC 4074, CCR 1707.2[b][3])

☐ 26.1.7. Operation of the pharmacy during the temporary absence of the pharmacist for breaks and meal periods including authorized duties of personnel, pharmacist's responsibilities for checking all work performed by ancillary staff, and pharmacist's responsibility for maintaining the security of the pharmacy. (CCR 1714.1[f])

☐ 26.1.8. Assuring confidentiality of medical information if your pharmacy maintains the required dispensing information for prescriptions, other than controlled substances, in a shared common electronic file. (CCR 1717.1[e])

☐ 26.1.9. Helping patients with limited or no English proficiency understand the information on the prescription container label in the patient's language, including the selected means to identify the patient's language and providing interpretive services in the patient's language. (CCR 1707.5)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

27. Compounding

Prior to allowing any drug product to be compounded in a pharmacy, the pharmacist-in-charge must complete the "Compounding Self-Assessment" Form 17M-39 (Rev. ~~02/12~~ 10/16). (CCR 1735.2~~[j]~~[i])

_____
PIC Initials

PHARMACIST-IN-CHARGE CERTIFICATION:

I, (please print) _____, RPH # _____ hereby certify that I have completed the self-assessment of this pharmacy of which I am the pharmacist-in-charge. Any deficiency identified herein will be corrected. I understand that all responses are subject to verification by the Board of Pharmacy. I further state under penalty of perjury of the laws of the State of California that the information that I have provided in this self-assessment form is true and correct.

Signature _____ Date _____
(Pharmacist-in-Charge)

ACKNOWLEDGEMENT BY HOSPITAL ADMINISTRATOR:

I, (please print) _____, hereby certify under penalty of perjury of the laws of the State of California that I have read and reviewed this completed self-assessment. I understand that failure to correct any deficiency identified in this self-assessment could result in the revocation of the pharmacy's license issued by the California State Board of Pharmacy.

Signature _____ Date _____

_____
PIC
Initials

The following **Legal References** are used in the self-assessment form. Many of these references can be viewed on the Board of Pharmacy Web site at www.pharmacy.ca.gov (see *Laws and Regulations),* at the California State Law Library, or at other libraries or Internet web sites.

California Code of Regulations (CCR), Title 16 and Title 24
Business and Professions Code (B&PC), Chapter 9, Division 2
Health and Safety Code (H&SC), Division 10, Uniform Controlled Substances Act
California Code of Regulations (CCR), Chapter 1, Division 5, Title 22
Code of Federal Regulations (CFR), Title 21, Chapter II, Drug Enforcement Administration (www.dea.gov)

California State Board of Pharmacy
1625 N. Market Blvd., Suite N219
Sacramento, California 95834
(916) 574-7900 FAX (916) 574-8618

WHOLESALER
DANGEROUS DRUGS & DANGEROUS DEVICES SELF-ASSESSMENT

All legal references used throughout this self-assessment form are explained on page 21.

All references to "drugs" throughout this self-assessment refer to dangerous drugs and dangerous devices as defined in Business & Professions Code (B&PC) section 4022. (http://www.pharmacy.ca.gov/laws_regs/lawbook.pdf).

Wholesaler Name _____

Address _____

Phone _____

Wholesaler E-mail address _____

Ownership: Please mark one

○ sole owner ○ partnership ○ corporation ○ LLC

○ non- licensed owner ○ Other (please specify) _____

CA Wholesaler Permit #_____ Expiration Date_____

Other Permit #_____ Expiration Date_____
(Use additional sheets if needed.)

DEA Registration #_____ Expiration Date_____

VAWD Accreditation # _____ Expiration Date_____

Date of most recent DEA Inventory _____

Hours: Weekdays _____Sat_____ Sun_____ 24 Hours ○

Designated representative-in-charge (DRIC) / pharmacist (RPH) _____

DRIC License # / RPH License #_____ Expiration Date_____

Website Address (optional):_____

DRAFT

Licensed Wholesaler Staff (designated representative (DR), pharmacist):

1. _____ ~~DR~~EXE#/RPH#_____ _____ Exp. Date

2. _____ ~~DR~~EXE#/RPH#_____ _____ Exp. Date

3. _____ ~~DR~~EXE#/RPH#_____ _____ Exp. Date

4. _____ ~~DR~~EXE#/RPH#_____ _____ Exp. Date

5. _____ ~~DR#~~EXE/RPH#_____ _____ Exp. Date

6. _____ ~~DR~~EXE#/RPH#_____ _____ Exp. Date

7. _____ ~~DR~~EXE#/RPH#_____ _____ Exp. Date

8. _____ ~~DR~~EXE#/RPH#_____ _____ Exp. Date

9. _____ ~~DR~~EXE#/RPH#_____ _____ Exp. Date

10_____ ~~DR~~EXE#/RPH#_____ _____ Exp. Date

DRAFT

Please mark the appropriate box for each question. If "NO," enter an explanation on the "CORRECTIVE ACTION OR ACTION PLAN" lines at the end of the section. If more space is needed, add additional sheets.

1. Ownership/Location

Yes No N/A

☐ ☐ ☐ 1.1. Review the current wholesaler permit for this business. Are the listed owners correct and is the listed address correct? If not, please indicate discrepancy. If either is incorrect, notify the board in writing immediately. (B&PC 4160[a][c][f]) **Attach a copy of the notification letter to the board to this document.**

☐ ☐ ☐ 1.2. Have you established and do you maintain a list of officers, directors, managers and other persons in charge of drug distribution, handling and storage? The list must contain a summary of the duties and qualifications for each job listed. (CCR 1780[f][3]) **Please attach a copy of the list to this document.** (This list should be dated.)

Note: Upon request, the owner must provide the board with the names of the owners, managers and employees and a brief statement of the capacity in which they are employed. (B&PC 4082)

CORRECTIVE ACTION OR ACTION PLAN _____

_____

2. Facility

2.1. Premises, fixtures and equipment:

Yes No N/A

☐ ☐ ☐ 2.1.1. Are clean and orderly

☐ ☐ ☐ 2.1.2. Are well ventilated

☐ ☐ ☐ 2.1.3. Are free from rodents and insects

☐ ☐ ☐ 2.1.4. Are adequately lit

☐ ☐ ☐ 2.1.5. Have plumbing in good repair

☐ ☐ ☐ 2.1.6. Have temperature & humidity monitoring to assure compliance with USP Standards. (The standards for various drugs may differ, see USP 1990 22nd Edition) (CCR 1780[b])

☐ ☐ ☐ 2.2. Is there a quarantine area for outdated, damaged, deteriorated, or misbranded drugs, drugs with the outer or secondary seal broken, partially used containers, or any drug returned under conditions that cast doubt on the drugs safety, identity, strength, quality or purity? (CCR 1780[e])

DRAFT

Yes No N/A

☐ ☐ ☐ 2.3. Are dangerous drugs and dangerous devices stored in a secured and locked area? (CCR 1780[a])

☐ ☐ ☐ 2.4. Is access to areas where dangerous drugs are stored limited to authorized personnel? (CCR 1780[c])

List personnel with keys to the area(s) where drugs are stored (list by name or job title):

_____

_____

_____

Yes No N/A

☐ ☐ ☐ 2.5. Does this business operate only when a designated representative or pharmacist is on the premises? (CCR 1781)

2.6. The wholesale premises is equipped with the following specific security features:

☐ ☐ ☐ 2.6.1. There is an alarm to detect after-hours entry. (CCR 1780[c][1]).

☐ ☐ ☐ 2.6.2. The outside perimeter of the building is well lit (CCR 1780[c][3]).

☐ ☐ ☐ 2.6.3. The security system provides protection against theft and diversion including tampering with computers and or electronic records. (CCR 1780[c][2]).

Explain how your security system complies with these requirements.

_____

_____

Yes No N/A

☐ ☐ ☐ 2.7. Is this business a "reverse distributor", that is, does the business act as an agent for pharmacies, drug wholesalers, third-party logistics provider, manufacturers and others, by receiving, inventorying and managing the disposition of outdated or nonsalable drugs? (B&PC 4040.5)

CORRECTIVE ACTION OR ACTION PLAN _____

_____

DRAFT

Yes No N/A

☐ ☐ ☐ 2.8. The facility is subscribed to the board's email ~~e-mail~~ notifications. (B&PC 4013)

Date Last Notification Received: _____

Email ~~E-mail~~ address registered with the board: _____

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Yes No N/A

☐ ☐ ☐ 2.9. The facility receives the board's email ~~e-mail~~ notifications through the owner's electronic notice system. (B&PC 4013[c])

Date Last Notification Received: _____

Email ~~E-mail~~ address registered with the board: _____

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 12 of this document.

3. Designated Representative-in-Charge / Owner Responsibilities

Yes No N/A

☐ ☐ ☐ 3.1. The owner and the designated representative-in-charge are both equally responsible for maintenance of the records and inventory. (B&PC 4081[b])

☐ ☐ ☐ 3.2. Is the designated representative-in-charge at least 18 years of age and is responsible for the wholesaler's compliance with all state and federal laws for the wholesale distribution of drugs? The designated representative-in-charge may be a pharmacist. (B&PC 4160[d], 4053.1(b))

☐ ☐ ☐ 3.3. The owner must notify the board within 30 days of termination of the designated representative-in-charge or pharmacist. (B&PC 4305.5[a])

☐ ☐ ☐ 3.4. The owner must identify and notify the board of the appointment of a new designated representative-in-charge within 30 days of the termination of the former designated representative-in-charge. (B&PC 4160[d], 4331[c]) The appropriate form for this notification is a "Change of Designated Representative-in-Charge," which is available on the board's website.

DRAFT

Yes No N/A

☐ ☐ ☐ 3.5. The designated representative-in-charge who ends his or her employment at a wholesaler, must notify the board within 30 days. (B&PC 4305.5[c], 4101[b]). This notification is in addition to that required of the owner.

CORRECTIVE ACTION OR ACTION PLAN _____

_____

4. Designated Representative/Pharmacist

Yes No N/A

☐ ☐ ☐ If a designated representative or pharmacist changes his/her name or personal address of record, he/she must notify the board in writing within 30 days. (B&PC 4100, CCR 1704)

CORRECTIVE ACTION OR ACTION PLAN _____

_____

5. Ordering Drugs by this Business for Future Sale/Transfer or Trade

Yes No N/A

☐ ☐ ☐ 5.1. Are drugs ordered only from a business licensed by this board or from a licensed manufacturer? (B&PC 4163[b], 4169)

☐ ☐ ☐ 5.2. If drugs are returned to your premises by a business that originally purchased the drugs from you, do you document the return with an acquisition record for your business and a disposition record for the business returning the drugs? (B&PC 4081, 4332)

☐ ☐ ☐ 5.3. For license verification, the wholesaler may use the licensing information displayed on the board's Internet web site. (B&PC 4106)

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 12 of this document.

DRAFT

6. Receipt of Drugs by this Business

Yes No N/A

☐ ☐ ☐ 6.1. When drugs are received by your business, are they delivered to the licensed wholesale premises, and received by and signed for only by a designated representative or a pharmacist? (B & P 4059.5[a])

☐ ☐ ☐ 6.2. When drugs are received by your business, are the outside containers visibly inspected to identify the drugs and prevent acceptance of contaminated drugs by detecting container damage? (CCR 1780[d][1])

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section ~~11~~ 12 of this document.

7. Drug Stock

Yes No N/A

☐ ☐ ☐ 7.1. Is all drug stock open for inspection during regular business hours? (B&PC 4081[a])

☐ ☐ ☐ 7.2. Are all drugs you order maintained in a secure manner at your licensed wholesale premises? You cannot order, obtain or purchase drugs that you are not able to store on your licensed premises. (B&PC 4167)

☐ ☐ ☐ 7.3. Do all drugs you sell conform to the standards and tests for quality and strength provided in the latest edition of United States Pharmacopoeia or Sherman Food Drug and Cosmetic Act? (B&PC 4342[a])

☐ ☐ ☐ 7.4. Do all drug containers you store on your premises have a manufacturer's expiration date? Any drug without an expiration date is considered expired and may not be distributed. (CCR 1718.1)

☐ ☐ ☐ 7.5. Are outdated, damaged, deteriorated or misbranded drugs held in a quarantine area physically separated from other drugs until returned to the supplier or sent for destruction? (CCR 1780[e], CFR 1307.21)

☐ ☐ ☐ 7.6. Are drugs with the outer or secondary seal broken, or partially used or returned drugs held in a quarantine area and physically separated from other drugs until returned to the supplier or sent for destruction? (CCR 1780[e], CFR1307.21)

DRAFT

Yes No N/A

☐ ☐ ☐ 7.7. When the conditions under which drugs were returned to your premises cast doubt on the drugs' safety, identity, strength, quality or purity, are the drugs quarantined and either returned to your supplier or destroyed? If testing or investigation proves the drugs meet USP standards, the drugs may be returned to normal stock. (CCR 1780[e], CFR 1307.21)

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 12 of this document.

8. Sale or Transfer of Drugs by this Business

Yes No N/A

☐ ☐ ☐ 8.1. Are drugs sold only to businesses or persons licensed by this board, licensed by a prescriber board, licensed as a manufacturer, or to a licensed health care entity authorized to receive drugs?

8.2. Describe how you verify a business or person is appropriately licensed. (B&PC 4059.5[a][b][d], B&PC 4169)

_____

_____

8.3. List any businesses or individuals that order drugs from you that are not licensed according to the list above:

_____

_____

Yes No N/A

☐ ☐ ☐ 8.4. Are drugs only furnished by your business to an authorized person? (B&PC 4163[a]) Note: An authorized person can be a business or natural person.

8.5. Does your business only receive drugs from a pharmacy if:

☐ ☐ ☐ 8.5.1. the pharmacy originally purchased the drugs from you?

☐ ☐ ☐ 8.5.2. your business is a "reverse distributor"?

☐ ☐ ☐ 8.5.3. the drugs are needed to alleviate a shortage? (and only a quantity sufficient to alleviate a specific shortage). (B&PC 4126.5[a])

DRAFT

Yes No N/A

☐ ☐ ☐ 8.6 Are all drugs that are purchased from another business or that are sold, traded or transferred by your business:

☐ ☐ ☐ 8.6.1. transacted with a business licensed with this board as a wholesaler or pharmacy?

☐ ☐ ☐ 8.6.2. free of adulteration as defined by the CA Health & Safety Code section 111250?

☐ ☐ ☐ 8.6.3. free of misbranding as defined by CA Health & Safety Code section 111335?

☐ ☐ ☐ 8.6.4. **confirmed** to not be beyond their use date (expired drugs)? (B&PC 4169)

8.7. List any incidents where adulterated, misbranded or expired drugs were purchased, sold, traded or transferred by this business in the past 2 years.

_____

_____

8.8. If your business sells, transfers, or delivers dangerous drugs or devices outside of California, either to another state within the United States or a foreign country, do you:

Yes No N/A

☐ ☐ ☐ 8.8.1. comply with all CA pharmacy laws related to the distribution of drugs?

☐ ☐ ☐ 8.8.2. comply with the pharmacy law of the receiving state within the United States?

☐ ☐ ☐ 8.8.3. comply with the statues and regulations of the Federal Food and Drug Administration and the Drug Enforcement Administration relating to the wholesale distribution of drugs?

☐ ☐ ☐ 8.8.4. comply with all laws of the receiving foreign country related to the wholesale distribution of drugs?

☐ ☐ ☐ 8.8.5. comply with all applicable federal regulations regarding the exportation of dangerous drugs?

8.9. Describe how you determine a business in a foreign country is authorized to receive dangerous drugs or dangerous devices. (B&PC 4059.5[e])

_____

_____

~~Yes No N/A~~

~~☐ ☐ ☐ 8.10. When you are not an authorized distributor for a drug, a pedigree must accompany the product when sold, traded, or transferred (Prescription Drug Marketing Act of 1987).~~

Yes No N/A

☐ ☐ ☐ <u>8.10. For products included in the Drug Supply Chain Security Act, transaction histories, transaction information, and transaction statements are provided to authorized trading partners when the products are sold, traded, or transferred. (Title II of the DQSA Section 582[c])</u>

DRAFT

☐ ☐ ☐ 8.11. If preferentially priced drugs are sold by your business, that sale complies with the Prescription Drug Marketing Act of 1987 and CA Pharmacy Law. (B&PC 4380)

Yes No N/A

☐ ☐ ☐ 8.12. Does your business' advertisements for dangerous drugs or devices contain false, fraudulent, misleading or deceptive claims? (B&PC 4341, B&PC 651, CCR 1766)

☐ ☐ ☐ 8.13. Do you offer or receive any rebates, refunds, commissions or preferences, discounts or other considerations for referring patients or customers? If your business has any of these arrangements, please list with whom. (B&PC 650)

_____

_____

☐ ☐ ☐ 8.14. Does your business sell dangerous drugs or devices to the master or first officer of an ocean vessel, after your business has received a written prescription? If so, describe how you comply with the ordering, delivery and record keeping requirements for drugs including controlled substances, and the requirement to notify the board of these sales. (B&PC 4066, CFR 1301.25)

_____

_____

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 12 of this document.

9. Donations of Medication to Voluntary Drug Repository and Distribution Programs (H&SC 150200, 150203, 150204)

Yes No N/A

☐☐☐ 9.1. The wholesaler donates medications to a county-approved drug repository and distribution program, provided the following requirements are met: (H&SC 150203, 150204)

☐☐☐ 9.2. No controlled substances shall be donated. (H&SC 150204[c][1])

DRAFT

Yes No N/A

☐☐☐ 9.3. Drugs that are donated are unused, unexpired and meet the following requirements: (H&SC 150204[c])

☐ 9.3.1. Have not been adulterated, misbranded, or stored under conditions contrary to standards set by the USP or the product manufacturer. (H&SC 150204[c][2])

☐ 9.3.2. Have never been in the possession of a patient or individual member of the public. (H&SC 150204[c][3])

☐ 9.3.3. Are in unopened, tamper-evident packaging or modified unit dose containers with lot numbers and expiration dates affixed. (H&SC 105204[d])

☐ 9.3.4. For donated medications that require refrigeration, are medications that are stored, packaged and transported at appropriate temperatures and in accordance with USP standards and pharmacy law. (H&SC 150204[m])

10. Outgoing Shipments of Drugs

Yes No N/A

☐ ☐ ☐ 10.1. Before you ship drugs to a purchaser, do you inspect the shipment to assure the drugs were not damaged while stored by your business? (CCR 1780[d][2])

☐ ☐ ☐ 10.2. Does your business use a common carrier (a shipping or delivery company — UPS, US Mail, FedEx, DHL) for delivery of drug orders to your customers? (B&PC 4166[a])

10.3. List the common carriers (shipping or delivery companies) you use.

_____

_____

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 12 of this document.

11. Delivery of Drugs

Yes No N/A

☐ ☐ ☐ 11.1. Are all drugs ordered by a pharmacy or another wholesaler delivered to the address of the buyer's licensed premises and signed for and received by a pharmacist or designated representative where allowed? (B&PC 4059.5[a])

DRAFT

Yes No N/A

☐ ☐ ☐ 11.2. Are all drugs ordered by a manufacturer or prescriber delivered to the manufacturer's or prescriber's licensed business address and signed for by a person duly authorized by the manufacturer or prescriber? (B&PC 4059.5[d])

☐ ☐ ☐ 11.3. All drugs delivered to a hospital are delivered either to the pharmacy premises or to a central receiving area within the hospital. (B&PC 4059.5[c])

☐ ☐ ☐ 11.4. If drugs are delivered to a pharmacy when the pharmacy is closed and a pharmacist is not on duty, documents are left with the delivery in the secure storage facility, indicating the name and amount of each dangerous drug delivered. (B&PC 4059.5[f])

CORRECTIVE ACTION OR ACTION PLAN _____

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12. **Controlled Substances**

Yes No N/A

☐ ☐ ☐ 12.1. Are there effective controls to prevent theft or diversion of controlled substances? (CFR 1301.71)

☐ ☐ ☐ 12.2. Are DEA requirements for storage of Schedule II controlled substances being met? (specific requirements are listed in CFR 1301.72[a])

☐ ☐ ☐ 12.3. Are DEA requirements for storage of Schedule III, IV and V controlled substances being met? (specific requirements are listed in CFR 1301.72[b])

☐ ☐ ☐ 12.4. Is a DEA inventory completed by your business every two years for all schedules (II - V) of controlled substances? (CFR 1304.11[a][c][e])

☐ ☐ ☐ 12.5. Is the biennial record of the DEA inventory required for Schedule II – V controlled substances conducted every 2 years, retained for 3 years? (CFR 1304.11, CCR 1718, 1780(f)[2])

☐ ☐ ☐ 12.6. Does the biennial inventory record document that the inventory was taken at the "close of business" or "opening of business." (CFR 1304.11)

☐ ☐ ☐ 12.7. Has the person within your business who signed the original DEA registration, or the last DEA registration renewal, created a power of attorney for each person allowed to order Schedule II controlled substances for this business? (CFR 1305.05)

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12.7.1. List the individuals at this location authorized by power of attorney to order controlled substances.

_____

_____

Yes No N/A

☐ ☐ ☐ 12.8. Does your business follow employee-screening procedures required by DEA to assure the security of controlled substances? (CFR 1301.90)

☐ ☐ ☐ 12.9. If any employee of this business possesses, sells, uses or diverts controlled substances, in addition to the criminal liability you must evaluate the circumstances of the illegal activity and determine what action you should take against the employee. (CFR 1301.92)

☐ ☐ ☐ 12.10. Are all controlled substances purchased, sold or transferred by your business, done so for legitimate medical purposes? (H & S 11153.5[a][b][c])

☐ ☐ ☐ 12.11. If your business distributes controlled substances through an agent (i.e. detail person), do you have adequate security measures in place to prevent theft or diversion of those controlled substances (CFR 1301.74[f])

☐ ☐ ☐ 12.12. If a person attempts to purchase controlled substances from your business and the person is unknown to you, you make a good faith effort to determine the person (individual or business) is appropriately licensed to purchase controlled substances. (CFR 1301.74 [a])

12.13. Explain how your business determines an unknown business or individual is appropriately licensed to purchase controlled substances

_____

_____

☐ ☐ ☐ 12.14. If your business uses a common carrier to deliver controlled substances, your business determines the common carrier has adequate security to prevent the theft or diversion of controlled substances. (CFR 1301.74[f])

☐ ☐ ☐ 12.15. If your business uses a common carrier to deliver controlled substances, are the shipping containers free of any outward indication that there are controlled substances within, to guard against storage or in-transit theft? (CFR 1301.74[e])

☐ ☐ ☐ 12.16. Are all Schedule II controlled substances ordered from your business using a fully completed DEA 222 order form? (CFR 1305.03, 1305.06)

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Yes No N/A

☐ ☐ ☐ 12.17. When your business fills orders for Schedule II controlled substances, is the date filled and the number of containers filled recorded on copies 1 and 2 of DEA 222 from? Is copy 1 retained and copy 2 sent to DEA at the close of the month the controlled substance order was filled? (CFR 1305.13 [b])

☐ ☐ ☐ 12.18. If a Schedule II controlled substance order cannot be filled, does your business return copy 1 and 2 of the DEA 222 order form to the buyer with a letter indicating why the order could not be filled? (CFR 1305.15)

☐ ☐ ☐ 12.19. When your business partially fills Schedule II controlled substances, is the balance provided within 60 days of the date of the order form? After the final partial filling, is copy 1 retained in your files and copy 2 of the completed DEA 222 order form sent to DEA by the close of that month? (CFR 1305.13[b])

☐ ☐ ☐ 12.20. For all Schedule II controlled substances received by your business, is copy 3 of the DEA 222 order form completed by writing in for each item received, the date received and the number of containers received? (CFR 1305.13[e])

☐ ☐ ☐ 12.21. Does your business use the online CSOS secure transmission system offered by the Drug Enforcement Administration in place of a paper DEA 222 Form for Schedule II controlled substances? (CFR 1305.21, 1305.22)

☐ ☐ ☐ 12.22. Does your business follow the procedure outlined by DEA to obtain Schedule II controlled substances when the original DEA 222 order form is lost or stolen? (CFR 1305.16(a))

☐ ☐ ☐ 12.23. Are all records of purchase and sale for all schedules of controlled substances for your business kept on your licensed business premises for 3 years from the making? (B&PC 4081, CCR 1718, CFR 1305.17[c], 1305.17[a] [b], and H&SC 11252, 11253, 1304.03)

☐ ☐ ☐ 12.24. Are records of Schedule II controlled substances stored separate from all others? (CFR 1304.04 [f][1])

☐ ☐ ☐ 12.25. Are records for Schedule III-V controlled substances stored so that they are easily retrievable? (CFR 1304.04 [f][2])

☐ ☐ ☐ 12.26. Before your business distributes carfentanil etorphine HCL and or diprenorphine, do you contact the DEA to determine the person (individual or business) is authorized to receive these drugs? (CFR 1301.75[g], 1305.16[b])

☐ ☐ ☐ 12.27. Do you separate records for the sale of carfentanil etorphine hydrochloride and or diprenorphine from all other records? (CFR 1305.17[d])

DRAFT

Yes No N/A

☐ ☐ ☐ 12.28. Does the owner of your business notify the DEA, on a DEA 106 form, of any theft or significant loss of controlled substances upon discovery of the theft? (CFR 1301.74[c])

☐ ☐ ☐ 12.29. Does the owner of your business notify the board of any loss of controlled substances within 30 days of discovering the loss? (CCR 1715.6)

CORRECTIVE ACTION OR ACTION PLAN _____

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13. Policies and Procedures

13.1. Does this business maintain and adhere to policies and procedures for the following: (CCR 1780[f])

Yes No N/A

☐ ☐ ☐ 13.1.1. Receipt of drugs

☐ ☐ ☐ 13.1.2. Security of drugs

☐ ☐ ☐ 13.1.3. Storage of drugs-(including maintaining records to document proper storage)

☐ ☐ ☐ 13.1.4. Inventory of drug-(including correcting inaccuracies in inventories)

☐ ☐ ☐ 13.1.5. Distributing drugs

☐ ☐ ☐ 13.1.6. Identifying, recording and reporting theft or losses

☐ ☐ ☐ 13.1.7. Correcting errors and inaccuracies in inventories

Physically quarantining and separating:

☐ ☐ ☐ 13.1.8. returned, damaged, outdated, deteriorated, misbranded or adulterated drugs

☐ ☐ ☐ 13.1.9. drugs that have been partially used~~?~~

☐ ☐ ☐ 13.1.10. drugs where the outer or secondary seals on the container have been broken

☐ ☐ ☐ 13.1.11. drugs returned to your business, when there is doubt about the safety, identity, strength, quality, or purity of the drug

☐ ☐ ☐ 13.1.12. drugs where the conditions of return cast doubt on safety, identity, strength, quality or purity (CCR 1780[e][f])

CORRECTIVE ACTION OR ACTION PLAN _____

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14. Training

Yes No N/A

☐ ☐ ☐ 14.1 Are training and experience provided to all employees to assure all personnel comply with all licensing requirements? (CCR 1780[f][4])

List the types of training you have provided to staff in the last calendar year and the dates of that training.

_____

_____

CORRECTIVE ACTION OR ACTION PLAN _____

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15. Dialysis Drugs

Yes No N/A

☐ ☐ ☐ 15.1. Does your business provide dialysis drugs directly to patients, pursuant to a prescription? (B&PC 4054) (4059[c]) If so, please complete the next 4 questions, if not proceed to Section ~~15.~~ 16.

☐ ☐ ☐ 15.2. Do home dialysis patients complete a training program provided by a dialysis center licensed by Department of Health Services? Prescriber must provide proof of completion of this training to your business. (B&PC 4059[d])

☐ ☐ ☐ 15.3. Do you have written or oral orders for authorized dialysis drugs for each dialysis patient being serviced. Are such orders received by either a designated representative or a pharmacist? Note: refill orders cannot be authorized for more than 6 months from the date of the original order. (CCR 1787[a][b][c])

☐ ☐ ☐ 15.4. Does your business provide an "expanded invoice" for dialysis drugs dispensed directly to the patient including name of drug, manufacturer, quantities, lot number, date of shipment, and name of the designated representative or pharmacist responsible for distribution? A copy of the invoice must be sent to the prescriber, the patient and a copy retained by this business. Upon receipt of drugs, the patient or patient agent must sign for the receipt for the drugs with any irregularities noted on the receipt. (CCR 1790)

☐ ☐ ☐ 15.5. Is each case or full shelf package of the dialysis drugs dispensed labeled with the patient name and the shipment? Note that additional information as required is provided with each shipment. (CCR 1791)

CORRECTIVE ACTION OR ACTION PLAN _____

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16. Record Keeping Requirements

Yes No N/A

☐ ☐ ☐ 16.1. Does your business' sales record for drugs include date of sale, your business name and address, the business name and address of the buyer, and the names and quantities of the drugs sold? (B&PC 4059[b])

☐ ☐ ☐ 16.2.~~1.~~ Does your business maintain transaction histories, transaction information, and transaction statements for products included in the Drug Supply Chain Security Act? (Title II of the DQSA Section 582[c])

☐ ☐ ☐ 16.3.~~2.~~ Are purchase and sales records for all transactions retained on your licensed premises for 3 years from the date of making? (B&PC 4081[a], 4105[c], 4081, 4332, 4059.5[a]) ~~Note: A drug pedigree is considered to be a part of the records of purchase and sale and must be retained for three years from the making.~~

☐ ☐ ☐ 16.4.~~3.~~ Are all purchase and sales records retained in a readily retrievable form? (B&PC 4105[a])

☐ ☐ ☐ 16.5.~~4.~~ Is a current accurate inventory maintained for all dangerous drugs? (B&PC 4081, 4332, 1718)

☐ ☐ ☐ 16.6.~~5.~~ If you temporarily remove purchase or sales records from your business, does your business retain on your licensed premises at all times, a photocopy of each record temporarily removed? (B&PC 4105[b])

☐ ☐ ☐ 16.7.~~6.~~ Are required records stored off-site only if a board issued written waiver has been granted?

16.8.~~7.~~ If your business has a written waiver, write the date the waiver was approved and the off-site address where the records are stored below. (CCR 1707[a])

Date _____ Address_____

☐ ☐ ☐ 16.9.~~8.~~ Is an off-site written waiver in place and is the storage area secure from unauthorized access? (CCR 1707[b][1])

☐ ☐ ☐ 16.10.~~9.~~ If an off-site written waiver is in place, are the records stored off-site retrievable within 2 business days? (CCR 1707[b][2])

☐ ☐ ☐ 16.11.~~10.~~ Can the records that are retained electronically be produced immediately in hard copy form by any designated representative, if the designated representative-in-charge is not present? (B & P 4105[d])

☐ ☐ ☐ 16.12.~~11.~~ Are records of training provided to employees to assure compliance with licensing requirements, retained for 3 years? (CCR 1780[f][4])

DRAFT

Yes No N/A

☐ ☐ ☐ 16.13.~~12.~~ Has this licensed premises, or the designated representative-in-charge or pharmacist, been cited, fined or disciplined by this board or any other state or federal agency within the last 3 years? If so list each incident with a brief explanation (B&PC 4162[a][4]):

_____

_____

☐ ☐ ☐ 16.14.~~13.~~ Has the licensed premises received any orders of correction from this board? A copy of the order and the corrective action plan must be on the licensed premises for 3 years. (B&PC 4083)

☐ ☐ ☐ 16.15.~~14.~~ Has this business received a letter of admonishment from this board? A copy must be retained on the premises for 3 years from the date of issue. (B&PC 4315[e])

☐ ☐ ☐ 16.16.~~15.~~ If this business dispenses dialysis drugs directly to patients, are the prescription records retained for 3 years, including refill authorizations and expanded invoices for dialysis patients? (CCR 1787[c], 1790)

CORRECTIVE ACTION OR ACTION PLAN _____

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Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 12 of this document.

17. Reporting Requirements to the Board

Yes No N/A

☐ ☐ ☐ 17.1. A designated representative-in-charge who terminates employment at this business, must notify the board within 30 days of the termination (B&PC 4101[b], 4305.5[c].

☐ ☐ ☐ 17.2. The owner must report to the board within 30 days the termination of the designated representative-in-charge or pharmacist (B&PC 4305.5[a])

☐ ☐ ☐ 17.3. The owner must report to the board within 30 days of discovery, any loss of controlled substances, including amounts and strengths of the missing drugs. (CCR 1715.6)

☐ ☐ ☐ 17.4. The owner must notify the DEA, on a DEA form 106, any theft or significant loss of controlled substances upon discovery. (CFR 1301.74[c])

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Yes No N/A

☐ ☐ ☐ 17.5. Do your employees know about their obligation to report any known diversion or loss of controlled substances to a responsible person within your business? (CFR 1301.91)

☐ ☐ ☐ 17.6. The owner must notify the board within 30 days of any change in the beneficial ownership of this business. (B&PC 4201[i], CCR 1709[b])

☐ ☐ ☐ 17.7. When called upon by the board, your business can report all sales of dangerous drugs or controlled substances subject to abuse. (B&PC 4164[a])

☐ ☐ ☐ 17.8. Effective January 1, 2006 your business will develop and maintain a tracking system for individual sales of dangerous drugs at preferential or contract prices to pharmacies that primarily or solely dispense prescription drugs to patients of long-term care facilities. Your system must:

1. identify pharmacies that primarily or solely dispense prescription drugs to patients of long term care facilities
2. identify purchases of any dangerous drugs at preferential or contract prices
3. identify current purchases that exceed prior purchases by 20 percent over the previous 12 calendar months. (B&PC 4164[b])

☐ ☐ ☐ 17.9. I understand that this wholesaler license is not transferable to a new owner. A change of ownership must be reported to this board, as soon as the parties have agreed to the sale. Before the ownership actually changes, an additional application for a temporary permit must be submitted to the board if the new owner wants to conduct business while the board is processing the change of ownership application and until the new permanent permit is issued. A company cannot transfer the ownership of the business via a contract with another individual or business, without the board's approval (B&PC 4201[g])

☐ ☐ ☐ 17.10. The owner of this business must immediately notify the board in writing if any assignment is made for the benefit of creditors, if the business enters into any credit compromise arrangement, files a petition in bankruptcy, has a receiver appointed, or enters into liquidation or any other arrangement that might result in the sale or transfer of drugs. (CCR 1705)

☐ ☐ ☐ 17.11. If this business is discontinued, the owner must notify the board in writing before the actual discontinuation of business. (CCR 1708.2). If the business holds a DEA registration, the owner must notify the DEA promptly of the discontinuation of business and all unused DEA 222 order forms must be returned to the DEA. (CFR 1301.52[a], 1305.14)

CORRECTIVE ACTION OR ACTION PLAN _____

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18. Additional Licenses/Permits Required

18.1. List all licenses and permits required to conduct this business, including local business licenses, wholesale licenses held in other states, permits or licenses required by foreign countries or other entities (B&PC 4059.5[e], 4107, CFR 1305.11[a]) Use additional sheets if necessary.

_____

_____

DESIGNATED REPRESENTATIVE-IN-CHARGE / PHARMACIST CERTIFICATION:

I, (please print) _____, DRIC# / RPH # _____ hereby certify that I have completed the self-assessment of this wholesale business of which I am the designated representative-in-charge (DRIC) / pharmacist (RPH). I understand that all responses are subject to verification by the Board of Pharmacy. I further state under penalty of perjury that the information contained in this self-assessment form is true and correct.

Signature _____ Date _____
Designated Representative-in-Charge (DRIC) / Pharmacist (RPH)

ACKNOWLEDGEMENT BY OWNER, PARTNER OR CORPORATE OFFICER:

I, (please print) _____, hereby certify under penalty of perjury of the laws of the State of California that I have read and reviewed this completed self-assessment. I understand that failure to correct any deficiency identified in this self-assessment could result in the revocation of the pharmacy's license issued by the California State Board of Pharmacy.

Signature _____ Date _____

Legal References

The following Legal References are used in the self-assessment form. Many of these references can be viewed on the Board of Pharmacy Web site at www.pharmacy.ca.gov (see *Laws and Regulations*), at the California State Law Library, or at other libraries or Internet Web sites:

California Code of Regulations (CCR), Title 16, unless otherwise noted

Business and Professions Code (B&PC), Chapter 9, Division 2, unless otherwise noted

Health and Safety Code (H&SC), Division 10, Uniform Controlled Substances Act

Health and Safety Code (H&SC), Division 104, Part 5, Sherman Food, Drug and Cosmetic Laws

United States Code of Federal Regulations (CFR), Title 21, Chapter II, Part 1300, Drug Enforcement Administration, Food and Drugs and Codified Controlled Substances Act (CSA)

~~**California Board of Pharmacy**~~
~~1625 N. Market Blvd., Suite N219~~
~~Sacramento, CA 95834~~
~~Phone: (916) 574-7900~~
~~Fax: (916) 574-8618~~
~~www.pharmacy.ca.gov~~

~~***Pharmacy Law*** may be obtained by contacting:~~
~~LawTech Publishing Co.~~
~~1060 Calle Cordillera, Suite 105~~
~~San Clements, CA 92673~~
~~Phone: (800) 498-0911 Ext. 5~~
~~www.lawtechpublishing.com~~

~~**Pharmacist Recovery Program**~~
~~Phone: (800) 522-9198 (24 hours a day)~~

~~***Prescriber Boards:***~~

~~**Medical Board of California**~~
~~2005 Evergreen St., Suite 1200~~
~~Sacramento, CA 95815~~
~~Phone: (800) 633-2322~~
~~Phone: (916) 263-2382~~
~~Fax: (916) 263-2944~~
~~http://www.mbc.ca.gov~~

~~**Dental Board of California**~~
~~2005 Evergreen St., Suite 1550~~
~~Sacramento, CA 95815~~
~~Phone: (916) 263-2300~~
~~Fax: (916) 263-2140~~
~~http://www.dbc.ca.gov~~

~~**Board of Registered Nursing**~~
~~1625 N. Market Blvd., Suite N217~~
~~Sacramento, CA 95834~~
~~Phone: (916) 322-7697~~
~~Fax: (916) 574-8637~~
~~http://www.rn.ca.gov/~~

~~**Board of Optometry**~~
~~2420 Del Paso Road, Suite 255~~
~~Sacramento, CA 95834~~
~~Phone: (916) 575-7170~~
~~Fax: (916) 575-7292~~
~~http://www.optometry.ca.gov/~~

~~**Osteopathic Medical Board of California**~~
~~1300 National Drive, Suite 150~~
~~Sacramento, CA 95834~~
~~Phone: (916) 928-8390~~
~~Fax: (916) 928-8392~~
~~http://www.ombc.ca.gov~~

~~**Physician Assistant Committee**~~
~~2005 Evergreen St., Suite 1100~~
~~Sacramento, CA 95815~~
~~Phone: (916) 561-8780~~
~~Fax: (916) 263-2671~~
~~http://www.pac.ca.gov~~

~~**Board of Podiatric Medicine**~~
~~2005 Evergreen St., Suite 1300~~
~~Sacramento, CA 95815~~
~~Phone: (916) 263-2647~~
~~Fax: (916) 263-2651~~
~~http://www.bpm.ca.gov~~

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~~**Veterinary Medical Board**~~
~~2005 Evergreen St., Suite 2250~~
~~Sacramento, CA 95815~~
~~Phone: (916) 263-2610~~
~~Fax: (916) 263-2621~~
~~http://www.vmb.ca.gov~~

~~***Federal Agencies:***~~

~~**Food and Drug Administration**~~
~~**– Industry Compliance**~~
~~http://www.fda.gov/oc/industry/centerlinks.html#drugs~~

~~The **Drug Enforcement Administration** may be contacted at:~~

~~**DEA Website:**~~
~~http://www.deadiversion.usdoj.gov~~
~~**Online Registration – New Applicants:**~~
~~http://www.deadiversion.usdoj.gov/drugreg/reg_apps/onlineforms_new.htm~~
~~**Online Registration – Renewal:**~~
~~www.deadiversion.usdoj.gov/drugreg/reg_apps/onlineforms.htm~~
~~**Registration Changes (Forms):**~~
~~http://www.deadiversion.usdoj.gov/drugreg/change_requests/index.html~~
~~**Online DEA 106 Theft/Loss Reporting:**~~
~~https://www.deadiversion.usdoj.gov/webforms/app106Login.jsp~~
~~**Controlled Substance Ordering System (CSOS):** http://www.deaecom.gov/~~

~~**DEA Registration Support (all of CA):**~~
~~(800) 882-9539~~

~~**DEA – Los Angeles**~~
~~255 East Temple Street, 20th Floor~~
~~Los Angeles, CA 90012~~
~~Registration: (888) 415-9822 or (213) 621-6960~~
~~Diversion or Investigation: (213) 621-6942~~

~~**DEA – San Francisco**~~
~~450 Golden Gate Avenue, 14th Floor~~
~~San Francisco, CA 94102~~
~~Registration: (888) 304-3251~~
~~Theft Reports or Diversion: (415) 436-7900~~

~~**DEA – Sacramento**~~
~~4328 Watt Avenue~~
~~Sacramento, CA 95821~~
~~Registration: (888) 304-3251 or (415) 436-7900~~
~~Diversion or Investigation: (916) 480-7250~~

~~**DEA – Riverside**~~
~~4470 Olivewood Avenue~~
~~Riverside, CA 92501-6210~~
~~Registration: (888) 415-9822 or (213) 621-6960~~
~~Diversion or Investigation: (951) 328-6200~~

~~**DEA – Fresno**~~
~~2444 Main Street, Suite 240~~
~~Fresno, CA 93721~~
~~Registration: (888) 304-3251 or (415) 436-7900~~
~~Diversion or Investigation: (559) 487-5406~~

~~**DEA – San Diego and Imperial Counties**~~
~~4560 Viewridge Avenue~~
~~San Diego, CA 92123-1637~~
~~Registration: (800) 284-1152~~
~~Diversion or Investigation: (858) 616-4100~~

~~**DEA – Oakland**~~
~~1301 Clay Street, Suite 460N~~
~~Oakland, CA 94612~~
~~Registration: (888) 304-3251~~
~~Diversion or Investigation: (510) 637-5600~~

~~**DEA – San Jose**~~
~~One North First Street, Suite 405~~
~~San Jose, CA 95113~~
~~Registration: (888) 304-3251~~
~~Diversion or Investigation: (408) 291-2631~~

~~**DEA – Redding**~~
~~310 Hensted Drive, Suite 310~~
~~Redding, CA 96002~~
~~Registration: (888) 304-3251 or (415) 436-7900~~
~~Diversion or Investigation: (530) 246-5043~~

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Attachment 15

Pharmacy Ownership, Management, and Control, Including Through Trusts

§ 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~~, ~~4141~~, ~~4149~~, ~~4160~~, ~~4161~~, ~~4196~~, 4201, 4302, 4304, 4305, 4307, 4308, and 4330, Business and Professions Code.

Attachment 16

Offsite Storage

§ 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.

Attachment 17

Naloxone Fact Sheet

§ 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.

Attachment 18

Compounding
§ 1735.1 and 1735.6

California State Board of Pharmacy
Specific Language to Amend Title 16. CCR §1735.1

Initial proposed changes indicated with single ~~strikethrough~~ for deletions and single underline for additions.

Amend Section 1735.1 Division 17 of Title 16 of California Code of Regulations to Read as follows:

§ 1735.1. Compounding Definitions.

(a) "Ante-area" means an area with ISO Class 8 or better air quality where personnel hand hygiene and garbing procedures, staging of components, and other high-particulate-generating activities are performed, that is adjacent to the area designated for sterile compounding. It is a transition area that begins the systematic reduction of particles, prevents large fluctuations in air temperature and pressures in the cleanroom, and maintains air flows from clean to dirty areas. ISO Class 7 or better air quality is required for ante-areas providing air to a negative pressure room.
(b) "Beyond use date" means the date, or date and time, after which administration of a compounded drug preparation shall not begin, the preparation shall not be dispensed, and the preparation shall not be stored (other than for quarantine purposes).
(c) "Biological Safety Cabinet (BSC)" means a ventilated cabinet for compounding sterile drug preparations, having an open front with inward airflow for personnel protection, downward HEPA-filtered laminar airflow for product protection, and HEPA-filtered exhausted air for environmental protection. Where hazardous drugs are prepared, the exhaust air from the biological safety cabinet shall be appropriately removed by properly designed external building ~~ventilation~~ exhaust. This external exhaust ~~venting~~ should be dedicated to one BSC or CACI.
(d) "Bulk drug substance" means any substance that, when used in the preparation of a compounded drug preparation, processing, or packaging of a drug, is an active ingredient or a finished dosage form of the drug, but the term does not include any intermediate used in the synthesis of such substances.
(e) "Cleanroom or clean area or buffer area" means a room or area with HEPA-filtered air that provides ISO Class 7 or better air quality where the primary engineering control (PEC) is physically located.
(1) For nonhazardous compounding a positive pressure differential of 0.02- to 0.05-inch water column relative to all adjacent spaces is required.
(2) For hazardous compounding at least 30 air changes per hour of HEPA-filtered supply air and a negative pressure of between 0.01 to 0.03 inches of water column relative to all adjacent spaces is required.
(f) "Compounding Aseptic Containment Isolator (CACI)" means a unidirectional HEPA-filtered airflow compounding aseptic isolator (CAI) designed to provide worker protection from

exposure to undesirable levels of airborne drug throughout the compounding and material transfer processes and to provide an aseptic environment for compounding sterile preparations. Air exchange with the surrounding environment should not occur unless the air is first passed through a microbial retentive filter (HEPA minimum) system capable of containing airborne concentrations of the physical size and state of the drug being compounded. Where hazardous drugs are prepared, the exhaust air from the isolator shall be appropriately removed by properly designed external building ventilation. This external venting should be dedicated to one BSC or CACI. Air within the CACI shall not be recirculated nor turbulent.

(g) "Compounding Aseptic Isolator (CAI)" means a form of isolator specifically designed for non-hazardous compounding of pharmaceutical ingredients or preparations while bathed with unidirectional HEPA-filtered air. It is designed to maintain an aseptic compounding environment within the isolator throughout the compounding and material transfer processes. Air exchange into the isolator from the surrounding environment should not occur unless the air has first passed through a microbial retentive filter (HEPA minimum) system capable of containing airborne concentrations of the physical size and state of the drug being compounded. Air within the CAI shall not be recirculated nor turbulent.

(h) "Controlled cold temperature" means 2 degrees to 8 degrees C (35 degrees to 46 degrees F).

(i) "Controlled freezer temperature" means -25 degrees to -10 degrees C (-13 degrees to 14 degrees F) or at a range otherwise specified by the pharmaceutical manufacturer(s) for that product.

(j) "Controlled room temperature" means 20 degrees to 25 degrees C (68 degrees to 77 degrees F).

(k) "Copy or essentially a copy" of a commercially available drug product includes all preparations that are comparable in active ingredients to commercially available drug products, except that it does not include any preparations in which there has been a change, made for an identified individual patient, which produces for that patient a clinically significant difference, as determined by a prescribing practitioner, between that compounded preparation and the comparable commercially available drug product.

(*l*) "Daily" means occurring every day the pharmacy is operating, except when daily monitoring of refrigerator and freezer temperature are required, then daily means every 24 hours.

(m) "Displacement airflow method" means a concept which utilizes a low pressure differential, high airflow principle to maintain segregation from the adjacent ante-area by means of specific pressure differentials. This principle of displacement airflow shall require an air velocity of 40 ft per minute or more, from floor to ceiling and wall to wall, from the clean area across the line of demarcation into the ante-area. The displacement concept may not be used to maintain clean area requirements for sterile compounds which originate from any ingredient that was at any time non-sterile, regardless of intervening sterilization of the ingredient, or for hazardous compounds.

(n) "Dosage unit" means a quantity sufficient for one administration to one patient.

(o) "Equipment" means items that must be calibrated, maintained or periodically certified.

(p) "First air" means the air exiting the HEPA filter in a unidirectional air stream that is essentially particle free.

(q) “Gloved fingertip sampling” means a process whereby compounding personnel lightly press each fingertip and thumb of each hand onto appropriate growth media, which are then incubated at a temperature and for a time period conducive to multiplication of microorganisms, and then examined for growth of microorganisms.
(r) “Hazardous” means all anti-neoplastic agents identified by the National Institute for Occupational Safety and Health (NIOSH) as meeting the criteria for a hazardous drug and any other drugs, compounds, or materials identified as hazardous by the pharmacist-in-charge.
(s) “Integrity” means retention of potency until the beyond use date provided on the label, so long as the preparation is stored and handled according to the label directions.
(t) “Lot” means one or more compounded drug preparation(s) prepared during one uninterrupted continuous cycle of compounding from one or more common active ingredient(s).
(u) “Media-fill test” means a test used to measure the efficacy of compounding personnel in aseptic techniques whereby compounding procedures are mimicked using a growth-based media and then the resulting preparation is evaluated for sterility. The media-fill test must mimic the most complex compounding procedures performed by the pharmacy.
(v) “Non-sterile-to-sterile batch” means any compounded drug preparation containing two (2) or more dosage units with any ingredient that was at any time non-sterile, regardless of intervening sterilization of that ingredient.
(w) “Parenteral” means a preparation of drugs administered in a manner other than through the digestive tract. It does not include topical, sublingual, rectal or buccal routes of administration.
(x) “Personal protective equipment” means clothing or devices that protect the employee from exposure to compounding ingredients and/or potential toxins and minimize the contamination of compounded preparations. These include shoe covers, head and facial hair covers, face masks, gowns, and gloves.
(y) “Potency” means active ingredient strength within +/- 10% (or the range specified in USP37-NF32, 37th Revision, Through 2nd Supplement Effective December 1, 2014) of the labeled amount. Sterile injectable products compounded solely from commercially manufactured sterile pharmaceutical products in a health care facility licensed under section 1250 of the Health and Safety Code are exempt from this definition. For those exempt, the range shall be calculated and defined in the master formula.
(z) “Preparation” means a drug or nutrient compounded in a licensed pharmacy; the preparation may or may not be sterile.
(aa) “Prescriber's office” or “prescriber office” means an office or suite of offices in which a prescriber regularly sees patients for outpatient diagnosis and treatment. This definition does not include any hospital, pharmacy, or other facility, whether or not separately licensed, that may be affiliated with, adjacent to, or co-owned by, the prescriber's practice environment.
(ab) “Primary Engineering Control (PEC)” means a device that provides an ISO Class 5 or better environment through the use of non-turbulent, unidirectional HEPA-filtered first air for compounding sterile preparations. Examples of PEC devices include, but are not limited to, laminar airflow workbenches, biological safety cabinets, sterile compounding automated robots, compounding aseptic isolators, and compounding aseptic containment isolators.

(ac) “Process validation” means demonstrating that when a process is repeated within specified limits, the process will consistently produce preparations complying with predetermined requirements. If any aspect of the process is changed, the process would need to be revalidated.
(ad) “Product” means a commercially manufactured drug or nutrient evaluated for safety and efficacy by the FDA.
(ae) “Quality” means the absence of harmful levels of contaminants, including filth, putrid, or decomposed substances, the absence of active ingredients other than those listed on the label, and the absence of inactive ingredients other than those listed on the master formula document.
(af) “Segregated sterile compounding area” means a designated space for sterile-to-sterile compounding where a PEC is located within either a demarcated area (at least three foot perimeter) or in a separate room. Such area or room shall not contain and shall be void of activities and materials that are extraneous to sterile compounding. The segregated sterile compounding area shall not be in a location that has unsealed windows or doors that connect to the outdoors, in a location with high traffic flow, or in a location that is adjacent to construction sites, warehouses, or food preparation. The segregated sterile compounding area shall not have a sink, other than an emergency eye-washing station, located within three feet of a PEC. The segregated sterile compounding area shall be restricted to preparation of sterile-to-sterile compounded preparations.
(1) The BUD of a sterile drug preparation made in a segregated sterile compounding area is limited to 12 hours or less as defined by section 1751.8(d).
(2) When the PEC in the segregated sterile compounding area is a CAI or a CACI and the documentation provided by the manufacturer shows it meets the requirements listed in section 1751.4(f)(1)-(3), the assigned BUD shall comply with section 1751.8(a-b) or (d).
(ag) “Strength” means amount of active ingredient per unit of a compounded drug preparation.

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052 and 4127, Business and Professions Code.

California State Board of Pharmacy
Specific Language to Amend Title 16. CCR §1735.6

Initial proposed changes indicated with single ~~strikethrough~~ for deletions and single underline for additions.

Amend Section 1735.6 Division 17 of Title 16 of California Code of Regulations to Read as follows:

§ 1735.6. Compounding Facilities and Equipment.

(a) Any pharmacy engaged in compounding shall maintain written documentation regarding the facilities and equipment necessary for safe and accurate compounding of compounded drug preparations. This shall include records of maintenance and cleaning of the facilities and equipment. Where applicable, this shall also include records of certification(s) of facilities or equipment.
(b) Any equipment used to compound drug preparations shall be stored, used, maintained, and cleaned in accordance with manufacturers' specifications.
(c) Any equipment that weighs, measures, or transfers ingredients used to compound drug preparations for which calibration or adjustment is appropriate shall be calibrated prior to use, on a schedule and by a method determined by the manufacturer's specifications, to ensure accuracy. Documentation of each such calibration shall be recorded in a form which is not alterable and these records of calibration shall be maintained and retained in the pharmacy.
(d) Any pharmacy engaged in any hazardous drug compounding shall maintain written documentation regarding appropriate cleaning of facilities and equipment to prevent cross-contamination with non-hazardous drugs.
(e) Hazardous drug compounding shall be completed in an externally exhausted ~~vented~~ physically separate room with the following requirements:
(1) Minimum of 30 air changes per hour except that 12 air changes per hour are acceptable for segregated compounding areas with a BSC or CACI when products are assigned a BUD of 12 hrs or less or when non sterile products are compounded; and
(2) Maintained at a negative pressure of 0.01 to 0.03 inches of water column relative to all adjacent spaces (rooms, above ceiling, and corridors); and
(3) Each ~~PEC~~ BSC and CACI in the room shall also be externally exhausted ~~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.