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DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

LEGISLATION AND REGULATION COMMITTEE

Greg Lippe, CPA, Chairperson, Public Member
Lavanza Butler, Vice-Chairperson, Licensee Member
Victor Law, Licensee Member
Valerie Munoz, Public Member
Albert Wong, PharmD, Licensee Member

LEGISLATION REPORT

The new legislative session started in December 2016. Since that time board staff has been monitoring new legislative proposals to be brought to both the committee and board for consideration. Such proposals generally impact either the board jurisdiction or board operations. The deadline to introduce bills this year is February 17, 2017.

As it is early in the session only a few measures have been identified and of those, a few consist of intent language only. Copies of all measures identified in section b of this report are provided as attachments. Board staff recommends that the committee be aware of these measures but not take positions at this time.

a. Board Sponsored Legislation

Attachment 1

During the October 2016 Board Meeting, the board voted to pursue a statutory proposal to amend Business and Professions Code section 4013(d)(1) to include designated representatives to the list of individuals required to join board's email notification list.

Board staff believes this change would be appropriate for inclusion in an omnibus bill and will be submitting the request to the Senate Business and Professions Committee for consideration.

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

Attachment 2

1. <u>AB 12 (Cooley) State Government: Administrative Regulations: Review</u>

   Version: As introduced December 5, 2016

   Status: May be heard in committee January 5, 2017

   Summary: AB 12 would require each state agency to, on or before January 1, 2020, review regulations, identify any regulations that are duplicative, overlapping,

inconsistent, or out of date, to revise those identified regulations, as provided, and report to the Legislature and Governor, as specified. The bill would repeal these provisions on January 1, 2021.

2. AB 29 (Nazarian) Pharmacy Benefits Managers

   Version: As Introduced December 5, 2016

   Status: May be heard in committee January 5, 2017

   Summary: AB 29 would state that it is the intent of the Legislature to enact legislation related to pharmacy benefits managers.

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

   Version: As Introduced December 5, 2016

   Status: May be heard in Committee January 5, 2017

   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. This bill contains other related provisions and other existing laws.

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

   Version: As Introduced December 5, 2016

   Status: May be acted upon on or after January 5, 2017

   Summary: SB 17 would state the intent of the Legislature to enact legislation requiring public and private purchasers of health care and health care coverage be given advance notice of price increases for the costs of prescription drugs in order to further the ability to predict and manage these costs and the public be given information about the justification, if any, for the prices of newly emerging medications and price increases for existing prescription drugs. This bill would include the findings and declarations of the Legislature in support of its intent.

5. SB 27 (Morrell) Professions and Vocations: Licenses: Military Service

   Version: As Introduced December 5, 2016

   Status: May be acted upon on or after January 5, 2017

   Summary: Would require every board within the Department of Consumer Affairs to grant a fee waiver for the application for and the issuance of an initial license to an applicant who supplies satisfactory evidence, as defined, to the board that the applicant has served as an active duty member of the California National Guard or the United States Armed Forces and was honorably discharged. The bill would require that

a veteran be granted only one fee waiver, except as specified.

6. SB 70 (Bates) Health Care Professionals

   Version: As Introduced January 9, 2017

   Status: May be acted upon on or after February 9, 2017

   Summary: SB 70 would amend existing legislative intent language regarding the Legislatures intent to address matters through the Health Care Professional Disaster Response Act.

c. Legislative Items for Future Meeting

During this portion of the meeting, the committee may only discuss other items of legislation in sufficient detail to determine if the measure should be placed on a future agenda.

REGULATION REPORT

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

Regulations Adding Title 16 CCR sections 1730 & 1730.1 and Amending section 1749 Related to Advanced Practice Pharmacists

In July 2015, the board initiated a formal rulemaking to add Title 16 CCR sections 1730, 1730.1, and amend section 1749 related to the licensing requirements for advanced practice pharmacist. At the August 2016 board meeting, the board adopted the final regulation language. Pursuant to the Administrative Procedure Act (APA), following review and approval by the Department of Consumer Affairs (DCA) and Agency, the rulemaking was submitted to the Office of Administrative Law (OAL) for final review on October 31, 2016. OAL approved the rulemaking on December 13, 2016 with an immediate effective date.

A copy of the adopted text is provided in **Attachment 3**.

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

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

   Timeline:

   Approved by Board: July 29, 2015
   Rulemaking Initiated: September 4, 2015
   Adopted by Board: April 27, 2016
   Submitted to DCA: August 4, 2016

Submitted to OAL: November 30, 2016

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 to implement SB 1441 (Ridley-Thomas, Chapter 548, Statutes of 2008).

A copy of the final adopted text is provided in **Attachment 4.** Additionally, the revised disciplinary guidelines can be found on the board's website: http://www.pharmacy.ca.gov/laws_regs/1760_mdg.pdf

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

Timeline:

Approved by Board: April 21, 2015
Rulemaking Initiated: September 25, 2015
Adopted by Board: July 27, 2016
Submitted to DCA: August 17, 2016
Submitted to OAL: December 20, 2016

Summary of Regulation:

This amended regulation implements the provisions contained in AB 1136 (Levine, Chapter 304, Statutes of 2013) to include a written warning label and updated the drug classes requiring the written warning label.

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

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

Timeline:

Approved by Board: January 28, 2015
Rulemaking Initiated: October 23, 2015
Adopted by Board: August 31, 2016
Submitted to DCA: September 21, 2016
Submitted to OAL: Pending

Summary of Regulation:

This regulation modifies the patient-centered labeling requirements including "generic for" on the prescription label. Additionally, the regulation was amended to require that pharmacies have policies and procedures in place to provide translation services to patients with limited or no English proficiency.

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

4. Proposed Regulations to Amend Title 16 CCR sections 1732.05, 1732,2 and 1732,5 Related to Continuing Education

Timeline:

Approved by Board: October 29, 2015
Rulemaking Initiated: November 13, 2015
Adopted by Board: September 22, 2016
Submitted to DCA: October 3, 2016
Submitted to OAL: Pending

Summary of Regulation:

This regulation amends board's continuing education requirements. Specifically, the amended regulation grants CE credit for serving on a committee developing the California Practice Standards and Jurisprudence Examination (CPJE), grants CE credit for attending Board meetings or committee meetings, and defines a specialized subject area necessary to meet the CE hour requirement.

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

5. Proposed Regulations to Amend Title 16 CCR section 1776 et seq. Related to Prescription Drug Take-Back

Timeline:

Approved by Board: January 19, 2016
Rulemaking Initiated: February 12, 2016
Adopted by Board: October 26, 2016
Submitted to DCA: December 12, 2016
Submitted to OAL: Pending

Summary of Regulation:

This regulation established 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 8**.

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

Timeline:

Approved by Board: February 24, 2016
Rulemaking Initiated: April 22, 2016
Adopted by Board: July 27, 2016
Submitted to DCA: October 27, 2016
Submitted to OAL: Pending

Summary of Regulation:

This regulation updates 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 9**.

c. Board Adopted – Rulemaking File Being Prepared by Staff for Submission and Review by the Department of Consumer Affairs or the Office of Administrative Law:

Proposed Regulations to Amend and/or Add Title 16 CCR sections 1702, 1702.1, 1702,2 and 1702.5 Related to Renewal Requirements

Timeline:

Approved by Board: July 30, 2013
Rulemaking Initiated: August 12, 2016
Adopted by Board: December 14, 2016
Submitted to DCA: Pending
Submitted to OAL: Pending

Summary of Regulation:

This regulation establishes standardized reporting of convictions and discipline at the time of renewal for pharmacists, pharmacy technicians and designated representatives, as well as 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 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**

As the board was advised during the October 2016 Board Meeting, DCA and Agency will now be performing a pre-review of all regulations prior to the board publishing a notice and initiating a comment period.

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

Timeline:

Approved by Board: October 26, 2016
Submitted to DCA for Pre-Notice Review: Pending
Rulemaking Initiated: Pending
Adopted by Board: Pending
Submitted to DCA: Pending
Submitted to OAL: Pending

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 the result of SB 1039 (Hill, Chapter 799, Statutes of 2016).

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

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 1780 – 1783 et seq. Related to Third-Party Logistics Providers
   Timeline:
   Approved by Board: October 26, 2016
   Rulemaking Initiated: Pending
   Adopted by Board: Pending
   Submitted to DCA: Pending
   Submitted to OAL: Pending

   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 12**.

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 Relation to the Pharmacy Technician Certification Programs
   Timeline:
   Approved by Board: October 26, 2016
   Rulemaking Initiated: Pending
   Adopted by Board: Pending
   Submitted to DCA: Pending
   Submitted to OAL: Pending

   Summary of Regulation:
   This regulation establishes the training requirements, certification programs, and updates the application for licensure of a pharmacy technician. 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 13.**

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

Timeline:

Approved by Board: December 14, 2016
Rulemaking Initiated: Pending
Adopted by Board: Pending
Submitted to DCA: Pending
Submitted to OAL: Pending

Summary of Regulation:

This regulation updates self-assessment form 17M-39 (rev. 10/16) as incorporated by reference in 16 CCR section 1735.2. Board staff is currently compiling the initial rulemaking file to submit to DCA for pre-notice review.

A copy of the approved regulation language and the self-assessment form is provided in **Attachment 14.**

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

Timeline:

Approved by Board: October 27, 2016
Rulemaking Initiated: Pending
Adopted by Board: Pending
Submitted to DCA: Pending
Submitted to OAL: Pending

Summary of Regulation:

This regulation updates update self-assessment forms 17M-13 (rev. 10/16), 17M-14 (rev. 10/16), and 17M-26 (rev. 10/16) as incorporated by reference. Board staff is currently compiling the initial rulemaking file to submit to DCA for pre-notice review.

A copy of the approved regulation language and the self-assessment forms are provided in **Attachment 15.**

5. Proposed Regulation to Amend Title 16 CCR Section 1709 Related to Trust Ownership

Timeline:

Approved by Board: October 27, 2016
Rulemaking Initiated: Pending
Adopted by Board: Pending
Submitted to DCA: Pending
Submitted to OAL: Pending

Summary of Regulation:

This regulation amends the Board's regulations regarding ownership to include provisions relating to trust ownership of pharmacies. 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.**

FUTURE MEETING DATES

Provided below are the meeting dates for the remainder of 2017:

- April 12, 2017
- June 27, 2017
- October 18, 2017

Attachment 1

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

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

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

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

(d) (1) Each pharmacist, intern pharmacist, pharmacy technician, <u>designated representative,</u> 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.

Attachment 2

ASSEMBLY BILL No. 12

Introduced by Assembly Member Cooley

December 5, 2016

An act to add and repeal Chapter 3.6 (commencing with Section 11366) of Part 1 of Division 3 of Title 2 of the Government Code, relating to state agency regulations.

LEGISLATIVE COUNSEL'S DIGEST

AB 12, as introduced, Cooley. State government: administrative regulations: review.

Existing law authorizes various state entities to adopt, amend, or repeal regulations for various specified purposes. The Administrative Procedure Act requires the Office of Administrative Law and a state agency proposing to adopt, amend, or repeal a regulation to review the proposed changes for, among other things, consistency with existing state regulations.

This bill would require each state agency to, on or before January 1, 2020, review that agency's regulations, identify any regulations that are duplicative, overlapping, inconsistent, or out of date, to revise those identified regulations, as provided, and report to the Legislature and Governor, as specified. The bill would repeal these provisions on January 1, 2021.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Chapter 3.6 (commencing with Section 11366) is added to Part 1 of Division 3 of Title 2 of the Government Code, to read:

Chapter 3.6. Regulatory Reform

Article 1. Findings and Declarations

11366. The Legislature finds and declares all of the following:

(a) The Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340), Chapter 4 (commencing with Section 11370), Chapter 4.5 (commencing with Section 11400), and Chapter 5 (commencing with Section 11500)) requires agencies and the Office of Administrative Law to review regulations to ensure their consistency with law and to consider impacts on the state's economy and businesses, including small businesses.

(b) However, the act does not require agencies to individually review their regulations to identify overlapping, inconsistent, duplicative, or out-of-date regulations that may exist.

(c) At a time when the state's economy is slowly recovering, unemployment and underemployment continue to affect all Californians, especially older workers and younger workers who received college degrees in the last seven years but are still awaiting their first great job, and with state government improving but in need of continued fiscal discipline, it is important that state agencies systematically undertake to identify, publicly review, and eliminate overlapping, inconsistent, duplicative, or out-of-date regulations, both to ensure they more efficiently implement and enforce laws and to reduce unnecessary and outdated rules and regulations.

Article 2. Definitions

11366.1. For the purposes of this chapter, the following definitions shall apply:

(a) "State agency" means a state agency, as defined in Section 11000, except those state agencies or activities described in Section 11340.9.

(b) "Regulation" has the same meaning as provided in Section 11342.600.

Article 3. State Agency Duties

11366.2. On or before January 1, 2020, each state agency shall do all of the following:

(a) Review all provisions of the California Code of Regulations adopted by that state agency.

(b) Identify any regulations that are duplicative, overlapping, inconsistent, or out of date.

(c) Adopt, amend, or repeal regulations to reconcile or eliminate any duplication, overlap, inconsistencies, or out-of-date provisions, and shall comply with the process specified in Article 5 (commencing with Section 11346) of Chapter 3.5, unless the addition, revision, or deletion is without regulatory effect and may be done pursuant to Section 100 of Title 1 of the California Code of Regulations.

(d) Hold at least one noticed public hearing, which shall be noticed on the Internet Web site of the state agency, for the purposes of accepting public comment on proposed revisions to its regulations.

(e) Notify the appropriate policy and fiscal committees of each house of the Legislature of the revisions to regulations that the state agency proposes to make at least 30 days prior to initiating the process under Article 5 (commencing with Section 11346) of Chapter 3.5 or Section 100 of Title 1 of the California Code of Regulations.

(g) (1) Report to the Governor and the Legislature on the state agency's compliance with this chapter, including the number and content of regulations the state agency identifies as duplicative, overlapping, inconsistent, or out of date, and the state agency's actions to address those regulations.

(2) The report shall be submitted in compliance with Section 9795 of the Government Code.

11366.3. (a) On or before January 1, 2020, each agency listed in Section 12800 shall notify a department, board, or other unit within that agency of any existing regulations adopted by that department, board, or other unit that the agency has determined may be duplicative, overlapping, or inconsistent with a regulation

adopted by another department, board, or other unit within that agency.

(b) A department, board, or other unit within an agency shall notify that agency of revisions to regulations that it proposes to make at least 90 days prior to a noticed public hearing pursuant to subdivision (d) of Section 11366.2 and at least 90 days prior to adoption, amendment, or repeal of the regulations pursuant to subdivision (c) of Section 11366.2. The agency shall review the proposed regulations and make recommendations to the department, board, or other unit within 30 days of receiving the notification regarding any duplicative, overlapping, or inconsistent regulation of another department, board, or other unit within the agency.

11366.4. An agency listed in Section 12800 shall notify a state agency of any existing regulations adopted by that agency that may duplicate, overlap, or be inconsistent with the state agency's regulations.

11366.45. This chapter shall not be construed to weaken or undermine in any manner any human health, public or worker rights, public welfare, environmental, or other protection established under statute. This chapter shall not be construed to affect the authority or requirement for an agency to adopt regulations as provided by statute. Rather, it is the intent of the Legislature to ensure that state agencies focus more efficiently and directly on their duties as prescribed by law so as to use scarce public dollars more efficiently to implement the law, while achieving equal or improved economic and public benefits.

Article 4. Chapter Repeal

11366.5. This chapter shall remain in effect only until January 1, 2021, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2021, deletes or extends that date.

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ASSEMBLY BILL No. 29

Introduced by Assembly Member Nazarian

December 5, 2016

An act relating to pharmacy benefit managers.

LEGISLATIVE COUNSEL'S DIGEST

AB 29, as introduced, Nazarian. Pharmacy benefit managers.

Existing law imposes specified requirements on an audit of pharmacy services provided to beneficiaries of a health benefit plan and defines a "pharmacy benefit manager" for those purposes as 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 3rd-party payer, either directly or through an intermediary, manages the prescription drug coverage provided by the carrier, plan sponsor, or other 3rd-party payer.

This bill would state the intent of the Legislature to enact legislation relating to pharmacy benefit managers.

Vote: majority. Appropriation: no. Fiscal committee: no. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. It is the intent of the Legislature to enact legislation relating to pharmacy benefit managers.

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ASSEMBLY BILL No. 40

Introduced by Assembly Member Santiago

December 5, 2016

An act to amend Sections 11165.1 and 11165.2 of the Health and Safety Code, relating to controlled substances, and declaring the urgency thereof, to take effect immediately.

LEGISLATIVE COUNSEL'S DIGEST

AB 40, as introduced, Santiago. CURES database: health information technology system.

Existing law classifies certain controlled substances into designated schedules. Existing law requires the Department of Justice to maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of the prescribing and dispensing of Schedule II, Schedule III, and Schedule IV controlled substances by a health care practitioner authorized to prescribe, order, administer, furnish, or dispense a Schedule II, Schedule III, or Schedule IV controlled substance.

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 bill would authorize a health information technology system to establish an integration with and submit queries to the CURES database if the system can certify, among other requirements, that the data received from the CURES database will not be used for any purpose other than delivering the data to an authorized

health care practitioner or performing data processing activities necessary to enable delivery, and that the system meets applicable patient privacy and information security requirements of state and federal law. The bill would also authorize the Department of Justice to require an entity operating a health information technology system to enter into a memorandum of understanding or other agreement setting forth terms and conditions with which the entity must comply.

Existing law authorizes the Department of Justice to conduct audits of the CURES database and its users.

This bill would authorize the Department of Justice to conduct audits of any authorized health information technology system integrated with the CURES database.

This bill would declare that it is to take effect immediately as an urgency statute.

Vote: ⅔. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

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 *through an online Internet Web portal* that is ~~stored on the Internet and~~ maintained ~~within the Department of Justice,~~ *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) 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 system can certify all of the following:

(i) The health information technology system can establish it has been 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 health information technology system 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 authenticates 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 maintains an audit trail documenting this authentication.

(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 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. Section 11165.2 of the Health and Safety Code is amended to read:

11165.2. (a) The Department of Justice may conduct audits of the CURES Prescription Drug Monitoring Program system and its ~~users.~~ *users, including any authorized health information technology system, as defined in subdivision (g) of Section 11165.1, integrated with the CURES database.*

(b) The Department of Justice may establish, by regulation, a system for the issuance to a CURES Prescription Drug Monitoring Program subscriber of a citation which may contain an order of abatement, or an order to pay an administrative fine assessed by the Department of Justice if the subscriber is in violation of any provision of this chapter or any regulation adopted by the Department of Justice pursuant to this chapter.

(c) The system shall contain the following provisions:

(1) Citations shall be in writing and shall describe with particularity the nature of the violation, including specific reference to the provision of law or regulation of the department determined to have been violated.

(2) Whenever appropriate, the citation shall contain an order of abatement establishing a reasonable time for abatement of the violation.

(3) In no event shall the administrative fine assessed by the department exceed two thousand five hundred dollars ($2,500) for each violation. In assessing a fine, due consideration shall be given to the appropriateness of the amount of the fine with respect to such factors as the gravity of the violation, the good faith of the subscribers, and the history of previous violations.

(4) An order of abatement or a fine assessment issued pursuant to a citation shall inform the subscriber that if the subscriber desires a hearing to contest the finding of a violation, a hearing shall be requested by written notice to the CURES Prescription Drug Monitoring Program within 30 days of the date of issuance of the citation or assessment. Hearings shall be held pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code.

(5) In addition to requesting a hearing, the subscriber may, within 10 days after service of the citation, request in writing an opportunity for an informal conference with the department regarding the citation. At the conclusion of the informal conference, the department may affirm, modify, or dismiss the citation, including any fine levied or order of abatement issued. The decision shall be deemed to be a final order with regard to the citation issued, including the fine levied or the order of abatement which could include permanent suspension to the system, a monetary fine, or both, depending on the gravity of the violation. However, the subscriber does not waive its right to request a hearing to contest a citation by requesting an informal conference. If the citation is affirmed, a formal hearing may be requested within 30 days of the date the citation was affirmed. If the citation is dismissed after the informal conference, the request for a hearing on the matter of the citation shall be deemed to be withdrawn. If the citation, including any fine levied or order of abatement, is modified, the citation originally issued shall be considered withdrawn and a new citation issued. If a hearing is requested for a subsequent citation, it shall be requested within 30 days of service of that subsequent citation.

(6) Failure of a subscriber to pay a fine within 30 days of the date of assessment or comply with an order of abatement within the fixed time, unless the citation is being appealed, may result in disciplinary action taken by the department. If a citation is not

contested and a fine is not paid, the subscriber account will be terminated:

(A) A citation may be issued without the assessment of an administrative fine.

(B) Assessment of administrative fines may be limited to only particular violations of law or department regulations.

(d) Notwithstanding any other provision of law, if a fine is paid to satisfy an assessment based on the finding of a violation, payment of the fine shall be represented as a satisfactory resolution of the matter for purposes of public disclosure.

(e) Administrative fines collected pursuant to this section shall be deposited in the CURES Program Special Fund, available upon appropriation by the Legislature. These special funds shall provide support for costs associated with informal and formal hearings, maintenance, and updates to the CURES Prescription Drug Monitoring Program.

(f) The sanctions authorized under this section shall be separate from, and in addition to, any other administrative, civil, or criminal remedies; however, a criminal action may not be initiated for a specific offense if a citation has been issued pursuant to this section for that offense, and a citation may not be issued pursuant to this section for a specific offense if a criminal action for that offense has been filed.

(g) Nothing in this section shall be deemed to prevent the department from serving and prosecuting an accusation to suspend or revoke a subscriber if grounds for that suspension or revocation exist.

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 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.

O

SENATE BILL No. 17

Introduced by Senator Hernandez

December 5, 2016

An act relating to health care.

LEGISLATIVE COUNSEL'S DIGEST

SB 17, as introduced, Hernandez. Prescription drugs: pricing: notification.

Existing law establishes various programs to assist individuals with the purchase of prescription drugs at affordable prices, including, among other programs, the California Rx Prescription Drug Web Site Program and the Golden Bear State Pharmacy Assistance Program.

This bill would state the intent of the Legislature to enact legislation requiring public and private purchasers of health care and health care coverage be given advance notice of price increases for the costs of prescription drugs in order to further the ability to predict and manage these costs and the public be given information about the justification, if any, for the prices of newly emerging medications and price increases for existing prescription drugs. This bill would include the findings and declarations of the Legislature in support of its intent.

Vote: majority. Appropriation: no. Fiscal committee: no. State-mandated local program: no.

The people of the State of California do enact as follows:

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

(a) Health care spending in the United States is twice the level of health care spending in other developed countries while life expectancy is often less.

(b) Health care spending in the United States has climbed from about $1,000 per person to almost $9,000 per person while the rate of growth for health care spending in other developed countries has been much more modest.

(c) High health care spending is paid for by individual consumers, employers, taxpayers, and other purchasers of health care services and coverage. While existing state and federal law limits the profit and overhead of health plans and health insurers, there are no similar limits on the profits and overhead of pharmaceutical manufacturers.

(d) The United States has experienced significant growth in spending on prescription drugs so that total prescription drug costs in the United States exceeded $450 billion, or 16.7 percent of personal health care spending in 2015, up from $367 billion or 15.4 percent of personal health care spending in 2012. For persons under 65 years of age, the cost of outpatient prescription drug spending amounts to 19 percent of the premium dollar, and that 19 percent spent on outpatient drugs does not account for drugs administered by a health professional, such as chemotherapy or drugs administered in a hospital or other health facility, which further compounds spending on prescription drugs.

(e) Specialty drug spending rose 30.9 percent between 2013 and 2014 while specialty drugs accounted for 1 percent of prescriptions in 2013. These drugs accounted for 25 percent of prescription drugs spending in 2013. Cancer drug prices doubled within the last decade, from an average of $5,000 per month to an average of $10,000 per month.

(f) Approximately 75 percent of the increase in Medicaid spending on prescription drugs between 2013 and 2104 was due to increases in price. Many prescription drugs had increases in unit prices, including Ativan, which increased 1,264 percent between 2014 and 2015, and five other drugs that had unit cost increases of more than 300 percent between 2014 and 2015. From the fourth quarter of 2013 to the second quarter of 2016, Epi-Pen prices increased 15 percent every other quarter so that the price had increased 548 percent since 2007. Of the 20 drugs with the highest per unit cost increases in Medicaid, nine were generic drugs and those products had increases in price ranging from 140 percent to nearly 500 percent between 2014 and 2015.

(g) The State of California spent more than $4 billion in taxpayer dollars on prescription drugs in the 2014–15 fiscal year and this amount did not include prescription drug spending for the almost ten million people enrolled in Medi-Cal managed care.

(h) The 2016 Kaiser Health Foundation tracking poll found that 77 percent of Americans say prescription drug costs are unreasonable, 86 percent of Americans favor requiring drug companies to release information to the public on how drug prices are set, and 78 percent of Americans support limiting the amount drug companies can charge for high cost drugs for illnesses like cancer or hepatitis.

(i) Despite intense public scrutiny and broad consumer concern about escalating prescription drug prices, prescription drug prices climbed by 7 percent in September 2016, while overall health care costs climbed only 2.1 percent with nondrug costs climbing even more modestly.

SEC. 2. It is the intent of the Legislature to enact legislation requiring public and private purchasers of health care and health care coverage be given advance notice of price increases for the costs of prescription drugs in order to further the ability to predict and manage these costs and the public be given information about the justification, if any, for the prices of newly emerging medications and price increases for existing prescription drugs.

O

SENATE BILL No. 27

Introduced by Senator Morrell

December 5, 2016

An act to add Section 114.6 to the Business and Professions Code, relating to professions and vocations.

LEGISLATIVE COUNSEL'S DIGEST

SB 27, as introduced, Morrell. Professions and vocations: licenses: military service.

Existing law provides for the licensure and regulation of various professions and vocations by boards within the Department of Consumer Affairs. Existing law authorizes any licensee or registrant whose license expired while he or she was on active duty as a member of the California National Guard or the United States Armed Forces to reinstate his or her license or registration without examination or penalty if certain requirements are met. Existing law also requires the boards to waive the renewal fees, continuing education requirements, and other renewal requirements, if applicable, of any licensee or registrant called to active duty as a member of the United States Armed Forces or the California National Guard, if certain requirements are met. Existing law requires each board to inquire in every application if the individual applying for licensure is serving in, or has previously served in, the military. Existing law requires a board within the Department of Consumer Affairs to expedite, and authorizes a board to assist with, the initial licensure process for an applicant who has served as an active duty member of the United States Armed Forces and was honorably discharged.

This bill would require every board within the Department of Consumer Affairs to grant a fee waiver for the application for and the issuance of an initial license to an applicant who supplies satisfactory evidence, as defined, to the board that the applicant has served as an

active duty member of the California National Guard or the United States Armed Forces and was honorably discharged. The bill would require that a veteran be granted only one fee waiver, except as specified.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Section 114.6 is added to the Business and Professions Code, to read:

114.6. (a) (1) Notwithstanding any other law, every board within the department shall grant a fee waiver for the application for and issuance of an initial license to an applicant who supplies satisfactory evidence to the board that the applicant has served as an active duty member of the California National Guard or the United States Armed Forces and was honorably discharged.

(2) For purposes of this section, "satisfactory evidence" means a completed "Certificate of Release or Discharge from Active Duty" (DD Form 214).

(b) (1) A veteran shall be granted only one fee waiver, except as specified in paragraph (2). After a fee waiver has been issued by any board within the department, the veteran is no longer eligible for a waiver.

(2) If a board charges a fee for the application for a license and another fee for the issuance of a license, the veteran shall be granted fee waivers for both the application for and issuance of a license.

(3) The fee waiver shall apply only to an application of and a license issued to an individual veteran and not to an application of or a license issued to an individual veteran on behalf of a business or other entity.

(4) A fee waiver shall not be issued for any of the following:

(A) Renewal of a license.

(B) The application for and issuance of an additional license, a certificate, a registration, or a permit associated with the initial license.

(C) The application for an examination.

O

SENATE BILL No. 70

Introduced by Senator Bates

January 9, 2017

An act to amend Section 921 of the Business and Professions Code, relating to healing arts.

LEGISLATIVE COUNSEL'S DIGEST

SB 70, as introduced, Bates. Health care professionals.

Existing law, the Health Care Professional Disaster Response Act, states findings of the Legislature regarding the shortage of qualified health care practitioners during times of national or state disasters, and authorizes a physician and surgeon, whose license has been expired for less than 5 years and who meets specified criteria, to obtain a license without paying fees.

This bill would make nonsubstantive changes to those findings.

Vote: majority. Appropriation: no. Fiscal committee: no. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Section 921 of the Business and Professions Code is amended to read:

921. (a) The Legislature finds and declares *both of* the following:

(1) In times of national or state disasters, a shortage of qualified health care practitioners may exist in areas throughout the state where they are desperately required to respond to public health emergencies.

(2) Health care practitioners with lapsed or inactive licenses could potentially serve in those areas where a shortage of qualified

health care practitioners exists, if licensing requirements were streamlined and fees curtailed.

(b) ~~It is, therefore,~~ *Therefore, it is* the intent of the Legislature to address these matters through the ~~provisions of the~~ Health Care Professional Disaster Response Act.

O

Attachment 3

Advanced Practice Pharmacist – 1730, 1730.1, and 1749

Title 16. BOARD OF PHARMACY

Order of Adoption

Add Article 3.5 of Division 17 of Title 16 of the California Code of Regulations and a new Article title as follows:

Article 3.5. Advanced Practice Pharmacist.

Add §1730 of Article 3.5 of Division 17 of Title 16 of the California Code of Regulations as follows:

§1730. Acceptable Certification Programs.

The board recognizes the pharmacy patient care certification programs that are accredited by the National Commission for Certifying Agencies for purposes of satisfying the requirements in Business and Professions Code section 4210, subdivision (a)(2)(A).

Note: Authority cited: Sections 4005 and 4210, Business and Professions Code. Reference: Section 4210, Business and Professions Code.

Add §1730.1 of Article 3.5 of Division 17 of Title 16 of the California Code of Regulations as follows:

§1730.1. Application Requirements for Advanced Practice Pharmacist Licensure.

(a) For purposes of Business and Professions Code section 4210, an applicant for advanced practice pharmacist licensure must satisfy two of the following subsections.

(1) Demonstrate possession of a current certification as specified in Business and Professions Code section 4210, subdivision (a)(2)(A), by providing either:

(A) A copy of the certification award that includes the name of the applicant pharmacist, the area of specialty and date of completion, or

(B) A letter from the certification program confirming the award of the certification that includes the name of the applicant pharmacist, the area of specialty and the date of completion.

(2) Demonstrate completion of a postgraduate residency earned in the United States through an accredited postgraduate institution as specified in Business and Professions Code section 4210, subdivision (a)(2)(B), by providing either:

(A) A copy of the residency certificate awarded by the postgraduate institution that includes the name of the applicant pharmacist, the area of specialty, and dates of participation and completion, or

(B) A letter of completion of a postgraduate residency, signed by the dean or residency program director of the postgraduate institution and sent directly to the board from the postgraduate institution, that lists the name of the applicant pharmacist, the area of specialty, and the dates of participation and completion. For an applicant who cannot satisfy this documentation requirement, the board may, for good cause shown, grant a waiver for this subsection.

(3) Demonstrate that experience earned under a collaborative practice agreement or protocol, as required by Business and Professions Code section 4210, subdivision (a)(2)(C), has been earned within 10 years of the time of application for advanced practice pharmacist licensure. Additionally, the one year of experience must include no fewer than 1,500 hours of experience providing clinical services to patients. The experience earned under a collaborative practice agreement or protocol must include initiating, adjusting, modifying or discontinuing drug therapy of patients as authorized by law. An applicant shall demonstrate possession of experience by providing both of the following:

(A) A written statement from the applicant attesting under penalty of perjury that he or she has:

(i) Earned the clinical experience within the required time frame; and

(ii) Completed the required number of hours of experience providing clinical services to patients, as specified in subsection (a)(3).

(I)The applicant shall provide a copy of the collaborative practice agreement or protocol.

(II)If a copy of the collaborative practice agreement or protocol is not available, the applicant shall provide a description of the collaborative practice agreement or protocol, including examples of the clinical services the applicant provided to patients.

(B) A written statement from the supervising practitioner, program director or health facility administrator attesting under penalty of perjury that the applicant has completed at least 1,500 hours of experience providing clinical services to patients. For an applicant who cannot satisfy this documentation requirement, the board may, for good cause shown, grant a waiver for this subsection.

(b) The experience an applicant offers to demonstrate compliance with one of the three criteria in subsection (a) above may not also be used to satisfy another of the criteria.

Note: Authority cited: Sections 4005 and 4210, Business and Professions Code. Reference: Sections 4052.1, 4052.2 and 4210, Business and Professions Code.

Relocate §§1730.2 and 1731 [renumbered], shown below, from Article 3 of Division 17 of Title 16 of the California Code of Regulations to Article 3.5 of Division 17 of Title 16 of the California Code of Regulations:

§1730.2. Certification Programs.

[Regulation text unchanged.]

Note: Authority cited: Sections 4005 and 4210, Business and Professions Code. Reference: Sections 4052.6, 4210 and 4233, Business and Professions Code.

§1731. Experimental Programs. [Renumbered]

[No regulation text.]

Note: Authority cited: Sections 4008, 4008.1, 4008.2, Business and Professions Code. Reference: Sections 4008, 4008.1, 4008.2, 4084.5, 4084.6 and 4416, Business and Professions Code.

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

§1749. Fee Schedule.

The fees for the issuance and renewal of licenses, certificates, and permits, and the penalties to be assessed for failure to renew in accordance with sections 163.5, 4110, 4210, 4127.5, 4128.2, 4196, and 4400 of the Business and Professions Code are hereby fixed as follows:

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

(b) The fee for the issuance of a temporary license is three hundred twenty-five dollars ($325).

(c) The fee for the issuance of a pharmacy technician license shall be one hundred five dollars ($105). The fee for the biennial renewal of a pharmacy technician license shall be one hundred thirty dollars ($130). The penalty for failure to renew a pharmacy technician license is sixty-five dollars ($65).

(d) The fee for application and examination as a pharmacist is two hundred sixty dollars ($260).

(e) The fee for regrading an examination is one hundred fifteen dollars ($115).

(f)(1) The fee for the issuance of an original pharmacist license is one hundred ninety-five dollars ($195).

(2) The fee for application of an advanced practice pharmacist license is three hundred dollars ($300). If granted, there is no fee for the initial license issued, which will expire at the same time the pharmacist's license expires.
(g)(1) The fee for the biennial renewal of a pharmacist's license is one hundred ninety-five dollars ($195) ~~two hundred seven dollars ($207)~~. The penalty fee for failure to renew is ninety-seven dollars fifty cents ($97.50).
(2) The fee for the biennial renewal of an advanced practice pharmacist license is three hundred dollars ($300). The penalty fee for failure to renew is one hundred fifty dollars ($150). The fees in this paragraph are in addition to the fees required to renew the pharmacist's license as specified in paragraph 1.
(h) The fee for the issuance or renewal of a wholesaler's license is seven hundred eighty dollars ($780). The penalty for failure to renew is one hundred fifty dollars ($150).
(i) The fee for the issuance or renewal of a hypodermic license is one hundred sixty five dollars ($165). The penalty for failure to renew is eighty two dollars fifty cents ($82.50).
(j) The fee for the issuance of a license as a designated representative pursuant to Section 4053 of the Business and Professions Code shall be three hundred thirty dollars ($330). The fee for the annual renewal of a license as a designated representative shall be one hundred ninety-five dollars ($195). The penalty for failure to renew is ninety seven dollars and fifty cents ($97.50).
(k) The fee for the issuance or renewal of a license as a nonresident wholesaler is seven hundred eighty dollars ($780). The penalty for failure to renew is one hundred fifty dollars ($150).
(*l*) The fee for an intern pharmacist license is one hundred fifteen dollars ($115). The fee for transfer of intern hours or verification of licensure to another state is thirty dollars ($30).
(m) The fee for the reissuance of any permit, license, or certificate, or renewal thereof, which must be reissued because of change in the information, other than name change, is one hundred dollars ($100).
(n) The fee for evaluation of continuing education courses for accreditation is forty dollars ($40) for each hour of accreditation requested.
(o) The fee for the issuance of a clinic license is five hundred twenty dollars ($520). The fee for the annual renewal of a clinic license is three hundred twenty-five dollars ($325). The penalty for failure to renew is one hundred fifty dollars ($150).
(p) The fee for the issuance of a nongovernmental license, or renewal of a license, to compound sterile drug products is seven hundred eighty dollars ($780). The penalty for failure to renew is one hundred fifty dollars ($150).
(q) The fee for the issuance of a license as a designated representative for a veterinary food-animal drug retailer shall be three hundred thirty dollars ($330). The fee for the annual renewal of a license as a designated representative shall be one hundred and ninety-five dollars ($195). The penalty for failure to renew is ninety-seven dollars and fifty cents ($97.50).
(r) The fee for a veterinary food-animal drug retailer license is four hundred twenty-five dollars ($425). The annual renewal fee for a veterinary food-animal drug retailer is three hundred twenty-five dollars ($325). The fee for the issuance of a temporary license is two hundred and fifty dollars ($250). The penalty for failure to renew is one hundred twenty-five dollars ($125).
(s) The fee for the issuance of a retired pharmacist license shall be forty-five dollars ($45).

(t) The fee for the issuance of a centralized hospital packaging pharmacy license shall be $800. The annual renewal fee for a centralized hospital packaging pharmacy license shall be $800. The penalty for failure to renew is one hundred fifty dollars.

Note: Authority cited: Sections 163.5 and 4005, Business and Professions Code. Reference: Sections 163.5, 4005, 4110, 4112(h), 4120, 4128.2, 4196, 4200, 4210, 4400, 4401 and 4403, Business and Professions Code.

_____

Virginia Herold
Executive Officer
California State Board of Pharmacy

Attachment 4

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

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

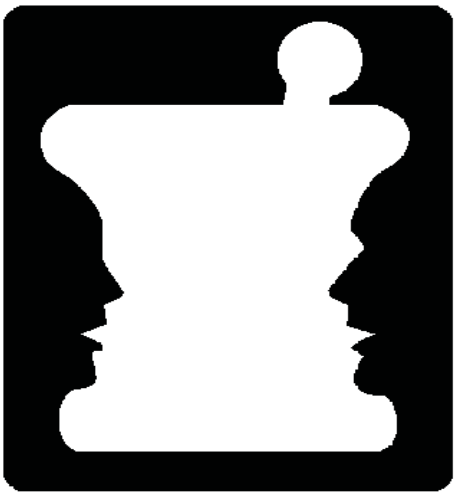
§ 1760. Disciplinary Guidelines.
In reaching a decision on a disciplinary action under the Administrative Procedure Act (Government Code section 11400 et seq.) the board shall consider the disciplinary guidelines entitled "Disciplinary Guidelines" (Rev. ~~10/2007 7/2015~~ 10/2015), which are hereby incorporated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

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

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

DISCIPLINARY GUIDELINES

A Manual of Disciplinary Guidelines
and Model Disciplinary Orders



BE AWARE & TAKE CARE:
Talk to your pharmacist!

California State Board of Pharmacy
Department of Consumer Affairs
(Rev. ~~10/2007~~ ~~7/2015~~ 10/2015)

STATE BOARD OF PHARMACY

DEPARTMENT OF CONSUMER AFFAIRS

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Additional copies of these disciplinary guidelines
may be downloaded from the board's website

BOARD OF PHARMACY

DISCIPLINARY GUIDELINES

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DEPARTMENT OF CONSUMER AFFAIRS
STATE BOARD OF PHARMACY

DISCIPLINARY GUIDELINES
(Rev. ~~10/2007~~ ~~7/2015~~ 10/2015)

INTRODUCTION

The Board of Pharmacy (board) is responsible for the enforcement of statutes and regulations related to the practice of pharmacy (the Pharmacy Law) and to the regulation of controlled substances (the Uniform Controlled Substances Act). The board serves the public by:

- protecting the health, safety, and welfare of the people of California;
- advocating the highest quality of affordable pharmaceutical care;
- providing the best available information on pharmaceutical care; and
- promoting education, wellness and quality of life.

Pharmacists and intern pharmacists are patient advocates and vital members of the clinical care team who provide pharmaceutical care and exercise clinical judgment ~~for the citizens of California~~ for their patients~~,~~. They also exercise critical vigilance and control over medication stocks, drug inventories, and quality assurance protocols. Pharmacy technicians provide crucial assistance to pharmacists and intern pharmacists in all of their pharmacy tasks. Pharmacists and intern pharmacists enlighten their patients ~~enlightening them~~ about their drug ~~therapy~~ therapies through effective communicating and listening, assessing, collaborating, understanding and intervening. They also, under appropriate conditions, initiate or terminate drug therapies, compound drug preparations, ensure safety and security of drug stocks, and otherwise contribute to clinical safety and performance. Also, pharmacists and intern pharmacists are always vigilant to ensure that drug therapies are being appropriately and effectively utilized. When a pharmacist takes on the responsibility of a pharmacist-in-charge, the pharmacist also ensures the pharmacy's compliance with state and federal law, quality assurance responsibilities, and inventory controls. Likewise, the premises and other individuals licensed by the board help to ensure the reliability, safety, and security of the dangerous drug and/or dangerous device supply chain, so that patients and prescribers can be confident in the drugs or devices prescribed. Enforcement officials act quickly, consistently and efficiently in the public's interest to ensure the safe, effective delivery of these services.

The board recognizes the importance of ensuring the safe and effective delivery of dangerous drugs and/or dangerous devices and controlled substances for therapeutic purposes. At the same time, and given the historical and current abuse and diversion of drugs, particularly controlled substances, the board believes there should be no tolerance for licensees who traffic in drugs or who, in the absence of appropriate evidence of rehabilitation, personally abuse drugs or alcohol.

In accordance with Section 1760 of the California Code of Regulations, and the provisions contained in Sections 1771-1774, the board has produced this booklet for those involved in and affected by the disciplinary process: the general public, board licensees, attorneys from the Office of the Attorney General, administrative law judges from the Office of Administrative Hearings, defense attorneys, ~~board licensees~~, the courts, board staff, and board members who review and vote on proposed decisions and stipulations.

These guidelines are to be followed in Board of Pharmacy disciplinary actions. Subject to judicial review, the board has the final authority over the disposition of its cases, and, to complete its work, it uses the services of the Office of the Attorney General and the Office of Administrative Hearings. The board recognizes that individual cases may necessitate a departure from these guidelines. In such cases, the mitigating or aggravating circumstances shall be detailed in any proposed decision or any transmittal memorandum accompanying a proposed stipulation, especially where Category III or IV violations are involved.

In general, the position of the board is that revocation should always be an option whenever grounds for discipline are found to exist. Board policy is that revocation is generally an appropriate order where a respondent is in default, such as when he or she fails to file a notice of defense or fails to appear at a disciplinary hearing.

Board policy is that a suspension, where imposed, should be at least 30 days for an individual and at least 14 days for a licensed premises.

The board seeks recovery of all investigative and prosecution costs up to the hearing in all disciplinary cases. This includes all charges of the Office of the Attorney General, including, but not limited to, those for legal services, and includes charges by expert consultants. The board believes that the burden of paying for disciplinary cases should fall on those whose conduct requires investigation and prosecution, not ~~upon~~ on the profession as a whole.

The board recognizes there may be situations where an individual licensee deserves a stronger penalty than the pharmacy for which he or she works~~, but the board also believes in holding a pharmacy owner, manager, and/or pharmacist-in-charge responsible for the acts of pharmacy personnel~~. Similarly, the board recognizes that in some cases a licensed premises may well be more culpable than any individual licensed by or registered with the board. Typically, the board also believes in holding a pharmacy owner, manager, and/or pharmacist-in-charge responsible for the acts of pharmacy personnel.

For purposes of these guidelines, "board" includes the board and/or its designees.

FACTORS TO BE CONSIDERED IN DETERMINING PENALTIES

Section 4300 of the Business and Professions Code provides that the board may discipline the holder of, and suspend or revoke, any certificate, license or permit issued by the board.

In determining whether the minimum, maximum, or an intermediate penalty is to be imposed in a given case, factors such as the following should be considered:

1. actual or potential harm to the public
2. actual or potential harm to any consumer
3. prior disciplinary record, including level of compliance with disciplinary order(s)
4. prior warning(s), including but not limited to citation(s) and fine(s), letter(s) of admonishment, and/or correction notice(s)
5. number and/or variety of current violations
6. nature and severity of the act(s), offense(s) or crime(s) under consideration
7. aggravating evidence
8. mitigating evidence
9. rehabilitation evidence
10. compliance with terms of any criminal sentence, parole, or probation
11. overall criminal record
12. if applicable, evidence of proceedings for case being set aside and dismissed pursuant to Section 1203.4 of the Penal Code
13. time passed since the act(s) or offense(s)
14. whether the conduct was intentional or negligent, demonstrated incompetence, or, if the respondent is being held to account for conduct committed by another, the respondent had knowledge of or knowingly participated in such conduct
15. financial benefit to the respondent from the misconduct.
16. ~~consideration of~~ other licenses held by the respondent and license history of those licenses.
17. Uniform Standards Regarding Substance-Abusing Healing Arts Licensees (see Business and Professions Code Section 315)

No single one or combination of the above factors is required to justify the minimum and/or maximum penalty in a given case, as opposed to an intermediate one.

MITIGATING EVIDENCE

A respondent is permitted to present mitigating circumstances at a hearing or in the settlement process and has the burden of demonstrating any rehabilitative or corrective measures he, ~~or~~ she, or it has taken. The board does not intend, by the following references to written statements, letters, and reports, to waive any evidentiary objections to the form or admissibility of such evidence. The respondent must produce admissible evidence in the form required by law in the absence of a stipulation to admissibility by the complainant.

The following are examples of appropriate evidence a respondent may submit to demonstrate his or her rehabilitative efforts and competency:

a. Recent, dated, written statements and/or performance evaluations from persons in positions of authority who have on-the-job knowledge of the respondent's current competence in the practice ~~of pharmacy~~ relevant to the disciplinary proceeding, including the period of time and capacity in which the person worked with the respondent. Such reports must be signed under penalty of perjury and will be subject to verification by board staff.
b. Recent, dated, letters from counselors regarding the respondent's participation in a rehabilitation or recovery program, which should include at least a description and requirements of the program, a psychologist's diagnosis of the condition and current state of recovery, and the psychologist's basis for determining rehabilitation. Such letters and reports will be subject to verification by board staff.
c. Recent, dated, letters describing the respondent's participation in support groups, (e.g., Alcoholics Anonymous, Narcotics Anonymous, professional support groups, etc.). Such letters and reports will be subject to verification by board staff.
d. Recent, dated, laboratory analyses or drug screen reports, confirming abstention from drugs and alcohol. Such analyses and reports will be subject to verification by board staff.
e. Recent, dated, physical examination/ ~~or~~ assessment report(s) by a licensed physician, confirming the absence of any physical impairment that would prohibit the respondent from practicing safely. Such ~~assessments and~~ report(s) will be subject to verification by board staff.
f. Recent, dated, letters from probation or parole officers regarding the respondent's participation in and/or compliance with terms and conditions of probation or parole, which should include at least a description of the terms and conditions, and the officer's basis for determining compliance. Such letters and reports will be subject to verification by board staff.
g. Recent, dated, letters from persons familiar with respondent in either a personal or professional capacity regarding their knowledge of: the respondent's character; the respondent's rehabilitation, if any; the conduct of which the respondent is accused; or any other pertinent facts that would enable the board to better decide the case. Such letters must be signed under penalty of perjury and will be subject to verification by board staff.
h. For premises licensees, recent, dated letters from appropriate licensees or representatives of licensees of the board in good standing, or from appropriate consultants and/or experts in the field, written by persons familiar with respondent in either a personal or professional capacity regarding their knowledge of: the character and rehabilitation, if any, of respondent's owner(s), officer(s), or managerial employee(s); the conduct of which the respondent is accused; the details of respondent's operation(s); or any other pertinent facts that would enable the board to

better decide the case. Such letters must be signed under penalty of perjury and will be subject to verification by board staff.

TERMS OF PROBATION – ~~PHARMACIST/INTERN PHARMACIST~~ INDIVIDUAL LICENSEES (PHARMACIST, ADVANCED PRACTICE PHARMACIST, INTERN PHARMACIST, PHARMACY TECHNICIAN, DESIGNATED REPRESENTATIVE AND DESIGNATED REPRESENTATIVE-3PL)

A minimum three-year probation period has been established by the board as appropriate in most cases where probation is imposed. A minimum five-year probation period has been established by the board as appropriate ~~where self-administration or diversion of controlled substances is involved~~ in cases involving self-administration or diversion of controlled substances or dangerous drugs and/or dangerous devices, or abusive use of alcohol. Terms and conditions are imposed to provide consumer protection and to allow the probationer to demonstrate rehabilitation. A suspension period may also be required as part of the probation order. The board prefers that any stayed order be for revocation rather than for some period of suspension. The board ~~is~~ also ~~guided by~~ uses the Uniform Standards Regarding Substance-Abusing Licensees developed by the Substance Abuse Coordinating Committee of the Department of Consumer Affairs (2011). ~~Where appropriate and to the extent practicable, the terms and conditions that are specified below incorporate and/or are impacted by those Uniform Standards.~~

Probation conditions are divided into two categories: (1) standard conditions that shall appear in all probation cases, and (2) optional conditions that depend on the nature and circumstances of a particular case. These conditions may vary depending on the nature of the offense(s).

The board may also impose any other condition appropriate to the case where the condition is not contrary to public policy.

CATEGORIES OF VIOLATIONS AND RECOMMENDED PENALTIES

The California Pharmacy Law identifies offenses for which the board may take disciplinary action against the license. Included among grounds for discipline are violations of the Pharmacy Law itself, violations of regulations promulgated by the board, and violations of other state or federal statutes or regulations.

For those licenses issued to individuals (pharmacists, intern pharmacists, pharmacy technicians, and designated representatives, designated representatives-3PL, and advanced practice pharmacists), the board has identified four (4) categories of violations and their associated recommended minimum and maximum penalties. These categories of violations are arranged in ascending order from the least serious (Category I) to the most serious (Category IV), although any single violation in any category, or any combination of violation(s) in one or more categories, may merit revocation. For pharmacy technicians and designated representatives, the board believes an order of revocation is typically the appropriate penalty when any grounds for discipline are established, and that if revocation is not imposed that a minimum Category III level of discipline should be imposed.

~~The following are categories of possible violations used by the board to determine appropriate disciplinary penalties. These categories represent the judgment of the board as to the perceived seriousness of particular offenses~~.

~~Under each category, the board has grouped statutes and regulations where violations would typically merit the recommended range of minimum to maximum penalties for that category. These lists are representative, and are not intended to be comprehensive or exclusive.~~ For

each violation category, the board has given offense descriptions and examples where violations would typically merit the recommended range of minimum to maximum penalties for that category. These descriptions and examples are representative, and are not intended to be comprehensive or exclusive. Where a violation not included in these lists is a basis for disciplinary action, the appropriate penalty for that violation may be best derived by comparison to any analogous violation(s) that are included. Where no such analogous violation is listed, the category descriptions may be consulted.

These categories assume a single violation ~~of each listed statute or regulation~~. For multiple violations, the appropriate penalty shall increase accordingly. Moreover, if an individual has committed violations in more than one category, the minimum and maximum penalties shall be those recommended in the highest category.

The board also has the authority, pursuant to Business and Professions Code section 4301(n), to impose discipline based on disciplinary action taken by another jurisdiction. The discipline imposed by the board will depend on the discipline imposed by the other jurisdiction, the extent of the respondent's compliance with the terms of that discipline, the nature of the conduct for which the discipline was imposed, and other factors set forth in these guidelines.

CATEGORY I

Minimum: Revocation; Revocation stayed; ~~one~~ two years probation. All standard terms and conditions shall be included and optional terms and conditions as appropriate.

Maximum: Revocation

Category I discipline is recommended for violations ~~which are~~ that are less serious ~~that~~ than Category 2 through 4 but are potentially harmful. These may include:

- violations ~~which are relatively minor but are potentially harmful~~ of recordkeeping requirements, scope of practice requirements, or inventory control requirements;
- ~~repeated violations of a relatively minor nature:~~ smaller or isolated failure(s) to abide by or enforce prescription or refill requirements, drug-substitution requirements, or labeling requirements;
- violation(s) of obligations to supply or update information to the board, or to other enforcement or regulatory agencies;
- failure(s) to adequately supervise staff or ensure security and sanitation of premises, dangerous drugs and/or dangerous devices, or controlled substances; and
- violation(s) of packaging requirements, security control requirements, or reporting requirements.
- violation(s) involving the improper compounding of drug products
- violation(s) resulting from the misuse of education or licensing privileges irrespective of whether it occurs outside of an entity licensed by the board.

~~Violations of the following codes are representative of this category:~~

~~**BUSINESS AND PROFESSIONS CODE**~~

~~**Article 3. Scope of Practice and Exemptions**~~

~~4052.1 Skin Puncture by Pharmacist; Conditions Permitting~~
~~4052.5 Pharmacist May Select Different Form of Medication with Same Active Chemical~~

~~Ingredients; Exceptions~~
~~4052.7 Repackage Previously Dispensed Drugs; Requirements~~
~~4053 Exemptee Supervisor of Manufacturer, etc.: Requirements~~
~~4054 Supply by Manufacturer, etc. of Certain Dialysis Drugs and Devices~~
~~4055 Sale of Devices to Licensed Clinics, etc.~~
~~4056 Purchase of Drugs at Wholesale – Hospital Containing 100 Beds or Less~~
~~4057 Exceptions to Application of this Chapter~~
~~4058 Display of Original License~~
~~4062 Furnishing Dangerous Drugs During Emergency~~
~~4064 Emergency Refill of Prescription Without Prescription Authorization~~
~~4065 Injection Card System; Requirements of Administration~~
~~4066 Furnishing Dangerous Drugs to Master or First Officer of Vessel~~
~~4068 Dispense Dangerous Drug or Controlled Substance to Emergency Room Patient; Requirements~~

~~Article 4. Requirements for Prescription~~

~~4070 Reduction of Oral or Electronic Prescription to Writing~~
~~4071 Prescriber May Authorize Agent to Transmit Prescription; Schedule II Excluded~~
~~4072 Oral or Electronic Transmission of Prescription – Health Care Facility~~
~~4073 Substitution of Generic Drug – Requirements and Exceptions~~
~~4074 Drug Risk: Informing Patient; Providing Consultation for Discharge Medications~~
~~4076 Prescription Container – Requirements for Labeling~~
~~4077 Dispensing Dangerous Drug in Incorrectly Labeled Container~~

~~Article 5. Authority of Inspectors~~

~~4082 Names of Owners, Managers and Employees Open for Inspection~~

~~Article 6. General Requirements~~

~~4100 Change of Address or Name – Notification to Board~~
~~4103 Blood Pressure – Taking by Pharmacist~~

~~Article 7. Pharmacies~~

~~4114 Intern Pharmacist: Activities Permitted~~
~~4119 Furnish Prescription Drug to Licensed Health Care Facility – Secured~~
~~4119.1 Pharmacy May Provide Services to Health Facility~~
~~4119.5 Transfer or Repackaging Dangerous Drugs by Pharmacy~~
~~4121 Advertisement for Prescription Drug: Requirements; Restrictions~~
~~4122 Required Notice at Availability of Prescription Price Information, General Product Availability, Pharmacy Services; Providing Drug Price Information; Limitations on Price Information Requests~~
~~4123 Compounding Drug for Other Pharmacy for Parenteral Therapy; Notice to Board~~
~~4124 Dispensing Replacement Contact Lenses: Requirements; Patient Warnings; Registration with Medical Board; Application of Section to Nonresident Pharmacies~~

~~Article 9. Hypodermic Needles and Syringes~~

~~4141 Furnishing Without License~~
~~4142 Prescription Required~~
~~4143 Exemption: Sale to Other Entity, Physician, etc.~~
~~4144 Industrial Use Exception~~

~~4145 Exception: Furnishing for Administration of Insulin, Adrenaline, or Specified Animal Uses; Conditions~~
~~4148 Confiscation if Found Outside Licensed Premises~~
~~4149 Sale by Distributor~~

~~Article 10. Pharmacy Corporations~~

~~4151 Licensure Requirements~~
~~4152 Corporate Name Requirements~~
~~4153 Shareholder Income While Disqualified~~
~~4156 Unprofessional Conduct by Corporation~~

~~Article 11. Wholesalers and Manufacturers~~

~~4161 Nonresident Wholesaler: When License Required; Application~~
~~4162 Issuance or Renewal of Wholesaler License; Surety Bond~~
~~4163 Unauthorized Furnishing by Manufacturer or Wholesaler~~
~~4165 Sale or Transfer of Dangerous Drug or Device Into State: Furnishing Records to Authorized Officer on Demand; Citation for Non-compliance~~
~~4166 Shipping of Dangerous Drugs or Devices – Wholesaler or Distributor~~
~~4167 Wholesaler: Bar on Obtaining Dangerous Drugs or Devices It Cannot Maintain on Licensed Premises~~

~~Article 13. Non-Profit or Free Clinics~~

~~4180 Purchase of Drugs at Wholesale Only with License: Eligible Clinics~~
~~4181 License Requirements; Policies and Procedures; Who May Dispense~~
~~4182 Duties of Professional Director; Consulting Pharmacist Required~~
~~4183 No Professional Dispensing Fee~~
~~4184 Dispensing Schedule II Substance Prohibited~~
~~4186 Automated Drug Delivery Systems~~

~~Article 14. Surgical Clinics~~

~~4190 Purchase of Drugs at Wholesale: Permitted Uses of Drugs; Required Records and Policies; License Required~~
~~4191 Compliance with Department of Health Services Requirements; Who May Dispense Drugs~~
~~4192 Duties of Professional Director; Providing Information to Board~~
~~4193 Clinic Not Eligible for Professional Dispensing Fee; Ban on Offering Drugs for Sale~~
~~4194 Dispensing of Schedule II Substance by Clinic Prohibited; Physician May Dispense; Administration Authorized in Clinic~~

~~Article 15. Veterinary Food-Animal Drug Retailers~~

~~4196 License Required: Temporary License on Transfer of Ownership; Persons Authorized in Storage Area~~
~~4197 Minimum Standards: Security; Sanitation; Board Regulations; Waivers~~
~~4198 Written Policies and Procedures Required: Contents; Training of Personnel; Quality Assurance; Consulting Pharmacist~~

~~Article 17. Continuing Education~~

~~4231 Requirements for Renewal of Pharmacist License: Clock Hours; Exemption for New Licensee~~
~~4232 Content of Course~~

~~Article 18. Poisons~~

~~4240 Application of Act~~

~~Article 20. Prohibitions and Offenses~~

~~4341 Advertisement of Prescription Drugs or Devices~~
~~4343 Buildings: Prohibition Against Use of Certain Signs Unless Licensed Pharmacy Within~~

~~CALIFORNIA CODE OF REGULATIONS, TITLE 16~~

~~1704 Change of Address~~
~~1705 Notification of Bankruptcy, Receivership or Liquidation~~
~~1708.2 Discontinuance of Business~~
~~1708.4 Pharmacist Handling Radioactive Drugs~~
~~1708.5 Pharmacy Furnishing Radioactive Drugs~~
~~1709 Names of Owners and Pharmacist in Charge~~
~~1712 Use of Pharmacist Identifiers~~
~~1714 Operational Standards and Security~~
~~1715.6 Reporting Drug Loss~~
~~1716 Variation From Prescriptions~~
~~1717 Pharmaceutical Practice~~
~~1717.1 Common Electronic Files~~
~~1717.4 Electronic Transmission of Prescriptions~~
~~1718.1 Manufacturer's Expiration Date~~
~~1726 Supervision of Intern Pharmacists~~
~~1728 Requirements for Examination~~
~~1732.1 Requirements for Accredited Providers~~
~~1732.3 Requirements for Continuing Education Courses~~
~~1732.4 Provider Audit Requirements~~
~~1732.5 Renewal Requirements for Pharmacist~~
~~1744 Drug Warnings~~
~~1746 Emergency Contraception~~
~~1751 Sterile Injectable Compounding Area~~
~~1751.01 Facility and Equipment Standards for Sterile Injectable Compounding from Non-Sterile Ingredients~~
~~1751.02 Policies and Procedures~~
~~1751.1 Laminar Flow Biological Safety Cabinet~~
~~1751.2 Labeling Requirements~~
~~1751.3 Recordkeeping Requirements~~
~~1751.4 Attire~~
~~1751.5 Training of Staff, Patient, and Caregiver~~
~~1751.6 Disposal of Waste Material~~

~~1751.7 Quality Assurance and Process Evaluation~~
~~1751.9 Reference Materials~~
~~1751.11 Furnishing to Home Health Agencies and Licensed Hospices~~
~~1751.12 Obligations of a Pharmacy Furnishing Portable Containers~~
~~1771 Posting Notice of Suspension~~
~~1772 Disciplinary Condition of Suspension~~
~~1780 Minimum Standards for Wholesalers~~
~~1780.1 Minimum Standards for Veterinary Food-Animal Drug Retailers~~
~~1781 Exemption Certificate~~
~~1786 Exemptions~~
~~1787 Authorization to Distribute Hemodialysis Drugs and Devices~~
~~1790 Assembling and Packaging~~
~~1791 Labeling~~
~~1792 Receipt for Shipment~~

~~HEALTH AND SAFETY CODE~~

~~11100 Report of Certain Chemical: Chemicals Included; Exclusions; Penalties~~
~~11100.1 Report of Chemicals Received from Outside State; Penalties~~
~~11151 Limitation on Filling Prescriptions From Medical Students~~
~~11158 Prescription Required for Schedule II, III, IV, or V Controlled Substance; Exception for Limited Dispensing, Administration~~
~~11159 Chart Order Exemption for Patient in County or Licensed Hospital; Maintaining Record for Seven Years~~
~~11159.1 Chart Order Exemption for Clinic Patient; Maintaining Record for Seven Years~~
~~11159.2 Exception to Triplicate Prescription Requirement~~
~~11167 Emergency Dispensing of Schedule II Substance: Circumstances and Requirements~~
~~11167.5 Oral or Electronic Prescriptions for Scheduled II Controlled Substances for Specified Inpatients, Residents, and Home Hospice Patients; Requirements~~
~~11171 Prescribing, etc. Controlled Substance Only as Authorized~~
~~11172 Antedating or Postdating Prescription Prohibited~~
~~11175 Prohibition on Obtaining or Possessing Nonconforming Prescription; Prohibition on Obtaining Controlled Substance by Nonconforming Prescription~~
~~11180 Prohibition on Controlled Substance Obtained or Possessed by Nonconforming Prescription~~
~~11200 Restrictions on Dispensing or Refilling; Refill of Schedule II Prescription Barred~~
~~11201 Emergency Refill of Schedule III, IV, or V Prescription; Circumstances; Requirements~~
~~11205 Maintenance and Retention of Records in Separate File~~
~~11206 Required information on Prescription~~
~~11209 Delivery and Receiving Requirements for Schedule II, III, and IV Substances; Violation~~
~~11210 Issuing Prescription: By Whom; For What Purpose; Quantity to Be Prescribed~~
~~11250 Authorized Retail Sale by Pharmacists to Physicians, etc.; Required Order Form~~
~~11251 Authorized Wholesale Sale by Pharmacists~~
~~11252 Preservation of Federally Required Forms~~
~~11253 Duration of Retention~~
~~11255 Actions Constituting Sale~~
~~11256 Required Report of Order By or Sale to Out-of-State Wholesaler or Manufacturer~~
~~111225 to~~

~~111655 Adulterated or Misbranded Drugs or Devices~~

~~CODE OF FEDERAL REGULATIONS, TITLE 21~~

~~1301.11 Persons required to register.~~
~~1301.12 Separate registrations for separate locations.~~
~~1301.71 Security requirements generally.~~
~~1301.72 Physical security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs; storage areas.~~
~~1301.73 Physical security controls for non-practitioners; compounders for narcotic treatment programs; manufacturing and compounding areas.~~
~~1301.74 Other security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs.~~
~~1301.75 Physical security controls for practitioners.~~
~~1301.76 Other security controls for practitioners.~~
~~1301.90 Employee screening procedures.~~
~~1301.91 Employee responsibility to report drug diversion.~~
~~1301.92 Illicit activities by employees.~~
~~1302.03 Symbol required; exceptions.~~
~~1302.04 Location and size of symbol on label and labeling.~~
~~1302.05 Effective dates of labeling requirements.~~
~~1302.06 Sealing of controlled substances.~~
~~1302.07 Labeling and packaging requirements for imported and exported substances.~~
~~1304.11 Inventory requirements.~~
~~1304.21 Inventories of importers and exporters~~
~~1304.31 Reports from manufacturers importing narcotic raw materials.~~
~~1304.32 Reports of manufacturers importing coca leaves.~~
~~1304.33 Reports to ARCOS.~~
~~1305.03 Distributions requiring a Form 222 or a digitally signed electronic order.~~
~~1305.04 Persons entitled to order Schedule I and II controlled substances.~~
~~1305.05 Power of attorney.~~
~~1305.06 Persons entitled to fill orders for Schedule I and II controlled substances.~~
~~1305.11 Procedure for obtaining DEA Forms 222.~~
~~1305.12 Procedure for executing DEA Forms 222.~~
~~1305.14 Procedure for endorsing DEA Forms 222.~~
~~1305.15 Unaccepted and defective DEA Forms 222.~~
~~1305.16 Lost and stolen DEA Forms 222.~~
~~1306.03 Persons entitled to issue prescriptions.~~
~~1306.05 Manner of issuance of prescriptions.~~
~~1306.14 Labeling of substances and filling of prescriptions.~~
~~1306.24 Labeling of substances and filing of prescriptions.~~
~~1306.25 Transfer between pharmacies of prescription information for Schedules III, IV, and V controlled substances for refill purposes.~~
~~1306.26 Dispensing without a prescription.~~
~~1307.11 Distribution by dispenser to another practitioner or reverse distributor.~~
~~1307.12 Distribution to supplier or manufacture.~~
~~1307.13 Incidental manufacture of controlled substances.~~
~~1307.21 Procedure for disposing of controlled substances.~~
~~1700.1 to~~
~~1707.15 Child-resistant containers.~~

CATEGORY II

Minimum: Revocation; Revocation stayed, three years probation (five years probation ~~where self-administration or diversion of controlled substances is involved~~ in cases involving self-administration or diversion of controlled substances or dangerous drugs and/or dangerous devices, or abusive use of alcohol). All standard terms and conditions shall be included and optional terms and conditions as appropriate.

Maximum: Revocation

Category II discipline is recommended for violation(s) with serious potential for harm, as well as for violations involving disregard for public safety or for the laws or regulations pertaining to pharmacy and/or to dispensing or distributing of dangerous drugs and/or dangerous devices or controlled substances, violations that reflect on ethics, competence, or diligence, and criminal convictions not involving alcohol, dangerous drugs and/or dangerous devices, or controlled substances. Violations in this category may include:

- failure(s) to abide by prohibitions on referral rebates or discounts (kickbacks) and/or volume or percentage-based lease agreements;
- violation(s) of advertising or marketing limitations, including use of false or misleading advertising or marketing;
- repeat or serious violation(s) of recordkeeping requirements, scope of practice requirements, or inventory control requirements;
- violation(s) of controlled substance secure prescription requirements, inventory controls, or security requirements;
- failure(s) to meet compliance requirements, including pharmacist-in-charge or designated representative-in-charge designation and duties;
- violation(s) of monitoring and reporting requirements with regard to chemically, mentally, or physically impaired licensees or employees;
- repeat or serious failure(s) to adequately supervise staff or ensure security and sanitation of premises, dangerous drugs and/or dangerous devices, or controlled substances;
- violation(s) of law governing controlled substances, dangerous drugs and/or dangerous devices, or alcohol, including smaller cases of diversion or self-administration or abusive use of a controlled substance, dangerous drug and/or dangerous device, or alcohol;
- unlawful possession(s) of dangerous drugs and/or dangerous devices, controlled substances, hypodermic needles and syringes, or drug paraphernalia;
- smaller scale dispensing or furnishing of dangerous drug(s) and/or dangerous device(s) via the internet without valid prescription(s);
- purchasing, trading, selling, or transferring dangerous drug(s) and/or dangerous device(s) to or from unauthorized person(s);
- failure(s) to make required reports to the board or other regulatory agencies, including CURES obligations and reporting to DEA;
- violation(s) of quality assurance and self-assessment obligations, failure(s) to clarify erroneous or uncertain prescription(s);
- gross immorality, incompetence, gross negligence, ~~clearly~~ excessive furnishing of controlled substances, moral turpitude, dishonesty, or fraud;
- criminal conviction(s) not involving alcohol, dangerous drugs and/or dangerous devices, or controlled substances;
- violating, or assisting in or abetting violation of, or conspiring to violate the laws and regulations governing pharmacy; and

- subverting or attempting to subvert an investigation conducted by the board.
- repeated violation(s) involving the improper compounding of drug products
- violations resulting from the misuse of education or licensing privileges irrespective of whether these violations occur in a entity regulated by the board.
- ~~violations with a serious potential for harm~~
- ~~violations which involve greater disregard for pharmacy law and public safety~~
- ~~violations which reflect on ethics, care exercised or competence or a criminal conviction not involving dangerous drugs or controlled substances or involving possession or use of dangerous drugs or controlled substances.~~

~~Violations of the following codes are representative of this category:~~

~~BUSINESS AND PROFESSIONS CODE~~

~~650 Rebates or Discounts for Referral Prohibited~~
~~650.1 Lease Prohibition – Hospitals or Prescribers~~
~~651 Professional Advertising Requirements~~

~~Article 3. Scope of Practice and Exemptions~~

~~4051(b) Conduct Authorized by Pharmacist~~
~~4052 Furnishing to Prescriber; Permissible Procedures by Pharmacist in Health Care Facility or Clinic or for Other Health Care Provider~~
~~4060 Controlled Substance – Prescription Required; Exceptions~~
~~4061 Distribution of Drug as Sample; Written Request Required~~
~~4063 Refill of Prescription for Dangerous Drug or Device; Prescriber Authorization~~
~~4067 Internet; Dispensing Dangerous Drugs or Devices without Prescription~~
~~4075 Proof of Identity Required – Oral or Electronic Prescription~~
~~4078 False or Misleading Label on Prescription~~

~~Article 6. General Requirements~~

~~4101 Pharmacist in Charge, Exemptee: Termination of Employment; Notification to Board~~
~~4104 Licensed Employee, Theft or Impairment: Pharmacy Procedures~~
~~4105 Retaining Records of Dangerous Drugs and Devices on Licensed Premises; Temporary Removal; Waivers; Access to Electronically Maintained Records~~

~~Article 7. Pharmacies~~

~~4112 Nonresident Pharmacy: Registration; Provision of Information to Board; Maintaining Records; Patient Consultation~~
~~4113 Pharmacist in Charge: Notification to Board; Responsibilities~~
~~4115 Pharmacy Technician: Activities Permitted; Required Supervision; Activities Limited to Pharmacist; Registration; Requirements for Registration; Ratios~~
~~4115.5 Pharmacy Technician Trainee; Placement; Supervisions; Requirements~~
~~4116 Security of Dangerous Drugs and Devices in Pharmacy: Pharmacist Responsibility for Individuals on Premises; Regulations~~
~~4117 Admission to Area Where Narcotics are Stored, etc. – Who May Enter~~
~~4120 Nonresident Pharmacy: Registration Required~~
~~4125 Pharmacy Quality Assurance Program Required; Records Considered Peer Review Documents~~

~~**Article 9. Hypodermic Needle and Syringes**~~

~~4140 Unlawful Possession~~
~~4147 Disposal of Needle or Syringe~~

~~**Article 11. Wholesalers and Manufacturers**~~

~~4160 Wholesaler: License Required~~
~~4163 Unauthorized Furnishing by Manufacturer or Wholesaler~~
~~4164 Reports Required~~
~~4169(a)(1) Prohibited Acts~~

~~**Article 13. Non-Profit of Free Clinics**~~

~~4185 Inspection Permitted~~

~~**Article 14. Surgical Clinics**~~

~~4195 Inspection Permitted~~

~~**Article 19. Disciplinary Proceedings**~~

~~4301 Unprofessional Conduct - subsections (a)-(h), (j), and (l)-(q)~~
~~4302 Discipline of Corporate Licensee for Conduct of Officer, Director, Shareholder~~
~~4303 Nonresident Pharmacy: Grounds for Discipline~~
~~4304 Out-of-state Distributor: Authority to Discipline~~
~~4305 Disciplinary Grounds: Failure of Pharmacy, Pharmacist to Notify Board of Termination of Pharmacist in Charge; Continuing to Operate Without Pharmacist~~
~~4305.5 Disciplinary Grounds: Failure of Other Entity Licensed by Board, of Pharmacist or Exemptee to Notify Board of Termination of Pharmacist in Charge or Exemptee; Continuing to Operate Without Pharmacist or Exemptee~~
~~4306 Violation of Professional Corporation Act as Unprofessional Conduct~~
~~4306.5 Misuse of Education, etc. by Pharmacist Outside Course of Practice of Pharmacy as Unprofessional Conduct~~

~~**Article 20. Prohibitions and Offenses**~~

~~4326 Misdemeanor: Obtaining Needle or Syringe by Fraud, etc.; Unlawful Use of Needle or Syringe Obtained from Another~~
~~4328 Misdemeanor: Permitting Compounding, Dispensing, or Furnishing by Non-pharmacist~~
~~4330 Misdemeanor: Non-pharmacist Owner Failing to Place Pharmacist in Charge, Dispensing or Compounding Except by Pharmacist, Interfering with Pharmacist in Charge~~
~~4331 Misdemeanor: Medical Device Retailer, Wholesaler, Veterinary Food-Animal Drug Retailer Failing to Place Pharmacist or Exemptee in Charge, Permitting Dispensing or Compounding Except by Pharmacist or Exemptee~~
~~4333 Maintaining Prescriptions, Other Drug Records on Premises, Open to Inspection; Waiver; Willful Failure to Keep or Permit Inspection of Records of Prescriptions, Other Records as Misdemeanor~~
~~4340 Unlawful Advertising by Nonresident Pharmacy Not Registered with Board~~

~~Article 22. Unfair Trade Practices~~

~~4380 Resale of Preferentially Priced Drugs: Prohibition; Exceptions~~
~~4381 Violation of Section 4380 as Unfair Competition; Right of Private Action to Enforce~~
~~4382 Board May Audit Sales to Walk-in Customers~~

~~CALIFORNIA CODE OF REGULATIONS, TITLE 16~~

~~1707.1 Duty to Maintain Medication Profiles (Patient Medication Records)~~
~~1707.2 Notice to Consumers and Duty to Consult~~
~~1707.3 Duty to Review Drug Therapy and Patient Medication Record Prior to Delivery~~
~~1709.1 Designation of Pharmacist in Charge~~
~~1714.1 Pharmacy Operations During the Temporary Absence of a Pharmacist~~
~~1715 Self-Assessment of a Pharmacy by the Pharmacist-in-Charge~~
~~1715.5 Implementation of Electronic Monitoring of Schedule II Prescriptions~~
~~1716.1 Compounding Unapproved Drugs for Prescriber Office Use~~
~~1716.2 Record Requirements-Compounding for Future Furnishing~~
~~1717.3 Preprinted, Multiple Checkoff Prescription Blanks~~
~~1723.1 Confidentiality of Examination Questions~~
~~1745 Partial Filling of Schedule II Prescriptions~~
~~1751.10 Furnishing to Parenteral Patient at Home~~
~~1761(a) Erroneous or Uncertain Prescriptions~~
~~1764 Unauthorized Disclosure of Prescriptions~~
~~1765 Commissions, Gratuities, and Rebates~~
~~1766 False or Misleading Advertising~~
~~1775.3 Compliance with Orders of Abatement~~
~~1782 Reporting Sales of Drugs Subject to Abuse~~
~~1783 Manufacturer or Wholesaler Furnishing Drugs or Devices~~
~~1793.1 Duties of a Pharmacist~~
~~1793.2 Duties of a Pharmacy Technician~~
~~1793.3 Other Non-Licensed Pharmacy Personnel~~
~~1793.7 Requirements for Pharmacies Employing Pharmacy Technicians~~
~~1793.8 Technicians in Hospitals with Clinical Pharmacy Programs~~

~~HEALTH AND SAFETY CODE~~

~~11103 Report of Theft, Loss, or Shipping Discrepancy~~
~~11150 Persons Authorized to Write or Issue a Prescription~~
~~11152 Nonconforming Prescriptions Prohibited~~
~~11154 Prescription, etc, Must Be for Treatment; Knowing Solicitation of Unlawful Prescription, etc.~~
~~11156 Prescribing, etc. Controlled Substances to Addict Only as Authorized~~
~~11164 Prescriptions for Schedule II, III, IV and V Controlled Substances: Form and Content; Record of Practitioner Dispensing Schedule II Controlled Substances~~
~~11166 Time Limit for Filling Schedule II Prescription; Knowingly Filling Mutilated, Forged, or Altered Prescription Prohibited~~
~~11170 Prohibition on Prescribing, etc. Controlled Substance for Self~~
~~11179 Retention of Controlled Substance Prescription~~

~~11207 Only Pharmacist or Intern Authorized to Fill Prescription~~
~~11209 Delivery and Receiving Requirements for Schedule II, III, and IV Substances; Violation~~
~~11350 Possession of Specified Controlled Substance~~
~~11377 Unlawful Possession of Specified Substance~~
~~11165(d) CURES Transmission~~
~~150204 Surplus Medication Collection and Distribution Program~~

~~CODE OF FEDERAL REGULATIONS, TITLE 21~~

~~1304.03 Persons required to keep records and file reports.~~
~~1304.04 Maintenance of records and inventories.~~
~~1304.11 Inventory requirements .~~
~~1304.21 General requirements for continuing records.~~
~~1304.22 Records for manufacturers.~~
~~1305.07 Special procedure for filling certain orders.~~
~~1305.13 Procedure for filling DEA Forms 222.~~
~~1306.04 Purpose of issue of prescription.~~
~~1306.06 Persons entitled to fill prescriptions.~~
~~1306.07 Administering or dispensing of narcotic drugs.~~
~~1306.11 Requirement of prescription.~~
~~1306.12 Refilling prescription.~~
~~1306.13 Partial filling of prescriptions.~~
~~1306.21 Requirement of prescription.~~
~~1306.22 Refilling of prescriptions.~~
~~1306.23 Partial filling of prescriptions.~~

CATEGORY III

Minimum: Revocation; Revocation stayed, 90 days actual suspension, three to five years probation (five years probation ~~where self-administration or diversion of controlled substances is involved~~ in cases involving self-administration or diversion of controlled substances or dangerous drugs and/or dangerous devices, or abusive use of alcohol). All standard terms and conditions and optional terms and conditions as appropriate.

Maximum: Revocation

Category III discipline is recommended for violations where potential for harm is greater, more imminent, or more serious than it is for Category II violations, as well as for violations that involve knowingly or willfully violating laws or regulations pertaining to pharmacy and/or to the dispensing or distributing of dangerous drugs and/or dangerous devices or controlled substances, and most criminal convictions involving alcohol, dangerous drugs and/or dangerous devices or controlled substances. Violations in this category may include:

- violation(s) involving creation, manipulation, perpetuation, or disregard of drug shortages;
- failure(s) to deploy or abide by ~~track and trace, pedigree, transaction history~~ Drug Supply Chain Security Act requirements, and other similar requirements for dangerous drugs and/or dangerous devices;
- violation(s) of licensee's corresponding responsibility to ensure the proper prescribing and dispensing of controlled substances;

- dispensing or furnishing without valid prescription, dispensing or furnishing to unauthorized person(s);
- violation(s) involving fraudulent acts committed in connection with the licensee's practice;
- repeat or serious violation(s) of controlled substance secure prescription requirements, inventory controls, or security requirements;
- violation(s) of laws governing controlled substances, dangerous drugs and/or dangerous devices, or alcohol, including repeat or serious diversion or self-administration, or abuse;
- violation(s) of law governing self-administration of controlled substances that ~~could lead to~~ create a potential infection control risk.
- repeat or serious unlawful possession(s) of dangerous drugs and/or dangerous devices, controlled substances, hypodermic needles or syringes, or drug paraphernalia;
- larger scale dispensing or furnishing of dangerous drug(s) and/or dangerous device(s) via the internet,
  without valid prescription(s);
- purchasing, trading, selling, or transferring adulterated, misbranded, or expired dangerous drug(s) and/or dangerous device(s);
- removal, sale, or disposal of embargoed dangerous drug(s) and/or dangerous device(s);
- failing to maintain record(s) of acquisition and disposition of dangerous drug(s) and/or dangerous device(s);
- resale(s) of preferentially priced drugs, contract bid diversion, or other instances of improper sale(s) or resale(s);
- repeat or serious violation(s) of quality assurance and self-assessment obligations, failure(s) to ensure properly trained staff and conduct practice safely;
- repeat or serious failure(s) to perform drug utilization reviews, monitor patient medication profiles, or promote safety and efficacy of prescribed drugs;
- forgery of prescriptions, passing of forged prescriptions, or other unlawful means of acquiring dangerous drug(s) and/or dangerous device(s) or controlled substance(s);
- repeat or serious acts violating, assisting in or abetting violation of, or conspiring to violate the laws and regulations governing pharmacy; and
- violation(s) involving providing or offering to provide controlled substance(s) to addict(s).
  - ~~most criminal convictions involving dangerous drugs or controlled substances~~
  - ~~knowing or willfully violating laws or regulations pertaining to dispensing or distributing dangerous drugs or controlled substances~~
  - ~~fraudulent acts committed in connection with the licensee's practice~~
  - ~~drug shortages~~
  - ~~violation of a licensee's corresponding responsibility.~~
- repeat or serious violation(s) involving the improper compounding of drug products
- repeat or serious violation(s) resulting from the misuse of education or licensing privileges irrespective of whether ~~is~~ it occurs outside of an entity licensed by the board.

~~Violations of the following codes are representative of this category:~~

~~**BUSINESS AND PROFESSIONS CODE**~~

~~**Article 3. Scope of Practice and Exemptions**~~

~~4034 Pedigree~~
~~4051(a) Conduct Limited To Pharmacist~~
~~4059 Furnishing Dangerous Drugs or Devices Prohibited Without Prescription: Exceptions~~
~~4059.5 Who May Order Dangerous Drugs or Devices: Exceptions~~

~~Article 5. Authority of Inspectors~~

~~4080 Stock of Dangerous Drugs and Devices Kept Open for Inspection~~
~~4081 Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory~~
~~4085(a) Unlawful to Remove, Sell, Dispose of Embargoed Dangerous Drug or Dangerous Device~~

~~Article 6. General Requirements~~

~~4105 Retaining Records of Dangerous Drugs and Devices on Licensed Premises; Temporary Removal; Waivers; Access to Electronically Maintained Records~~

~~Article 7. Pharmacies~~

~~4110 Licensed Required; Temporary Permit Upon Transfer of Ownership~~
~~4111 Restrictions on Prescriber Ownership~~

~~Article 11. Wholesalers and Manufacturers~~

~~4169(a)(2) to~~
~~4169(a)(5) Prohibited Acts~~

~~Article 15. Veterinary Food-Animal Retailers~~

~~4199 Labeling Requirements; Maintaining Prescription Records~~

~~Article 19. Disciplinary Proceedings~~

~~4301 Unprofessional Conduct - subsections (i) - (k) and (o)~~
~~4307 Prohibition of Association of Individual with Entity License by Board: Length of Prohibition; Individuals Covered; Imposition of Prohibition Through Administrative Act Proceeding~~
~~4308 Prohibited Association: Notification of Affected Licensees Known to Board~~

~~Article 20. Prohibitions and Offenses~~

~~4322 Misdemeanor or Infraction: False Representations to Secure License for Self or Others; False Representation of Licensure; Penalties~~
~~4323 Misdemeanor: False Representation of Self as Physician, Agent of Physician, etc. to Obtain Drug~~
~~4324 Felony or Misdemeanor: Forgery of Prescription; Possession of Drugs Obtained Through Forged Prescription~~
~~4325 Misdemeanor: Manufacture, Possession, etc. of False Prescription Blank~~
~~4327 Misdemeanor: Sale, Dispensing, or Compounding While Under the Influence of Drugs or Alcoholic Beverages~~
~~4329 Misdemeanor: Non-pharmacist Acting as Manager, Compounding, Dispensing or Furnishing Drugs~~
~~4332 Misdemeanor: Failure or Refusal to Maintain or Produce Required Drug or Device Records; Willful Production of False Records~~

~~4335 Voided License: Knowing Failure to Arrange for Disposition of Stock as Misdemeanor~~
~~4336 Felony: Knowing or Willful Use of Minor to Violate Specified Sections of Pharmacy Law: Exception for Pharmacist Furnishing Pursuant to a Prescription~~

~~Article 22. Unfair Trade Practices~~

~~4380 Resale of Preferentially Priced Drugs: Prohibition; Exceptions~~

~~CALIFORNIA CODE OF REGULATIONS, TITLE 16~~

~~1707 Waiver Requirements for Off-Site Storage of Records~~
~~1718 Current Inventory Defined~~
~~1761(b) Erroneous or Uncertain Prescriptions~~
~~1771 Posting of Notice of Suspension~~
~~1772 Disciplinary Condition of Suspension~~
~~1773 Disciplinary Conditions of Probation of Pharmacist~~
~~1774 Disciplinary Conditions of Probation of Permit~~

~~HEALTH AND SAFETY CODE~~

~~11104 Providing Chemical for Illicit Manufacturing; Evasion of Reporting Requirements; Penalties~~
~~11105 False Statement in Report~~
~~11150 Persons Authorized to Write or Issue a Prescription~~
~~11153 Responsibility for Legitimacy of Prescription; Corresponding Responsibility of Pharmacist; Knowing Violation~~
~~11153.5 Wholesaler or Manufacturer Furnishing Controlled Substance Other Than for Legitimate Medical Purpose; Knowing Violation; Factors in Assessing Legitimacy~~
~~11157 No False or Fictitious Prescriptions~~
~~11162.5 Counterfeiting or Possession of Counterfeit Triplicate Prescription Blank; Penalty~~
~~11173 Fraud, Deceit, Misrepresentation or False Statement; False Representation; False Label~~
~~11174 Prohibition on Providing False Name or Address in Connection with Prescription, etc.~~
~~11351 Possession or Purchase for Sale of Specified Controlled Substance~~
~~11368 Forged or Altered Prescriptions~~
~~11375 Possession for Sale or Selling Specified Substance~~
~~11378 Possession for Sale~~
~~11550 Using or Being Under Influence of Controlled Substance~~
~~11167.5 Pharmacy Generated Prescription for Schedule II Controlled Substances in a Skilled Nursing Facility~~
~~111295 Manufacturing, Selling, or Offering for Sale an Adulterated Drug or Device~~
~~111300 Unlawful to Adulterate a Drug~~
~~111305 Unlawful to Receive in Commerce an Adulterated Drug~~
~~111440 Unlawful Manufacturer, Selling a Misbranded Drug~~
~~111445 Unlawful for a Person to Misbrand~~
~~111450 Unlawful to Receive into Commerce a Drug that is Misbranded~~

CATEGORY IV

Penalty: Revocation

Category IV discipline (~~R~~revocation) is recommended for the most serious violations of laws or regulations pertaining to pharmacy and/or to the dispensing or distributing of dangerous drugs and/or dangerous devices or controlled substances. Violations in this category may include: ~~the Uniform Controlled Substance Act (Heath and Safety Code 11000 et seq.) involving:~~

- ~~possession for sale~~ violations involving possession for sale, transportation, importation, and/or use of a minor for unlawful sale of controlled substances;
- ~~transportation~~ criminal convictions involving the above, or repeat convictions involving diversion or abuse of alcohol, dangerous drugs and/or dangerous devices, or controlled substances; ~~and~~
- repeated or serious example(s) of conduct described in Category I, Category II, or Category III.
- violation(s) of law governing self-administration of controlled substances that ~~could lead to~~ create a potential infection control risk.
- ~~importation~~
- ~~sale~~
- ~~use of a minor for the unlawful sale of controlled substances~~

Revocation is also recommended ~~when:~~ where a respondent fails to file a notice of defense to an Accusation or Petition to Revoke Probation or to appear at a disciplinary hearing, where a respondent violates the terms and conditions of probation from a previous disciplinary order, or where prior discipline has been imposed on the license.

- ~~a respondent fails to file a notice of defense or to appear at a disciplinary hearing where the board has requested revocation in the accusation~~
- ~~a respondent violates the terms and conditions of probation from a previous disciplinary order~~
- ~~prior discipline has been imposed, as progressive discipline unless the respondent can demonstrate satisfactory evidence of rehabilitation.~~

~~Violations of the following codes are representative of this category:~~

~~**HEALTH AND SAFETY CODE**~~

~~11352 Importing, Selling, Furnishing Controlled Substance~~
~~11353 Adult Inducing Minor to Violate Provisions~~
~~11379 Transporting, Importing, Selling Controlled Substance~~
~~11380 Adult Using, Soliciting or Intimidating Minor for Violation~~

MODEL DISCIPLINARY LANGUAGE - ~~PHARMACIST/INTERN PHARMACIST~~ INDIVIDUAL LICENSEES (PHARMACIST, INTERN PHARMACIST, PHARMACY TECHNICIAN, DESIGNATED REPRESENTATIVE, DESIGNATED REPRESENTATIVE – 3PL, ADVANCED PRACTICE PHARMACIST)

The following standardized language shall be used in every decision where the order or condition is imposed. Where brackets appear, drafters should choose the appropriate term or consider the text instructional.

Revocation

License number _____, issued to respondent _____,is revoked.

Respondent shall relinquish ~~his or her~~ [his/her] ~~wall~~ license, including any indicia of licensure issued by the board, ~~and pocket renewal license~~ to the board within 10 days of the effective date of this decision. Respondent may not reapply or petition the board for reinstatement of ~~his or her~~ [his/her] revoked license for three years from the effective date of this decision.

~~Respondent shall pay to the board its costs of investigation and prosecution in the amount of $_____ within fifteen (15) days of the effective date of this decision.~~

~~**Option:**~~ As a condition precedent to reinstatement of ~~his or her~~ [his/her]revoked license, respondent shall reimburse the board for its costs of investigation and prosecution in the amount of
$_____. Said amount shall be paid in full prior to the ~~reapplication or~~ reinstatement of his or her license unless otherwise ordered by the board.

Option: Respondent shall pay to the board its costs of investigation and prosecution in the amount of $_____ within fifteen (15) days of the effective date of this decision.

Suspension

As part of probation, respondent is suspended from ~~the~~ practice as a [insert license type] for _____[day(s)/month(s)/year(s)] ~~of pharmacy for~~ _____beginning the effective date of this decision.

During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, third-party logistics provider, veterinary food-animal drug retailer, or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area where dangerous drugs and/or dangerous devices or controlled substances are maintained.

Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs and/or dangerous devices or controlled substances.

During suspension, ~~R~~respondent shall not engage in any activity that requires the professional judgment of and/or licensure as a ~~pharmacist~~ [insert license type]. Respondent shall not direct or control any aspect of the practice of pharmacy or of the manufacturing, distributing, wholesaling, or retailing of dangerous drugs and/or dangerous devices or controlled substances. ~~Respondent~~

~~shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.~~

~~Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.~~

Failure to comply with this suspension shall be considered a violation of probation.

Revocation, stayed, ~~Standard Stay/~~Probation Order

License number _____, issued to respondent is revoked; however, the revocation is stayed and respondent is placed on probation for _____ years upon the following terms and conditions:

Issuance of Probationary License (In cases where a Statement of Issues has been filed.)

Upon satisfaction of all statutory and regulatory requirements for issuance of a [insert license type] license, a [insert license type] license shall be issued to respondent and immediately revoked; the order of revocation is stayed and respondent is placed on probation for _____ years upon the following terms and conditions:

Option: (Intern Pharmacist Only)
Should the board subsequently issue a license to practice as a pharmacist to respondent during the period of probation, the intern license shall be cancelled and the pharmacist ~~said~~ license shall be immediately revoked. The revocation of such license shall be stayed, and the probation imposed by this decision and order will continue. Respondent shall remain subject to the same terms and conditions imposed by this disciplinary order. Notwithstanding this provision, the ~~Board~~ board reserves the right to deny respondent's application for the pharmacist licensure exam. If the board issues a pharmacist license to respondent, the following additional terms and conditions shall be included as part of the disciplinary order:

Surrender

Respondent surrenders license number _____as of the effective date of this decision. Respondent shall relinquish ~~his or her~~ [his/her]~~wall~~ license, including any indicia of licensure issued by the board, ~~and/or pocket renewal license~~ to the board within ten (10) days of the effective date of this decision.

The surrender of respondent's license and the acceptance of the surrendered license by the board shall constitute the imposition of discipline against respondent. This decision constitutes a record of discipline and shall become a part of respondent's license history with the board.

Respondent may only seek a new or reinstated license ~~form~~ from the board by way of a new application for licensure. Respondent ~~understands and agrees that if he or she [he/she] ever files an application for licensure or a petition for reinstatement in the State of California, the board shall treat it as a new application for licensure~~ shall not be eligible to petition for reinstatement of licensure.

Respondent may not apply for any license, permit, or registration from the board for three years from the effective date of this decision. Respondent stipulates that should ~~he or she~~ [he/she] apply for any license from the board on or after the effective date of this decision, all allegations set forth in the [accusation or petition to revoke probation] shall be deemed to be true, correct and admitted by respondent when the board determines whether to grant or deny the application. Respondent shall satisfy all requirements applicable to that license as of the date the application is submitted to the board, including, but not limited to, taking and passing licensing examination(s) as well as fulfilling any education or experience requirements ~~the California Pharmacist Licensure Examination~~ prior to the issuance of a new license. Respondent is required to report this surrender as disciplinary action.

Respondent further stipulates that ~~he or she~~ [he/she] shall reimburse the board for its costs of investigation and prosecution in the amount of $_____within _____days of the effective date of this decision.

Option: Respondent stipulates that should ~~he or she~~ [he/she] apply for any license from the board on or after the effective date of this decision the investigation and prosecution costs in the amount of $_____shall be paid to the board prior to issuance of the new license.

Public ~~Reprimand~~ Reproval

It is hereby ordered that a public ~~reprimand~~ reproval be issued against licensee, _____. Respondent is required to report this ~~reprimand~~ reproval as a disciplinary action.

License Reinstatement with Conditions Precedent (Pharmacists and Pharmacy Technicians Only)

It is hereby ordered that the petition for reinstatement is granted. Upon satisfaction of the following conditions precedent to licensure, Petitioner's License No._____ will be reinstated:

OPTION (Pharmacists Only)

a. Petitioner shall take and pass the [North American Pharmacist Licensure Examination (NAPLEX) and/or the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE)/~~Pharmacy Technician Certification Board exam~~] within one (1) year of the effective date of this order. Failure to take and pass ~~both~~ the examination(s) within one (1) year of the effective date of this order shall invalidate the order granting the petition for reinstatement, Petitioner shall be deemed to have failed the conditions
precedent for re-licensure, and Petitioner's License No._____ shall remain [revoked or surrendered]."

b. Petitioner must pay the fee(s) in place at the time for [this/these] examinations.

c. Petitioner must pay ~~a reinstatement fee~~ all applicable application and licensing fees as well as any cost recovery owed from the prior action ~~in the amount of $~~.

Option (Pharmacy Technicians Only)

a. Petitioner shall take and pass the Pharmacy Technician Certification Board exam] within one (1) year of the effective date of this order. Failure to take and pass the examinations within one (1) year of the effective date of this order shall invalidate the order granting the petition for reinstatement, Petitioner shall be deemed to have failed the conditions precedent for re-licensure, and Petitioner's License No. _____ shall remain [revoked or surrendered]."

b. Petitioner must pay the fee(s) in place at the time for [this/these] examinations.

c. Petitioner must pay ~~a reinstatement fee~~ all applicable application and licensing fees as well as any cost recovery owed from the prior action ~~in the amount of $~~.

~~**Option:** Petitioner pays the Board's cost recovery or fine amount owed to the Board in the amount of $_____.~~

Upon completion of the foregoing conditions precedent, Petitioner's license shall be reinstated and immediately revoked, with revocation stayed and Petitioner placed on probation for a period of _____year(s)] on the following terms and conditions.

License Reinstatement

It is hereby ordered that the petition for reinstatement filed by _____ is hereby ~~GRANTED~~ granted and Petitioner's license shall be ~~REINSTATED~~ reinstated. Petitioner's license shall be reinstated and immediately revoked, with revocation stayed and Petitioner placed on probation
for a period of _____year(s)] on the following terms and conditions:

~~**Adoption of Stipulation**~~

~~It is understood by respondent that, in deciding whether to adopt this stipulation, the board may receive oral and written communication from its staff and the Office of the Attorney General. Communications pursuant to this paragraph shall not disqualify the board or other persons from future participation in this or any other matter affecting respondent. In the event this settlement is not adopted by the board, the stipulation will not become effective and may not be used for any purpose, except this paragraph, which shall remain in effect.~~

STANDARD CONDITIONS - To be included in all probation decisions/orders.

1. Obey All Laws
2. Report to the Board
3. Interview with the Board
4. Cooperate with Board Staff
5. Continuing Education
6. Reporting of Employment and Notice to Employers
7. Notification of Change(s) in Name, Employment, Address(es), or Phone Number(s)

~~7.~~8. ~~No Supervision of Interns, Serving as Pharmacist-In-Charge (PIC), or Serving as a Consultant~~ Restrictions on Supervision and Oversight of Licensed Facilities

~~8~~ 9. Reimbursement of Board Costs

~~9~~ 10. Probation Monitoring Costs

~~10~~ 11. Status of License

~~11~~ 12. License Surrender While on Probation/Suspension

~~12. Notification of a Change in Name, Residence Address, Mailing Address or Employment~~

13. Certification Prior to Resuming Work

~~14. Notification of Departure~~

~~13.~~ ~~15.~~ 14. ~~Tolling of Probation~~ ~~License~~ Practice Requirement – ~~Tolling~~ Extension of Probation

~~14.~~ ~~16.~~ 15. Violation of Probation

~~15.~~ ~~17.~~ 16. Completion of Probation

OPTIONAL CONDITIONS

~~18.~~ 17. Suspension

~~16.~~ ~~19.~~ 18. Restricted Practice

~~17.~~ ~~20.~~ 19. Pharmacist Examination

~~18.~~ ~~21.~~ 20. ~~Mental Health Examination~~ Clinical Diagnostic Evaluation

~~19.~~ ~~22.~~ 21. Psychotherapy

~~20.~~ ~~23.~~ 22. Medical Evaluation

~~21.~~ ~~24.~~ 23. Pharmacists Recovery Program (PRP)

~~22.~~ ~~25.~~ 24. ~~Random Drug Screening~~ Drug and Alcohol Testing

25. Notification of Departure

~~23.~~ 26. Abstain from Drugs and Alcohol ~~Use~~

~~24.~~ 27. Prescription Coordination and Monitoring of Prescription Use

28. Facilitated Group Recovery and/or Support Meetings

29. Attend Substance Abuse Recovery Relapse Prevention and Support Groups

30. Work Site Monitor

~~25.~~ 31. Community Service Program

~~26.~~ 32. Restitution

~~27.~~ 33. Remedial Education

34. Ethics Course

~~28. Pharmacy Self-Assessment Mechanism (PSAM)~~

~~29. 34. Intern Pharmacist Experience~~

~~30.~~ 35. Supervised Practice

~~31. No Supervision of Ancillary Personnel~~

~~32.~~36. No Ownership or Management of Licensed Premises

~~33.~~37. Separate File of Controlled Substances Records

~~34.~~38. Report of Controlled Substances

~~35.~~39. No Access to Controlled Substances

~~36.~~40. Criminal Probation/Parole Reports

~~37. Consultant for Owner or Pharmacist-In-Charge~~

41. Tolling of Suspension

~~39.~~42. Surrender of DEA Permit
~~40.43. Ethics Course~~

STANDARD CONDITIONS: TO BE INCLUDED IN ALL PROBATIONS

1. Obey All Laws

Respondent shall obey all state and federal laws and regulations.

Respondent shall report any of the following occurrences to the board, in writing, within seventy-two (72) hours of such occurrence:

- an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws
- a plea of guilty, or nolo ~~contender~~ contendere, no contest, or similar, in any state or federal criminal proceeding to any criminal complaint, information or indictment
- a conviction of any crime
- ~~discipline, citation, or other~~ the filing of a disciplinary pleading, issuance of a citation, or initiation of another administrative action filed by any state or federal agency which involves respondent's _____license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling, distributing, billing, or charging for any drug, device or controlled substance.

Failure to timely report such occurrence shall be considered a violation of probation.

2. Report to the Board

Respondent shall report to the board quarterly, on a schedule and in a form or format~~,~~ as directed by the board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, respondent shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation. Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the board.

3. Interview with the Board

Upon receipt of reasonable prior notice, respondent shall appear in person for interviews with the board or its designee, at such intervals and locations as are determined by the board or its designee. Failure to appear for any scheduled interview without prior notification to board staff, or failure to appear for two (2) or more scheduled interviews with the board or its designee during the period of probation, shall be considered a violation of probation.

4. Cooperate with Board Staff

Respondent shall timely cooperate with the board's inspection program and with the board's monitoring and investigation of respondent's compliance with the terms and conditions of ~~his or her~~ [his/her] probation, including but not limited to: timely responses to requests for information by board staff; timely compliance with directives from board staff regarding requirements of any term or condition of probation; and timely completion of documentation pertaining to a term or condition of probation. Failure to timely cooperate shall be considered a violation of probation.

5. Continuing Education (Pharmacists Only)

Respondent shall provide evidence of efforts to maintain skill and knowledge as a pharmacist as directed by the board or its designee.

6. Reporting of Employment and Notice to Employers (Standard 3)

During the period of probation, respondent shall notify all present and prospective employers of the decision in case number _____and the terms, conditions and restrictions imposed on respondent by the decision, as follows:

Within thirty (30) days of the effective date of this decision, and within ~~fifteen (15)~~ ten (10) days of undertaking any new employment, respondent shall report to the board in writing the name, physical address, and mailing address of ~~all~~ each of [his/her] employer(s), and the name(s) and telephone number(s) of all of [his/her] direct supervisor(s), as well as any pharmacist(s)-in- charge, designated representative(s)-in-charge, responsible manager, or other compliance supervisor(s) and the work schedule, if known. Respondent shall also include the reason(s) for leaving the prior employment. Respondent shall sign and return to the board a written consent authorizing the board or its designee to communicate with all of respondent's employer(s) and supervisor(s), and authorizing those employer(s) or supervisor(s) to communicate with the board or its designee, concerning respondent's work status, performance, and monitoring. Failure to comply with the requirements or deadlines of this condition shall be considered a violation of probation.

Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment, respondent shall cause (a) ~~his or her~~ [his/her] direct supervisor, (b) [his/her] pharmacist-in-charge, designated representative-in-charge, responsible manager, or other compliance supervisor, ~~(including each new pharmacist-in-charge employed during respondent's tenure of employment)~~ and (c) the owner or owner representative of ~~his or her~~ [his/her]employer, to report to the board in writing acknowledging that the listed individual(s) has/have read the decision in case number _____, and terms and conditions imposed thereby. If one person serves in more than one role described in (a), (b), or (c), the acknowledgment shall so state. It shall be the respondent's responsibility to ensure that these acknowledgment(s) are timely submitted to the board. In the event of a change in the person(s) serving the role(s) described in (a), (b), or (c) during the term of probation, respondent shall cause the person(s) taking over the role(s) to report to the board in writing within fifteen (15) days of the change acknowledging that he or she has read the decision in case number _____, and the terms and conditions imposed thereby. ~~It shall be respondent's responsibility to ensure that his or her employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board.~~

If respondent works for or is employed by or through ~~a pharmacy~~ an employment service, respondent must notify the person(s) described in (a), (b), and (c) above at every entity licensed by the board~~,~~ of the decision in case number _____, and the terms and conditions imposed thereby in advance of respondent commencing work at such licensed entity ~~his or her direct supervisor, pharmacist-in-charge, and owner at every entity licensed by the board of the terms and conditions of the decision in case number~~ _____~~in advance of the respondent commencing work at each licensed entity~~. A record of this notification must be provided to the board upon request.

Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment by or through ~~a pharmacy~~ an employment service, respondent shall cause the person(s) described in (a), (b), and (c) above ~~his or her direct supervisor with the pharmacy~~ at the employment service to report to the board in writing acknowledging that he or she has read the decision in case number _____, and the terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that these acknowledgment(s) are timely submitted to the board ~~his or her employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board~~.

Failure to timely notify present or prospective employer(s) or failure to cause the identified person(s) with that/those employer(s) to submit timely written acknowledgments to the board shall be considered a violation of probation.

> "Employment" within the meaning of this provision ~~shall~~ includes any full-time, part-time, temporary, relief, or employment/management service position as a [insert license type], or any position for which a [insert license type] license ~~or pharmacy management service as a pharmacist or any position for which a pharmacist license~~ is a requirement or criterion for employment, whether the respondent is an employee, independent contractor or volunteer.

7. Notification of Change(s) in ~~Employment,~~ Name, Address(es), or Phone Number(s)[1]

~~Respondent shall notify the board in writing within ten (10) days of any change of employment. Said notification shall include the reasons for leaving, the address of the new employer, the name of the supervisor and owner, and the work schedule, if known.~~ Respondent shall further notify the board in writing within ten (10) days of any change in name, residence address, mailing address, e-mail address or phone number.

Failure to timely notify the board of any change in employer, name, address, or phone number shall be considered a violation of probation.

~~7~~8. ~~No Supervision of Interns, Serving as Pharmacist-in-Charge (PIC), Serving as Designated Representative-in-Charge, or Serving as a Consultant~~ Restrictions on Supervision and Oversight of Licensed Facilities[2]
(Not appropriate for Pharmacy Technicians)

During the period of probation, respondent shall not supervise any intern pharmacist, be the pharmacist-in-charge, ~~or~~ designated representative-in-charge, responsible manager or other compliance supervisor of any entity licensed by the board, nor serve as a consultant ~~unless otherwise specified in this order~~. Assumption of any such unauthorized supervision responsibilities shall be considered a violation of probation.

Option 1(To be included along with standard language when appropriate): During the period of probation, respondent shall not supervise any ancillary personnel, including, but not limited to, pharmacy technicians, designated representatives, designated representative-3PL in any entity licensed by the board. Assumption of any such

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[1] ~~This term was renamed and renumbered from previous term 12.~~
[2] ~~This term was renamed and consolidated with two additional terms: No Supervision of Ancillary Personnel and Consultant for Owner of Pharmacist-in-Charge.~~

unauthorized ancillary personnel supervision responsibilities shall be considered a violation of probation.

Option 2 (To be used in place of standard language when appropriate): During the period of probation, respondent shall not supervise any intern pharmacist or serve as a consultant to any entity licensed by the board. Respondent may be a pharmacist-in-charge, designated representative-in-charge, responsible manager or other compliance supervisor of any single entity licensed by the board, but only if respondent or that entity retains, at ~~his/her/its~~ [his/her] expense, an independent consultant who shall be responsible for reviewing the operations of the entity on a [monthly/quarterly] basis for compliance by respondent and the entity with state and federal laws and regulations governing the practice of the entity, and compliance by respondent with the obligations of ~~his or her~~ [his/her] supervisory position. Respondent may serve in such a position at only one entity licensed by the board, only upon approval by the board or its designee ~~and at only one entity licensed by the board~~. ~~This~~ Any such approval shall be ~~is~~ site specific. The consultant shall be a pharmacist licensed by and not on probation with the board, who has been approved by the board or its designee to serve in this position. Respondent shall submit the name of the proposed consultant to the board or its designee for approval within thirty (30) days of the effective date of the decision or prior to assumption of duties allowed in this term. Assumption of any unauthorized supervision responsibilities shall be considered a violation of probation. In addition, failure to timely seek approval for, timely retain, or ensure timely reporting by the consultant shall be considered a violation of probation.

~~8~~9. Reimbursement of Board Costs

As a condition precedent to successful completion of probation, respondent shall pay to the board its costs of investigation and prosecution in the amount of $_____. Respondent shall make said payments as follows: _____.

There shall be no deviation from this schedule absent prior written approval by the board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

~~**Option:**~~ Respondent shall be permitted to pay these costs in a payment plan approved by the board or its designee, so long as full payment is completed no later than one (1) year prior to the end date of probation.

~~The filing of bankruptcy by respondent shall not relieve respondent of his or her responsibility to reimburse the board its costs of investigation and prosecution.~~

~~9~~10. Probation Monitoring Costs

Respondent shall pay any costs associated with probation monitoring as determined by the board each and every year of probation. Such costs shall be payable to the board on a schedule as directed by the board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

~~10~~11. Status of License

Respondent shall, at all times while on probation, maintain an active, current [insert license type] license with the board, including any period during which suspension or probation is tolled. Failure to maintain an active, current [insert license type] license shall be considered a violation of probation.

If respondent's [insert license type] license expires or is cancelled by operation of law or

otherwise at any time during the period of probation, including any extensions thereof due to tolling or otherwise, upon renewal or reapplication respondent's ~~[insert license type]~~ license shall be subject to all terms and conditions of this probation not previously satisfied.

~~11~~12. License Surrender While on Probation/Suspension

Following the effective date of this decision, should respondent cease practice due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, respondent ~~may tender [his/her] [insert license type] license to the board for~~ ~~shall~~ may relinquish [his/her] license, including any indicia of licensure issued by the board, along with a request to surrender the license ~~for surrender~~. The board or its designee shall have the discretion whether to ~~grant~~ accept the ~~request for~~ surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the ~~[insert license type]~~ license, respondent will no longer be subject to the terms and conditions of probation. This surrender constitutes a record of discipline and shall become a part of the respondent's license history with the board.

Upon acceptance of the surrender, respondent shall relinquish [his/her] pocket and/or wall license, including any indicia of licensure not previously provided to the board within ten (10) days of notification by the board that the surrender is accepted if not already provided. Respondent may not reapply for any license from the board for three (3) years from the effective date of the surrender. Respondent shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board, including any outstanding costs.

~~**12. Notification of a Change in Name, Residence Address, Mailing Address or Employment**~~

~~Respondent shall notify the board in writing within ten (10) days of any change of employment. Said notification shall include the reasons for leaving, the address of the new employer, the name of the supervisor and owner, and the work schedule if known. Respondent shall further notify the board in writing within ten (10) days of a change in name, residence address, mailing address, or phone number(s).~~

~~Failure to timely notify the board of any change in employer(s), name(s), address(es), or phone number(s) shall be considered a violation of probation.~~

13. Certification Prior to Resuming Work (Pharmacy Technicians Only)

Respondent shall be suspended, and shall not work as a pharmacy technician, until [he/she] has been certified as defined by Business and Professions Code section 4202, subdivision (a)(4), has submitted proof of certification to the board, and has been notified by the board or its designee that [he/she] may begin work. Failure to achieve certification within six (6) months of the effective date shall be considered a violation of probation. ~~Respondent shall not resume working as a pharmacy technician until notified by the board.~~

During ~~any such~~ suspension, respondent shall not enter any pharmacy area or any portion of any other board licensed premises of a wholesaler, third-party logistics provider, veterinary food-animal drug retailer or any other distributor of drugs~~)~~ which is licensed by the board, or any manufacturer, or any area where dangerous drugs and/or dangerous devices or controlled substances are maintained.

Respondent shall not do any act involving drug selection, selection of stock, manufacturing, compounding or dispensing; nor shall respondent manage, administer, or assist any licensee of the board. Respondent shall not have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs and/or dangerous devices or controlled

substances.

During ~~any such~~ this suspension, respondent shall not engage in any activity that requires licensure as a pharmacy technician. Respondent shall not direct or control any aspect of the practice of pharmacy or of the manufacture, distribution, wholesaling, or retailing of dangerous drugs and/or dangerous devices, or controlled substances.

Failure to comply with ~~this~~ any such suspension shall be considered a violation of probation.

Option: Respondent shall maintain an active, current certification as defined by Business and Professions Code section 4202, subdivision (a)(4), for the entire period of probation, and shall submit proof of re-certification or renewal of certification to the board within ten (10) days of receipt. Failure to maintain active, current certification or to timely submit proof of same shall be considered a violation of probation.

~~**14. Notification of Departure**~~

~~Prior to leaving the probationary geographic area designated by the board or its designee for a period greater than twenty-four (24) hours, respondent shall notify the board verbally and in writing of the dates of departure and return. Failure to comply with this provision shall be considered a violation of probation.~~

~~13.~~~~15.~~14. ~~Tolling of Probation~~ ~~License~~ Practice Requirement – ~~Tolling~~ Extension of Probation

Except during periods of suspension, respondent shall, at all times while on probation, be employed as a ~~pharmacist~~ [insert license type] in California for a minimum of _____hours per calendar month. Any month during which this minimum is not met shall ~~toll the period of probation, i.e.,~~ extend the period of probation ~~shall be extended~~ by one month ~~for each month during which this minimum is not met~~. During any such period of ~~tolling of probation~~ insufficient employment, respondent must nonetheless comply with all terms and conditions of probation, unless respondent ~~is notified otherwise~~ receives a waiver in writing ~~by~~ from the board or its designee.

~~Should respondent, regardless of residency, for any reason (including vacation) cease practicing as a pharmacist for a minimum of _____ hours per calendar month in California~~, If respondent does not practice as a [insert license type] in California for ~~a~~ the minimum number of _____ hours in any calendar month, for any reason (including vacation), respondent shall ~~must~~ notify the board in writing within ten (10) days of the ~~cessation of practice, and must further notify the board in writing within ten (10) days of the resumption of practice.~~ conclusion of that calendar month. This notification shall include at least: the date(s), location(s), and hours of last practice; the reason(s) for the interruption or ~~decline~~ reduction in practice; and the anticipated date(s) on which respondent will resume practice at the required level. Respondent shall further notify the board in writing within ten (10) days following the next calendar month during which respondent practices as a [insert license type] in California for ~~a~~ the minimum of hours. Any failure to timely provide such notification(s) shall be considered a violation of probation.

It is a violation of probation for respondent's probation to ~~remain tolled~~ be extended pursuant to the provisions of this condition for a total period, counting consecutive and non-consecutive months, exceeding thirty-six (36) months. The board or its designee may post a notice of the extended probation period on its website.

~~"Cessation of practice" means any calendar month during which respondent is not practicing as a pharmacist for at least _____hours, as defined by Business and Professions Code section 4000 et seq . "Resumption of practice" means any calendar month during which respondent is practicing as a pharmacist for at least _____ hours as a pharmacist as defined by Business and Professions Code section 4000 et seq.~~

~~**Option 1:** As a condition precedent to successful completion of probation, during the period of probation respondent shall practice as a [insert license type] in a licensed _____ in California that dispenses dangerous drugs and/or dangerous devices for a minimum of one (1) year. After the first year or probation, the board or its designee may consider a modification of this requirement. Failure to comply with this requirement (or as modified) shall be considered a violation of probation.~~

~~Respondent is required to practice as a pharmacist in a licensed pharmacy setting that dispenses medication for a minimum of one year prior to the completion of probation. After the first year of probation, the board or its designee may consider a modification of this requirement. If respondent fails to comply with this requirement or a subsequent modification thereto, such failure shall be considered a violation of probation.~~

Option ~~2~~: ~~(First year p~~Pharmacist interns only) During respondent's ~~first academic year of~~ enrollment in a school or college of pharmacy, no minimum practice hours shall be required. Instead, respondent shall report to the board quarterly in writing, in a format and schedule as directed by the board or its designee, on [his/her] compliance with academic and vocational requirements, and on [his/her] academic progress. ~~This exemption shall apply only once, and only during respondent's first academic year.~~ Respondent must comply with all other terms and conditions of probation, unless notified in writing by the board or its designee.

~~14.~~16.15. Violation of Probation

If ~~a~~ respondent has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondent, and the board shall provide notice to respondent that probation shall automatically be extended, until all terms and conditions have been satisfied or the board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed. The board or its designee may post a notice of the extended probation period on its website

If respondent violates probation in any respect, the board, after giving respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. ~~Notice and opportunity to be heard are not required for those provisions stating that a violation thereof may lead to automatic termination of the stay and/or revocation of the license.~~ If a petition to revoke probation or an accusation is filed against respondent during probation, or the preparation of an accusation or petition to revoke probation is requested from the Office of the Attorney General, the board shall have continuing jurisdiction and the period of probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided.

~~15.~~~~17.~~16. Completion of Probation

Upon written notice by the board or its designee indicating successful completion of probation, respondent's license will be fully restored.

OPTIONAL CONDITIONS OF PROBATION

~~18.~~17. Suspension

As part of probation, respondent is suspended from practice as a [insert license type] for _____ [day(s)/month(s)/year(s)] beginning the effective date of this decision.

During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, third-party logistics provider, veterinary food-animal drug retailer, or any other distributor of drugs ~~which~~ that is licensed by the board, or any manufacturer, or any area where dangerous drugs and/or dangerous devices or controlled substances are maintained.

Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs and/or dangerous devices or controlled substances.

During this suspension, respondent shall not engage in any activity that requires the professional judgment of and/or licensure as a [insert license type]. Respondent shall not direct or control any aspect of the practice of pharmacy or of the manufacturing, distributing, wholesaling, or retailing of dangerous drugs and/or dangerous devices or controlled substances.

Failure to comply with ~~any such~~ this suspension shall be considered a violation of probation.

Option ~~1~~: During the period of suspension, respondent shall not leave California for any period exceeding ten (10) days, regardless of purpose (including vacation). Any such absence in excess of ten (10) days during the period of suspension shall be considered a violation of probation, and shall toll the suspension, i.e., the suspension shall be extended by one day for each day over ten (10) days respondent is absent from California. During any such period of tolling of suspension, respondent must nonetheless comply with all terms and conditions of probation, unless respondent is notified otherwise in writing by the board or its designee.

Respondent shall notify the board or its designee in writing within ten (10) days of any departure from California, for any period, and shall further notify the board or its designee in writing within ten (10) days of return. Failure to timely provide such notification(s) shall be considered a violation of probation. Upon such departure and return, respondent shall not resume practice until notified by the board or its designee that the period of suspension has been satisfactorily completed.

~~16.~~~~19.~~18. Restricted Practice

Respondent's practice as a [insert license type] ~~of pharmacy~~ shall be restricted to [specify setting or type of practice] for the first _____year(s) of probation. Respondent shall submit proof satisfactory to the board or its designee of compliance with this term of probation.

Option: Respondent shall not prepare, oversee, or participate in the preparation of ~~injectable~~ sterile ~~products~~ compounds during the first _____year(s) of probation. Upon request, respondent ~~Respondent~~ shall submit to the board or its designee on writing, satisfactory proof ~~satisfactory~~ of compliance with this restriction, including but not limited to a written acknowledgment of this restriction signed by (a) respondent's direct supervisor, (b) the pharmacist-in-charge, and (c) the owner or owner representative of his or her employer, which explains whether the workplace in question compounds drug ~~products~~ preparations and how

this restriction will be enforced ~~term of probation~~. Failure to abide by this restriction or to timely submit proof to the board or its designee ~~of compliance therewith~~ shall be considered a violation of probation.

~~17.~~~~20.~~19. Pharmacist Examination (Pharmacists Only)

Respondent shall take and pass the [California Pharmacist Jurisprudence Examination (CPJE) [and/or] the North American Pharmacist Licensure Examination (NAPLEX)] within six (6) months of the effective date of this decision. If respondent fails to take and pass the examination(s) within six (6) months ~~after~~ of the effective of this decision, respondent shall be automatically suspended from practice. Respondent shall not resume the practice of pharmacy until ~~he or she~~ [he/she] takes and passes the [CPJE and/or NAPLEX] and is notified, in writing, that ~~he or she~~ [he/she] has passed the examination(s) and may resume practice. Respondent shall bear all costs of the examination(s) required by the board.

During any ~~such~~ suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, third-party logistics provider, veterinary food-animal drug retailer, or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area where dangerous drugs and/or dangerous devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs and/or dangerous devices and controlled substances. ~~Respondent shall not resume practice until notified by the board.~~

During any ~~such~~ suspension, respondent shall not engage in any activity that requires the professional judgment of and/or licensure as a pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy or of the manufacturing, distributing, wholesaling, or retailing of dangerous drugs and/or dangerous devices and controlled susbtances. ~~Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.~~

~~Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.~~

Failure to comply with ~~this~~ any ~~such~~ suspension shall be considered a violation of probation.

Failure to take and pass the examination(s) within ~~one (1) year~~ ~~six (6)~~ twelve (12) months of the effective date of this decision shall be considered a violation of probation.

If respondent fails to take and pass the [CPJE and/or NAPLEX] after four attempts, respondent shall successfully complete, at a minimum, sixteen (16) additional semester units of pharmacy education as approved by the board. Respondent shall complete the coursework, and submit proof of completion satisfactory to the board or its designee, within three (3) months of the fourth failure of the examination. Failure to complete coursework or provide proof of such completion as required shall be considered a violation of probation.

~~18.~~20. ~~Mental Health Examination~~ Clinical Diagnostic Evaluation (Appropriate for those cases where evidence demonstrates that ~~mental illness~~ psychiatric disorders, ~~[~~mental illness, emotional disturbance, gambling addiction), diversion, self-administration, or abuse of alcohol or drugs, or disability was a contributing cause of the violation(s).) **(Standards 1 & 6)**

Within thirty (30) days of the effective date of this decision, and on a periodic basis thereafter if ~~as may be~~ required by the board or its designee, respondent shall undergo, at ~~his or her~~ [his/her] own expense, ~~psychiatric~~ clinical diagnostic evaluation(s) by a ~~board-appointed or board-approved~~ licensed ~~mental health~~ practitioner selected or approved prior to the evaluation by the board or its designee. The approved evaluator shall be provided with a copy of the board's [accusation, ~~or~~ petition to revoke probation, or other pleading] and decision. Respondent shall sign a release authorizing the evaluator to furnish the board with a current diagnosis and a written report regarding the respondent's judgment and ability to function independently as a ~~pharmacist~~ [insert license type] with safety to the public. ~~Respondent shall comply with all the recommendations of the evaluator if directed by the board or its designee.~~ If the evaluator recommends restrictions or conditions on respondent's practice, including but not limited to other terms and conditions listed in these guidelines (e.g., required psychotherapy, inpatient treatment, prescription coordination and monitoring, restricted practice), the board or
its designee may by written notice to respondent adopt ~~these~~ any such restrictions or conditions as additional probation terms and conditions, violation of which shall be considered a violation of probation. Failure to comply with any requirement or deadline stated by this paragraph shall be considered a violation of probation.
~~If the evaluator recommends, and the board or its designee directs, respondent shall undergo psychotherapy. Within thirty (30) days of notification by the board that a recommendation for psychotherapy has been accepted, respondent shall submit to the board or its designee, for prior approval, the name and qualification of a licensed mental health practitioner of respondent's choice. Within thirty (30) days of approval thereof by the board, respondent shall submit documentation to the board demonstrating the commencement of psychotherapy with the approved licensed mental health practitioner. Should respondent, for any reason, cease treatment with the approved licensed mental health practitioner, respondent shall notify the board immediately and, within thirty (30) days of ceasing treatment therewith, submit the name of a replacement licensed mental health practitioner of respondent's choice to the board for its prior approval. Within thirty (30) days of approval thereof, respondent shall submit documentation to the board demonstrating the commencement of psychotherapy with the approved replacement. Failure to comply with any requirement or deadline stated by this paragraph shall be considered a violation of probation.~~

~~Upon approval of the initial or any subsequent licensed mental health practitioner, respondent shall undergo and continue treatment with that therapist, at respondent's own expense, until the therapist recommends in writing to the board, and the board or its designee agrees by way of a written notification to respondent, that no further psychotherapy is necessary. Upon receipt of such recommendation from the treating therapist, and before determining whether to accept or reject said recommendation, the board or its designee may require respondent to undergo, at respondent's expense, a mental health evaluation by a separate board-appointed or board-approved evaluator. If the approved evaluator recommends that respondent continue psychotherapy, the board or its designee may require respondent to continue psychotherapy.~~

~~Psychotherapy shall be at least once a week unless otherwise approved by the board. Respondent shall provide the therapist with a copy of the board's [accusation or petition to revoke probation] and decision no later than the first therapy session. Respondent shall take all necessary steps to ensure that the treating therapist submits written quarterly reports to the board concerning respondent's fitness to practice, progress in treatment, and other such information as may be required by the board or its designee.~~

If at any time the approved evaluator or therapist determines that respondent is unable to practice safely or independently ~~as a pharmacist~~, the licensed mental health practitioner shall notify the board immediately by telephone and follow up by written letter within three (3) working days. Upon notification from the board or its designee of this determination, respondent shall be automatically suspended and shall not resume practice until notified by the board or its

designee that practice may ~~be~~ resume~~d~~.

Failure to comply with any requirement or deadline stated by this term shall be considered a violation of probation.

Option 1: (Appropriate for those cases where evidence demonstrates abuse of alcohol or drugs. Option language to be used in addition to standard language): **(Standards 1, 2 & 6)** Commencing on the effective date of this decision, respondent is suspended from practice and shall not practice as a [insert license type] until:

- Respondent has undergone and completed clinical diagnostic evaluation(s);
- The report(s) of the evaluation(s) has/have been received by the board or its designee;
- One or more report(s) has concluded that respondent is safe to return to practice as a [insert license type];
- The board or its designee is satisfied that respondent is safe to return to practice as a [insert license type];
- Respondent receives written notice from the board or its designee that practice may resume.

For all such evaluations, a final written report shall be provided to the board no later than ten (10) days from the date the evaluator is assigned the matter unless the evaluator requests additional information to complete the evaluation, not to exceed thirty (30) days.

During any ~~such~~ suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, third-party logistics provider, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area where dangerous drugs and/or dangerous devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs and/or dangerous devices or controlled substances.

During any ~~such~~ suspension, respondent shall not engage in any activity that requires the professional judgment of and/or licensure as a [insert license type]. Respondent shall not direct or control any aspect of the practice of pharmacy, or of the manufacturing, distributing, wholesaling, or retailing of dangerous drugs and/or dangerous devices or controlled substances.

Failure to comply with any requirement, including any suspension or deadline stated by this term shall be considered a violation of probation.

Option 2 Option language to be used in addition to standard language when deemed appropriate: Commencing on the effective date of this decision, respondent is suspended from practice and shall not ~~engage in the practice of pharmacy~~ practice as a [insert license type] until ~~notified in writing by the board that respondent has been deemed psychologically fit to practice pharmacy safely, and the board or its designee approves said recommendation~~ the evaluator recommends that respondent return to practice, this recommendation is accepted by the board or its designee, and respondent receives written notice from the board or its designee that practice may resume.

The final written report of the evaluation shall be provided to the board no later than ten (10) days from the date the evaluator is assigned the matter unless the evaluator requests additional information to complete the evaluation, not to exceed thirty (30) days.

During any ~~such~~ suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, third-party logistics provider, veterinary food-animal drug retailer, or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area where dangerous drugs and/or dangerous devices or controlled substances are maintained.

Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs and/or dangerous devices ~~and~~ or controlled substances. ~~Respondent shall not resume practice until notified by the board.~~

During any ~~such~~ suspension, respondent shall not engage in any activity that requires the professional judgment of and/or licensure as a ~~pharmacist~~ [insert license type]. Respondent shall not direct or control any aspect of the practice of pharmacy, or of the manufacturing, distributing, wholesaling, or retailing of dangerous drugs and/or dangerous devices or controlled substances. ~~Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.~~

~~Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.~~

~~Failure to comply with this any such suspension shall be considered a violation of probation~~. Failure to comply with any requirement or deadline stated by this term shall be considered a violation of probation.

~~(Option language to be used in addition to standard language)~~

Option 3: If recommended by the ~~evaluating licensed mental health practitioner and approved by the board, respondent shall be suspended from practicing pharmacy until respondent's treating therapist recommends, in writing, stating the basis therefor, that respondent can safely practice pharmacy, and the board or its designee approves said recommendation.~~ evaluator, the board or its designee may suspend respondent from practice as a [insert license type] by providing written notice of suspension to the respondent. Upon suspension, respondent shall not resume practice as a [insert license type] until: 1) another evaluation is done at respondent's expense by a licensed practitioner selected or approved by the board or its designee; 2) the evaluator recommends that respondent return to practice; 3) the board or its designee accepts the recommendation; 4) and the board notifies the respondent in writing that practice may resume.

The report(s) from any such additional evaluation(s) shall be provided to the board or its designee in writing by the evaluator no later than ten (10) days from the date the evaluator is assigned the matter unless the evaluator requests additional information to complete the evaluation, not to exceed thirty (30) days.

During any ~~such~~ suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, third-party logistics provider, veterinary food-animal drug retailer, or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area where dangerous drugs and/or dangerous devices or controlled substances are maintained.

Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs and/or dangerous devices or ~~and~~ controlled substances. ~~Respondent shall not resume practice until notified by the board.~~

During any ~~such~~ suspension, respondent shall not engage in any activity that requires the professional judgment of and/or licensure as a ~~pharmacist~~ [insert license type]. Respondent shall not direct or control any aspect of the practice of pharmacy, or of the manufacturing, distributing, wholesaling, or retailing of dangerous drugs and/or dangerous devices or controlled substances. ~~Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.~~

~~Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.~~

~~Failure to comply with this any such suspension shall be considered a violation of probation~~. Failure to comply with any requirement or deadline stated by this term shall be considered a violation of probation.

~~19.~~21. Psychotherapy (Appropriate for those cases where the evidence demonstrates ~~mental illness~~ psychiatric disorders (mental illness, emotional disturbance, gambling addiction) or alcohol or drug abuse was involved in the violation(s).)

Within thirty (30) days of the effective date of this decision, respondent shall submit to the board or its designee, for prior approval, the name and qualifications of a licensed mental health practitioner of respondent's choice. Within thirty (30) days of approval thereof, respondent shall submit documentation to the board demonstrating the commencement of psychotherapy with the approved licensed mental health practitioner. Should respondent, for any reason, cease treatment with the approved licensed mental health practitioner, respondent shall notify the board immediately and, within thirty (30) days of ceasing treatment, submit the name of a replacement psychotherapist or licensed mental health practitioner of respondent's choice to the board for its prior approval. Within thirty (30) days of approval thereof, respondent shall submit documentation to the board demonstrating the commencement of psychotherapy with the approved replacement. Failure to comply with any requirement or deadline stated by this paragraph shall be considered a violation of probation.

Upon approval of the initial or any subsequent licensed mental health practitioner, respondent shall undergo and continue treatment with that therapist, at respondent's own expense, until the therapist recommends in writing to the board, and the board or its designee agrees by way of a written notification to respondent, that no further psychotherapy is necessary. Upon receipt of such recommendation from the treating therapist, and before determining whether to accept or reject said recommendation, the board or its designee may require respondent to undergo, at respondent’s own expense, a mental health evaluation by a board-appointed or board-approved psychiatrist or psychologist. If the approved evaluator recommends that respondent continue psychotherapy, the board or its designee may require respondent to continue psychotherapy.

Psychotherapy shall be at least once a week unless otherwise approved by the board. Respondent shall provide the therapist with a copy of the board’s accusation and decision no later than the first therapy session. Respondent shall take all necessary steps to ensure that the treating therapist submits written quarterly reports to the board concerning respondent’s fitness to practice, progress in treatment, and such other information ~~as may be~~ required by the

board or its designee.

If at any time the treating therapist determines that respondent cannot practice safely or independently, the therapist shall notify the board immediately by telephone and follow up by written letter within three (3) working days. Upon notification from the board or its designee of this determination, respondent shall be automatically suspended and shall not resume practice until notified by the board that practice may be resumed.

During any ~~such~~ suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, third-party logistics provider, veterinary food-animal drug retailer, or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area where dangerous drugs and/or dangerous devices or controlled substances are maintained.

Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs and/or dangerous devices or ~~and~~ controlled substances. Respondent shall not resume practice until notified by the board.

During any ~~such~~ suspension, respondent shall not engage in any activity that requires the professional judgment of and/or licensure as a [insert license type]. Respondent shall not direct or control any aspect of the practice of pharmacy, or of the manufacturing, distributing, wholesaling, or retailing of dangerous drugs and/or dangerous devices or controlled substances

~~During suspension, respondent shall not engage in any activity that requires the professional judgment of a pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy. Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.~~

~~Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.~~

~~Failure to comply with any such this suspension shall be considered a violation of probation.~~ Failure to comply with any requirement or deadline stated by this term shall be considered a violation of probation.

~~20~~.22. Medical Evaluation (Appropriate for those cases where the evidence demonstrates that the respondent has had a physical problem/disability which was a contributing cause of the violations and which may affect the respondent's ability to practice.)

Within thirty (30) days of the effective date of this decision, and on a periodic basis thereafter as may be required by the board or its designee, respondent shall undergo a medical evaluation, at respondent's own expense, by a board-appointed or board-approved physician who shall furnish a medical report to the board. The approved physician shall be provided with a copy of the board's [accusation, ~~or~~ petition to revoke probation, or other pleading] and decision. A record of this notification must be provided to the board upon request. Respondent shall sign a release authorizing the physician to furnish the board with a current diagnosis and a written report regarding the respondent's ability to function independently as ~~a pharmacist~~ [insert license type] with safety to the public. ~~Respondent shall comply with all the recommendations of the physician if directed by the board or its designee.~~ If the physician recommends

restrictions or conditions on respondent's practice, including but not limited to other terms and conditions listed in these guidelines (e.g., required psychotherapy, inpatient treatment, prescription coordination and monitoring, restricted practice), the board or its designee may by written notice to respondent adopt any such restrictions or conditions as additional probation terms and conditions, violation of which shall be considered a violation of probation.

If the physician recommends, and the board or its designee directs, that respondent undergo medical treatment, respondent shall, within thirty (30) days of written notice from the board, submit to the board or its designee, for prior approval, the name and qualifications of a licensed physician of respondent's choice. Within thirty (30) days of approval thereof, respondent shall submit documentation to the board demonstrating the commencement of treatment with the approved physician. Should respondent, for any reason, cease treatment with the approved physician, respondent shall notify the board immediately and, within thirty (30) days of ceasing treatment, submit the name of a replacement physician of respondent's choice to the board or its designee for prior approval. Within thirty (30) days of approval thereof, respondent shall submit documentation to the board demonstrating the commencement of treatment with the approved replacement. Failure to comply with any deadline stated by this paragraph shall be considered a violation of probation.

Upon approval of the initial or any subsequent physician, respondent shall undergo and continue treatment with that physician, at respondent's own expense, until the treating physician recommends in writing to the board, and the board or its designee agrees by way of a written notification to respondent, that no further treatment is necessary. Upon receipt of such recommendation from the treating physician, and before determining whether to accept or reject said recommendation, the board or its designee may require respondent to undergo, at respondent's own expense, a medical evaluation by a separate board-appointed or board-approved physician. If the approved evaluating physician recommends that respondent continue treatment, the board or its designee may require respondent to continue treatment.

Respondent shall take all necessary steps to ensure that any treating physician submits written quarterly reports to the board concerning respondent's fitness to practice, progress in treatment, and other such information as may be required by the board or its designee.

If at any time an approved evaluating physician or respondent's approved treating physician determines that respondent is unable to practice safely or independently as a ~~pharmacist~~ [insert license type], the evaluating or treating physician shall notify the board immediately by telephone and follow up by written letter within three (3) working days. Upon notification from the board or its designee of this determination, respondent shall be automatically suspended and shall not resume practice until notified by the board that practice may be resumed.

During any ~~such~~ suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, third-party logistics providers, veterinary food-animal drug retailer, or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area where dangerous drugs and/or dangerous devices or controlled substances are maintained.

Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs and/or dangerous devices or ~~and~~ controlled substances. ~~Respondent shall not resume practice until notified by the board.~~

During any ~~such~~ suspension, respondent shall not engage in any activity that requires the

professional judgment of and/or licensure as a ~~pharmacist~~ [insert license type]. Respondent shall not direct or control any aspect of the practice of pharmacy, or of the manufacturing, distributing, wholesaling, or retailing of dangerous drugs and/or dangerous devices or controlled substances. ~~Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.~~

~~Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.~~

~~Failure to comply with this any such suspension shall be considered a violation of probation.~~ Failure to comply with any requirement or deadline stated by this term shall be considered a violation of probation.

(Option language to be used in addition to standard language when suspension is warranted until the evaluation is completed.)
Option 1: Commencing on the effective date of this decision, respondent shall not engage in the practice ~~of pharmacy~~ as a [insert license type] until notified in writing by the board that respondent has been deemed medically fit to practice safely and independently, and the board or its designee approves said recommendation.

During ~~any such~~ this suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, third-party logistics provider, veterinary food-animal drug retailer, or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area where dangerous drugs and/or dangerous devices or controlled substances are maintained.

Respondent shall not practice ~~pharmacy~~ as a [insert license type] nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs and/or dangerous devices or controlled substances. Respondent shall not resume practice until notified by the board.

During ~~any such~~ this suspension, respondent shall not engage in any activity that requires the professional judgment of and/or licensure as a ~~pharmacist~~ [insert license type]. Respondent shall not direct or control any aspect of the practice of pharmacy, or of the manufacturing, distributing, wholesaling, or retailing of dangerous drugs and/or dangerous devices or controlled substances. ~~Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.~~

~~Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.~~

~~Failure to comply with this any such suspension shall be considered a violation of probation.~~ Failure to comply with any requirement or deadline stated by this term shall be considered a violation of probation.

~~*(Option language to be used in addition to standard language)*~~
~~**Option 2:** If recommended by the evaluating physician and approved by the board, respondent shall be suspended from practicing pharmacy as a [insert license type] until the treating physician recommends, in writing, stating the basis therefor, that respondent can safely and independently resume the practice of a pharmacist, and the board or its designee approves said~~

~~recommendation. Respondent shall not resume practice until notified by the board that practice may be resumed.~~

~~During any such suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, third-party logistics provider, veterinary food-animal drug retailer, or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area where dangerous drugs and/or dangerous devices or controlled substances are maintained. Respondent shall not practice pharmacy as a [insert license type] nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs and or devices or controlled substances. Respondent shall not resume practice until notified by the board.~~

~~During any such suspension, respondent shall not engage in any activity that requires the professional judgment of and/or licensure as a pharmacist [insert license type]. Respondent shall not direct or control any aspect of the practice of pharmacy, or of the manufacturing, distributing, wholesaling, or retailing of dangerous drugs and/or dangerous devices or controlled substances. Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.~~

~~Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.~~

~~Failure to comply with this any such suspension shall be considered a violation of probation~~.

~~21.~~23. Pharmacists Recovery Program (PRP) (Appropriate for those cases where evidence demonstrates substance abuse ~~chemical dependency (alcohol, drugs)~~, or psychiatric disorders (mental illness, emotional disturbance, gambling addiction) (Pharmacists and Pharmacist Interns Only)

By no later than ten (10) days after ~~Within thirty (30) days of~~ the effective date of this decision, respondent shall have completed all of the following: contacted the Pharmacists Recovery Program (PRP) for evaluation; enrolled in the PRP; completed, signed, and returned the treatment contract ~~plus~~ as well as any addendums required or suggested by the PRP; successfully completed registration for any drug or alcohol testing mandated by the treatment contract and/or by enrollment in the PRP; and begun compliance with the drug or alcohol testing protocol(s). ~~contact the Pharmacists Recovery Program (PRP) for evaluation, and shall immediately thereafter enroll, successfully participate in, and complete the treatment contract and any subsequent addendums as recommended and provided by the PRP and as approved by the board or its designee~~. Respondent shall successfully participate in the PRP and complete the treatment contract and any addendums required or suggested by the PRP ~~and approved by the board or its designee~~. The costs for PRP participation shall be borne by the respondent.

If respondent is currently enrolled in the PRP, said participation is now mandatory and as of the effective date of this decision is no longer considered a self-referral under Business and Professions Code section 4362~~(c)~~ (a)(2). Respondent shall successfully participate in and complete his or her current contract and any subsequent addendums with the PRP.

Respondent shall pay administrative fees as invoiced by the PRP or its designee. Fees not timely paid to the PRP shall constitute a violation of probation. The board will collect unpaid administrative fees as part of the annual probation monitoring costs if not submitted to the PRP.

~~Failure to timely contact or enroll in the PRP, complete the treatment contract and any addendums, complete testing registration, comply with testing, and/or successfully participate in and complete the treatment contract and/or any addendums, shall result in the automatic suspension of practice by respondent and shall be considered a violation of probation. Respondent shall not resume practice until notified in writing by the board or its designee.~~

Any of the following shall result in the automatic suspension of practice by respondent and shall be considered a violation of probation:

- Failure to contact, complete enrollment, and execute and return the treatment contract with the PRP, including any addendum(s), within ten (10) days of the effective date of the decision as directed by the PRP;
- Failure to complete registration for any drug or alcohol testing mandated by the treatment contract and/or by the PRP, and begin compliance with the testing protocol(s), within ten (10) days of the effective date of the decision as directed by the PRP;
- Failure to comply with testing protocols regarding daily check-in and/or failure to complete a mandated test as directed by the PRP;
- Any report from the PRP of material non-compliance with the terms and conditions of the treatment contract and/or any addendum(s); or
- Termination by the PRP for non-compliance, failure to derive benefit, or as a public risk.

Respondent may not result the practice of pharmacy until notified by the board in writing.

Probation shall be automatically extended until respondent successfully completes the PRP. ~~Any person terminated from the PRP program shall be automatically suspended by the board. Respondent may not resume the practice of pharmacy until notified by the board in writing.~~ The board will provide notice of any such suspension or extension of probation.

~~Any confirmed positive test for alcohol or for any drug not lawfully prescribed by a licensed practitioner as part of a documented medical treatment shall result in the automatic suspension of practice by respondent and shall be considered a violation of probation. Respondent may not resume the practice of pharmacy until notified by the board in writing.~~

During any ~~such~~ suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, third-party logistics provider, veterinary food-animal drug retailer, or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area where dangerous drugs and/or dangerous devices or controlled substances are maintained. Respondent shall not practice ~~pharmacy~~ as a [insert license type] nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs and/or dangerous devices or controlled substances. ~~Respondent shall not resume practice until notified by the board.~~

During any ~~such~~ suspension, respondent shall not engage in any activity that requires the professional judgment of and/or licensure as a ~~pharmacist~~ [insert license type]. Respondent shall not direct or control any aspect of the practice of pharmacy, or of the manufacturing, distributing, wholesaling, or retailing of dangerous drugs and/or dangerous devices or controlled substances. ~~Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.~~

~~Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.~~

~~Failure to comply with any such this suspension shall be considered a violation of probation~~. Failure to comply with any requirement or deadline stated by this term shall be considered a violation of probation.

(Option language to be used in addition to standard language when appropriate to ensure licensee works in an access position while being monitored.)
Option: Respondent shall work in a pharmacy setting with access to controlled substances for six (6) consecutive months before successfully completing ~~probation~~ the PRP. If respondent fails to do so, probation shall be automatically extended until this condition has been met. Failure to satisfy this condition within six (6) months beyond the original date of expiration of the term of probation shall be considered a violation of probation.

~~22.~~ 24. ~~Random Drug Screening~~ Drug and Alcohol Testing (~~If PRP provision is required, this term is also to be included to allow for continued fluid monitoring by the Board in cases where a respondent successfully completes the PRP before completion of the probation period; terms is also appropriate for those cases where the evidence demonstrates that the respondent may have a problem with chemical dependency (drugs, alcohol) but where the PRP is not required~~ (Appropriate for those cases where the evidence demonstrates substance use.)
(Standards 4, 8, 9 & 10)

Respondent, at ~~his or her~~ [his/her] own expense, shall participate in ~~random~~ testing~~, including but not limited to biological fluid testing (urine, blood), breathalyzer, hair follicle testing, or other drug screening program~~ as directed by the board or its designee~~. Respondent may be required to participate in testing for the entire probation period and the frequency of testing will be determined by the board or its designee. At all times, respondent shall fully cooperate with the board or its designee, and shall, when directed, submit to such tests and samples~~ for the detection of alcohol, ~~narcotics, hypnotics~~ controlled substances, and dangerous drugs and/or dangerous devices. ~~or other controlled substances as the board or its designee may direct. Failure to timely submit to testing as directed shall be considered a violation of probation. Upon request of the board or its designee, respondent shall provide documentation from a licensed practitioner that the prescription for a detected drug was legitimately issued and is a necessary part of the treatment of the respondent. Failure to timely provide such documentation shall be considered a violation of probation. Any confirmed positive test for alcohol or for any drug not lawfully prescribed by a licensed practitioner as part of a documented medical treatment shall be considered a violation of probation and shall result in the automatic suspension of practice of pharmacy by respondent. Respondent may not resume the practice of pharmacy until notified by the board in writing.~~ Testing protocols may include biological fluid testing (urine, blood), breathalyzer, hair follicle testing, or other testing protocols as directed by the board or its designee. All testing must be pursuant to an observed testing protocol, unless respondent is informed otherwise in writing by the board or its designee. Respondent may be required to participate in testing for the entire probation period and frequency of testing will be determined by the board or its designee.

By no later than thirty (30) days after the effective date of this decision, respondent shall have completed all of the following tasks: enrolled and registered with an approved drug and alcohol testing vendor; provided that vendor with any necessary information and documentation, and any information necessary for payment by respondent; commenced testing protocols, including all required contacts with the testing vendor to determine testing date(s); and begun testing. At all times, respondent shall fully cooperate with the testing vendor, and with the board or its designee, with regard to enrollment, registration, and payment for, and compliance with, testing.

Any failure to cooperate timely shall be considered a violation of probation.

Respondent may be required to test on any day, including weekends and holidays. Respondent is required to make daily contact with the testing vendor to determine if a test is required, and if a test is required must submit to testing on the same day.

Prior to any vacation or other period of absence from the geographic area of the approved testing vendor, respondent shall seek and receive approval from the board or its designee of an alternate testing vendor in the geographic area to be visited or resided in by respondent. Upon approval, respondent shall enroll and register with the approved alternate drug testing vendor, provide that alternate vendor with any necessary information and documentation, including any necessary payment by respondent. During the period of visitation or residence in the alternate geographic area, respondent shall commence testing protocols with the alternate vendor, including required daily contacts with the testing vendor to determine if testing is required, and required testing. Any failure to timely seek or receive approval from the board or its designee, or to timely enroll and register with, timely commence testing protocols with, or timely undergo testing with, the alternate testing vendor, shall be considered a violation of probation.

Upon detection ~~through testing~~ of a an illicit drug, controlled substance or dangerous drug ~~and/or dangerous device~~, the board or its designee may require respondent to timely provide documentation from a licensed practitioner authorized to prescribe the detected substance demonstrating that the substance was administered or ingested pursuant to a legitimate prescription issued as a necessary part of treatment. All such documentation shall be provided by respondent within ten (10) days of being requested.

Any of the following shall be considered a violation of probation and shall result in respondent being immediately suspended from practice as a [insert license type] until notified by the board in writing that [he/she] may resume practice: failure to timely complete all of the steps required for enrollment/registration with the drug testing vendor, including making arrangements for payment; failure to timely commence drug testing protocols; failure to contact the drug testing vendor as required to determine testing date(s); failure to test as required; failure to timely supply documentation demonstrating that a detected substance was taken pursuant to a legitimate prescription issued as a necessary part of treatment; and/or detection through testing of alcohol, or of an illicit drug, or of a controlled substance or dangerous drug ~~and/or dangerous device~~ absent documentation that the detected substance was taken pursuant to a legitimate prescription and a necessary treatment. In the event of a suspension ordered after detection through testing of alcohol, an illicit drug, or of a controlled substance or dangerous drug ~~and/or dangerous device~~ absent documentation that the detected substance was taken pursuant to a legitimate prescription and a necessary treatment, the board or its designee shall inform respondent of the suspension and inform [him/her] to immediately leave work, and shall notify respondent's employer(s) and work site monitor(s) of the suspension.[3]

During any such suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, third-party-logistics provider, veterinary food-animal drug retailer, or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area where dangerous drugs and/or dangerous devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs and/or dangerous devices and controlled substances. ~~Respondent shall not resume practice until notified by the board.~~

During any such suspension, respondent shall not engage in any activity that requires the professional judgment of and/or licensure as a ~~pharmacist~~ [insert license type]. Respondent

shall not direct or control any aspect of the practice of pharmacy, or of the manufacturing, distributing, wholesaling, or retailing of dangerous drugs and/or dangerous devices. ~~Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.~~
~~Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.~~

Failure to comply with ~~this~~ any such suspension shall be considered a violation of probation. Failure to comply with any requirement or deadline stated by this term shall be considered a violation of probation.

25. Notification of Departure

Prior to leaving the probationary geographic area designated by the board or its designee for a period greater than twenty-four (24) hours, respondent shall notify the board verbally and in writing of the dates of departure and return. Failure to comply with this provision shall be considered a violation of probation.

~~23.~~~~25.~~ 26. Abstain from Drugs and Alcohol ~~Use~~
(Appropriate for those cases where the evidence demonstrates substance use.) **(Standard 4)**

Respondent shall completely abstain from the possession or use of alcohol, controlled substances, illicit drugs, dangerous drugs and/or dangerous devices, or ~~and~~ their associated ~~paraphernalia,~~ except when possessed

~~2. The Terms of Probation Designated Representative are now consolidated into "Terms of Probation – Individual Licensees."~~

or used pursuant to a legitimate prescription issued as a necessary part of treatment. ~~the drugs are lawfully prescribed by a licensed practitioner as part of a documented medical treatment. Upon request of the board or its designee, respondent shall provide documentation from the licensed practitioner that the prescription for the drug was legitimately issued and is a necessary part of the treatment of the respondent. Failure to timely provide such documentation shall be considered a violation of probation.~~ Respondent shall ensure that ~~he or she~~ [he/she] is not in the same physical location as individuals who are using illicit substances even if respondent is not personally ingesting the drugs. Any possession or use of alcohol, dangerous drugs and/or dangerous devices or controlled substances, or their associated paraphernalia ~~not supported by~~ for which a legitimate prescription has not been issued as a necessary part of treatment, ~~the documentation timely provided~~, ~~and/or~~ or any physical proximity to persons using illicit substances, shall be considered a violation of probation.

~~24.~~~~26.~~ 27. Prescription Coordination and Monitoring of Prescription Use (Appropriate for those cases where the evidence demonstrates substance use ~~chemical dependency (alcohol, drugs),~~ or psychiatric disorders (mental illness, emotional disturbance, gambling addiction)

Within thirty (30) days of the effective date of this decision, respondent shall submit to the board, for its prior approval, the name and qualifications of a single physician, nurse practitioner, physician assistant, or psychiatrist of respondent's choice, who shall be aware of the respondent's history [with the use of alcohol, illicit drugs, controlled substances, and/or dangerous drugs ~~and/or dangerous devices~~, and/or of mental illness, and/or of gambling addiction] and who will coordinate and monitor any prescriptions for respondent for dangerous drugs and/or dangerous devices, controlled substances or mood-altering drugs. The approved practitioner shall be provided with a copy of the board's [accusation, ~~or~~ petition to revoke probation, or other pleading] and decision. A record of this notification must be provided to the

board or its designee upon request. Respondent shall sign a release authorizing the practitioner to communicate with the board or its designee about respondent's treatment(s). The coordinating physician, nurse practitioner, physician assistant, or psychiatrist shall report to the board on a quarterly basis for the duration of probation regarding respondent's compliance with this condition. If any substances considered addictive have been prescribed, the report shall identify a program for the time limited use of any such substances. The board or its designee may require that the single coordinating physician, nurse practitioner, physician assistant or psychiatrist be a specialist in addictive medicine, or consult a specialist in addictive medicine. Should respondent, for any reason, cease supervision by the approved practitioner, respondent shall notify the board or its designee immediately and, within thirty (30) days of ceasing ~~treatment~~ supervision, submit the name of a replacement physician, nurse practitioner, physician assistant, or psychiatrist of respondent's choice to the board or its designee for its prior approval. Failure to timely submit the selected practitioner or replacement practitioner to the board or its designee for approval, or to ensure the ~~required reporting thereby on the quarterly reports~~ required quarterly reporting thereby, shall be considered a violation of probation.

If at any time an approved practitioner determines that respondent is unable to practice safely or independently as a ~~pharmacist~~ [insert license type], the practitioner shall notify the board or its designee immediately by telephone and follow up by written letter within three (3) working days. Upon notification from the board or its designee of this determination, respondent shall be automatically suspended and shall not resume practice as a [insert license type] until notified by the board or its designee that practice may be resumed.

During any ~~such~~ suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, third-party logistics provider, veterinary food-animal drug retailer, or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area where dangerous drugs and/or dangerous devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs and/or dangerous devices and controlled substances. Respondent shall not resume practice until notified by the board.

During any ~~such~~ suspension, respondent shall not engage in any activity that requires the professional judgment and/or licensure as a [insert license type] ~~of a pharmacist~~. Respondent shall not direct or control any aspect of the practice of pharmacy or of the manufacturing, distributing, wholesaling, or retailing of dangerous drugs and/or dangerous devices or controlled substances. ~~Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.~~

~~Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.~~

~~Failure to comply with any such this suspension shall be considered a violation of probation~~. Failure to comply with any requirement or deadline stated by this term shall be considered a violation of probation.

~~39.~~28. Facilitated Group Recovery and/or Support Meetings (Appropriate for those cases where the evidence demonstrates substance use. Pharmacists and Pharmacist Interns Only) **(Standard 5)**

Within thirty (30) days of the effective date of this decision, respondent shall begin regular

attendance at a group recovery and/or support meeting that is run by a trained facilitator approved in advance by the board or its designee. The required frequency of group meeting attendance shall be determined by the board or its designee. Respondent shall continue regular attendance as directed at an approved facilitated group meeting until the board or its designee advises the respondent in writing that [he/she] may cease regular attendance.

Respondent shall provide signed and dated documentation of attendance as required with each quarterly report. Failure to attend as required or to submit documentation of attendance shall be considered a violation of probation.

If respondent is required to participate in the PRP, compliance with this term can be demonstrated through that program. Where respondent is enrolled in the PRP, participation as required in a facilitated group meeting approved by the PRP shall be sufficient for satisfaction of this requirement. Any deviation from participation requirements for the PRP-approved group shall be considered a violation of probation.

~~40.~~29. Attend Substance Abuse Recovery Relapse Prevention and Support Groups
(Appropriate for those cases where the evidence demonstrates substance use.)
(Standard 5)

Within thirty (30) days of the effective date of this decision, respondent shall begin regular attendance at a recognized and established substance abuse recovery support group in California (e.g., Alcoholics Anonymous, Narcotics Anonymous, etc.) which has been approved by the board or its designee. Respondent must attend ~~at least one~~ the number of group meetings per week or month ~~unless otherwise~~ directed by the board or its designee, which shall typically be at least one per week. Respondent shall continue regular attendance and submit signed and dated documentation confirming attendance with each quarterly report for the duration of probation. Failure to attend or submit documentation thereof shall be considered a violation of probation.

~~If respondent is required to participate in the PRP, compliance with this term can be demonstrated through that program.~~ Where respondent is enrolled in the PRP, participation as required in a recovery group meeting approved by the PRP shall be sufficient for satisfaction of this requirement. Any deviation from participation requirements for the PRP-approved group shall be considered a violation of probation.

~~41.~~30. Work Site Monitor (Appropriate for those cases where the evidence demonstrates substance use.)[4] **(Standard 7)**

Within ten (10) days of the effective date of this decision, respondent shall identify a work site monitor, for prior approval by the board or its designee, who shall be responsible for supervising respondent during working hours. Respondent shall be responsible for ensuring that the work site monitor reports in writing to the board monthly or on another schedule as directed by the board or its designee. Should the designated work site monitor suspect at any time during the probationary period that respondent has abused alcohol or drugs, he or she shall notify the board immediately.

~~The initial~~ In the event of suspected abuse, the monitor shall make at least oral notification ~~shall be made orally~~ within one (1) business day of the occurrence, and shall be followed by written notification within two (2) business days of the occurrence. If, for any reason, including change of employment, respondent is no longer able to be monitored by the approved work site monitor, within ten (10) days respondent shall designate a new work site monitor for approval by the board or its designee. Failure to timely identify an acceptable initial or replacement work site monitor, or to ensure monthly reports are submitted to the board by the monitor, shall be considered a violation of probation.

[4] ~~This probationary term is not new, but is being moved from the previous section "Pharmacy Technician – Standard Terms and Conditions" for purposes of consolidation. The language of this term is also changing from the previous version.~~

Within thirty (30) days of being approved by the board or its designee, the work site monitor shall sign an affirmation that he or she has reviewed the terms and conditions of respondent's disciplinary order and agrees to monitor respondent. The work site monitor shall at least:

1) Have regular face-to-face contact with respondent in the work environment, at least once per week or with greater frequency if required by the board or its designee;
2) Interview other staff in the office regarding respondent's behavior, if applicable; and
3) Review respondent's work attendance.

The written reports submitted to the board or its designee by the work site monitor shall include at least the following information: respondent's name and license number; the monitor's name, license number (if applicable) and work site location; the date(s) the monitor had face-to-face contact with respondent; the staff interviewed, if applicable; an attendance report; notes on any changes in respondent's behavior or personal habits; notes on any indicators that may lead to substance abuse; and the work site monitor's signature.

Respondent shall complete any required consent forms and sign any required agreement with the work site monitor and/or the board to allow the board or its designee to communicate freely on the subject of respondent's work performance and sobriety with the work site monitor.

Option (Alternate language that is appropriate for respondents enrolled in PRP or who are given the PRP enrollment term: It is a condition of respondent's enrollment in the Pharmacists Recovery Program (PRP) that [he/she] is required to have a work site monitor approved by the PRP who shall be responsible for supervising respondent during working hours. Respondent shall be responsible for ensuring that the work site monitor reports in writing to the PRP monthly or on another schedule as directed by the PRP. Should the designated work site monitor suspect at any time during the probationary period that respondent has abused alcohol or drugs, he or she shall notify the PRP immediately. The initial notification shall be made orally within one (1) business day of the occurrence, ~~and~~ which shall be followed by written notification within two (2) business days of the occurrence. If, for any reason, including change of employment, respondent is not longer able to be monitored by the approved work site monitor, within ten (10) days of commencing new employment for prior approval by the PRP. Failure to identify an acceptable initial or replacement work site monitor, or to ensure monthly reports are submitted to the PRP by the work site monitor, shall be considered a violation of probation.

Within thirty (30) days of being approved by the PRP, the work site monitor shall sign an affirmation that he or she has reviewed the terms and conditions of respondent's disciplinary order and agrees to monitor respondent. The work site monitor shall at least:

1) Have regular face-to-face contact with respondent in the work environment, at least once per week or with greater frequency if required by the board or its designee;
2) Interview other staff in the office regarding respondent's behavior, if applicable; and
3) Review respondent's work attendance.

The written reports submitted to the PRP by the work site monitor shall include at least the following information: respondent's name and license number; the monitor's name, license number (if applicable) and work site location; the date(s) the monitor had face-to-face contact with respondent; the staff interviewed, if applicable; an attendance report; notes on any changes in respondent's behavior or personal habits; notes on any indicators that may lead to substance abuse; and the work site monitor's signature.

Respondent shall complete any required consent forms and sign any required agreement with the work site monitor and/or the PRP to allow the PRP to communicate freely on the subject of respondent's work performance and sobriety with the work site monitor.

~~25.~~~~27.~~31. Community Service~~s~~ Program

Within sixty (60) days of the effective date of this decision, respondent shall submit to the board or its designee, for prior approval, a community service program in which respondent shall provide free [insert type of service, e.g., health-care related services] on a regular basis to a community or charitable facility or agency for at least _____hours per _____for the first _____of probation. Within thirty (30) days of board approval thereof, respondent shall submit documentation to the board or its designee demonstrating commencement of the community service program. ~~A record of this notification must be provided to the board upon request.~~ Respondent shall report on progress with the community service program in the quarterly reports and provide satisfactory documentary evidence of such progress to the board or its designee upon request. Failure to timely submit, commence, or comply with the program shall be considered a violation of probation.

~~26.~~~~28.~~32. Restitution (Appropriate in cases of drug diversion, theft, fraudulent billing, or patient harm resulting from negligence or incompetence.)

Within _____days of the effective date of this decision, respondent shall pay restitution to _____in the amount of $ _____. Failure to make restitution by this deadline shall be considered a violation of probation.

~~27.~~~~29.~~33. Remedial Education

Within [thirty (30), sixty (60), ninety (90)] days of the effective date of this decision, respondent shall submit to the board or its designee, for prior approval, an appropriate program of remedial education related to [the grounds for discipline]. The program of remedial education shall consist of at least _____hours, which shall be completed within _____months/year at respondent's own expense. All remedial education shall be in addition to, and shall not be credited toward, continuing education (CE) courses used for license renewal purposes for pharmacists.

Failure to timely submit for approval or complete the approved remedial education shall be considered a violation of probation. The period of probation will be automatically extended until such remedial education is successfully completed and written proof, in a form acceptable to the board, is provided to the board or its designee.

Following the completion of each course, the board or its designee may require the respondent, at ~~his or her~~ [his/her] own expense, to take an approved examination to test the respondent's knowledge of the course. If the respondent does not achieve a passing score on the examination~~, this failure shall be considered a violation of probation. Any such examination failure shall require~~ that course shall not count towards satisfaction of this term. ~~r~~Respondent ~~to~~ shall take another course approved by the board in the same subject area.

Option: Respondent shall be restricted from the practice of [areas where a serious deficiency has been identified] until the remedial education program has been successfully completed.

~~40.~~~~38.~~34. Ethics Course (Pharmacists, Advanced Practice Pharmacists and Pharmacist Intern Only)

Within sixty (60) calendar days of the effective date of this decision, respondent shall enroll in a

course in ethics, at respondent's expense, approved in advance by the board or its designee that complies with Title 16 California Code of Regulations section 1773.5. Respondent shall provide proof of enrollment upon request. Within five (5) days of completion, respondent shall submit a copy of the certificate of completion to the board or its designee. Failure to timely enroll in an approved ethics course, to initiate the course during the first year of probation, to successfully ~~and~~ complete it before the end of ~~within~~ the second year of probation, or to timely submit proof of completion to the board or its designee, shall be considered ~~is~~ a violation of probation.

~~Respondent shall submit a certificate of completion to the board or its designee within five days after completing the course.~~

~~28. Pharmacy Self-Assessment Mechanism~~

~~Within the first year of probation, respondent shall complete the Pharmacist Self-Assessment Mechanism (PSAM) examination provided by the National Association of Boards of Pharmacy (NABP). Respondent shall submit a record of completion to the board demonstrating he/she has completed this examination. Respondent shall bear all costs for the examination. Continuing education hours received for this examination shall not be used as part of the required continuing education hours for renewal purposes.~~

~~Failure to timely complete the PSAM or submit documentation thereof shall be considered a violation of probation.~~

~~**Option A:** Respondent shall waive any rights to confidentiality and provide examination results to the board or its designee.~~

~~**Option B:** (This term must be accompanied by the "Remedial Education" term. [Include/Modify Remedial Education Term to Conform].) Respondent shall waive any rights to confidentiality and provide examination results to the board or its designee. Based on the results of the examination, the board shall determine which courses are appropriate for remedial education~~.

~~29. 30. Intern Pharmacist Experience (Intern Pharmacist Only)~~

~~Within ninety (90) days of the effective date of this decision, respondent shall submit to the board or its designee, for prior approval, a pharmacy intern training program consisting of _____ hours to be served as an intern pharmacist in a community and/or institutional pharmacy as directed. Respondent shall successfully complete the intern hours within the first year of probation and shall, by no later than one (1) year and ten (10) days from the effective date of this decision, submit proof satisfactory to the board of completion of this experience signed under penalty of perjury by both the respondent and supervising pharmacist. Failure to timely complete or document the required intern experience shall be considered a violation of probation.~~

30. ~~31.~~35. Supervised Practice (~~This term is not appropriate~~ See Option for Pharmacy Technicians.)

~~During the period of probation, respondent shall practice only under the supervision of a licensed pharmacist not on probation with the board. Upon and after the effective date of this decision, respondent shall not practice pharmacy and his or her license shall be automatically suspended until a supervisor is approved by the board or its designee. The supervision shall be, as required by the board or its designee, either:~~ Within thirty (30) days of the effective date of this decision, respondent shall submit to the board or its designee, for prior approval, the name of a [insert license type] licensed by and not on probation with the board, to serve as respondent's practice supervisor. As part of the documentation submitted, respondent shall

cause the proposed practice supervisor to report to the board in writing acknowledging that he or she has read the decision in case number [insert case number], and is familiar with the terms and conditions imposed thereby, including the level of supervision required by the board or its designee. This level will be determined by the board or its designee, will be communicated to the respondent on or before the effective date of this decision and shall be one of the following:

Continuous – At least 75% of a work week
Substantial - At least 50% of a work week
Partial - At least 25% of a work week
Daily Review - Supervisor's review of probationer's daily activities within 24 hours

Respondent may practice only under the required level of supervision by an approved practice supervisor. If, for any reason, including change of employment, respondent is no longer supervised at the required level by an approved practice supervisor, within ten (10) days of this change in supervision respondent shall submit to the board or its designee, for prior approval, the name of a [insert license type] licensed by and not on probation with the board, to serve as respondent's replacement practice supervisor. As part of the documentation submitted, respondent shall cause the proposed replacement practice supervisor to report to the board in writing acknowledging that he or she has read the decision in case number [insert case number], and is familiar with the terms and conditions imposed thereby, including the level of supervision required.

Any of the following shall result in the automatic suspension of practice by a respondent and shall be considered a violation of probation:

- Failure to nominate an initial practice supervisor, and to have that practice supervisor report to the board in writing acknowledging the decision, terms and conditions, and supervision level, within thirty (30) days;
- Failure to nominate a replacement practice supervisor, and to have that practice supervisor report to the board in writing acknowledging the decision, terms and conditions, and supervision level, within ten (10) days;
- Practicing in the absence of an approved practice supervisor beyond the initial or replacement nomination period; or
- Any failure to adhere to the required level of supervision.

Respondent shall not resume practice until notified in writing by the board or its designee.

~~Any of the following shall be considered a violation of probation: failure to timely nominate either an initial or a replacement practice supervisor; failure to cause the practice supervisor to timely report to the board in writing acknowledging the decision, terms and conditions, and supervision level; practicing in the absence of an approved practice supervisor after lapse of the nomination period; and/or failure to adhere to the level of supervision required by the board or its designee. If any of these obligations or prohibitions is not met, respondent shall be automatically suspended from practice as a [insert license type] and may not resume such practice until notified by the board or its designee in writing..~~

~~Within thirty (30) days of the effective date of this decision, respondent shall have his or her supervisor submit notification to the board in writing stating that the supervisor has read the decision in case number _____ and is familiar with the required level of supervision as determined by the board or its designee. It shall be the respondent's responsibility to ensure that his or her employer(s), pharmacist-in-charge and/or supervisor(s) submit timely acknowledgement(s) to the board. Failure to cause the direct supervisor and the pharmacist-in-charge to submit timely acknowledgements to the board shall be considered a violation of~~

~~probation.~~

~~If respondent changes employment, it shall be the respondent's responsibility to ensure that his or her employer(s), pharmacist-in-charge and/or supervisor(s) submit timely acknowledgement(s) to the board. Respondent shall have his or her new supervisor, within fifteen (15) days after employment commences, submit notification to the board in writing stating the direct supervisor and pharmacist-in-charge have read the decision in case number _____ and is familiar with the level of supervision as determined by the board. Respondent shall not practice pharmacy and his or her license shall be automatically suspended until the board or its designee approves a new supervisor. Failure to cause the direct supervisor and the pharmacist-in-charge to submit timely acknowledgements to the board shall be considered a violation of probation.~~

~~Within ten (10) days of leaving employment, respondent shall notify the board in writing.~~

During any ~~such~~ suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, third-party logistics provider, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area where dangerous drugs and/or dangerous devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs and/or dangerous devices or controlled substances. ~~Respondent shall not resume practice until notified by the board.~~

During any ~~such~~ suspension, respondent shall not engage in any activity that requires the professional judgment and/or licensure as a [insert license type]~~of a pharmacist~~. Respondent shall not direct or control any aspect of the practice of pharmacy or of the manufacture, distribution, wholesaling, or retailing of dangerous drugs and/or dangerous devices or controlled substances. ~~Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.~~

~~Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.~~

Failure to comply with ~~this~~ any ~~such~~ suspension shall be considered a violation of probation.

Option: (For Pharmacy Technicians Only)

Within thirty (30) days of the effective date of this decision, respondent shall submit to the board or its designee, for prior approval, the name of a pharmacist licensed by and not on probation with the board, to serve as respondent's practice supervisor. As part of the documentation submitted, respondent shall cause the proposed practice supervisor to report to the board in writing acknowledging that her or she has read the decision in case number [insert case number], and is familiar with the terms and conditions imposed thereby, including the level of supervision required by the board or its designee. Respondent may have multiple supervisors approved by the board if necessary to meet respondent's work requirements.

Any of the following shall be considered a violation of probation: failure to timely nominate either an initial or a replacement practice supervisor; failure to cause the practice supervisor to timely report to the board in writing acknowledging the decision, terms and conditions, and supervision level; practicing in the absence of an approved practice supervisor after lapse of the nomination period; and/or failure to adhere to the level of supervision required by the board or

its designee. If any of these obligations or prohibitions is not met, respondent shall be prohibited from practice as a [insert license type] and may not resume such practice until notified by the board or its designee in writing.

~~31. No Supervision of Ancillary Personnel~~[2]

~~During the period of probation, respondent shall not supervise any ancillary personnel, including, but not limited to, pharmacy technicians or designated representatives in any entity licensed by the board.~~

~~Failure to comply with this provision shall be considered a violation of probation.~~

~~32.~~36. No Ownership or Management of Licensed Premises

Respondent shall not own, have any legal or beneficial interest in, ~~or~~ nor serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board. Respondent shall sell or transfer any legal or beneficial interest in any entity licensed by the board within ninety (90) days following the effective date of this decision and shall immediately thereafter provide written proof thereof to the board. Failure to timely divest any legal or beneficial interest(s) or provide documentation thereof shall be considered a violation of probation.

Option (To be used in place of the standard language in those circumstances where respondent is permitted to continue existing ownership of a licensed entity): Respondent shall not acquire any new ownership, legal or beneficial interest nor serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any additional business, firm, partnership, or corporation licensed by the board. If respondent currently owns or has any legal or beneficial interest in, or serves as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board, respondent may continue to serve in such capacity or hold that interest, but only to the extent of that position or interest as of the effective date of this decision. Violation of this restriction shall be considered a violation of probation.

~~33.~~37. Separate File of Controlled Substances Records (~~For pharmacist~~ Pharmacist owners and pharmacists-in-charge)

Respondent shall maintain and make available for inspection a separate file of all records pertaining to the acquisition or disposition of all controlled substances. Failure to maintain such file or make it available for inspection shall be considered a violation of probation.

~~34.~~38. Report of Controlled Substances (~~For pharmacist~~ Pharmacist owners and pharmacists-in-charge)

Respondent shall submit ~~quarterly~~ reports to the board detailing the total acquisition and disposition of such controlled substances as the board or its designee may direct. Respondent shall specify the manner of disposition (e.g., by prescription, due to burglary, etc.) or acquisition (e.g., from a manufacturer, from another retailer, etc.) of such controlled substances. Respondent shall report on a quarterly basis or as directed by the board or its designee. The report shall be delivered or mailed to the board no later than ten (10) days following the end of the reporting period as determined by the board or its designee. Failure to timely prepare or submit such reports shall be considered a violation of probation.

~~35.~~39. No Access to Controlled Substances

During the period of probation and as directed by the board or its designee, respondent shall not order, possess, dispense or otherwise have access to any controlled substance(s) in Schedules I, II, III, IV or V (Health and Safety Code sections ~~11055~~ 11054 -11058 inclusive). Respondent shall not order, receive or retain any security prescription forms. Failure to comply with this restriction shall be considered a violation of probation.

~~36.~~40. Criminal Probation/Parole Reports

~~Respondent shall provide a copy of the conditions of any criminal probation/parole to the board, in writing, within ten (10) days of the issuance or modification of those conditions. Respondent shall provide the name of his or her [his/her] probation/parole officer to the board, in writing, within ten (10) days after that officer is designated or a replacement for that officer is designated. Respondent shall provide a copy of all criminal probation/parole reports to the board within ten (10) days after respondent receives a copy of such a report. Failure to timely make any of the submissions required hereby shall be considered a violation of probation.~~

Within ten (10) days of the effective date of this decision, or within ten (10) days of the issuance or assignment/replacement of same, whichever is earlier, respondent shall provide the board or its designee in writing: a copy of the conditions of any criminal probation/parole applicable to respondent; and the name and contact information of any probation, parole or similar supervisory officer assigned to respondent. On an following the effective date, respondent shall provide a copy of all criminal probation/parole reports to the board within ten (10) days after such report is issued. Failure to timely make any of the submissions required hereby shall be considered a violation of probation.

~~37. Consultant for Owner or Pharmacist-In-Charge~~

~~(Option #1 for pharmacist owners - primarily intended for appropriate cases where the respondent is the sole owner and pharmacist-in-charge of his or her own pharmacy, the standard language should be used in most cases.)~~

~~During the period of probation, respondent shall not supervise any intern pharmacist or serve as a consultant to any entity licensed by the board. Respondent may be a pharmacist-in-charge. However, if during the period of probation respondent serves as a pharmacist-in-charge, respondent shall retain an independent consultant at his or her own expense who shall be responsible for reviewing pharmacy operations on a [monthly/quarterly] basis for compliance by respondent with state and federal laws and regulations governing the practice of pharmacy and for compliance by respondent with the obligations of a pharmacist-in-charge. The consultant shall be a pharmacist licensed by and not on probation with the board and whose name shall be submitted to the board or its designee, for prior approval, within thirty (30) days of the effective date of this decision. Respondent shall not be a pharmacist-in-charge at more than one pharmacy or at any pharmacy of which he or she is not the sole owner. Failure to timely retain, seek approval of, or ensure timely reporting by the consultant shall be considered a violation of probation.~~

~~(Option #2 - appropriate for pharmacists who are not pharmacy owners, but who wish, because of their current employment, to remain as the pharmacist-in-charge, and have provided documented mitigating evidence to warrant this option.)~~

~~During the period of probation, respondent shall not supervise any intern pharmacist, or serve as a consultant to any entity licensed by the board. In the event that the respondent is currently the pharmacist-in-charge of a pharmacy, the pharmacy shall retain an independent consultant at its own expense who shall be responsible for reviewing pharmacy operations on a [monthly/quarterly] basis for compliance by respondent with state and federal laws and regulations governing the practice of pharmacy and for compliance by respondent with the~~

~~obligations of a pharmacist-in-charge. The consultant shall be a pharmacist licensed by and not on probation with the board and whose name shall be submitted to the board or its designee, for prior approval. Within thirty (30) days of the effective date of this decision. Respondent shall not be a pharmacist-in-charge at more than one pharmacy or at any pharmacy of which he or she is not the current PIC. The board may, in case of an employment change by respondent or for other reasons as deemed appropriate by the board or its designee, preclude the respondent from acting as a pharmacist-in-charge. Failure to timely retain, seek approval of, or ensure timely reporting by the consultant shall be considered a violation of probation.~~

~~38. Tolling of Suspension~~

~~During the period of suspension, respondent shall not leave California for any period exceeding ten (10) days, regardless of purpose (including vacation). Any such absence in excess of the (10) days during suspension shall be considered a violation of probation. Moreover, any absence from California during the period of suspension exceeding ten (10) days shall toll the suspension, i.e., the suspension shall be extended by one day for each day over ten (10) days respondent is absent from California. During any such period of tolling of suspension, respondent must nonetheless comply with all terms and conditions of probation.~~

~~Respondent must notify the board in writing within ten (10) days of departure, and must further notify the board in writing within ten (10) days of return. The failure to provide such notification(s) shall constitute a violation of probation. Upon such departure and return, respondent shall not resume the practice of pharmacy until notified by the board that the period of suspension has been satisfactorily completed.~~

~~39~~ ~~37.~~ 42. Surrender of DEA Permit (Pharmacists, Advanced Practice Pharmacists and Pharmacist Intern Only)

Within thirty (30) days of the effective date of this decision, respondent shall surrender ~~his or her~~ [his/her] federal Drug Enforcement Administration (DEA) permit to the DEA~~,~~ for cancellation. Respondent shall provide documentary proof of such cancellation to the board or its designee. Respondent is prohibited from ~~prescribing~~ dispensing, furnishing, or otherwise providing dangerous drugs and/or dangerous devices or controlled substances until the board has received satisfactory proof of cancellation. Thereafter, respondent shall not apply/reapply for a DEA registration number without the prior written consent of the board or its designee.

Option 1: Respondent may obtain a DEA permit restricted to Schedule(s) _____controlled substance(s).

Option 2: Respondent shall not order, receive, or retain any federal order forms, including DEA form 222 forms, for controlled substances.

~~PHARMACY TECHNICIAN~~

~~The board files cases against pharmacy technicians where the violation(s) involve significant misconduct on the part of the licensee. The board believes that revocation is typically the appropriate penalty when grounds for discipline are found to exist. Grounds for discipline include, but are not limited to the following violation(s) of law(s) involving:~~

- ~~Possession of dangerous drugs and/or controlled substances~~
- ~~Use of dangerous drugs and/or controlled substances~~
- ~~Possession for sale of dangerous drugs and/or controlled substances~~
- ~~Personal misuse of drugs or alcohol~~

~~If revocation is not imposed, the board recommends a minimum Category III level of discipline~~

~~be imposed on the pharmacy technician. This would include suspension and probation.~~

~~In addition, a pharmacy technician would be required to obtain certification as defined by Business and Professions Code section 4202(a)(4) prior to resuming work as a pharmacy technician. The board believes that certification prior to resuming work is always warranted in cases where a pharmacy technician license is disciplined but not revoked.~~

~~Pharmacy technicians are issued a license based on minimal education, training requirements or certification. No examination is required for issuance of the registration. Pharmacy technicians are not independent practitioners and must work under the supervision of a pharmacist. To place a pharmacy technician on probation places an additional burden on the pharmacist (who may or may not be on probation) to ensure that the respondent pharmacy technician complies with the terms and conditions of his or her probation.~~

~~TERMS OF PROBATION – PHARMACY TECHNICIAN~~[4]

~~A minimum three-year probation period has been established by the board as appropriate in most cases where probation is imposed. A minimum five-year probation period has been established by the board as appropriate where self-administration or diversion of controlled substances is involved. Terms and conditions are imposed to provide consumer protection and to allow the probationer to demonstrate rehabilitation. A suspension period may also be required as part of the probation order. The board prefers that any stayed order be for revocation rather than for some period of suspension.~~

~~Probation conditions are divided into two categories: (1) standard conditions that shall appear in all probation cases, and (2) optional conditions that depend on the nature and circumstances of a particular case. These conditions may vary depending on the nature of the offense(s).~~

~~The board may also impose any other condition appropriate to the case where the condition is not contrary to public policy.~~

~~**CATEGORY OF VIOLATIONS AND RECOMMENDED PENALTIES**~~

~~**CATEGORY III - Penalty**~~

~~Minimum: Revocation; Revocation stayed, 90 days actual suspension, three years probation. All standard terms and conditions shall be included and optional terms and conditions as appropriate.~~

~~Maximum: Revocation~~

~~Applies to all applicable statutes and regulations~~

~~**MODEL DISCIPLINARY LANGUAGE – PHARMACY TECHNICIAN**~~[5]

~~The following standardized language shall be used in every decision where the order of condition is imposed.~~

~~**Revocation**~~

~~Pharmacy technician license number _____, issued to respondent _____is revoked. Respondent shall relinquish his or her technician license to the board within ten (10) days of the effective date of this decision. Respondent may not reapply or petition the board for reinstatement of his or her revoked technician license for three (3) years from the effective date of this decision.~~

~~A condition of reinstatement shall be that the respondent is certified as defined in Business and Professions Code section 4202(a)(4) and provides satisfactory proof of certification to the board.~~

~~Respondent shall pay to the board its costs of investigation and prosecution in the amount of $_____within fifteen (15) days of the effective date of this decision.~~

~~**Option:** As a condition precedent to reinstatement of his or her revoked technician license respondent shall reimburse the board for its costs of investigation and prosecution in the amount of $_____. Said amount shall be paid in full prior to the reapplication or reinstatement of his or her revoked technician license, unless otherwise ordered by the board.~~

~~**Suspension**~~

~~As part of probation, respondent is suspended from working as a pharmacy technician for _____beginning the effective date of this decision.~~

~~During suspension, respondent shall not enter any pharmacy area or any portion of or any other board licensed premises (wholesaler, veterinary food-animal drug retailer or any other distributor of drugs) any drug manufacturer, or any other location where dangerous drugs and devices or controlled substances are maintained. Respondent shall not do any act involving drug selection, selection of stock, manufacturing, compounding or dispensing; nor shall respondent manage, administer, or assist any licensee of the board. Respondent shall not have~~

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[5] ~~All information specific to Pharmacy Technician is being removed and consolidated into Terms of Probation – Individual Licensees.~~

~~access to or control the ordering, manufacturing or dispensing of dangerous drugs and devices or controlled substances.~~

~~Respondent shall not direct, control or perform any aspect of the practice of pharmacy. Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.~~

~~Failure to comply with this suspension shall be considered a violation of probation.~~

~~Standard Stay/Probation Order~~

~~Pharmacy technician license number _____is revoked; however the revocation is stayed and respondent is placed on probation for _____years upon the following terms and conditions:~~

~~Issuance of Probationary License~~ ~~(In cases where a Statement of Issues has been filed.)~~

~~Upon satisfaction of all statutory and regulatory requirements for issuance of a license, a license shall be issued to respondent and immediately revoked; the order of revocation is stayed and respondent is placed on probation for _____years upon the following terms and conditions:~~

~~Surrender~~

~~Respondent surrenders pharmacy technician license number _____as of the effective date of this decision. Respondent shall relinquish his or her pharmacy technician license to the board within ten (10) days of the effective date of this decision.~~

~~The surrender of respondent's license and the acceptance of the surrendered license by the board shall constitute the imposition of discipline against respondent. This decision constitutes a record of discipline and shall become a part of respondent's license history with the board.~~

~~Respondent understands and agrees that if he or she ever files an application for licensure or a petition for reinstatement in the State of California, the board shall treat it as a new application for licensure.~~

~~Respondent may not apply for any license, permit, or registration from the board for three (3) years from the effective date of this decision. Respondent stipulates that should he or she apply for any license from the board on or after the effective date of this decision, all allegations set forth in the [accusation or petition to revoke probation] shall be deemed to be true, correct and admitted by respondent when the board determines whether to grant or deny the application. Respondent shall satisfy all requirements applicable to that license as of the date the application is submitted to the board, including, but not limited to certification by a nationally recognized body prior to the issuance of a new license. Respondent is required to report this surrender as disciplinary action.~~

~~Respondent further stipulates that he or she shall reimburse the board for its costs of investigation and prosecution in the amount of $_ _____within _____days of the effective date of this decision.~~

~~**Option:** Respondent stipulates that should he or she apply for any license from the board on or after the effective date of this decision, investigation and prosecution costs in the amount of $_____shall be paid to the board prior to issuance of the license.~~

~~**Public Reprimand**~~

~~It is hereby ordered that a public reprimand be issued against pharmacy technician license, _____. Respondent is required to report this reprimand as a disciplinary action.~~

~~**Adoption of Stipulation**~~

~~It is understood by respondent that, in deciding whether to adopt this stipulation, the board may receive oral and written communication from its staff and the Office of the Attorney General. Communications pursuant to this paragraph shall not disqualify the board or other persons from future participation in this or any other matter affecting respondent. In the event this settlement is not adopted by the board, the stipulation will not become effective and may not be used for any purpose, except this paragraph, which shall remain in effect.~~

~~**STANDARD CONDITIONS** – To be included in all probation decisions/orders.~~

1. ~~Certification Prior to Resuming Work~~
2. ~~Obey All Laws~~
3. ~~Report to the Board~~
4. ~~Interview with the Board~~
5. ~~Cooperate with Board Staff~~
6. ~~Notice to Employers~~
7. ~~Reimbursement of Board Costs~~
8. ~~Probation Monitoring Costs~~
9. ~~Status of License~~
10. ~~License Surrender While on Probation/Suspension~~
11. ~~Notification of a Change in Name, Residence Address, Mailing Address or Employment~~
12. ~~Tolling of Probation~~
13. ~~Violation of Probation~~
14. ~~Completion of Probation~~

~~**OPTIONAL CONDITIONS**~~

15. ~~No Ownership of Licensed Premises~~
16. ~~Attend Substance Abuse Recovery Relapse Prevention and Support Groups~~
17. ~~Random Drug Screening~~
18. ~~Work Site Monitor~~
19. ~~Notification of Departure~~
20. ~~Abstain from Drugs and Alcohol Use~~
21. ~~Tolling of Suspension~~
22. ~~Restitution~~

~~STANDARD CONDITIONS: TO BE INCLUDED IN ALL PROBATIONS~~

~~1. Certification Prior to Resuming Work~~

~~Respondent shall be automatically suspended from working as a pharmacy technician until he or she is certified as defined by Business and Professions Code section 4202(a)(4) and provides satisfactory proof of certification to the board. Respondent shall not resume working as a pharmacy technician until notified by the board. Failure to achieve certification within one (1) year shall be considered a violation of probation. Respondent shall not resume working as a pharmacy technician until notified by the board.~~

~~During suspension, respondent shall not enter any pharmacy area or any portion of any other board licensed premises (wholesaler, veterinary food-animal drug retailer or any other distributor of drugs) any drug manufacturer, or any other location where dangerous drugs and devices or controlled substances are maintained. Respondent shall not do any act involving drug selection, selection of stock, manufacturing, compounding or dispensing; nor shall respondent manage, administer, or assist any licensee of the board. Respondent shall not have access to or control the ordering, manufacturing or dispensing of dangerous drugs and devices or controlled substances. Respondent shall not resume work until notified by the board.~~

~~Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises by the board in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.~~

~~Failure to comply with this suspension shall be considered a violation of probation.~~

~~2. Obey All Laws~~

~~Respondent shall obey all state and federal laws and regulations.~~

~~Respondent shall report any of the following occurrences to the board, in writing, within seventy-two (72) hours of such occurrence:~~

- ~~an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws~~
- ~~a plea of guilty or nolo contendre in any state or federal criminal proceeding to any criminal complaint, information or indictment~~
- ~~a conviction of any crime~~
- ~~discipline, citation, or other administrative action filed by any state or federal agency which involves respondent's _____license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling, distributing, billing, or charging for any drug, device or controlled substance.~~

~~Failure to timely report any such occurrence shall be considered a violation of probation.~~

~~3. Report to the Board~~

~~Respondent shall report to the board quarterly, on a schedule as directed by the board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, respondent shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation. Failure to submit timely reports~~

~~in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the board.~~

~~4. Interview with the Board~~

~~Upon receipt of reasonable prior notice, respondent shall appear in person for interviews with the board or its designee, at such intervals and locations as are determined by the board or its designee. Failure to appear for any scheduled interview without prior notification to board staff, or failure to appear at two (2) or more scheduled interviews with the board or its designee during the period of probation, shall be considered a violation of probation.~~

~~5. Cooperate with Board Staff~~

~~Respondent shall cooperate with the board's inspection program and with the board's monitoring and investigation of respondent's compliance with the terms and conditions of his or her probation. Failure to cooperate shall be considered a violation of probation.~~

~~6. Notice to Employers~~

~~During the period of probation, respondent shall notify all present and prospective employers of the decision in case number~~ _____ ~~and the terms, conditions and restrictions imposed on respondent by the decision, as follows:~~

~~Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment, respondent shall cause his or her direct supervisor, pharmacist-in-charge (including each new pharmacist-in-charge employed during respondent's tenure of employment) and owner to report to the board in writing acknowledging that the listed individual(s) has/have read the decision in case number~~ _____ ~~and the terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that his or her employer(s) and/or supervisor(s) submit timely acknowledgement(s) to the board.~~

~~If respondent works for or is employed by or through a pharmacy employment service, respondent must notify his or her direct supervisor, pharmacist-in-charge and owner at every pharmacy of the terms and conditions of the decision in case number~~ _____ ~~in advance of the respondent commencing work at each pharmacy. A record of this notification must be provided to the board upon request.~~

~~Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment by or through a pharmacy employment service, respondent shall cause his or her direct supervisor with the pharmacy employment service to report to the board in writing acknowledging that he or she has read the decision in case number~~ _____ ~~and the terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that his or her employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board.~~

~~Failure to timely notify present or prospective employer(s) or to cause that/those employer(s) to submit timely acknowledgements to the board shall be considered a violation of probation.~~

~~"Employment" within the meaning of this provision shall include any full-time, part-time, temporary or relief service or pharmacy management service as a pharmacy technician or in any position for which a pharmacy technician license is a requirement or criterion for employment, whether the respondent is considered an employee, independent contractor or volunteer.~~

~~7. Reimbursement of Board Costs~~

~~As a condition precedent to successful completion of probation, respondent shall pay to the board its costs of investigation and prosecution in the amount of $_____. Respondent shall make said payments as follows: _____. There shall be no deviation from this schedule absent prior written approval by the board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.~~

~~The filing of bankruptcy by respondent shall not relieve respondent of his or her responsibility to reimburse the board its costs of investigation and prosecution.~~

~~8. Probation Monitoring Costs~~

~~Respondent shall pay any costs associated with probation monitoring as determined by the board each and every year of probation. Such costs shall be payable to the board on a schedule as directed by the board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.~~

~~9. Status of License~~

~~Respondent shall, at all times while on probation, maintain an active, current pharmacy technician license with the board, including any period during which suspension or probation is tolled. Failure to maintain an active, current license shall be considered a violation of probation.~~

~~If respondent's pharmacy technician license expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof due to tolling or otherwise, upon renewal or reapplication respondent's license shall be subject to all terms and conditions of this probation not previously satisfied.~~

~~10. License Surrender While on Probation/Suspension~~

~~Following the effective date of this decision, should respondent cease work due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, respondent may tender his or her pharmacy technician license to the board for surrender. The board or its designee shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondent will no longer be subject to the terms and conditions of probation. This surrender constitutes a record of discipline and shall become a part of the respondent's license history with the board.~~

~~Upon acceptance of the surrender, respondent shall relinquish his or her pharmacy technician license to the board within ten (10) days of notification by the board that the surrender is accepted. Respondent may not reapply for any license, permit, or registration from the board for three (3) years from the effective date of the surrender. Respondent shall meet all~~

~~requirements applicable to the license sought as of the date the application for that license is submitted to the board.~~

~~11. Notification of a Change in Name, Residence Address, Mailing Address or Employment~~

~~Respondent shall notify the board in writing within ten (10) days of any change of employment. Said notification shall include the reasons for leaving, the address of the new employer, the name of the supervisor and owner, and the work schedule if known. Respondent shall further notify the board in writing within ten (10) days of a change in name, residence address and mailing address, or phone number.~~

~~Failure to timely notify the board of any change in employer(s), name(s), address(es), or phone number(s) shall be considered a violation of probation.~~

~~12. Tolling of Probation~~

~~Except during periods of suspension, respondent shall, at all times while on probation, be employed as a pharmacy technician in California for a minimum of _____hours per calendar month. Any month during which this minimum is not met shall toll the period of probation, i.e., the period of probation shall be extended by one month for each month during which this minimum is not met. During any such period of tolling of probation, respondent must nonetheless comply with all terms and conditions of probation.~~

~~Should respondent, regardless of residency, for any reason (including vacation) cease working as a pharmacy technician for a minimum of _____hours per calendar month in California, respondent must notify the board in writing within ten (10) days of cessation of work and must further notify the board in writing within ten (10) days of the resumption of the work. Any failure to provide such notification(s) shall be considered a violation of probation.~~

~~It is a violation of probation for respondent's probation to remain tolled pursuant to the provisions of this condition for a total period, counting consecutive and non-consecutive months, exceeding thirty-six (36) months.~~

> ~~"Cessation of work" means calendar month during which respondent is not working for at least _____hours as a pharmacy technician, as defined in Business and Professions Code section 4115. "Resumption of work" means any calendar month during which respondent is working as a pharmacy technician for at least _____hours as a pharmacy technician as defined by Business and Professions Code section 4115.~~

~~13. Violation of Probation~~

~~If a respondent has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondent, and probation shall automatically be extended, until all terms and conditions have been satisfied or the board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed.~~

~~If respondent violates probation in any respect, the board, after giving respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. Notice and opportunity to be heard are not required for those provisions stating that a~~

~~violation thereof may lead to automatic termination of the stay and/or revocation of the license. If a petition to revoke probation or an accusation is filed against respondent during probation, the board shall have continuing jurisdiction, and the period of probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided.~~

~~14. Completion of Probation~~

~~Upon written notice by the board indicating successful completion of probation, respondent's pharmacy technician license will be fully restored.~~

~~OPTIONAL CONDITIONS OF PROBATION~~

~~15. No Ownership of Licensed Premises~~

~~Respondent shall not own, have any legal or beneficial interest in, or serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board. Respondent shall sell or transfer any legal or beneficial interest in any entity licensed by the board within ninety (90) days following the effective date of this decision and shall immediately thereafter provide written proof thereof to the board. Failure to timely divest any legal or beneficial interest(s) or provide documentation thereof shall be considered a violation of probation.~~

~~Option:~~ ~~Respondent shall not acquire any new ownership, legal or beneficial interest nor serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any additional business, firm, partnership, or corporation licensed by the board. If respondent currently owns or has any legal or beneficial interest in, or serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board, respondent may continue to serve in such capacity or hold that interest, but only to the extent of that position or interest as of the effective of this decision. Violation of this restriction shall be considered a violation of probation.~~

~~16. Attend Substance Abuse Recovery Relapse Prevention and Support Groups~~ ~~(Appropriate for those cases with chemical dependency (alcohol, drugs))~~

~~Within thirty (30) days of the effective date of this decision, respondent shall begin regular attendance at a recognized and established substance abuse recovery support group in California, (e.g., Alcoholics Anonymous, Narcotics Anonymous, etc.) which has been approved by the board or its designee. Respondent must attend at least one group meeting per week unless otherwise directed by the board or its designee. Respondent shall continue regular attendance and submit signed and dated documentation confirming attendance with each quarterly report for the duration of probation. Failure to attend or submit documentation thereof shall be considered a violation of probation.~~

~~17. Random Drug Screening~~ ~~(Appropriate for those cases with chemical dependency (alcohol, drugs))~~

~~Respondent, at his or her own expense, shall participate in random testing, including but not limited to biological fluid testing (urine, blood), breathalyzer, hair follicle testing, or other drug screening program as directed by the board or its designee. Respondent may be required to participate in testing for the entire probation period and the frequency of testing will be~~

~~determined by the board or its designee. At all times respondent shall fully cooperate with the board or its designee, and shall, when directed, submit to such tests and samples for the detection of alcohol, narcotics, hypnotics, dangerous drugs or other controlled substances as the board or its designee may direct. Failure to timely submit to testing as directed shall be considered a violation of probation. Upon request of the board or its designee, respondent shall provide documentation from a licensed practitioner that the prescription for a detected drug was legitimately issued and is a necessary part of the treatment of the respondent. Failure to timely provide such documentation shall be considered a violation of probation. Any confirmed positive test for alcohol or for any drug not lawfully prescribed by a licensed practitioner as part of a documented medical treatment shall be considered a violation of probation and shall result in the automatic suspension of work by respondent. Respondent may not resume work as a pharmacy technician until notified by the board in writing.~~

~~During suspension, respondent shall not enter any pharmacy area or any portion of or any other board licensed premises (wholesaler, veterinary food-animal drug retailer or any other distributor of drugs) any drug manufacturer, or any other location where dangerous drugs and devices or controlled substances are maintained. Respondent shall not do any act involving drug selection, selection of stock, manufacturing, compounding or dispensing; nor shall respondent manage, administer, or assist any licensee of the board. Respondent shall not have access to or control the ordering, manufacturing or dispensing of dangerous drugs and devices or controlled substances. Respondent shall not resume work until notified by the board.~~

~~Respondent shall not direct, control or perform any aspect of the practice of pharmacy. Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.~~

~~Failure to comply with this suspension shall be considered a violation of probation.~~

~~**18. Work Site Monitor** (Appropriate for those cases with chemical dependency (alcohol, drugs))~~

~~Within ten (10) days of the effective date of this decision, respondent shall identify a work site monitor, for prior approval by the board, who shall be responsible for supervising respondent during working hours. Respondent shall be responsible for ensuring that the work site monitor reports in writing to the board quarterly. Should the designated work site monitor determine at any time during the probationary period that respondent has not maintained sobriety, he or she shall notify the board immediately, either orally or in writing as directed. Should respondent change employment, a new work site monitor must be designated, for prior approval by the board, within ten (10) days of commencing new employment. Failure to identify an acceptable initial or replacement work site monitor, or to ensure quarterly reports are submitted to the board, shall be considered a violation of probation.~~

~~**19. Notification of Departure** (Appropriate for those cases with chemical dependency (alcohol, drugs))~~

~~Prior to leaving the probationary geographic area designated by the board or its designee for a period greater than twenty-four (24) hours, respondent shall notify the board verbally and in writing of the dates of departure and return. Failure to comply with this provision shall be considered a violation of probation.~~

~~**20. Abstain from Drugs and Alcohol Use** (Appropriate for those cases with chemical dependency (alcohol, drugs))~~

~~Respondent shall completely abstain from the possession or use of alcohol, controlled substances, dangerous drugs and their associated paraphernalia except when the drugs are lawfully prescribed by a licensed practitioner as part of a documented medical treatment. Upon request of the board or its designee, respondent shall provide documentation from the licensed practitioner that the prescription for the drug was legitimately issued and is a necessary part of the treatment of the respondent. Failure to timely provide such documentation shall be considered a violation of probation. Respondent shall ensure that he or she is not in the same physical location as individuals who are using illicit substances even if respondent is not personally ingesting the drugs. Any possession or use of alcohol, controlled substances, or their associated paraphernalia not supported by the documentation timely provided, and/or any physical proximity to persons using illicit substances, shall be considered a violation of probation.~~

~~**21. Tolling of Suspension**~~

~~During the period of suspension, respondent shall not leave California for any period exceeding ten (10) days, regardless of purpose (including vacation). Any such absence in excess of ten (10) days during suspension shall be considered a violation of probation. Moreover, any absence from California during the period of suspension exceeding ten (10) days shall toll the suspension, i.e., the suspension shall be extended by one day for each day over ten (10) days respondent is absent from California. During any such period of tolling of suspension, respondent must nonetheless comply with all terms and conditions of probation.~~

~~Respondent must notify the board in writing within ten (10) days of departure, and must further notify the board in writing within ten (10) days of return. The failure to provide such notification(s) shall constitute a violation of probation. Upon such departure and return, respondent shall not return to work until notified by the board that the period of suspension has been satisfactorily completed.~~

~~**22. Restitution** (Appropriate in cases of drug diversion, theft, fraudulent billing, or patient harm resulting from negligence or incompetence.)~~

~~Within _____days of the effective date of this decision, respondent shall pay restitution to _____in the amount of $ _____. Failure to make restitution by this deadline shall be considered a violation of probation.~~

~~DESIGNATED REPRESENTATIVE~~

~~The board files cases against designated representatives where the violation(s) involve significant misconduct on the part of the licensee. The board believes that revocation is typically the appropriate penalty when grounds for discipline are found to exist. Grounds for discipline include, but are not limited to, the following violation(s) of law(s) involving:~~

- ~~Possession of dangerous drugs and/or controlled substances~~
- ~~Use of dangerous drugs and/or controlled substances~~
- ~~Possession for sale of dangerous drugs and/or controlled substances~~
- ~~Personal misuse of drugs or alcohol~~

~~If revocation is not imposed, the board recommends a minimum Category III level of discipline be imposed on the designated representative. This would include suspension and probation.~~

~~TERMS OF PROBATION – DESIGNATED REPRESENTATIVE~~[6]

~~A minimum three-year probation period has been established by the board as appropriate in most cases where probation is imposed. A minimum five-year probation period has been established by the board as appropriate where self-administration or diversion of controlled substances is involved. Terms and conditions are imposed to provide consumer protection and to allow the probationer to demonstrate rehabilitation. A suspension period may also be required as part of the probation order. The board prefers that any stayed order be for revocation rather than for some period of suspension.~~

~~Probation conditions are divided into two categories: (1) standard conditions that shall appear in all probation cases, and (2) optional conditions that depend on the nature and circumstances of a particular case. These conditions may vary depending on the nature of the offense(s).~~

~~The board may also impose any other condition appropriate to the case where the condition is not contrary to public policy.~~

~~CATEGORY OF VIOLATIONS AND RECOMMENDED PENALTIES~~

~~CATEGORY III - Penalty~~

~~Minimum: Revocation; Revocation stayed, 90 days actual suspension, three years probation. All standard terms and conditions shall be included and optional terms and conditions as appropriate.~~

~~Maximum: Revocation~~

~~Applies to all applicable statutes and regulations~~

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[6] ~~All information specific to Designated Representative is being removed and consolidated into Terms of Probation – Individual Licensees.~~

~~MODEL DISCIPLINARY LANGUAGE – DESIGNATED REPRESENTATIVE~~

~~The following standardized language shall be used in every decision where the order of condition is imposed.~~

~~Revocation~~

~~Designated Representative license number _____, issued to respondent _____ is revoked. Respondent shall relinquish his or her designated representative license to the board within ten (10) days of the effective date of this decision. Respondent may not petition the board for reinstatement of his or her revoked designated representative license for three (3) years from the effective date of this decision.~~

~~Respondent shall pay to the board its costs of investigation and prosecution in the amount of $_____within fifteen (15) days of the effective date of this decision.~~

~~**Option:** As a condition precedent to reinstatement of his or her revoked designated representative license respondent shall reimburse the board for its costs of investigation and prosecution in the amount of $_____. Said amount shall be paid in full prior to the reinstatement of his or her revoked designated representative license, unless otherwise ordered by the board.~~

~~Suspension~~

~~As part of probation, respondent is suspended from working as a designated representative for _____beginning the effective date of this decision.~~

~~During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs licensed by the board, or any drug manufacturer, or any other location where dangerous drugs and devices or controlled substances are maintained. Respondent shall not perform any of the duties of a designated representative, nor do any act involving drug selection, selection of stock, manufacturing, dispensing; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and devices and controlled substances. Respondent shall not resume work until notified by the board.~~

~~Respondent shall not direct, control or perform any aspect involving the distribution of dangerous drugs and devices and controlled substances. Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed entity in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.~~

~~Failure to comply with this suspension shall be considered a violation of probation.~~

~~Standard Stay/Probation Order~~

~~Designated representative license number _____is revoked; however, the revocation is stayed and respondent is placed on probation for _____years upon the following terms and conditions:~~

~~**Issuance of Probationary License** (In cases where a Statement of Issues has been filed.)~~

~~Upon satisfaction of all statutory and regulatory requirements for issuance of a license, a license shall be issued to respondent and immediately revoked; the order of revocation is stayed and respondent is placed on probation for _____years upon the following terms and conditions:~~

~~**Surrender**~~

~~Respondent surrenders designated representative license number _____as of the effective date of this decision. Respondent shall relinquish his or her designated representative license to the board within ten (10) days of the effective date of this decision.~~

~~The surrender of respondent's license and the acceptance of the surrendered license by the board shall constitute the imposition of discipline against respondent. This decision constitutes a record of discipline and shall become a part of respondent's license history with the board.~~

~~Respondent understands and agrees that if he or she ever files an application for licensure or a petition for reinstatement in the State of California, the board shall treat it as a new application for licensure.~~

~~Respondent may not apply for any license, permit or registration from the board for three (3) years from the effective date of this decision. Respondent stipulates that should he or she apply for any license from the board on or after the effective date of this decision, all allegations set forth in the [accusation or petition to revoke probation] shall be deemed to be true, correct and admitted by respondent when the board determines whether to grant or deny the application. Respondent shall satisfy all requirements applicable to that license as of the date the application is submitted to the board prior to issuance of a new license. Respondent is required to report this surrender as disciplinary action.~~

~~Respondent further stipulates that he or she shall reimburse the board for its costs of investigation and prosecution in the amount of $_ _____within _____days of the effective date of this decision.~~

~~**Option:** Respondent stipulates that should he or she apply for any license from the board on or after the effective date of this decision, investigation and prosecution costs in the amount of $_____shall be paid to the board prior to issuance of the new license.~~

~~**Public Reprimand**~~

~~It is hereby ordered that a public reprimand be issued against designated representative license, _____. Respondent is required to report this reprimand as a disciplinary action.~~

~~Adoption of Stipulation~~

~~It is understood by respondent that, in deciding whether to adopt this stipulation, the board may receive oral and written communication from its staff and the Office of the Attorney General. Communications pursuant to this paragraph shall not disqualify the board or other persons from future participation in this or any other matter affecting respondent. In the event this settlement is not adopted by the board, the stipulation will not become effective and may not be used for any purpose, except this paragraph, which shall remain in effect.~~

~~**STANDARD CONDITIONS** – To be included in all probation decisions/orders.~~

1. ~~Obey All Laws~~
2. ~~Report to the Board~~
3. ~~Interview with the Board~~
4. ~~Cooperate with Board Staff~~
5. ~~Notice to Employers~~
6. ~~No Being Designated Representative-in-Charge~~
7. ~~Reimbursement of Board Costs~~
8. ~~Probation Monitoring Costs~~
9. ~~Status of License~~
10. ~~License Surrender While on Probation/Suspension~~
11. ~~Notification of a Change in Name, Residence Address, Mailing Address or Employment~~
12. ~~Tolling of Probation~~
13. ~~Violation of Probation~~
14. ~~Completion of Probation~~

~~**OPTIONAL CONDITIONS**~~

15. ~~No Ownership of Licensed Premises~~
16. ~~Attend Substance Abuse Recovery Relapse Prevention and Support Groups~~
17. ~~Random Drug Screening~~
18. ~~Work Site Monitor~~
19. ~~Notification of Departure~~
20. ~~Abstain from Drugs and Alcohol Use~~
21. ~~Tolling of Suspension~~
22. ~~Restitution~~

~~STANDARD CONDITIONS - TO BE INCLUDED IN ALL PROBATIONS~~

~~1. Obey All Laws~~

~~Respondent shall obey all state and federal laws and regulations.~~

~~Respondent shall report any of the following occurrences to the board, in writing, within seventy-two (72) hours of such occurrence:~~

- ~~an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws~~
- ~~an arrest or issuance of a criminal complaint for violation of any state or federal law~~
- ~~a plea of guilty or nolo contendre in any state or federal criminal proceeding to any criminal complaint, information or indictment~~
- ~~a conviction of any crime~~
- ~~discipline, citation, or other administrative action filed by any state or federal agency which involves respondent's _____license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling or distribution or billing or charging for of any drug, device or controlled substance.~~

~~Failure to timely report any such occurrence shall be considered a violation of probation.~~

~~2. Report to the Board~~

~~Respondent shall report to the board quarterly, on a schedule as directed by the board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, respondent shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation. Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the board.~~

~~3. Interview with the Board~~

~~Upon receipt of reasonable prior notice, respondent shall appear in person for interviews with the board or its designee, upon request at such intervals and locations as are determined by the board or its designee. Failure to appear for any scheduled interview without prior notification to board staff, or failure to appear for two (2) or more scheduled interviews with the board or its designee during the period of probation, shall be considered a violation of probation.~~

~~4. Cooperate with Board Staff~~

~~Respondent shall cooperate with the board's inspection program and with the board's monitoring and investigation of respondent's compliance with the terms and conditions of his or her probation. Failure to cooperate shall be considered a violation of probation.~~

~~5. Notice to Employers~~

~~During the period of probation, respondent shall notify all present and prospective employers of the decision in case number _____and the terms, conditions and restrictions imposed on respondent by the decision, as follows:~~

~~Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment, respondent shall cause his or her direct supervisor, designated representative-in-charge (including each new designated representative-in-charge employed during respondent's tenure of employment) and owner to report to the board in writing acknowledging that the listed individual(s) has/have read the decision in case number _____and terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that his or her employer(s) and/or supervisor(s) submit timely acknowledgement(s) to the board.~~

~~If respondent works for or is employed by or through a pharmacy employment service, respondent must notify his or her direct supervisor, designated representative-in-charge and owner at each entity licensed by the board of the terms and conditions of the decision in case number _____in advance of the respondent commencing work at each licensed entity. A record of this notification must be provided to the board upon request.~~

~~Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment by or through a pharmacy employment service, respondent shall cause his or her direct supervisor with the pharmacy employment service to report to the board in writing acknowledging that he or she has read the decision in case number _____and the terms and conditions imposed thereby. It shall be the respondent's responsibility to ensure that his or her employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board.~~

~~Failure to timely notify present or prospective employer(s) or to cause that/those employer(s) to submit timely acknowledgements to the board shall be considered a violation of probation.~~

> ~~"Employment" within the meaning of this provision shall include any full-time, part-time, temporary or relief service or pharmacy management service as a designated representative or in any position for which a designated representative license is a requirement or criterion for employment, whether the respondent is considered an employee or independent contractor or volunteer.~~

~~6. No Being Designated Representative-in-Charge~~

~~During the period of probation, respondent shall not be the designated representative-in-charge of any entity licensed by the board unless otherwise specified in this order. Assumption of any such unauthorized supervision responsibilities shall be considered a violation of probation.~~

~~7. Reimbursement of Board Costs~~

~~As a condition precedent to successful completion of probation, respondent shall pay to the board its costs of investigation and prosecution in the amount of $_____. Respondent shall make said payments as follows: _____. There shall be no deviation from this schedule absent prior written approval by the board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.~~

~~The filing of bankruptcy by respondent shall not relieve respondent of his or her responsibility to reimburse the board its costs of investigation and prosecution.~~

~~8. Probation Monitoring Costs~~

~~Respondent shall pay any costs associated with probation monitoring as determined by the board each and every year of probation. Such costs shall be payable to the board on a schedule as directed by the board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.~~

~~9. Status of License~~

~~Respondent shall, at all times while on probation, maintain an active, current designated representative license with the board, including any period during which suspension or probation is tolled. Failure to maintain an active, current license shall be considered a violation of probation.~~

~~If respondent's designated representative license expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof due to tolling or otherwise, upon renewal or reapplication respondent's license shall be subject to all terms and conditions of this probation not previously satisfied.~~

~~10. License Surrender While on Probation/Suspension~~

~~Following the effective date of this decision, should respondent cease work due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, respondent may tender his or her designated representative license to the board for surrender. The board or its designee shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondent will no longer be subject to the terms and conditions of probation. This surrender constitutes a record of discipline and shall become a part of the respondent's license history with the board.~~

~~Upon acceptance of the surrender, respondent shall relinquish his or her designated representative license to the board within ten (10) days of notification by the board that the surrender is accepted. Respondent may not reapply for any license, permit, or registration from the board for three (3) years from the effective date of the surrender. Respondent shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board.~~

~~11. Notification of a Change in Name, Residence Address, Mailing Address or Employment~~

~~Respondent shall notify the board in writing within ten (10) days of any change of employment. Said notification shall include the reasons for leaving and the address of the new employer, supervisor and owner and work schedule, if known. Respondent shall further notify the board in writing within ten (10) days of a change in name, residence address and mailing address, or phone number.~~
~~Failure to timely notify the board of any change in employer(s), name(s), address(es), or phone number(s) shall be considered a violation of probation.~~

~~12. Tolling of Probation~~

~~Except during periods of suspension, respondent shall, at all times while on probation, be employed as a designated representative in California for a minimum of _____hours per calendar month. Any month during which this minimum is not met shall toll the period of probation, i.e., the period of probation shall be extended by one month for each month during which this minimum is not met. During any such period of tolling of probation, respondent must nonetheless comply with all terms and conditions of probation.~~

~~Should respondent, regardless of residency, for any reason (including vacation) cease working as a designated representative for a minimum of _____hours in California, respondent must notify the board in writing within ten (10) days of cessation of work and must further notify the board in writing within ten (10) days of the resumption of work. Any failure to provide such notification(s) shall be considered a violation of probation.~~

~~It is a violation of probation for respondent's probation to remain tolled pursuant to the provisions of this condition for a total period, counting consecutive and non-consecutive months, exceeding thirty-six (36) months.~~

> ~~"Cessation of work" means any calendar month during which respondent is not working as a designated representative for at least _____hours as a designated representative as defined by Business and Professions Code section 4053.~~
> ~~"Resumption of work" means any calendar month during which respondent is working as a designated representative for at least _____hours as a designated representative as defined by Business and Professions Code section 4053.~~

~~13. Violation of Probation~~

~~If a respondent has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondent, and probation shall automatically be extended until all terms and conditions have been satisfied or the board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed.~~

~~If respondent violates probation in any respect, the board, after giving respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. Notice and opportunity to be heard are not required for those provisions stating that a violation thereof may lead to automatic termination of the stay and/or revocation of the license. If a petition to revoke probation or an accusation is filed against respondent during probation, the board shall have continuing jurisdiction, and the period of probation shall be automatically extended, until the petition to revoke probation or accusation is heard and decided.~~

~~14. Completion of Probation~~

~~Upon written notice by the board indicating successful completion of probation, respondent's designated representative license will be fully restored.~~

~~**OPTIONAL CONDITIONS OF PROBATION**~~

~~**15. No Ownership of Licensed Premises**~~

~~Respondent shall not own, have any legal or beneficial interest in, or serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board. Respondent shall sell or transfer any legal or beneficial interest in any entity licensed by the board within ninety (90) days following the effective date of this decision and shall immediately thereafter provide written proof thereof to the board. Failure to timely divest any legal or beneficial interest(s) or provide documentation thereof shall be considered a violation of probation.~~

~~**Option:** Respondent shall not acquire any new ownership, legal or beneficial interest nor serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any additional business, firm, partnership, or corporation licensed by the board. If respondent currently owns or has any legal or beneficial interest in, or serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board, respondent may continue to serve in such capacity or hold that interest, but only to the extent of that position or interest as of the effective date of this decision. Violation of this restriction shall be considered a violation of probation.~~

~~**16. Attend Substance Abuse Recovery Relapse Prevention and Support Groups** (Appropriate for those cases with chemical dependency (alcohol, drugs))~~

~~Within thirty (30) days of the effective date of this decision, respondent shall begin regular attendance at a recognized and established substance abuse recovery support group in California, (e.g., Alcoholics Anonymous, Narcotics Anonymous, etc.) which has been approved by the board or its designee. Respondent must attend at least one group meeting per week unless otherwise directed by the board or its designee. Respondent shall continue regular attendance and submit signed and dated documentation confirming attendance with each quarterly report for the duration of probation. Failure to attend or submit documentation thereof shall be considered a violation of probation.~~

~~**17. Random Drug Screening** (Appropriate for those cases with chemical dependency (alcohol, drugs))~~

~~Respondent, at his or her own expense, shall participate in random testing, including but not limited to biological fluid testing (urine, blood), breathalyzer, hair follicle testing, or other drug screening program as directed by the board or its designee. Respondent may be required to participate in testing for the entire probation period and the frequency of testing will be determined by the board or its designee. At all times respondent shall fully cooperate with the board or its designee, and shall, when directed, submit to such tests and samples for the detection of alcohol, narcotics, hypnotics, dangerous drugs or other controlled substances as the board or its designee may direct. Failure to timely submit to testing as directed shall be considered a violation of probation. Upon request of the board or its designee, respondent shall provide documentation from a licensed practitioner that the prescription for a detected drug was legitimately issued and is a necessary part of the treatment of the respondent. Failure to timely provide such documentation shall be considered a violation of probation. Any confirmed positive test for alcohol or for any drug not lawfully prescribed by a licensed practitioner as part of a documented medical treatment shall be considered a violation of probation and shall result~~

~~in the automatic suspension of work by respondent. Respondent may not resume work as a designated representative until notified by the board in writing.~~

~~During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs licensed by the board, or any drug manufacturer, or any other location where dangerous drugs and devices or controlled substances are maintained. Respondent shall not perform any of the duties of a designated representative, nor do any act involving drug selection, selection of stock, manufacturing, dispensing; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and devices and controlled substances. Respondent shall not resume work until notified by the board.~~

~~Respondent shall not direct, control or perform any aspect involving the distribution of dangerous drugs and devices and controlled substances. Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed entity in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.~~

~~Failure to comply with this suspension shall be considered a violation of probation.~~

~~**18. Work Site Monitor** (Appropriate for those cases with chemical dependency (alcohol, drugs))~~

~~Within ten (10) days of the effective date of this decision, respondent shall identify a work site monitor, for prior approval by the board, who shall be responsible for supervising respondent during working hours. Respondent shall be responsible for ensuring that the work site monitor reports in writing to the board quarterly. Should the designated work site monitor determine at any time during the probationary period that respondent has not maintained sobriety, he or she shall notify the board immediately, either orally or in writing as directed. Should respondent change employment, a new work site monitor must be designated, for prior approval by the board, within ten (10) days of commencing new employment. Failure to identify an acceptable initial or replacement work site monitor, or to ensure quarterly reports are submitted to the board, shall be considered a violation of probation.~~

~~**19. Notification of Departure** (Appropriate for those cases with chemical dependency (alcohol, drugs))~~

~~Prior to leaving the probationary geographic area designated by the board or its designee for a period greater than twenty-four (24) hours, respondent shall notify the board verbally and in writing of the dates of departure and return. Failure to comply with this provision shall be considered a violation of probation.~~

~~**20. Abstain from Drugs and Alcohol Use** (Appropriate for those cases with chemical dependency (alcohol, drugs))~~

~~Respondent shall completely abstain from the possession or use of alcohol, controlled substances, dangerous drugs and their associated paraphernalia except when the drugs are lawfully prescribed by a licensed practitioner as part of a documented medical treatment. Upon request of the board or its designee, respondent shall provide documentation from the licensed practitioner that the prescription for the drug was legitimately issued and is a necessary part of~~

~~the treatment of the respondent. Failure to timely provide such documentation shall be considered a violation of probation. Respondent shall ensure that he or she is not in the same physical location as individuals who are using illicit substances even if respondent is not personally ingesting the drugs. Any possession or use of alcohol, controlled substances, or their associated paraphernalia not supported by the documentation timely provided, and/or any physical proximity to persons using illicit substances, shall be considered a violation of probation.~~

~~21. Tolling of Suspension~~

~~During the period of suspension, respondent shall not leave California for any period exceeding ten (10) days, regardless of purpose (including vacation). Any such absence in excess of ten (10) days during suspension shall be considered a violation of probation. Moreover, any absence from California during the period of suspension exceeding ten (10) days shall toll the suspension, i.e., the suspension shall be extended by one day for each day over ten (10) days respondent is absent from California. During any such period of tolling of suspension, respondent must nonetheless comply with all terms and conditions of probation.~~

~~Respondent must notify the board in writing within ten (10) days of departure, and must further notify the board in writing within ten (10) days of return. The failure to provide such notification(s) shall constitute a violation of probation. Upon such departure and return, respondent shall not resume work until notified by the board that the period of suspension has been satisfactorily completed.~~

~~22. Restitution~~ ~~(Appropriate in cases of drug diversion, theft, fraudulent billing, or patient harm resulting from negligence or incompetence.)~~

~~Within _____days of the effective date of this decision, respondent shall pay restitution to _____in the amount of $ _____. Failure to make restitution by this deadline shall be considered a violation of probation.~~

TERMS OF PROBATION – PREMISES

A ~~minimum~~ three-year probation period has been established by the board as the minimum appropriate length in most cases where probation is imposed. A minimum five-year probation period has been established by the board as appropriate where self-administration or diversion of dangerous drugs or devices or controlled substances has occurred at a licensed premises. Terms and conditions are imposed to provide consumer protection. A suspension period may also be required as part of the probation order. The board prefers that any stayed order be for revocation rather than for some period of suspension.

Probation conditions are divided into two categories: (1) standard conditions that shall appear in all probation cases, and (2) optional conditions that depend on the nature and circumstances of a particular case. These conditions may vary depending on the nature of the offense(s).

The board may also impose any other condition appropriate to the case where the condition is not contrary to public policy.

CATEGORIES OF VIOLATIONS AND RECOMMENDED PENALTIES

The California Pharmacy Law identifies offenses for which the board may take disciplinary action against a license. Included among grounds for discipline are violations of the Pharmacy Law itself, violations of regulations promulgated by the board, and violations of other state or federal statutes or regulations.

~~The following are categories of possible violations used by the board to determine appropriate disciplinary penalties. These categories represent the judgment of the board as to the perceived seriousness of particular offenses.~~

For those licenses issued to premises the board has identified four (4) categories of violations and associated recommended minimum and maximum penalties for each. These categories of violations are arranged in ascending order from the ~~less~~ least serious (Category I) to the most serious (Category IV), although any violation in any category, or any combination of violation(s) in one or more categories, may merit revocation.

~~Under each category, the board has grouped statutes and regulations where violations would typically merit the recommended range of minimum to maximum penalties for that category. These lists are representative, and are not intended to be comprehensive or exclusive.~~ For each violation category, the board has given offense descriptions and examples where violations would typically merit the recommended range of minimum to maximum penalties for that category. These descriptions and examples are representative, and are not intended to be comprehensive or exclusive. Where a violation not included in these lists is a basis for disciplinary action, the appropriate penalty for that violation may be best derived by comparison to any analogous violation(s) that are included. Where no such analogous violation is listed, the category descriptions may be consulted.

These categories assume a single violation ~~of each listed statute or regulation~~. For multiple violations, the appropriate penalty shall increase accordingly. Moreover, if a~~n~~ ~~individual~~ respondent has committed violations in more than one category, the minimum and maximum penalties shall be those recommended in the highest category.

The board also has the authority, pursuant to Business and Professions Code section 4301(n), to impose discipline based on disciplinary action taken by another jurisdiction. The discipline imposed by the board will depend on the discipline imposed by the other jurisdiction, the extent of the respondent's compliance with the terms of that discipline, the nature of the conduct for which the discipline was imposed, and other factors set forth in these guidelines.

CATEGORY I

Minimum: Revocation; Revocation stayed; ~~one~~ two years probation. All standard terms and conditions shall be included and the disciplinary order may include optional terms and conditions, as appropriate.

Maximum: Revocation

Category I discipline is recommended for violations which are less serious than Categories II through IV but are potentially harmful:

- violation(s) of recordkeeping requirements, scope of practice requirements, or inventory control requirements;
- smaller or isolated failure(s) to abide by or enforce prescription or refill requirements, drug-substitution requirements, or labeling requirements;
- violation(s) of obligations to supply or update information to the board, or to other enforcement or regulatory agencies;
- failure(s) to adequately supervise staff to ensure security and sanitation of premises, dangerous drugs and/or dangerous devices or controlled substances;
- violation(s) of packaging requirements, security control requirements, or reporting requirements; and
- failure(s) to display original license(s), or to supply name(s) of owner(s), manager(s), or employee(s).
- violation(s) involving the improper compounding of drug products
- ~~violations which are relatively minor but are potentially harmful~~
- ~~repeated violations of a relatively minor nature~~

~~Violations of the following codes are representative of this category:~~

~~**BUSINESS AND PROFESSIONS CODE**~~

~~**Article 3. Scope of Practice and Exemptions**~~

~~4053 Exemptee Supervisor of Manufacturer, etc.: Requirements~~
~~4054 Supply by Manufacturer, etc. of Certain Dialysis Drugs and Devices~~
~~4056 Purchase of Drugs at Wholesale – Hospital Containing 100 Beds or Less~~
~~4057 Exceptions to Application of this Chapter~~
~~4058 Display of Original License~~
~~4062 Furnishing Dangerous Drugs During Emergency~~
~~4064 Emergency Refill of Prescription Without Prescriber Authorization~~
~~4065 Injection Card System; Requirements for Administration~~
~~4066 Furnishing Dangerous Drugs to Master or First Officer of Vessel~~

~~Article 4. Requirements for Prescription~~

~~4070 Reduction of Oral or Electronic Prescription to Writing~~
~~4071 Prescriber May Authorize Agent to Transmit Prescription; Schedule II Excluded~~
~~4072 Oral or Electronic Transmission of Prescription - Health Care Facility~~
~~4073 Substitution of Generic Drug - Requirements and Exceptions~~
~~4074 Drug Risk: Informing Patient; Providing Consultation for Discharge Medications~~
~~4076 Prescription Container - Requirements for Labeling~~
~~4077 Dispensing Dangerous Drug in Incorrectly Labeled Container~~

~~Article 5. Authority of Inspectors~~

~~4082 Names of Owners, Managers and Employees Open for Inspection~~

~~Article 6. General Requirements~~

~~4100 Change of Address or Name – Notification to Board~~
~~4103 Blood Pressure - Taking by Pharmacist~~

~~Article 7. Pharmacies~~

~~4114 Intern Pharmacist: Activities Permitted~~
~~4119.5 Transfer or Repackaging Dangerous Drugs by Pharmacy~~
~~4120 Nonresident Pharmacy: Registration Required~~
~~4121 Advertisement for Prescription Drug: Requirements; Restrictions~~
~~4122 Required Notice at Availability of Prescription Price Information, General Product Availability, Pharmacy Services; Providing Drug Price Information; Limitations on Price Information Requests~~
~~4123 Compounding Drug for Other Pharmacy for Parenteral Therapy; Notice to Board~~
~~4124 Dispensing Replacement Contact Lenses: Requirements; Patient Warnings; Registration with Medical Board; Application of Section to Nonresident Pharmacies~~

~~Article 9. Hypodermic Needles and Syringes~~

~~4141 Furnishing Without License~~
~~4142 Prescription Required~~
~~4143 Exemption: Sale to Other Entity, Physician, etc.~~
~~4144 Industrial Use Exception~~
~~4145 Exception: Furnishing for Administration of Insulin, Adrenaline, or Specified Animal Uses; Conditions~~
~~4148 Confiscation if Found Outside Licensed Premises~~
~~4149 Sale by Distributor~~

~~Article 10. Pharmacy Corporations~~

~~4151 Licensure Requirements~~
~~4152 Corporate Name Requirements~~
~~4153 Shareholder Income While Disqualified~~
~~4156 Unprofessional Conduct by Corporation~~

~~Article 11. Wholesalers and Manufacturers~~

~~4161 Nonresident Wholesaler: When License Required; Application~~

~~4162 Issuance or Renewal of Wholesaler License; Surety Bond~~
~~4164 Reports Required~~
~~4165 Sale or Transfer of Dangerous Drug or Device Into State: Furnishing Records to Authorized Officer on Demand; Citation for Non-compliance~~
~~4166 Shipping of Dangerous Drugs or Devices – Wholesaler or Distributor~~
~~4167 Wholesaler: Bar on Obtaining Dangerous Drugs or Devices It Cannot Maintain on Licensed Premises~~

~~Article 13. Non-Profit or Free Clinics~~

~~4180 Purchase of Drugs at Wholesale Only with License: Eligible Clinics~~
~~4181 License Requirements; Policies and Procedures; Who May Dispense~~
~~4182 Duties of Professional Director; Consulting Pharmacist Required~~
~~4183 No Professional Dispensing Fee~~
~~4184 Dispensing Schedule II Substance Prohibited~~
~~4186 Automated Drug Delivery Systems~~

~~Article 14. Surgical Clinics~~

~~4190 Purchase of Drugs at Wholesale: Permitted Uses of Drugs; Required Records and Policies; License Required~~
~~4191 Compliance with Department of Health Services Requirements; Who May Dispense Drugs~~
~~4192 Duties of Professional Director; Providing Information to Board~~
~~4193 Clinic Not Eligible for Professional Dispensing Fee; Ban on Offering Drugs for Sale~~
~~4194 Dispensing of Schedule II Substance by Clinic Prohibited; Physician May Dispense; Administration Authorized in Clinic~~

~~Article 15. Veterinary Food-Animal Drug Retailers~~

~~4196 License Required: Temporary License on Transfer of Ownership; Persons Authorized in Storage Area~~
~~4197 Minimum Standards: Security; Sanitation; Board Regulations; Waivers~~
~~4198 Written Policies and Procedures Required: Contents; Training of Personnel; Quality Assurance; Consulting Pharmacist~~

~~Article 17. Continuing Education~~

~~4231 Requirements for Renewal of Pharmacist License: Clock Hours; Exemption for New Licensee~~
~~4232 Content of Courses~~

~~Article 18. Poisons~~

~~4240 Application of Act~~

~~Article 20. Prohibitions and Offenses~~

~~4341 Advertisement of Prescription Drugs or Devices~~
~~4343 Buildings: Prohibition Against Use of Certain Signs Unless Licensed Pharmacy Within~~

~~CALIFORNIA CODE OF REGULATIONS, TITLE 16~~

~~1704 Change of Address~~
~~1705 Notification of Bankruptcy, Receivership or Liquidation~~
~~1708.2 Discontinuance of Business~~
~~1708.4 Pharmacist Handling Radioactive Drugs~~
~~1708.5 Pharmacy Furnishing Radioactive Drugs~~
~~1709 Names of Owners and Pharmacist in Charge~~
~~1714 Operational Standards and Security~~
~~1715.6 Reporting Drug Loss~~
~~1716 Variation from Prescriptions~~
~~1717 Pharmaceutical Practice~~
~~1717.1 Common Electronic Files~~
~~1717.4 Electronic Transmission of Prescriptions~~
~~1718.1 Manufacturer's Expiration Date~~
~~1726 Supervision of Intern Pharmacists~~
~~1728 Requirements for Examination~~
~~1732.1 Requirements for Accredited Providers~~
~~1732.3 Requirements for Continuing Education Courses~~
~~1732.4 Provider Audit Requirements~~
~~1732.5 Renewal Requirements for Pharmacist~~
~~1744 Drug Warnings~~
~~1751 Sterile Injectable Compounding Area~~
~~1751.01 Facility and Equipment Standards for Sterile Injectable Compounding from Non-Sterile Ingredients~~
~~1751.02 Policies and Procedures~~
~~1751.11 Furnishing to Home Health Agencies and Licensed Hospices~~
~~1751.12 Obligations of a Pharmacy Furnishing Portable Containers~~
~~1771 Posting of Notice of Suspension~~
~~1772 Disciplinary Condition of Suspension~~
~~1780 Minimum Standards for Wholesalers~~
~~1780.1 Minimum Standards for Veterinary Food-Animal Drug Retailers~~
~~1781 Exemption Certificate~~
~~1786 Exemptions~~
~~1787 Authorization to Distribute Hemodialysis Drugs and Devices~~
~~1790 Assembling and Packaging~~
~~1791 Labeling~~
~~1792 Receipt for Shipment~~

~~HEALTH AND SAFETY CODE~~

~~11100 Report of Certain Chemical: Chemicals Included; Exclusions; Penalties~~
~~11100.1 Report of Chemicals Received from Outside State; Penalties~~
~~11151 Limitation on Filling Prescriptions From Medical Students~~
~~11158 Prescription Required for Schedule II, III, IV, or V Controlled Substance; Exception for Limited Dispensing, Administration~~
~~11159 Chart Order Exemption for Patient in County or Licensed Hospital; Maintaining Record for Seven Years~~

~~11159.1 Chart Order Exemption for Clinic Patient; Maintaining Record for Seven Years~~
~~11159.2 Exception to Triplicate Prescription Requirement~~
~~11167 Emergency Dispensing of Schedule II Substance: Circumstances and Requirements~~
~~11167.5 Oral or Electronic Prescriptions for Schedule II Controlled Substance for Specified Inpatients, Residents, and Home Hospice Patients; Requirements~~
~~11171 Prescribing, etc. Controlled Substance Only as Authorized~~
~~11172 Antedating or Postdating Prescription Prohibited~~
~~11175 Prohibition on Obtaining or Possessing Nonconforming Prescription; Prohibition on Obtaining Controlled Substance by Nonconforming Prescription~~
~~11180 Prohibition on Controlled Substance Obtained or Possessed by Nonconforming Prescription~~
~~11200 Restrictions on Dispensing or Refilling; Refill of Schedule II Prescription Barred~~
~~11201 Emergency Refill of Schedule III, IV, or V Prescription; Circumstances; Requirements~~
~~11205 Maintenance and Retention of Records in Separate File~~
~~11206 Required Information on Prescription~~
~~11209 Delivery and Receiving Requirements for Schedule II, III, and IV Substances; Violation~~
~~11210 Issuing Prescription: By Whom; For What Purpose; Quantity to Be Prescribed~~
~~11250 Authorized Retail Sale by Pharmacists to Physicians, etc.; Required Order Form~~
~~11251 Authorized Wholesale Sale by Pharmacists~~
~~11252 Preservation of Federally Required Forms~~
~~11253 Duration of Retention~~
~~11255 Actions Constituting Sale~~
~~11256 Required Report of Order By or Sale to Out-of-State Wholesaler or Manufacturer~~
~~111225 to~~
~~111655 Adulterated or Misbranded Drugs or Devices~~

~~CODE OF FEDERAL REGULATIONS, TITLE 21~~

~~1301.13 Application for registration; time for application; expiration date; registration for independent activities; application forms, fees, contents and signature; coincident activities.~~
~~1301.14 Filing of application; acceptance for filing; defective applications.~~
~~1301.71 Security requirements generally.~~
~~1301.72 Physical security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs; storage areas.~~
~~1301.73 Physical security controls for non-practitioners; compounders for narcotic treatment programs; manufacturing and compounding areas.~~
~~1301.74 Other security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs.~~
~~1301.77 Security controls for freight forwarding facilities.~~
~~1301.90 Employee screening procedures.~~
~~1301.91 Employee responsibility to report drug diversion.~~
~~1301.92 Illicit activities by employees.~~
~~1302.03 Symbol required; exceptions.~~
~~1302.04 Location and size of symbol on label and labeling.~~
~~1302.05 Effective dates of labeling requirements.~~
~~1302.06 Sealing of controlled substances.~~
~~1302.07 Labeling and packaging requirements for imported and exported substances.~~

~~1304.11 Inventory requirements.~~
~~1304.31 Reports from manufacturers importing narcotic raw material.~~
~~1304.32 Reports of manufacturers importing coca leaves.~~
~~1304.33 Reports to ARCOS.~~
~~1305.03 Distributions requiring a Form 222 or a digitally signed electronic order.~~
~~1305.04 Persons entitled to order Schedule I and II controlled substances.~~
~~1305.05 Power of attorney.~~
~~1305.06 Persons entitled to fill orders for Schedule I and II controlled substances.~~
~~1305.11 Procedure for obtaining DEA Forms 222.~~
~~1305.12 Procedure for executing DEA Forms 222.~~
~~1305.14 Procedure for endorsing DEA Forms 222.~~
~~1305.15 Unaccepted and defective DEA Forms 222.~~
~~1305.16 Lost and stolen DEA Forms 222.~~
~~1306.03 Persons entitled to issue prescriptions.~~
~~1306.05 Manner of issuance of prescriptions.~~
~~1306.14 Labeling of substances and filling of prescriptions.~~
~~1306.24 Labeling of substances and filing of prescriptions.~~
~~1306.25 Transfer between pharmacies of prescription information for Schedules III, IV, and V controlled substances for refill purposes.~~
~~1306.26 Dispensing without a prescription.~~
~~1307.11 Distribution by dispenser to another practitioner or reverse distributor.~~
~~1307.12 Distribution to supplier or manufacturer.~~
~~1307.13 Incidental manufacture of controlled substances.~~
~~1307.21 Procedure for disposing of controlled substances.~~
~~1700.1 to~~
~~1707.15 Child-resistant containers.~~

CATEGORY II

Minimum: Revocation; Revocation stayed, three years probation (five years probation where self-administration or diversion of dangerous drugs and/or dangerous devices or controlled substances occurred at the licensed premises). All standard terms and conditions shall be included and the disciplinary order may include optional terms and conditions, as appropriate.

Maximum: Revocation

Category II discipline is recommended for violations with serious potential for harm, as well as for violations involving disregard for public safety or for laws or regulations pertaining to pharmacy and/or to the dispensing or distributing of dangerous drugs and/or dangerous devices or controlled substances, violations that reflect on ethics, competency, or diligence, and criminal convictions not involving alcohol, dangerous drugs and/or dangerous devices, or controlled substances. Violations in this category may include:

- failure(s) to abide by prohibitions on referral rebates or discounts (kickbacks) and/or volume or percentage-based lease agreements;
- violation(s) of advertising or marketing limitations, including use of false or misleading advertising or marketing;
- repeat or serious violation(s) of recordkeeping requirements, scope of practice requirements, or inventory control requirements;

- violation(s) of controlled substance secure prescription requirements, inventory controls, or security requirements;
- failure(s) to meet compliance requirements, including pharmacist-in-charge or designated representative-in-charge designation and duties;
- violation(s) of monitoring and reporting requirements with regard to chemically, mentally, or physically impaired licensees or employees;
- repeat or serious failure(s) to adequately supervise staff or ensure security and sanitation of premises, dangerous drugs and/or dangerous devices or controlled substances;
- violation(s) of laws governing dangerous drugs and/or dangerous devices and controlled substances, including smaller cases of diversion or self-administration;
- unlawful possession(s) of dangerous drugs and/or dangerous devices, controlled substances, hypodermic needles or syringes, or drug paraphernalia;
- smaller scale dispensing or furnishing of dangerous drugs and/or dangerous devices via the internet, without a valid prescription;
- purchasing, trading, selling, or transferring dangerous drugs and/or dangerous devices to or from unauthorized person(s);
- failure(s) to make required reports to the board or to other regulatory agencies, including CURES obligations and reporting to the DEA;
- violation(s) of quality assurance and self-assessment obligations, failure(s) to ensure properly trained staff and conduct practice safely;
- failure~~(s)~~ to perform drug utilization reviews, monitor patient medication profiles, or promote safety and efficacy of prescribed drugs or devices or controlled substances;
- repeat or serious deviation(s) from the requirements of prescription(s) or failure(s) to clarify erroneous or uncertain prescription(s);
- gross immorality, incompetence, gross negligence, clearly excessive furnishing of controlled substances, moral turpitude, dishonestly, or fraud;
- criminal conviction(s) not involving alcohol, dangerous drugs and/or dangerous devices or controlled substances;
- violating, assisting in or abetting violation of, or conspiring to violate the laws and regulations governing pharmacy; and
- subverting or attempting to subvert an investigation conducted by the board.
- repeat or serious violation(s) involving the improper compounding of drug products

- ~~violations with a serious potential for harm~~
- ~~violations which involve greater disregard for pharmacy law and public safety~~
- ~~violations which reflect on ethics, care exercised or competence or a criminal conviction not involving dangerous drugs or controlled substances or involving possession or use of dangerous drugs or controlled substances.~~

~~Violations of the following codes are representative of this category:~~

~~BUSINESS AND PROFESSIONS CODE~~

~~650 Rebates or Discounts for Referral Prohibited~~
~~650.1 Lease Prohibition – Hospitals or Prescribers~~
~~651 Professional Advertising Requirements~~

~~Article 3. Scope of Practice and Exemptions~~

~~4051(b) Conduct Authorized by Pharmacist~~
~~4052 Furnishing to Prescriber; Permissible Procedures by Pharmacist in Health Care~~

~~Facility or Clinic or for Other Health Care Provider~~
~~4060 Controlled Substance – Prescription Required; Exceptions~~
~~4061 Distribution of Drug as Sample; Written Request Required~~
~~4064 Emergency Refill of Prescription Without Prescriber Authorization~~
~~4067 Internet; Dispensing Dangerous Drugs or Devices without Prescription~~
~~4075 Proof of Identity Required – Oral or Electronic Prescription~~
~~4078 False or Misleading Label on Prescription~~

~~Article 6. General Requirements~~

~~4101 Pharmacist in Charge, Exemptee: Termination of Employment; Notification to Board~~
~~4104 Licensed Employee, Theft or Impairment: Pharmacy Procedures~~
~~4105 Retaining Records of Dangerous Drugs and Devices on Licensed Premises; Temporary Removal; Waivers; Access to Electronically Maintained Records~~

~~Article 7. Pharmacies~~

~~4112 Nonresident Pharmacy: Registration; Provision of Information to Board; Maintaining Records; Patient Consultation~~
~~4113 Pharmacist in Charge: Notification to Board; Responsibilities~~
~~4115 Pharmacy Technician: Activities Permitted; Required Supervision; Activities Limited to Pharmacist; Registration; Requirements for Registration; Ratios~~
~~4115.5 Pharmacy Technician Trainee; Placement; Supervision; Requirements~~
~~4116 Security of Dangerous Drugs and Devices in Pharmacy: Pharmacist Responsibility for Individuals on Premises; Regulations~~
~~4117 Admission to Area Where Narcotics are Stored, etc. – Who May Enter~~
~~4120 Nonresident Pharmacy: Registration Required~~
~~4125 Pharmacy Quality Assurance Program Required; Records Considered Peer Review Documents~~

~~Article 9. Hypodermic Needle and Syringes~~

~~4140 Unlawful Possession~~
~~4147 Disposal of Needle or Syringe~~

~~Article 11. Wholesalers and Manufacturers~~

~~4161 Nonresident Wholesaler: When License Required; Application~~
~~4163 Unauthorized Furnishing by Manufacturer or Wholesale~~
~~4164 Reports Required~~
~~4169(a)(1) Prohibited Acts~~

~~Article 13. Non-Profit of Free Clinics~~

~~4185 Inspection Permitted~~

~~Article 14. Surgical Clinics~~

~~4195 Inspection Permitted~~

~~Article 19. Disciplinary Proceedings~~

~~4301 Unprofessional Conduct - subsections (a)-(h), (j), and (l) - (q)~~

~~4302 Discipline of Corporate Licensee for Conduct of Officer, Director, Shareholder~~
~~4303 Nonresident Pharmacy: Grounds for Discipline~~
~~4304 Out-of-state Distributor: Authority to Discipline~~
~~4305 Disciplinary Grounds: Failure of Pharmacy, Pharmacist to Notify Board of Termination of Pharmacist in Charge; Continuing to Operate Without Pharmacist~~
~~4305.5 Disciplinary Grounds: Failure of Other Entity Licensed by Board, of Pharmacist or Exemptee to Notify Board of Termination of Pharmacist in Charge or Exemptee; Continuing to Operate Without Pharmacist or Exemptee~~
~~4306 Violation of Professional Corporation Act as Unprofessional Conduct~~
~~4306.5 Misuse of Education, etc. by Pharmacist Outside Course of Practice of Pharmacy as Unprofessional Conduct~~

~~Article 20. Prohibitions and Offenses~~

~~4326 Misdemeanor: Obtaining Needle or Syringe by Fraud, etc.; Unlawful Use of Needle or Syringe Obtained from Another~~
~~4328 Misdemeanor: Permitting Compounding, Dispensing, or Furnishing by Non-pharmacist~~
~~4330 Misdemeanor: Non-pharmacist Owner Failing to Place Pharmacist in Charge, Dispensing or Compounding Except by Pharmacist, Interfering with Pharmacist in Charge~~
~~4331 Misdemeanor: Medical Device Retailer, Wholesaler, Veterinary Food-Animal Drug Retailer Failing to Place Pharmacist or Exemptee in Charge, Permitting Dispensing or Compounding Except by Pharmacist or Exemptee~~
~~4333 Maintaining Prescriptions, Other Drug Records on Premises, Open to Inspection; Waiver; Willful Failure to Keep or Permit Inspection of Records of Prescriptions, Other Records as Misdemeanor~~
~~4340 Unlawful Advertising by Nonresident Pharmacy Not Registered with Board~~

~~Article 22. Unfair Trade Practices~~

~~4380 Resale of Preferentially Priced Drugs; Prohibition; Exceptions~~
~~4382 Board May Audit Sales to Walk-in Customers~~

~~CALIFORNIA CODE OF REGULATIONS, TITLE 16~~

~~1707.1 Duty to Maintain Medication Profiles (Patient Medication Records)~~
~~1707.2 Notice to Consumers and Duty to Consult~~
~~1707.3 Duty to Review Drug Therapy and Patient Medication Record Prior to Deliver~~
~~1709.1 Designation of Pharmacist in Charge~~
~~1714.1 Pharmacy Operation During Temporary Absence of a Pharmacist~~
~~1715 Self-Assessment of a Pharmacy by the Pharmacist-in-Charge~~
~~1715.5 Implementation of Electronic Monitoring of Schedule II Prescriptions~~
~~1716.1 Compounding Unapproved Drugs for Prescriber Office Use~~
~~1716.2 Record Requirements-Compounding for Future Furnishing~~
~~1717.2 Notice of Electronic Prescription Files~~
~~1717.3 Preprinted, Multiple Checkoff Prescription Blanks~~
~~1723.1 Confidentiality of Examination Questions~~
~~1745 Partial Filling of Schedule II Prescriptions~~
~~1751.10 Furnishing to Parenteral Patient at Home~~

~~1761(a) Erroneous or Uncertain Prescriptions~~
~~1764 Unauthorized Disclosure of Prescriptions~~
~~1765 Commissions, Gratuities, and Rebates~~
~~1766 False or Misleading Advertising~~
~~1775.3 Compliance with Orders of Abatement~~
~~1782 Reporting Sales of Drugs Subject to Abuse~~
~~1783 Manufacturer or Wholesaler Furnishing Drugs or Devices~~
~~1793.1 Duties of a Pharmacist~~
~~1793.2 Duties of a Pharmacy Technician~~
~~1793.3 Other Non-Licensed Pharmacy Personnel~~
~~1793.4 Qualifications for Registration as a Pharmacy Technician~~
~~1793.7 Requirements for Pharmacies Employing Pharmacy Technicians~~
~~1793.8 Technicians in Hospitals with Clinical Pharmacy Programs~~

~~HEALTH AND SAFETY CODE~~

~~11103 Report of Theft, Loss, or Shipping Discrepancy~~
~~11150 Persons Authorized to Write or Issue a Prescription~~
~~11152 Nonconforming Prescriptions Prohibited~~
~~11154 Prescription, etc. Must Be for Treatment; Knowing Soliciting of Unlawful Prescription, etc.~~
~~11156 Prescribing, etc. Controlled Substances to Addict Only as Authorized~~
~~11164 Prescriptions for Schedule II, III, IV and V Controlled Substance: Form and Content; Record of Practitioner Dispensing Schedule II Controlled Substance~~
~~11165(d) CURES Transmission~~
~~11166 Time Limit for Filling Schedule II Prescription; Knowingly Filling Mutilated, Forged, or Altered Prescription Prohibited~~
~~11170 Prohibition on Prescribing, etc. Controlled Substance for Self~~
~~11179 Retention of Controlled Substance Prescription~~
~~11207 Only Pharmacist or Intern Authorized to Fill Prescription~~
~~11209 Delivery and Receiving Requirements for Schedule II, III, and IV Substances; Violation~~
~~11350 Possession of Specified Controlled Substance~~
~~11377 Unlawful Possession of Specified Substance~~

~~CODE OF FEDERAL REGULATIONS, TITLE 21~~

~~1304.03 Persons required to keep records and file reports.~~
~~1304.04 Maintenance of records and inventories.~~
~~1304.11 Inventory requirements.~~
~~1304.21 General requirements for continuing records.~~
~~1304.22 Records for manufacturers, distributors, dispensers, researchers, importers and exporters.~~
~~1305.07 Special procedures for filling certain orders.~~
~~1305.13 Procedure for filling DEA Forms 222.~~
~~1306.04 Purpose of issue of prescription.~~
~~1306.06 Persons entitled to fill prescriptions.~~
~~1306.11 Requirement prescription.~~
~~1306.12 Refilling prescriptions.~~

~~1306.13 Partial filling of prescriptions.~~
~~1306.21 Requirement of prescription.~~
~~1306.22 Refilling of prescriptions.~~
~~1306.23 Partial filling of prescriptions.~~

CATEGORY III

Minimum: Revocation; Revocation stayed, 90 days actual suspension, three to five years probation (five years probation where self-administration or diversion of dangerous drugs and/or dangerous devices or controlled substances, or abusive use of alcohol, occurred at the licensed premises). All standard terms and conditions shall be included and the disciplinary order may include optional terms and conditions, as appropriate.

Maximum: Revocation

Category III discipline is recommended for violations where potential for harm is greater, more imminent, or more serious than it is for Category II violations, as well as for violations that involve knowingly or willfully violating laws or regulations pertaining to pharmacy and/or to the dispensing or distributing of dangerous drugs and/or dangerous devices or controlled substances, and most criminal convictions involving alcohol, dangerous drugs and/or dangerous devices or controlled substances. Violations in this category may include:

- violation(s) involving creation, manipulation, perpetuation, or disregard of drug shortages;
- failure(s) to deploy or abide by electronic pedigree requirements for dangerous drugs;
- violation(s) of licensee's corresponding responsibility to ensure the proper prescribing and dispensing of controlled substances;
- dispensing or furnishing without valid prescription, dispensing or furnishing to unauthorized person(s);
- violation(s) involving fraudulent acts committed in connection with the licensee's practice;
- repeat or serious unlawful possession(s) of dangerous drugs and/or dangerous devices,
  controlled substances, hypodermic needles or syringes, or drug paraphernalia;
- larger scale dispensing or furnishing of dangerous drug(s) and/or dangerous device(s) via the internet, without valid prescription(s);
- purchasing, trading, selling, or transferring adulterated, misbranded, or expired dangerous drug(s) and/or dangerous device(s);
- removal, sale, or disposal of embargoed dangerous drug(s) and/or dangerous device(s);
- failing to maintain record(s) of acquisition and disposition of dangerous drug(s) and/or dangerous devise(s) or controlled substances
- resale(s) of preferentially prices drugs, contract bid diversion, or other instances of improper sale(s) or resale(s);
- repeat or serious violation(s) of quality assurance and self-assessment obligations, failure(s) to ensure properly trained staff and conduct practice safely;
- repeat or serious failure(s) to perform drug utilization reviews, monitor patient medication profiles, or promote safety and efficacy of prescribed drugs;
- forgery of prescriptions, passing of forged prescriptions, or other unlawful means of acquiring dangerous drug(s) and/or dangerous device(s) or controlled substances(s);
- repeat or serious acts violating, assisting in or abetting violation of, or conspiring to

violate the laws and regulations governing pharmacy; and

- violation(s) involving providing or offering to provide controlled substance(s) to addict(s).
- repeat or serious violation(s) involving the improper compounding of drug products
- ~~most criminal convictions involving dangerous drugs or controlled substances~~
- ~~knowing or willfully violating laws or regulations pertaining to dispensing or distributing dangerous drugs or controlled substances~~
- ~~fraudulent acts committed in connection with the licensee's practice~~
- ~~drug shortages~~
- ~~violation of a licensee's corresponding responsibility.~~

~~Violations of the following codes are representative of this category:~~

~~**BUSINESS AND PROFESSIONS CODE**~~

~~**Article 3. Scope of Practice and Exemptions**~~

~~4051(a) Conduct Limited to Pharmacist~~
~~4059 Furnishing Dangerous Drugs or Devices Prohibited Without Prescription: Exceptions~~
~~4059.5 Who May Order Dangerous Drugs or Devices: Exceptions~~

~~**Article 5. Authority of Inspectors**~~

~~4080 Stock of Dangerous Drugs and Devices Kept Open for Inspection~~
~~4081 Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory~~
~~4085(a) Unlawful to Remove, Sell, Dispose of Embargoed Dangerous Drug or Dangerous Device~~

~~**Article 7. Pharmacies**~~

~~4110 License Required; Temporary Permit Upon Transfer of Ownership~~
~~4111 Restrictions on Prescriber Ownership~~

~~**Article 11. Wholesalers and Manufacturers**~~

~~4169(a)(2) to~~
~~4169(a)(5) Prohibited Acts~~

~~**Article 15. Veterinary Food-Animal Retailers**~~

~~4199 Labeling Requirements; Maintaining Prescription Records~~

~~**Article 19. Disciplinary Proceedings**~~

~~4301 Unprofessional Conduct - subsections (i) - (k) and (o)~~
~~4307 Prohibition of Association of Individual with Entity License by Board: Length of Prohibition; Individuals Covered; Imposition of Prohibition Through Administrative Act Proceeding~~
~~4308 Prohibited Association: Notification of Affected Licensees Known to Board~~

~~Article 20. Prohibitions and Offenses~~

~~4322 Misdemeanor or Infraction: False Representations to Secure License for Self or Others; False Representation of Licensure; Penalties~~
~~4323 Misdemeanor: False Representation of Self as Physician, Agent of Physician, etc. to Obtain Drug~~
~~4324 Felony or Misdemeanor: Forgery of Prescription; Possession of Drugs Obtained Through Forged Prescription~~
~~4325 Misdemeanor: Manufacture, Possession, etc. of False Prescription Blank~~
~~4327 Misdemeanor: Sale, Dispensing, or Compounding While Under the Influence of Drugs or Alcoholic Beverages~~
~~4329 Misdemeanor: Non-pharmacist Acting as Manager, Compounding, Dispensing or Furnishing Drugs~~
~~4332 Misdemeanor: Failure or Refusal to Maintain or Produce Required Drug or Device Records; Willful Production of False Records~~
~~4335 Voided License: Knowing Failure to Arrange for Disposition of Stock as Misdemeanor~~
~~4336 Felony: Knowing or Willful Use of Minor to Violate Specified Sections of Pharmacy Law: Exception for Pharmacist Furnishing Pursuant to a Prescription~~

~~Article 22. Unfair Trade Practices~~

~~4380 Resale of Preferentially Priced Drugs: Prohibition; Exceptions~~

~~CALIFORNIA CODE OF REGULATIONS, TITLE 16~~

~~1718 Current Inventory Defined~~
~~1761(b) Erroneous or Uncertain Prescriptions~~
~~1771 Posting of Notice of Suspension~~
~~1772 Disciplinary Condition of Suspension~~
~~1773 Disciplinary Conditions of Probation of Pharmacist~~
~~1774 Disciplinary Conditions of Probation of Permit~~

~~HEALTH AND SAFETY CODE~~

~~11104 Providing Chemical for Illicit Manufacturing; Evasion of Reporting Requirements; Penalties~~
~~11105 False Statement in Report~~
~~11150 Persons Authorized to Write or Issue a Prescription~~
~~11153 Responsibility for Legitimacy of Prescription; Corresponding Responsibility of Pharmacist~~
~~11153.5 Wholesaler or Manufacturer Furnishing Controlled Substance Other Than for Legitimate Medical Purpose; Knowing Violation; Factors in Assessing Legitimacy~~
~~11157 No False or Fictitious Prescriptions~~
~~11162.5 Counterfeiting or Possession of Counterfeit Triplicate Prescription Blank; Penalty~~
~~11167.5 Pharmacy Generated Prescription for Schedule II Controlled Substance in a Skilled Nursing Facility~~
~~11173 Fraud, Deceit, Misrepresentation or False Statement; False Representation; False Label~~

~~11174 Prohibition on Providing False Name or Address in Connection with Prescription, etc.~~
~~11351 Possession or Purchase for Sale of Specified Controlled Substance~~
~~11368 Forged or Altered Prescriptions~~
~~11375 Possession for Sale or Selling Specified Substance~~
~~11378 Possession for Sale~~
~~11550 Using or Being Under Influence of Controlled Substance~~
~~111295 Manufacturing, Selling or Offering for Sale an Adulterated Drug or Device~~
~~111300 Unlawful to Adulterate a Drug~~
~~111305 Unlawful to Receive in Commerce an Adulterated Drug~~
~~111440 Unlawful Manufacturer, selling a misbranded Drug~~
~~111445 Unlawful for a Person to Misbrand~~
~~111450 Unlawful to Receive into Commerce a Drug that is Misbranded~~

CATEGORY IV

Penalty: Revocation

Category IV discipline (~~Revocation~~ revocation) is recommended for the most serious violations of ~~the Uniform Controlled Substance Act (Heath and Safety Code 11000 et seq.) involving~~ laws or regulations pertaining to pharmacy and/or to the dispensing or distributing of dangerous drugs and/or dangerous devices or controlled substances. Violations in this category may include:

- violation(s) involving possession for sale, transportation, importation, and/or use of a minor for unlawful acquisition of sale, of controlled substances;
- criminal conviction(s) involving the above, or repeat convictions involving diversion or abuse of alcohol, dangerous drugs and/or dangerous devices, or controlled substances; and
- repeat or serious example(s) of conduct described in Category I, Category II, or Category III.
- ~~possession for sale~~
- ~~transportation~~
- ~~importation~~
- ~~sale~~
- ~~use of a minor for the unlawful sale of controlled substances~~

Revocation is also recommended ~~when~~ where a respondent fails to file a notice of defense to a pleading requiring a timely notice of defense or to appear at a disciplinary hearing, where a respondent violates the terms and conditions of probation from a previous disciplinary order, or where prior discipline has been imposed on the license.~~:~~

- ~~a respondent fails to file a notice of defense or to appear at a disciplinary hearing where the board has requested revocation in the accusation~~
- ~~a respondent violates the terms and conditions of probation from a previous disciplinary order~~
- ~~prior discipline has been imposed, as progressive discipline unless the respondent can demonstrate satisfactory evidence of rehabilitation.~~

~~Violations of the following codes are representative of this category:~~

~~**HEALTH AND SAFETY CODE**~~

~~11352 Importing, Selling, Furnishing Controlled Substance~~

~~11353 Adult Inducing Minor to Violate Provisions~~
~~11379 Transporting, Importing, Selling Controlled Substance~~
~~11380 Adult Using, Soliciting or Intimidating Minor for Violation~~

MODEL DISCIPLINARY LANGUAGE - PREMISES

The following standardized language shall be used in every decision where the order or condition is imposed.

Revocation

License number _____, issued to respondent _____, is revoked.

Respondent ~~owner~~ shall, by the effective date of this decision, arrange for the destruction of, the transfer to, sale of or storage in a facility licensed by the board of all dangerous drugs and/or dangerous devices or controlled substances and dangerous drugs and/or dangerous devices. Respondent shall further arrange for the transfer of all records of acquisition and disposition of dangerous drugs to premises licensed and approved by the board. Respondent ~~owner~~ shall provide written proof of such disposition, submit a completed Discontinuance of Business form and return the wall and renewal license to the board within five (5) days of disposition.

~~**Option:**~~ Respondent ~~owner~~ shall also, by the effective date of this decision, arrange for the continuation of care for ongoing patients of the pharmacy by, at minimum, providing a written notice to ongoing patients that specifies the anticipated closing date of the pharmacy and that identifies one or more area pharmacies capable of taking up the patients' care, and by cooperating as may be necessary in the transfer of records or prescriptions for ongoing patients. Within five (5) days of its provision to the pharmacy's ongoing patients, Respondent ~~owner~~ shall provide a copy of the written notice to the board. For the purposes of this provision, "ongoing patients" means those patients for whom the pharmacy has on file a prescription with one or more refills outstanding, or for whom the pharmacy has filled a prescription within the preceding sixty (60) days.

Suspension

License number _____, issued to respondent _____is suspended for a period of _____days beginning the effective of this decision.

Respondent shall cease all ~~pharmacy~~ operations as a [insert license type] during the period of suspension. Failure to comply with this suspension shall be considered a violation of probation.

Standard Stay/Probation Order

License number _____, issued to respondent, is revoked; however, the revocation is stayed and respondent is placed on probation for _____years ~~upon~~ on the following terms and conditions:

Issuance of Probationary License (In cases where a Statement of Issues has been filed.)

Upon satisfaction of all statutory and regulatory requirements for issuance of a [insert license type] license, a license shall be issued to respondent and immediately revoked; the order of revocation is stayed and respondent is placed on probation for _____years ~~upon~~ on the following terms and conditions:

Surrender

Respondent ~~owner~~ surrenders license number _____as of the effective date of this decision. Respondent ~~owner~~ shall relinquish the premises wall license and renewal license to the board within ten (10) days of the effective date of this decision.

The surrender of respondent's license and the acceptance of the surrendered license by the board shall constitute the imposition of discipline against respondent. This decision constitutes a record of discipline and shall become a part of respondent's license history with the board.

Respondent ~~owner~~ shall, within ten (10) days of the effective date, arrange for the destruction of, the transfer to, sale of or storage in a facility licensed and approved by the board of all controlled substances and dangerous drugs and/or dangerous devices. Respondent shall further arrange for the transfer of all records of acquisition and disposition of dangerous drugs to premises licensed and approved by the board. Respondent ~~owner~~ shall further provide written proof of such disposition and submit a completed Discontinuance of Business form according to board guidelines.

~~Respondent owner shall also, by the effective date of this decision, arrange for the continuation of care for ongoing patients of the pharmacy by, at minimum, providing a written notice to ongoing patients that specifies the anticipated closing date of the pharmacy and that identifies one or more area pharmacies capable of taking up the patients' care, and by cooperating as may be necessary in the transfer of records or prescriptions for ongoing patients. Within five days of its provision to the pharmacy's ongoing patients, Respondent owner shall provide a copy of the written notice to the board. For the purposes of this provision, "ongoing patients" means those patients for whom the pharmacy has on file a prescription with one or more refills outstanding, or for whom the pharmacy has filled a prescription within the preceding sixty (60) days.~~

~~Respondent owner understands and agrees that if he or she [he/she] ever files an application for a licensed premises or a petition for reinstatement in the State of California, the board shall treat it as a new application for licensure.~~

Respondent may only seek a new or reinstated license from the board by way of a new application for licensure. Respondent shall not be eligible to petition for reinstatement of licensure.

Respondent ~~owner~~ may not reapply for any license from the board for three (3) years from the effective date of this decision. Respondent ~~owner~~ stipulates that should ~~he or she~~ [he/she] apply for any license from the board on or after the effective date of this decision, all allegations set forth in the [accusation or petition to revoke probation] shall be deemed to be true, correct and admitted by respondent when the board determines whether to grant or deny the application. Respondent shall satisfy all requirements applicable to that license as of the date the application is submitted to the board. Respondent is required to report this surrender as disciplinary action.

Respondent ~~owner~~ further stipulates that ~~he or she~~ [he/she] shall reimburse the board for its costs of investigation and prosecution in the amount of $_____within _____days of the effective date of this decision.

~~**OPTION 1:**~~ (To be included if the respondent is a pharmacy.) Respondent ~~owner~~ shall also, by the effective date of this decision, arrange for the continuation of care for ongoing patients of the

pharmacy by, at minimum, providing a written notice to ongoing patients that specifies the anticipated closing date of the pharmacy and that identifies one or more area pharmacies capable of taking up the patients' care, and by cooperating as may be necessary in the transfer of records or prescriptions for ongoing patients. Within five days of its provision to the pharmacy's ongoing patients, Respondent ~~owner~~ shall provide a copy of the written notice to the board. For the purposes of this provision, "ongoing patients" means those patients for whom the pharmacy has on file a prescription with one or more refills outstanding, or for whom the pharmacy has filled a prescription within the preceding sixty (60) days.

Option 2: Respondent ~~owner~~ stipulates that should ~~he or she~~ [he/she] apply for any license from the board on or after the effective date of this decision the investigation and prosecution costs in the amount of $_____shall be paid to the board prior to issuance of the new license.

Public ~~Reprimand~~ Reproval

It is hereby ordered that a public ~~reprimand~~ reproval be issued against licensee, _____. Respondent ~~owner~~ is required to report this reproval as a disciplinary action.

~~**Adoption of Stipulation**~~

~~It is understood by respondent owner that, in deciding whether to adopt this stipulation, the board may receive oral and written communication from its staff and the Attorney General's Office. Communications pursuant to this paragraph shall not disqualify the board or other persons from future participation in this or any other matter affecting respondent. In the event this settlement is not adopted by the board, the stipulation will not become effective and may not be used for any purpose, except this paragraph, which shall remain in effect.~~

STANDARD CONDITIONS - To be included in all probation decisions/orders.

1. Definition: Respondent
~~1~~ 2. Obey All laws
~~2~~ 3. Report to the Board
~~3~~ 4. Interview with the Board
~~4~~ 5. Cooperate with Board Staff
~~5~~ 6. Reimbursement of Board Costs
~~6~~ 7. Probation Monitoring Costs
~~7~~ 8. Status of License
~~8~~ 9. License Surrender While on Probation/Suspension
10. Sale or Discontinuance of Business
~~9~~ 11. Notice to Employees
~~10~~ 12. Owners and Officers: Knowledge of the Law
13. Premises Open for Business
~~11~~ 14. Posted Notice of Probation
~~12~~ 15. Violation of Probation
~~13~~ 16. Completion of Probation

OPTIONAL CONDITIONS
17. Suspension
~~14.~~ 18. Community Services Program
~~15.~~ 19. Restitution
~~16.~~ 20. Separate File of Records
~~17.~~ 21. Report of Controlled Substances
~~18.~~ 22. Surrender of DEA Permit
~~19.~~ 23. Posted Notice of Suspension
24. Destruction of Dangerous Drugs and/or Dangerous Devices
25. No Additional Ownership or Management of Licensed Premises

STANDARD CONDITIONS: TO BE INCLUDED IN ALL PROBATIONS

1. Definition: Respondent

For the purposes of these terms and conditions, "respondent" shall refer to [insert name], ~~and~~ ~~a~~All terms and conditions stated herein shall bind and be applicable to the licensed premises and to all owners, managers, officers, administrators, members, directors, trustees, associates, or partners thereof. For purposes of compliance with any term or condition, any report, submission, filing, payment, or appearance required to be made by respondent to or before the board or its designee shall be made by an owner or executive officer with authority to act on behalf of and legally bind the licensed entity.

~~1~~ 2. Obey All Laws

Respondent ~~owner~~ shall obey all state and federal laws and regulations.

Respondent ~~owner~~ shall report any of the following occurrences to the board, in writing, within seventy-two (72) hours of such occurrence:

- an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws;
- a plea of guilty, or nolo ~~contender~~ contendere, no contest, or similar, in any state or federal criminal proceeding to any criminal complaint, information or indictment;

- a conviction of any crime; or
- discipline, citation, or other administrative action filed by any state or federal agency which involves respondent's _____license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling or distributing, billing, or charging for any dangerous drug~~,~~ and/or dangerous device or controlled substance.

Failure to timely report any such occurrence shall be considered a violation of probation.

~~2~~ 3. Report to the Board

Respondent ~~owner~~ shall report to the board quarterly, on a schedule and in a form or format as directed by the board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, respondent ~~owner~~ shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation. Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the board.

~~3~~ 4. Interview with the Board

Upon receipt of reasonable prior notice, respondent ~~owner~~ shall appear in person for interviews with the board or its designee, at such intervals and locations as are determined by the board or its designee. Failure to appear for any scheduled interview without prior notification to board staff, or failure to appear for two (2) or more scheduled interviews with the board or its designee during the period of probation, shall be considered a violation of probation.

4 5. Cooperate with Board Staff

Respondent ~~owner~~ shall timely cooperate with the board's inspection program and with the board's monitoring and investigation of respondent's compliance with the terms and conditions of ~~his or her~~ the probation, including but not limited to: timely responses to requests for information by board staff; timely compliance with directives from board staff regarding requirements of any term or condition of probation; and timely completion of documentation pertaining to a term or condition of probation. Failure to timely cooperate shall be considered a violation of probation.

~~5~~ 6. Reimbursement of Board Costs

As a condition precedent to successful completion of probation, respondent ~~owner~~ shall pay to the board its costs of investigation and prosecution in the amount of $_____. Respondent ~~owner~~ shall make said payments as follows: _____. There shall be no deviation from this schedule absent prior written approval by the board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

~~The filing of bankruptcy by respondent owner shall not relieve respondent of his or her responsibility to reimburse the board its costs of investigation and prosecution.~~

~~**OPTION:**~~ Respondent shall be permitted to pay these costs in a payment plan approved by the board or its designee, so long as full payment is completed no later than one (1) year prior to the end date of probation.

~~6~~ 7. Probation Monitoring Costs

Respondent ~~owner~~ shall pay any costs associated with probation monitoring as determined by the board each and every year of probation. Such costs shall be payable to the board on a schedule as directed by the board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

~~7~~ 8. Status of License

Respondent ~~owner~~ shall, at all times while on probation, maintain current [insert license type] ~~licensure~~ with the board. ~~If respondent owner submits an application to the board, and the application is approved, for a change of location, change of permit or change of ownership, the board shall retain continuing jurisdiction over the license, and the respondent shall remain on probation as determined by the board.~~ Failure to maintain current licensure shall be considered a violation of probation.

If respondent's license expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof or otherwise, upon renewal or reapplication respondent's license shall be subject to all terms and conditions of this probation not previously satisfied.

~~8~~ 9. License Surrender While on Probation/Suspension

Following the effective date of this decision, should respondent ~~owner~~ wish to discontinue business, respondent ~~owner~~ may tender the premises license to the board for surrender. The board or its designee shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondent will no longer be subject to the terms and conditions of probation.

Respondent may not apply for any new license from the board for three (3) years from the effective date of the surrender. Respondent shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board.

Respondent further stipulates that it shall reimburse the board for its costs of investigation and prosecution prior to the acceptance of the surrender.

OPTION ~~(To be included if the respondent is a pharmacy)~~: Upon acceptance of the surrender, respondent ~~owner~~ shall relinquish the premises wall and renewal license to the board within ten (10) days of notification by the board that the surrender is accepted. Respondent ~~owner~~ shall further submit a completed Discontinuance of Business form according to board guidelines and shall notify the board of the records inventory transfer within five (5) days. Respondent shall further arrange for the transfer of all records of acquisition and disposition of dangerous drugs and/or devices to premises licensed and approved by the board.

Respondent ~~owner~~ shall also, by the effective date of this decision, arrange for the continuation of care for ongoing patients of the pharmacy by, at minimum, providing a written notice to ongoing patients that specifies the anticipated closing date of the pharmacy and that identifies one or more area pharmacies capable of taking up the patients' care, and by cooperating as may be necessary in the transfer of records or prescriptions for ongoing patients. Within five days of its provision to the pharmacy's ongoing patients, Respondent ~~owner~~ shall provide a copy of the written notice to the board. For the purposes of this provision, "ongoing patients" means those patients for whom the pharmacy has on file a prescription with one or more refills outstanding, or for whom the pharmacy has filled a prescription within the preceding sixty (60)

days.

Respondent ~~owner~~ may not apply for any new ~~licensure~~ license from the board for three (3) years from the effective date of the surrender. Respondent ~~owner~~ shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board.

Respondent ~~owner~~ further stipulates that ~~he or she~~ it shall reimburse the board for its costs of investigation and prosecution prior to the acceptance of the surrender.

10. Sale or Discontinuance of Business

During the period of probation, should respondent sell, trade or transfer all or part of the ownership of the licensed entity, discontinue doing business under the license issued to respondent, or should practice at that location be assumed ~~by~~ by another full or partial owner, person, firm, business, or entity, under the same or a different premises license number, the board or its designee shall have the sole discretion to determine whether to exercise continuing jurisdiction over the licensed location, under the current or new premises license number, and/or carry the remaining period of probation forward to be applicable to the current or new premises license number of the new owner.

~~9~~ 11. Notice to Employees

Respondent ~~owner~~ shall, upon or before the effective date of this decision, ensure that all employees involved in permit operations are made aware of all the terms and conditions of probation, either by posting a notice of the terms and conditions, circulating such notice, or both. If the notice required by this provision is posted, it shall be posted in a prominent place and shall remain posted throughout the probation period. Respondent ~~owner~~ shall ensure that any employees hired or used after the effective date of this decision are made aware of the terms and conditions of probation by posting a notice, circulating a notice, or both. Additionally, respondent ~~owner~~ shall submit written notification to the board, within fifteen (15) days of the effective date of this decision, that this term has been satisfied. Failure to ~~submit~~ timely provide such notification to employees, or to timely submit such notification to the board, shall be considered a violation of probation.

> "Employees" as used in this provision includes all full-time, part-time, volunteer, temporary and relief employees and independent contractors employed or hired at any time during probation.

~~10~~ 12. Owners and Officers: Knowledge of the Law

Respondent shall provide, within thirty (30) days after the effective date of this decision, signed and dated statements from its owners, including any owner or holder of ten percent (10%) or more of the interest in respondent or respondent's stock, and ~~any~~ all of its officer, stating under penalty of perjury that said individuals have read and are familiar with state and federal laws and regulations governing the practice of pharmacy. The failure to timely provide said statements under penalty of perjury shall be considered a violation of probation.

13. Premises Open for Business

Respondent shall remain open and engaged in its ordinary business as a [insert license type] in

California for a minimum of _____ hours per calendar month. Any month during which this minimum is not met shall toll the period of probation, i.e., the period of probation shall be extended by one month for each month during with this minimum is not met. During any such period of tolling of probation, respondent must nonetheless comply with all terms and conditions of probation, unless respondent is informed otherwise in writing by the board or its designee. If respondent is not open and engaged in its ordinary business as a [insert license type] for a minimum of _____ hours in any calendar month, for any reason (including vacation), respondent shall notify the board in writing within ten (10) days of the conclusion of that calendar month. This notification shall include at minimum all of the following: the date(s) and hours respondent was open; the reason(s) for the interruption or why business was not conducted; and the anticipated date(s) on which respondent will resume business as required. Respondent shall further notify the board in writing with ten (10) days following the next calendar month during which respondent is open and engaged in its ordinary business as a [insert license type] in California for a minimum of _____ hours. Any failure to timely provide such notification(s) shall be considered a violation of probation.

~~11~~14. Posted Notice of Probation

Respondent ~~owner~~ shall prominently post a probation notice provided by the board or its designee in a place conspicuous to and readable by the public within two (2) days of receipt thereof from the board or its designee. Failure to timely post such notice, or to maintain the posting during the entire period of probation, shall be considered a violation of probation. ~~The probation notice shall remain posted during the entire period of probation.~~

Respondent ~~owner~~ shall not, directly or indirectly, engage in any conduct or make any statement which is intended to mislead or is likely to have the effect of misleading any patient, customer, member of the public, or other person(s) as to the nature of and reason for the probation of the licensed entity.

~~Failure to post such notice shall be considered a violation of probation.~~

~~12~~ 15. Violation of Probation

If ~~a~~ respondent ~~owner~~ has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondent ~~license~~, and probation shall be automatically extended, until all terms and conditions have been satisfied or the board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed.

If respondent ~~owner~~ violates probation in any respect, the board, after giving respondent ~~owner~~ notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. ~~Notice and opportunity to be heard are not required for those provisions stating that a violation thereof may lead to automatic termination of the stay and/or revocation of the license.~~ If a petition to revoke probation or an accusation is filed against respondent during probation, the board shall have continuing jurisdiction and the period of probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided.

~~13~~ 16. Completion of Probation

Upon written notice by the board or its designee indicating successful completion of probation, respondent's license will be fully restored.

OPTIONAL CONDITIONS OF PROBATION

~~14~~ 17. Suspension

As part of probation, respondent's license to operate a [insert license type] is suspended for _____[day(s)/month(s)/year(s)] beginning the effective date of this decision. Respondent shall cease all operations as a [insert license type] during the period of suspension. Failure to comply with this suspension shall be considered a violation of probation.

~~14.~~ ~~19.~~18. Community Service~~s~~ Program

Within sixty (60) days of the effective date of this decision, respondent ~~owner~~ shall submit to the board or its designee, for prior approval, a community service program in which respondent shall provide free health-care related services to a community or charitable facility or agency for at least _____hours per _____for the first _____of probation.

Within thirty (30) days of board approval thereof, respondent ~~owner~~ shall submit documentation to the board demonstrating commencement of the community service program. Respondent ~~owner~~ shall report on progress with the community service program in the quarterly reports.

Failure to timely submit, commence, or comply with the program shall be considered a violation of probation.

~~15.~~ ~~20.~~19. Restitution (Appropriate in cases of drug diversion, theft, fraudulent billing, or patient harm resulting from negligence or incompetence.)

Within _____days of the effective date of this decision, respondent ~~owner~~ shall pay restitution to _____in the amount of $ _____. Failure to make restitution by this deadline shall be considered a violation of probation.

~~16.~~ ~~21.~~20. Separate File of Controlled Substances Records

Respondent ~~owner~~ shall maintain and make available for inspection a separate file of all records pertaining to the acquisition or disposition of all controlled substances. Failure to maintain such file or make it available for inspection shall be considered a violation of probation.

~~17.~~ ~~22.~~21. Report of Controlled Substances

Respondent ~~owner~~ shall submit ~~quarterly~~ reports to the board detailing the total acquisition and disposition of such controlled substances as the board or its designee may direct. Respondent ~~owner~~ shall specify the manner of disposition (e.g., by prescription, due to burglary, etc.) or acquisition (e.g., from a manufacturer, from another retailer, etc.) of such controlled substances. Respondent ~~owner~~ shall report on a quarterly basis or as directed by the board or its designee. The report shall be delivered or mailed to the board no later than ten (10) days following the end of the reporting period as determined by the board or its designee. Failure to timely prepare or submit such reports shall be considered a violation of probation.

~~18.~~ ~~23.~~22. Surrender of DEA Permit

Within thirty (30) days of the effective date of this decision, respondent ~~pharmacy~~ shall surrender its federal Drug Enforcement Administration (DEA) permit to the DEA, for cancellation. Respondent ~~pharmacy~~ shall provide documentary proof of such cancellation to the board or its designee. Thereafter, respondent ~~pharmacy~~ shall not apply/reapply for a DEA

registration number without the prior written consent of the board or its designee.

Option**:** Respondent ~~pharmacy~~ may obtain a DEA permit restricted to Schedule(s) _____ controlled substance(s).

Option**:** Respondent ~~pharmacy~~ shall not order, receive, or retain any federal order forms, including DEA Form 222 ~~forms~~, for controlled substances.

~~19.~~ ~~18.~~23. Posted Notice of Suspension

Respondent ~~owner~~ shall prominently post a suspension notice provided by the board in a place conspicuous and readable to the public within two (2) days of receipt thereof from the board or its designee. The suspension notice shall remain posted during the entire period of suspension ordered by this decision. Failure to timely post such notice, or to maintain the posting during the entire period of suspension, shall be considered a violation of probation.

Respondent ~~owner~~ shall not, directly or indirectly, engage in any conduct or make any statement, orally, electronically or in writing, which is intended to mislead or is likely to have the effect of misleading any patient, customer, member of the public, or other person(s) as to the nature of and reason for the closure of the licensed entity.

24. Destruction of Dangerous Drugs and/or Dangerous Devices [To be used when the violations include misbranded or adulterated drugs.]

Respondent shall, by the effective date of this decision, arrange for the destruction of all dangerous drugs and/or dangerous devices or controlled substances and dangerous drugs and devices by a waste management company or reverse distributor. All products must be inventoried with an exact count prior to destruction. Respondent shall provide written proof of such destruction within five days of disposition.

Option: [To be used when the integrity, quality and strength of compounded drug products is at issue]

Respondent shall, by the effective date of this decision, arrange for the destruction of all compounded drug products and the components used to compound drug products by a waste management company. Respondent shall provide written proof of such destruction within five days of disposition. The Board or its designee shall have the right to retain a sample(s) of any and all compounded drug products or components used to compound drug products by Respondent.

25. No Additional Ownership or Management of Licensed Premises

Respondent shall not acquire any additional ownership, legal or beneficial interest in, nor serve as a manager, administrator, member, officer, director, associate, partner or any business, firm , partnership, or corporation currently or hereinafter licensed by the board except as approved by the board or its designee. Violations of this restriction shall be considered a violation of probation.

~~6/2007~~ ~~7/2015~~ 10/2015

Attachment 5

Drug Warnings

1744

Title 16. Board of Pharmacy

Modified Language

Changes made to the originally proposed language are shown by ~~double strikethrough~~ for deleted language and double underline for added language. (Additionally, the modified text is listed in red for color printers.)

To Amend Section 1744 of Article 5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1744. Drug Warnings

Pursuant to Business and Professions Code Section 4074, a pharmacist shall inform the patient or his or her representative of the harmful effects of certain drugs dispensed by prescription.

(a) Because ~~T~~the following classes of drugs may impair a person's ability to ~~drive~~ operate a ~~motor~~ vehicle or vessel, ~~operate machinery when taken alone or in combination with alcohol~~ a pharmacist shall include a written label on the drug container indicating that the drug may impair a person's ability to operate a vehicle or vessel:

(1) Muscle relaxants.

(2) ~~Analgesics with central nervous system depressant effects.~~

~~(3)~~ Antipsychotic drugs with central nervous system depressant effects ~~including phenothiazines~~

(~~4~~3) Antidepressants with central nervous system depressant effects.

(~~5~~4) Antihistamines, motion sickness agents, antipruritics, antinauseants, anticonvulsants and antihypertensive agents with central nervous system depressant effects.

(~~6~~5) All Schedule II, III, IV and V agents with central nervous system depressant effects. ~~or narcotic controlled substances as set forth in Health and Safety Code at Section 11055 et seq. prescribed in doses which could have an adverse effect on a person's ability to operate a motor vehicle.~~

(~~7~~6) Anticholinergic agents ~~and other drugs which~~ that may impair vision.

(7) Any other drug which, based on the pharmacist's professional judgment, may impair a patient's ability to operate a vehicle or vessel.

(b) Because ~~T~~the following ~~are examples~~ classes of drugs pose a substantial risk to the person consuming the drug when taken in combination with alcohol, a pharmacist shall ~~provide a written warning notice on the label to~~ include a written label on the drug container to alert the patient about possible potentiating effects: ~~which may have harmful effects when taken in combination with alcohol. These may or may not affect a person's ability to operate a motor vehicle:~~

(1) Disulfiram and other drugs (e.g., chlorpropamide, metronidazole) which may cause a disulfiram-like reaction.

(2) Mono amine oxidase inhibitors.

(3) Nitrates.

(4) Cycloserine.

(5) Antidiabetic agents including insulin and sulfonylureas (due to risk of hypoglycemia).

(6) Any other drug which, based upon a pharmacist's professional judgment, may pose a substantial risk to the person consuming the drug when taken in combination with alcohol.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4022~~, 4055~~ and 4074, Business and Professions Code.

Attachment 6

Patient-Centered Labels: Requirements

1707.5

Title 16. Board of Pharmacy

Second Modified Text

Changes made to the originally proposed text are shown by double strikethrough for deleted language and double underline for added language. (Additionally, the modified text is listed in red for color printers.)

Changes made to the first modified text are shown by bold wavy underline for added language. (Additionally, the modified text is listed in purple for color printers.)

To Amend Section 1707.5 of Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1707.5. Patient-Centered Labels for Prescription Drug Containers; Requirements.

(a) Labels on drug containers dispensed to patients in California shall conform to the following format:

(1) Each of the following items, and only these four items, shall be clustered into one area of the label that comprises at least 50 percent of the label. Each item shall be printed in at least a 12-point sans serif typeface, and listed in the following order:

(A) Name of the patient

(B) Name of the drug and strength of the drug. For the purposes of this section, "name of the drug" means either the manufacturer's trade name of the drug, or the generic name and the statement "generic for _____" where the brand name is inserted~~ into the parentheses~~. If, ~~it has been at least five years since the expiration of the brand name's patent or, if~~ in the professional judgment of the pharmacist, the brand name is no longer widely used, the label may list only the generic name of the drug and outside of the patient centered area, **may list** the name of the manufacturer.

(C) The directions for the use of the drug.

(D) The condition or purpose for which the drug was prescribed if the condition or purpose is indicated on the prescription.

(2) For added emphasis, the label shall also highlight in bold typeface or color, or use blank space to set off the items listed in subdivision (a)(1).

(3) The remaining required elements for the label specified in section 4076 of the Business and Professions Code, as well as any other items of information appearing on the label or the container, shall be printed so as not to interfere with the legibility or emphasis of the primary elements specified in paragraph (1) of subdivision (a). These additional elements may appear in any style, font, and size typeface.

(4) When applicable, directions for use shall use one of the following phrases:

(A) Take 1 [insert appropriate dosage form] at bedtime

(B) Take 2 [insert appropriate dosage form] at bedtime

(C) Take 3 [insert appropriate dosage form] at bedtime

(D) Take 1 [insert appropriate dosage form] in the morning

(E) Take 2 [insert appropriate dosage form] in the morning

(F) Take 3 [insert appropriate dosage form] in the morning

(G) Take 1 [insert appropriate dosage form] in the morning, and Take 1 [insert appropriate dosage form] at bedtime

(H) Take 2 [insert appropriate dosage form] in the morning, and Take 2 [insert appropriate dosage form] at bedtime

(I) Take 3 [insert appropriate dosage form] in the morning, and Take 3 [insert appropriate dosage form] at bedtime

(J) Take 1 [insert appropriate dosage form] in the morning, 1 [insert appropriate dosage form] at noon, and l [insert appropriate dosage form] in the evening

(K) Take 2 [insert appropriate dosage form] in the morning, 2 [insert appropriate dosage form] at noon, and 2 [insert appropriate dosage form] in the evening

(L) Take 3 [insert appropriate dosage form] in the morning, 3 [insert appropriate dosage form] at noon, and 3 [insert appropriate dosage form] in the evening

(M) Take 1 [insert appropriate dosage form] in the morning, 1 [insert appropriate dosage form] at noon, 1 [insert appropriate dosage form] in the evening, and 1 [insert appropriate dosage form] at bedtime

(N) Take 2 [insert appropriate dosage form] in the morning, 2 [insert appropriate dosage form] at noon, 2 [insert appropriate dosage form] in the evening, and 2 [insert appropriate dosage form] at bedtime

(O) Take 3 [insert appropriate dosage form] in the morning, 3 [insert appropriate dosage form] at noon, 3 [insert appropriate dosage form] in the evening, and 3 [insert appropriate dosage form] at bedtime

(P) If you have pain, take __ [insert appropriate dosage form] at a time. Wait at least __ hours before taking again. Do not take more than __ [appropriate dosage form] in one day

(b) By October 2011, and updated as necessary, the board shall publish on its Web site translation of the directions for use listed in subdivision (a)(4) into at least five languages other than English, to facilitate the use thereof by California pharmacies.

(c) The board shall collect and publish on its Web site examples of labels conforming to these requirements, to aid pharmacies in label design and compliance.

(d) The pharmacy shall have policies and procedures in place to help patients with limited or no English proficiency understand the information on the label as specified in subdivision (a) in the patient's language. The pharmacy's policies and procedures shall be specified in writing and shall include, at minimum, the selected means to identify the patient's language and to provide interpretive services <u>and translation services</u> in the patient's language. The pharmacy shall, at minimum, provide interpretive services in the patient's language, if interpretive services in such language are available, during all hours that the pharmacy is open, either in person by pharmacy staff or by use of a third-party interpretive service available by telephone at or adjacent to the pharmacy counter.

~~(e) The board shall re-evaluate the requirements of this section by December 2013 to ensure optimal conformance with Business and Professions Code section 4076.5.~~

~~(f)~~ (e) As used in this section, “appropriate dosage form” includes pill, caplet, capsule or tablet.

Note: Authority cited: Sections 4005 and 4076.5, Business and Professions Code. Reference: Sections 4005, 4076 and 4076.5, Business and Professions Code.

Attachment 7

Board Accredited Continuing Education - 1732.02, 1732.02, and 1732.5

Title 16. BOARD OF PHARMACY

Modified Language

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

Changes made to the originally proposed language are shown by ~~double strikethrough~~ for deleted language and double underline for added language. (Additionally, the modified text is listed in red for color printers.)

Proposal to amend § 1732.05 in Article 4 of Division 17 of Title 16 of the California Code of Regulations to read:

§1732.05. Accreditation Agencies for Continuing Education

(a) The following organizations are approved accreditation agencies:

(1) The Accreditation Council for Pharmacy Education.

(2) The ~~Pharmacy Foundation of California~~ California Pharmacists Association.

(b) Accreditation agencies shall:

(1) Evaluate each continuing education provider seeking accreditation in accordance with the provider's ability to comply with the requirements of section 1732.1 of this Division.

(2) Maintain a list of the name and address of the person responsible for the provider's continuing education program. The accreditation agency shall require that any change in the responsible person's identity shall be reported to the accreditation agency within 15 days of the effective date of the change.

(3) Provide the board with the names, addresses and responsible party of each provider, upon request.

(4) Respond to complaints from the board, providers or from pharmacists concerning activities of any of its accredited providers or their coursework.

(5) Review at least one course per year offered by each provider accredited by the agency for compliance with the agency's requirements and requirements of the board and, on request, report the findings of such reviews to the board.

(6) Take such action as is necessary to assure that the continuing education coursework offered by its providers meets the continuing education requirements of the board.

(7) Verify the completion of a specific continuing education course by an individual pharmacist upon request of the board.

(c) Substantial failure of an approved accreditation agency to evaluate continuing education providers as set forth in subdivision (b) shall constitute cause for revocation of its approval as an accreditation agency by the board.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4232, Business and Professions Code.

Proposal to amend § 1732.2 in Article 4 of Division 17 of Title 16 of the California Code of Regulations to read:

§ 1732.2. Board Accredited Continuing Education

(a) Individuals may petition the board to allow continuing education credit for specific coursework which is not offered by a provider but meets the standards of Section 1732.3.

(b) Notwithstanding subdivision (a) of this section, coursework which meets the standard of relevance to pharmacy practice and has been approved for continuing education by the Medical Board of California, the California Board of Podiatric Medicine, the California Board of Registered Nursing or the Dental Board of California shall, upon satisfactory completion, be considered approved continuing education for pharmacists.

(c) A pharmacist serving on a designated subcommittee of the board for the purpose of developing the California Practice Standards and Jurisprudence Examination for pharmacists pursuant to section 4200.2 of the Business and Professions Code may annually be awarded up to six (6) hours of continuing education for conducting a review of exam test questions. A subcommittee member shall not receive continuing education hours pursuant to this subdivision if that subcommittee member requests reimbursement from the board for time spent conducting a review of exam test questions.

(d) A pharmacist or pharmacy technician who attends a full day board meeting may be awarded six (6) hours of continuing education per renewal period. The board shall designate on its public agenda which day shall be eligible for continuing education credit. A pharmacist or pharmacy technician requesting continuing education pursuant to this subdivision must sign in and out on an attendance sheet at the board meeting that requires the individual to provide his or her first and last name, license number, time of arrival and time of departure from the meeting.

(e) A pharmacist or pharmacy technician who attends a full committee meeting of the board may be awarded two (2) hours of continuing education per renewal period. A pharmacist or pharmacy technician requesting continuing education hours pursuant to this subdivision must sign in and out on

an attendance sheet at the committee meeting that requires the individual to provide his or her first and last name, license number, time of arrival and time of departure from the meeting.

(f) An individual may be awarded three (3) hours of continuing education for successfully passing the examination administered by the Commission for Certification in Geriatric Pharmacy.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4232, Business and Professions Code.

Proposal to amend § 1732.5 of Article 4 of Division 17 of Title 16 of the California Code of Regulations to read:

§1732.5 Renewal Requirements for Pharmacists

(a) Except as provided in Section 4234 of the Business and Professions Code and Section 1732.6 of this Division, each applicant for renewal of a pharmacist license shall submit proof satisfactory to the board, that the applicant has completed 30 hours of continuing education in the prior 24 months.

(b) At least ~~six (6)~~ two (2) of the thirty (30) hours required for pharmacist license renewal shall be completed by participation in a Board provided CE course in Law and Ethics. ~~in one or more of the following subject areas:~~

~~(1) Emergency/Disaster Response~~

~~(2) Patient Consultation~~

~~(3) Maintaining Control of a Pharmacy's Drug Inventory~~

~~(4) Ethics~~

~~(5) Substance Abuse, Including Indications of Red Flags and a Pharmacist's Corresponding Responsibility~~

~~(6) Compounding~~

Pharmacists renewing their licenses which expire on or after July 1, ~~2018~~ 2019, shall be subject to the requirements of this subdivision.

~~(b)~~ (c) All pharmacists shall retain their certificates of completion for four (4) years following completion of a continuing education course.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4231 and 4232, Business and Professions Code.

Attachment 8

Prescription Drug Take-Back

1776-1776.6

Title 16. Board of Pharmacy

Third 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 bold underline for added language. (Additionally, the modified text is listed in red for color printers.)

Changes made to the second modified language are shown by ~~**bold double strikethrough and bold wavy underline**~~ for deleted language and **bold wavy underline** for added language. (Additionally, the modified text is listed in **purple** for color printers.)

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

Article 9.1. Prescription Drug Take-Back ~~Programs~~ 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 ~~Programs~~ Services: Authorization

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

~~All board-licensed authorized collectors should be vigilant to prevent the public patients or their agents from disposing of prohibited items through drug take-back collection methods. Federal, state and other laws prohibit the deposit in drug take-back receptacles of the following in pharmaceutical take-back receptacles: medical sharps and needles (e.g., insulin syringes), iodine-containing medications, mercury-containing thermometers, radiopharmaceuticals, hazardous medications (cancer chemotherapy drugs, cytotoxic drugs), illicit drugs, and compressed cylinders or aerosols (e.g., asthma inhalers).~~

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

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

Reference: Sections 4005, 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 assist patients seeking to destroy unwanted, previously dispensed prescription drugs as provided in this article. Provision of such services is voluntary.~~

~~(b)~~ (a) Pharmacies may provide take-back services to the public ~~patients as provided in sections 1776 - 1776.4~~. Retail pharmacies and hospital/clinics with onsite pharmacies may ~~establish~~ maintain collection receptacles in their facilities. Pharmacies may ~~operate collection receptacles~~ offer drug take-back services as specified ~~in~~ in section 1776.4 in skilled nursing facilities licensed under ~~California~~ Health and Safety Code section 1250(c).

~~(c)~~ (b) There are multiple federal, ~~and~~ state and local requirements governing the collection and destruction of dangerous drugs. Pharmacies are expected to know and adhere to these requirements when operating a prescription drug take-back program.

~~(d)~~ (c) For purposes of this article, prescription drugs means dangerous drugs as defined by ~~California~~ Business and Professions Code section 4022, which includes ~~including~~ controlled substances. Controlled substances may be commingled in collection receptacles or mail back ~~packages or~~ envelopes or packages with other dangerous drugs.

(d) Once drugs are deposited into a collection receptacle or mail back envelopes or packages by a consumer ~~patient~~, they are not to be removed, counted, sorted or otherwise individually handled ~~separated by pharmacy staff or others~~.

(e) ~~(d) The following dangerous drugs and devices are expressly prohibited from collection in a pharmacy's prescription drug take-back collection receptacles: medical sharps and needles (e.g., insulin syringes), iodine-containing medications, mercury-containing thermometers, radiopharmaceuticals, antineoplastic agents (cancer chemotherapy drugs, cytotoxic drugs), and compressed cylinders or aerosols (e.g., asthma inhalers). Signage informing the public that medical sharps and needles (e.g., insulin syringes) are of the items prohibited from being deposited shall be placed posted on collection receptacles as referenced in section 1776.3.~~

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

(g) As part of its drug take-back services, a Pharmacy shall not:

(1) ~~Pharmacy staff shall not r~~Review, accept, count, sort, or otherwise individually handle any prescription drugs ~~returned~~ from ~~the public~~ consumers.

(2) ~~A pharmacy shall not a~~Accept or possess prescription drugs returned to the pharmacy ~~by~~ from skilled nursing ~~homes~~ facilities, residential care homes, ~~other facilities,~~ health care practitioners or any other entity ~~entities in a collection receptacle~~.

(3) ~~A pharmacy shall not d~~Dispose of quarantined, recalled or outdated prescription drugs from pharmacy stock ~~in a drug take-back collection receptacle~~. ~~Instead the pharmacy must return these items to a reverse distributor~~.

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

~~(h)~~~~(g)~~(i) Any pharmacy that ~~operates~~ maintains a drug take-back collection receptacle ~~program~~ as authorized in this article shall notify the board in writing ~~on a form designated by the board~~ within 30 days of establishing the collection program. Additionally:

(1) Any pharmacy that ceases to ~~operate~~ maintain a drug take-back collection receptacle ~~program~~ shall notify the board in writing within 30 days ~~on a form designated by the board~~. ~~If the pharmacy later ceased to operate the collection receptacle, the pharmacy must notify the board within 30 days.~~

(2) Any pharmacy ~~operating a mail back program or~~ maintaining a collection receptacle~~s~~ shall disclose ~~identify~~ to the board that it provides such services annually at the time of renewal of the pharmacy license, and shall identify all locations where its collection receptacles are located.

(3) Any tampering with a ~~storage~~ collection receptacle or theft of deposited drugs shall be reported to the board 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.

~~(i)~~~~(h)~~(j) If the pharmacy ~~later~~ ceases to ~~operate~~ maintain ~~the~~ a registered collection receptacle, the pharmacy must notify the DEA ~~Drug Enforcement Administration~~ within 30 days.

~~(j)~~(k) A pharmacy shall not provide take-back services to consumers~~, as provided in sections 1776 – 1776.4,~~ if, in the professional judgment of the pharmacist-in-charge, the pharmacy cannot comply with the provisions of this article or the DEA ~~Drug Enforcement Administration~~ rules.

~~(j)~~(l) A pharmacy shall not provide take-back services to consumers~~, as provided in sections 1776 – 1776.4~~ if the pharmacy or the pharmacist-in-charge is on probation with the ~~B~~board, and, if the pharmacy had previously provided take-back services, the pharmacist-in-charge shall notify the ~~B~~board and the DEA ~~Drug Enforcement Administration~~ as required in subsections (h) and (i), 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 ~~Mail Back Package and Envelope Services from Pharmacies~~

(a) Pharmacies that provide prescription drug take-back services may do so by ~~establishing~~ providing ~~mail back services, whereby the public may obtain from the pharmacy~~ preaddressed mailing envelopes or packages ~~containers~~ to allow a consumer to ~~for~~ return~~ing~~ prescription drugs to an authorized DEA ~~Drug Enforcement Administration~~ destruction location.

(b) All envelopes and packages must be preaddressed to a location registered with the DEA ~~Drug Enforcement Administration~~ as a collector ~~that has onsite a method appropriate to destroy the prescription drugs~~. The pharmacy is responsible for ensuring that all preaddressed envelopes and packages it makes available to the public are preaddressed ~~to be delivered~~ 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 ~~certain~~ instructions for users that indicate the process to mail back drugs.

~~(e) The pharmacy distributing mail back envelopes and packages shall create and maintain records required by section 1776.6.~~

~~(f) Individuals who mail back prescription drugs as provided in this section do not need to identify themselves as the senders.~~

~~(g)~~ (e) ~~Once filled with unwanted prescription drugs, the~~ 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, ~~C~~ consumers shall be directed to mail the envelopes or packages ~~or deposit them into a pharmaceutical take-back receptacle~~. ~~shall be mailed and not accepted by the pharmacy for return, processing or holding.~~

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

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

1776.3 Collection Receptacles in Pharmacies

(a) A pharmacy ~~Pharmacies~~ may ~~that provide prescription drug take-back services to the public may do so by establishing~~ maintain a collection receptacle ~~in the pharmacy~~ ~~whereby~~ for the public to ~~may~~ deposit their unwanted prescription drugs for destruction. The

pharmacy is responsible for the management and maintenance of the receptacle. The receptacle shall be ~~securely locked and~~ 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. ~~In During hours when the pharmacy is closed, the collection receptacle shall not be accessible to the public for deposit of drugs. The pharmacy shall lock the deposit slot on the collection receptacle and physically block the public patients from access to the collection receptacle by some means.~~

(b) A ~~The~~ pharmacy ~~operating~~ maintaining ~~the~~ a collection receptacle must securely ~~install~~ fasten the receptacle to a permanent structure so it cannot be ~~moved or~~ removed. The receptacle shall be installed in an inside location ~~within the pharmacy premise., where,~~ 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 supervising responsible pharmacy is closed,~~** the collection receptacle shall be locked so that drugs may not be deposited into the collection receptacle. ~~When the collection receptacle is locked, the supervising pharmacy shall ensure that the collection receptacle is also physically blocked from public patient access by some means.~~

(d) The receptacle shall include a small opening that allows deposit of drugs into the inside of the receptacle directly into the inner liner, but does not allow for an individual to reach into the receptacle's contents. 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 ~~slot~~** on the collection receptacle.

(e) ~~The pharmacy is responsible for the management and maintenance of the receptacle.~~ A pharmacy shall direct consumers to directly deposit drugs into the collection receptacle. A Pharmacy ~~staff~~ shall not accept, count, sort or otherwise handle prescription drugs ~~returned~~ from ~~the public~~ consumers~~, but instead direct the public to deposit the drugs into the collection receptacle themselves~~.

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

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

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

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

or otherwise individually handled.

(h) If the liner is not already itself rigid or already inside of a rigid container when ~~as~~ it is removed from the collection receptacle, the liner must be immediately, 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. ~~Rigid containers may be of any color.~~ All rigid containers must meet standards of the United States Department of Transportation ~~for transport of medical waste~~. ~~**The containers shall be capable of being sealed and be kept clean and in good repair.**~~

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

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

(k) The pharmacy shall make and keep the records specified in 1776.6. ~~maintain a written log to record information about all liners that have been placed into or removed from a collection receptacle. The log shall contain:~~

~~(1) The unique identification numbers of all unused liners in possession of the pharmacy,~~

~~(2) The unique identification number and dates a liner is placed in the collection receptacle,~~

~~(3) The date the liner is removed from the collection receptacle,~~

~~(4) The names and signatures of the two pharmacy employees who removed and witnessed the removal of a liner from the collection receptacle, and~~

~~(5) The date the liner was provided to a licensed DEA-registered reverse distributor for destruction, and the signature of the two pharmacy employees who witnessed the delivery to the reverse distributor. If a common carrier is used to transport the liner to the reverse distributor, the company used, the signature of the driver, and any related paperwork (invoice, bill of lading) must be recorded.~~

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

(m) ~~The collection receptacle shall contain signage developed by the board advising the public that it is permissible to deposit Schedule II-V drugs into the receptacle, but not permissible to deposit any Schedule I drugs into the collection receptacle. Labeling The signage shall also identify informing the public that medical sharps and needles (e.g., insulin syringes), iodine-containing medications, mercury-containing thermometers, radiopharmaceuticals, antineoplastic agents (cancer chemotherapy drugs, cytotoxic drugs), and compressed cylinders or aerosols (e.g., asthma inhalers) may not be deposited into the receptacle. The name and phone number of the collector pharmacy responsible for the receptacle shall~~

also be affixed to the collection receptacle.

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.

(n) The board shall develop signage to appear on the collection receptacle to provide consumer information about the collection process.

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

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

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

1776.4 Collection Drug Take-Back Services in Skilled Nursing Facilities

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

(a) (a) Skilled nursing facility personnel employees or person lawfully entitled to dispose of the resident decedent's property may dispose of a current resident's unwanted or unused prescription drugs by using mail back packages or envelopes and or packages based upon a request by the resident patient. Mail back envelopes and packages shall conform to the requirements specified in section 1776.2. **The pharmacy may allow skilled nursing facility employees to distribute mail back envelopes or packages to consumers.** The pharmacy shall require Records shall be kept by the 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) (b) Only retail pharmacies and hospitals/clinics with onsite pharmacies may establish collection receptacles in skilled nursing facilities for the collection and ultimate disposal of unwanted prescription drugs. A pharmacy and hospital/clinic with an onsite pharmacy maintaining a collection receptacle in a skilled nursing facility shall:

(1) Any pharmacy and hospital/clinic with an onsite pharmacy operating maintaining collection receptacles in skilled nursing facilities shall b Be registered and maintain registration with the DEA as a collector s.

(2) Any pharmacy or hospital/clinic with an onsite pharmacy that operates maintains a collection receptacle at a skilled nursing facility shall n Notify the board in writing within 30 days of establishing a collection receptacle on a form designated by the board.

(3) Any pharmacy or hospital/clinic with an onsite pharmacy Notify the board in writing within 30 days when they that cease s to operate maintain a the collection site receptacle at a skilled nursing facility shall notify the board within 30 days on a form designated by the board.

(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) ~~Any pharmacy operating a collection receptacle site at a skilled nursing facility shall l~~ List all collection receptacles it ~~operates~~ maintains annually at the time of renewal of the pharmacy license.

~~(c) (c) When a pharmacy or hospital/clinic with an onsite pharmacy installs a collection receptacle in a skilled nursing facility, only the pharmacy shall remove, seal, transfer, and store or supervise the removal, sealing, transfer and storage of sealed inner liners at long-term care facilities as specified in this section.~~

~~(d) Every pharmacy and hospital/clinic pharmacy that operates maintains a collection site receptacle at any skilled nursing facility shall notify the board within 14 days of any loss or theft from the collection receptacle or secured storage location for the storage of removed liners.~~

~~(e)~~ (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.

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

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

~~(h)~~ (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 ~~viewed,~~ removed, sorted, counted, or otherwise individually handled ~~counted~~.

(2) If the liner is not already itself rigid or already inside of a rigid container ~~as~~ when it is removed from the collection receptacle, the liner must be immediately placed in a rigid container for storage, handling and transport. A rigid container may be disposable, reusable, or recyclable. Rigid containers shall be leak resistant, have **sealable** tight-fitting covers, and be kept clean and in good repair. ~~Rigid containers may be of any color.~~ All rigid containers must meet standards of the United States Department of Transportation ~~for transport of medical waste~~. ~~**The rigid containers shall be capable of being sealed and be kept clean and in good repair.**~~

~~(i)~~ (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 ~~or~~ 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 ~~established by the pharmacy or pre-entered onto the liner by the liner's manufacturer~~.

~~(j)~~ (i) ~~The collection receptacle shall prominently display a sign indicating that prescription drugs and controlled drugs in Schedules II – V may be deposited. The name and phone number of the collector pharmacy responsible for the receptacle shall also be affixed to the collection receptacle.~~

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.

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

~~(l)~~ (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.

~~(m)~~ (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.

~~(n)~~ (m) Liners still housed in a rigid container may be delivered to a reverse distributor for destruction ~~by two pharmacy employees delivering the sealed inner liners in the rigid containers and their contents directly to a reverse distributor's registered location, or~~ by common or contract carrier or by reverse distributor pickup at the skilled nursing facility.

~~(o)~~ (n) A pharmacy maintaining a collection receptacle in a skilled nursing facility shall make and keep the records as specified in 1776.6. ~~Records of the pickup, delivery and destruction shall be maintained that provide the date each sealed inner liner is transferred for destruction, the address and registration number of the reverse distributor or distributor to whom each sealed inner was transferred, the unique identification number and the size (e.g., 5 gallon, 10 gallon) of each liner transferred, and if applicable, the names and signatures of the two employees who transported each liner.~~

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

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

1776.5 Reverse Distributors

(a) A licensed reverse distributor (either a reverse wholesaler or a reverse third-party logistics provider) registered with the DEA ~~as a collector~~ may accept the sealed inner liners of collection receptacles 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, ~~or~~ survey, or otherwise analyze ~~count, inventory or otherwise sort or x-ray~~ the contents of inner liners. All liners shall be ~~incinerated~~ destroyed by an appropriately licensed and registered DEA reverse distributor in a manner that makes the drugs irretrievable.

(c) **If a reverse distributor picks up the sealed inner liners from the collector's authorized location, at least ~~T~~t**wo employees of the reverse distributor shall **be present. ~~pick up or accept the receipt of inner liners from DEA registrants.~~ 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) Each reverse distributor with an incineration site shall maintain a record of the destruction on DEA form 41. The records shall be complete, accurate, and include the name and signature of the two employees who witness the destruction.~~

~~(f)~~(e) For each sealed liner or mail back envelopes or packages received ~~**from collectors or law enforcement**~~ 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) ~~Inventory~~ 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 ~~number~~ name and signature of the two employees of the registrant that witnessed the destruction.

(f) 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, and 1317.55 Title 21 Code of Federal Regulations.

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

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

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

~~(a) When obtaining unused mail-back packages and envelopes for future distribution:~~

~~(1) The collector pharmacy shall maintain records that identify: the date the envelope or package was obtained by the pharmacy, the number of packages/envelopes made available to the public, and the unique identification number of each package.~~

~~(2) For unused packages and envelopes provided to a skilled nursing facility or third party to make available to patients and other authorized individuals: the name of the third party and physical address of the location receiving the unused packages, date sent, and the number of unused packages sent with the corresponding unique identification number.~~

~~(b) For each mail-back package or envelope distributed by a pharmacy, the pharmacy shall record the serial number of each package or envelope distributed and the date distributed.~~

~~(c) For sealed mail-back packages received by the reverse distributor: the date of receipt and the unique identification of the individual package or envelope,~~

~~(d) For sealed mail back packages destroyed onsite by the reverse distributor collector: number of sealed mail-back packages destroyed, the date and method of destruction, the unique identification number of each mail-back package destroyed, and the names and signatures of the two employees of the registrant who witness the destruction.~~

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

(1) Date each unused liner is acquired, its unique identification number and size (e.g., ~~five~~ 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., ~~five-~~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 ~~each~~ 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)~~and the signature of the driver~~.

(b) ~~For each reverse distributor (wholesaler or third-party logistics provider) accepting sealed mail-back packages: the date of receipt and the unique identification of the individual package or envelope.~~

~~(c) For each reverse distributor that will destroy the mail-back packages: the number of sealed mail-back packages destroyed, the date and method of destruction, the unique identification number of each mail-back package destroyed, and the names and signatures of the two employees of the registrant who witness the destruction.~~

~~(f)~~ (d) ~~For each reverse distributor (wholesaler or third-party logistics provider) accepting liners, the following records must be maintained, with recording taking place immediately upon receipt of a liner:~~

~~(1) The date of receipt of each liner, the unique serial number of the liner, the pharmacy from which the liner was received, the method by which the liner was delivered to the reverse distributor (e.g., personal delivery by two pharmacy staff, shipping via common carrier or pick-up by reverse distributor).~~

~~(2) For each liner destroyed by the reverse distributor collector: the method and date of destruction, listed by the unique identification number of liner and other items required by (f)(1), and the names and signatures of the two employees of the registrant who witness the destruction.~~

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005, Business and Professions Code and Section ~~1317.22~~ 1304.22, Title 21 Code of Federal Regulations

Attachment 9

Delegation of Certain Function

1703

Title 16. Board of Pharmacy

PROPOSED LANGUAGE

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

§ 1703. Delegation of Certain Functions.

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

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

Attachment 10

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 11

Fee Schedule

16 CCR 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 12

Third-Party Logistics Providers

§ 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 13

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.

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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 14

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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www.pharmacy.ca.gov

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): _____

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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: _____

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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])

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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: _____

_____

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: _____

_____

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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PIC Initials

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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:

_____

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: _____

_____

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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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.

CORRECTIVE ACTION OR ACTION PLAN: _____

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PIC Initials

DRAFT

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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PIC Initials

☐☐☐ 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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PIC Initials

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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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PIC Initials

DRAFT

☐☐☐ 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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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 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 _____

DRAFT

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PIC Initials

Attachment 15

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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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~~). 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): _____

_____
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: _____

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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?

_____
PIC Initials

☐☐☐ 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: _____

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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 (insert section??)
- ☐ 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)

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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])~~

PIC Initials

☐☐☐ ~~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)

PIC Initials

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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PIC Initials _____

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~~3. 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)

Comment [AFS1]: Giny will research

☐ 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.

☐☐☐ 26.4. 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

☐☐☐ 26.4. 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: _____

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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: _____

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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])

PIC Initials

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: _____

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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: _____

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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: _____

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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: _____

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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])

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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: _____

_____

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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PIC
Initials

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: _____

_____

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: _____

_____

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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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: _____

_____

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: _____

_____

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: _____

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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])

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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: _____

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26. Policies and Procedures

Yes No N/A

☐☐☐ 26.1. There are written policies and procedures in place for:

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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: _____

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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])

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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 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 _____

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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 _____

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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 _____

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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 _____

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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 _____

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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 _____

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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 _____

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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 _____

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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 _____

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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)

DRAFT

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)

DRAFT

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])

DRAFT

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 16

Trust Ownership

§ 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.