LEGISLATION AND REGULATION COMMITTEE

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Part 1: LEGISLATION REPORT

a. Board Sponsored Legislation

SB 1193 (Hill) California State Board of Pharmacy: Executive Officer
Version: February 18, 2016 - Introduced
Location: Senate Business Professions and Economic Development

This measure would extend the operations of the California Board of Pharmacy and the board’s authority to appoint an executive officer until January 1, 2021. A copy of the bill and a staff analysis are provided in Attachment 1.

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

Copies of each bill and related documents are provided in Attachment 2.

1. AB 45 (Mullin) Household Hazardous Waste

Version: January 21, 2016 Amended
Location: Senate Environmental Quality Committee
Position: Oppose Unless Amended (prior version: 4/30/15)

The bill adds Article 3.4 “Household Hazardous Waste Collection and Reduction” to the Public Resources Code. The bill would require the Department of Resources Recycling and Recovery (CalRecycle) to adopt one or more model ordinances for a comprehensive program for the collection of household hazardous waste, and then post the ordinance(s) on CalRecycle’s web site. Thereafter, a local jurisdiction that provides for the residential collection and disposal of solid waste that proposes to enact an ordinance governing the collection and diversion of household hazardous waste may adopt one of the model ordinances posted by CalRecycle.
The bill establishes various definitions, including but not limited to “comprehensive program for the collection of household hazardous waste,” “household hazardous waste,” and “home-generated pharmaceutical waste.”

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bill would specify if CalRecycle makes no such determination by December 31, 2018, then the provisions of the bill are repealed on January 1, 2019.

For the prior version of the bill (4/30/15) the board voted to oppose unless amended, and to seek amendments that would require mail back of dangerous drugs. The requested amendments were not accepted.

2. **AB 1069 (Gordon) Prescription Drugs: Collection and Distribution Program**
   - **Version:** July 1, 2015 Amended
   - **Location:** Senate Appropriations Committee (7/7/2015)
   - **Position:** Oppose Unless Amended

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

   Board staff has worked with the author’s office to secure amendments to address many of the legal conflicts the measure initially contained, but there are still some concerns with the bill in its current form. Currently, the bill would remove a pharmacist from several aspects of the redistribution program of prescription drugs; would allow a “participating entity” to transfer drugs like a distributor without appropriate licensure and control; and would permit what is currently unlawful repackaging and co-mingling of previously dispensed medications, including donated medications from various sources, all to the detriment of patient safety. Staff continues to reach out to the author’s office and will provide updates – if any are available – at the committee meeting.

3. **AB 1386 (Low) Emergency Medical Care: Epinephrine Auto-Injectors**
   - **Version:** January 13, 2016 Amended
   - **Location:** Senate Health
   - **Coauthors:** Assembly Members Chang, Daly and Wilk, and Senator Huff

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

   Version: February 16, 2016 Introduced
   Location: Referred to Assembly Health

   As introduced, AB 1977 would make changes to the Health and Safety Code and to the Insurance Code regarding coverage of abuse-deterrent opioid analgesic drug products. In its current form the measure does not appear to impact the board’s jurisdiction or board operations. Board staff was advised that the measure will most likely be amended to include provisions that would impact the board. Board staff was unable to secure a copy of the proposed amendments and the amended version is not yet in print. As such, neither the bill nor an analysis is provided. Board staff will continue to monitor this measure and will bring it to the full board during the April Board Meeting if appropriate.

5. **AB 2144 (Rodriguez) Pharmacy: Prescriptions**
   Version: February 17, 2016 Introduced

   The author’s office has advised that this bill is a spot bill. As such, no analysis is provided. Staff will continue to watch this measure and will provide the committee with any updates, as needed. A copy of the bill only is provided in Attachment 2.

6. **AB 2592 (Cooper) Prescriptions**
   Version: February 19, 2016 Introduced

   The author’s office has advised that this bill is a spot bill. As such, no analysis is provided. Staff will continue to watch this measure and will provide the committee with any updates, as needed. A copy of the bill only is provided in Attachment 2.

7. **SB 482 (Lara) Controlled Substances: CURES database**
   Version: April 30, 2015
   Location: Held at Assembly Desk (5/28/15)

   This measure would require a prescriber to access the CURES system under specified conditions, to include checking the system before prescribing a Schedule II or Schedule III medication for the first time and at least annually.
8. **SB 999 (Pavley) Health Insurance: Contraceptives: Annual Supply**
   Version: February 10, 2016 Introduced
   Status: Referred to Senate Business, Professions and Economic Development and to Senate Health
   Hearing: April 4, 2016 Senate Business, Professions and Economic Development

   SB 999 would require a health care service plan or health insurance policy, on or after January 1, 2017, to cover a 12-month supply of a self-administered hormonal contraception dispensed at one time by a prescriber or dispenser. This bill would also authorize a pharmacist to dispense prescribed, FDA-approved, self-administered hormonal contraceptives either as prescribed or, at the patient's request, in a 12-month supply, unless the prescriber specifically indicates no change to quantity.

9. **SB 1217 (Stone) Healing Arts: Reporting Requirements: Professional Liability**
   Version: February 18, 2016 Introduced
   Location: Senate Business, Professions and Economic Development
   Hearing: April 11, 2016

   This measure would increase the mandatory reporting from $3,000 to $10,000 where there is a judgment or settlement requiring the licensee or licensee’s insurer to pay damages for any claim that injury or death was proximately caused by the licensee’s negligence, error or omission in practice, or rendering unauthorized professional service.

10. **SB 1229 (Senator Jackson and Assembly Member Stone) Pharmacies: Secure Drug Take-Back Bins**
    Version: February 18, 2016 Introduced
    Location: Senate Environmental Quality
    Hearing: April 6, 2016

    Senate Bill 1229 would require a pharmacy that owns or operates a secure drug take-back bin, as defined, in a publicly accessible location to take reasonable steps to ensure the proper disposal of the pharmaceutical waste contained in the bins. The bill would provide that the owner or operator is not liable for civil damages arising from the use of the secure drug take-back bin if the owner or operator takes reasonable steps, as specified, to ensure the health and safety of consumers and employees and the proper disposal in the waste stream of the pharmaceutical waste contained in the bins.

    The author’s office has indicated that SB 1229, as introduced, is a substantive spot bill, and that amendments are expected to be in print by the end of March. Staff will provide the committee with an update, if any is available, at the meeting.
11. SB 1230 (Stone) Pharmacies: Compounding

Version: February 18, 2016 Introduced
Location: Senate Business, Professions and Economic Development
Hearing: April 11, 2016

This bill would allow a pharmacy to compound nonpatient-specific medications, as specified, to a clinic if a professional compounding services agreement is in place.


Version: February 19, 2016 Introduced
Location: Senate Business, Professions and Economic Development
Hearing: April 4, 2016

This measure would allow a pharmacist to provide medication guides via e-mail at the request of a patient.

13. SB 1454 (Stone) Pharmacy

Version: February 19, 2016 Introduced
Location: Senate Rules

The author’s office has indicated that SB 1454, as introduced, is a spot bill. Staff will continue to watch this measure and will provide the committee with any updates, as needed. A copy of the bill only is provided in Attachment 2.

c. Legislation Impacting Board Operations

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

Version: August 19, 2015
Location: Last location was Senate Appropriations / Held under submission
Position: Oppose (4/22/15 text version)

AB 12 would require state agencies to review, adopt, amend or repeal any regulations that are duplicative, overlapping, and inconsistent or out-of-date by January 1, 2018, and establish reporting requirements. The bill was amended on August 19, 2015, but there are no substantive differences from the prior version. Staff recommends the board maintain its oppose position.
2. **AB 1939 (Patterson) Licensing Requirements**  
   Version: February 12, 2016 Introduced  
   Location: Assembly Business & Professions  
   
   The author’s office has indicated that this is a spot bill. No analysis is provided, and staff will continue to monitor this measure. If needed, staff will provide an update to the committee at the meeting.

d. **Other Pieces of Legislation Impacting the Practice of Pharmacy, the Board’s Jurisdiction or Board Operations**

**Part 2: Regulation Report**

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

1. **Proposed Regulations to Amend Title 16 California Code of Regulations (CCR) Sections 1715 and 1784 related to Self-Assessment Forms for Community Pharmacies/Hospital Outpatient Pharmacies (17M-13), Hospital Pharmacies (17M-14), and Wholesalers (17M-26)**

   In March 2015, the board initiated a formal rulemaking process to amend the text of Title 16 CCR sections 1715 and 1784 and to amend the Self-Assessment Forms incorporated by reference therein. Existing regulation requires a pharmacy, wholesaler and hospital to complete a self-assessment by July 1 of each odd-numbered year, and at other times, as specified in the regulation(s). On January 19, 2016, following the completion of two 45-day comment periods, the board adopted the final regulation text. The final rulemaking file was submitted to the Office of Administrative Law for final review on March 10, 2016.

   A copy of the adopted regulation language is provided in Attachment 3.

2. **Proposed Regulations to Add Title 16 CCR section 1746.4 related to Vaccinations**

   In July 2015, the board initiated a formal rulemaking to add Section 1746.4 to Title 16 of the California Code of Regulations to specify the requirements for a pharmacist to administer vaccinations. On January 19, 2016, following the completion of a 45-day comment period and two 15-day comment periods, the board adopted the final regulation text. The final rulemaking file was submitted to the Department of Consumer Affairs for final review on January 29, 2016.

   A copy of the adopted regulation language is provided in Attachment 3.
3. **Proposed Regulations to Amend Title 16 CCR sections 1735 and 1751 et seq. related to Compounding**

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

A copy of the adopted regulation language is provided in Attachment 3.

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

1. **Proposed Regulations to Add Title 16 CCR sections 1730, 1730.1 and 1749 related to Advanced Practice Pharmacists**

In July 2015, staff initiated a formal rulemaking to add Sections 1730, 1730.1, and amend section 1749 of Title 16 of the California Code of Regulations related to the licensing requirements for advanced practice pharmacist. On January 19, 2016, following the completion of a 45-day comment period and two 15-day comment periods, the board adopted the final regulation text. Upon drafting the final rulemaking package to submit for administrative review by the Department of Consumer Affairs and the Office of Administrative Law, board staff identified comments received during the 45-day and two 15-day comment periods that were not brought to the board for review. These comments were brought to the board at the February 2016 board meeting. Board staff is currently drafting the final rulemaking package to submit for administrative review by the Department of Consumer Affairs and the Office of Administrative Law.

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

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

At the November 2015 Board Meeting, the board approved proposed text to add Section 1730.2 of Title 16 of the California Code of Regulations, establishing the certification program criteria for advanced practice pharmacist. The 45-day comment period began on December 25, 2015 and ended February 8, 2016. At the February 2016 board meeting, the board adopted the final regulation text. Board staff is currently
drafting the final rulemaking package to submit for administrative review by the Department of Consumer Affairs and the Office of Administrative Law.

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

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

In September 2015, staff initiated a formal rulemaking to amend Section 1760 to Title 16 of the California Code of Regulations related to the board’s disciplinary guidelines. At the February 2016 board meeting, the board adopted the final regulation text. Upon drafting the final rulemaking package to submit for administrative review by the Department of Consumer Affairs and the Office of Administrative Law, board staff identified documents that needed to be added to the rulemaking file. Board staff will be submitting a 15-day notice to add the documents to the rulemaking file and, upon completion, the file will be routed for final approval with the Department of Consumer Affairs and the Office of Administrative Law.

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

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

At the June 2015 Board Meeting, the board approved proposed text to add Section 1746.5 of Title 16 CCR, related to the furnishing of travel medications. On January 19, 2016, following the completion of a 45-day comment period and a 15-day comment period, the board adopted the final regulation text. This regulation will be discussed during the March 28, 2016 teleconference meeting. An updated on the issue will be provided during the committee meeting.

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

c. Board Approved – Comment Period Closed; Awaiting Action by Board / Licensing Committee

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

At the April 2015 Board Meeting, the board approved proposed text to amend Section 1744 of Title 16 of the California Code of Regulations to amend the drug warnings label requirements. The 45-day comment period closed on November 9, 2015. The comments are pending review by the full Board in April.
2. Proposed Regulations to Amend Title 16 CCR section 1707.5 related to Patient-Centered Labels

At the October 2014 Board Meeting, the board approved proposed text to amend section 1707.5(a)(1)(B) of Title 16 CCR to add “Generic for _____” and translation services. The 45-day comment period closed on December 7, 2015, and the comments are pending review by the full board at the April 2016 board meeting.

A copy of the language released for the 45-day comment period is provided in Attachment 5.

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

At the July 2015 Board Meeting, the board approved proposed text to add Section 1715.65 of Title 16 of the California Code of Regulations related to reconciliation and inventory of controlled substances. The 45-day comment period ended on November 30, 2015. The comments are pending review by the full Board in April.

A copy of the language released for the 45-day comment period is provided in Attachment 5.

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

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

A copy of the language released for the 45-day comment period is provided in Attachment 5.
d. Board Approved – Currently Undergoing 15-Day Comment Period

1. Proposed Regulation to Add Title 16 CCR section 1746.1 related to Self-Administered Hormonal Contraception

   In May 2015, the board initiated a formal rulemaking to add Section 1746.1 Title 16 California Code of Regulations related to Self-Administered Hormonal Contraception. On January 19, 2016, the Board adopted the final regulation text. On March 2, 2016, the Office of Administrative Law requested that additional information be added to the Initial Statement of Reasons. On March 9, 2016, a revised Initial Statement of Reasons was noticed for a 15-day comment period. The comment period closes on March 24, 2016.

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

e. Board Approved – Awaiting Notice

1. Proposed Regulation to Amend Title 16 CCR section 1703 (Title 1, CCR, Section 100 changes)

   At the October 2013 Board Meeting, the board approved proposed text to amend Section 1703 of Title 16 of the California Code of Regulations related to “Section 100” requirements which delegate to the Executive Officer the authority to initiate a rulemaking to adopt “changes without regulatory effect.” Additionally, at the February 2016 Board Meeting, the board approved proposed text to delegate to the Executive Officer the authority to “approve waivers pursuant to Section 4076.5(e)” regarding patient-centered labels. Board staff is preparing the required notice documents and anticipates initiating the rulemaking process in April 2016.

   A copy of the board-approved language (not yet noticed) is provided in Attachment 7.

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

   At the July 2013 Board Meeting, the board approved proposed text to amend Sections 1702, 1702.1, 1702.2, and 1702.5 of Title 16 of the California Code of Regulations related to standardized reporting of convictions and discipline at the time of renewal for pharmacists, pharmacy technicians and designated representatives, as well as require nonresident wholesalers and nonresident pharmacies to report disciplinary actions by other entities at the time of renewal. This regulatory change is currently pending. Board staff anticipates initiating the rulemaking process in May 2016.

   A copy of the board-approved language (not yet noticed) is provided in Attachment 7.
3. **Proposed Regulations to Amend and/or Add Title 16 CCR sections 1780 – 1786, et seq., related to Third Party Logistics Providers**

At the July 2015 Board Meeting, the board approved proposed text to amend and/or add Sections 1780 et seq. to Title 16 of the California Code of Regulations to establish the regulatory requirements for Third-Party Logistics Providers. Board staff is preparing the required notice documents and anticipates initiating the rulemaking process in April 2016.

A copy of the board-approved language (not yet noticed) is provided in Attachment 7.
Attachment 1
**BILL ANALYSIS**

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<th>SB 1193</th>
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<tr>
<td>Current Version:</td>
<td>As Introduced February 18, 2016</td>
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<tr>
<td>Author:</td>
<td>Hill</td>
</tr>
<tr>
<td>Topic:</td>
<td>California State Board of Pharmacy</td>
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<td>Board Position:</td>
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**Affected Sections:** Section 4001 and 4003 of the Business and Professions Code

**Status:** Referred to Senate Committee on Business, Professions and Economic Development

**SUMMARY:**
This measure extends the operations of the California Board of Pharmacy and the board’s authority to appoint an executive officer until January 1, 2021.

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

**THIS BILL WOULD:**
Amend Section 4001(f) to extend the board’s sunset date to January 1, 2021.

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

**STAFF COMMENTS:**
The board president and executive staff provided testimony during a joint hearing of the Senate and Assembly oversight committee on March 14, 2016. As part of the hearing, information on specific issues was provided at the request of the committee. Those topics included background on the board, enforcement priorities, licensing backlog, fund condition and staffing levels and implementation of recently enacted legislation including SB 493 regulations.

As part of the Sunset review process, the board will have the opportunity to also provide written responses to all of the issues identified by the joint oversight committee.
FISCAL IMPACT ON THE BOARD:

In its current form, board staff does not anticipate any fiscal impact. It is anticipated that the measure will be further amended either at the request of the joint committee and/or the board as the bill moves through the process. Board staff will monitor its progress and update the fiscal impact if necessary.

HISTORY:

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<td>From printer. May be acted upon on or after March 20.</td>
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<td>02/18/16</td>
<td>Introduced. Read first time. To Com. on RLS. for assignment. To print.</td>
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An act to amend Sections 4001 and 4003 of the Business and Professions Code, relating to healing arts.

LEGISLATIVE COUNSEL’S DIGEST

SB 1193, as introduced, Hill. California State Board of Pharmacy: executive officer.

The Pharmacy Law provides for the licensure and regulation of the practice of pharmacy by the California State Board of Pharmacy, which is within the Department of Consumer Affairs, and authorizes the board to appoint, with the approval of the Director of Consumer Affairs, an executive officer, as specified. Existing law repeals the provisions establishing the board and authorizing the board to appoint an executive officer as of January 1, 2017. Under existing law, the board is subject to evaluation by the Joint Sunset Review Committee upon its repeal.

This bill would extend the operation of the board and the board’s authorization to appoint an executive officer until January 1, 2021.


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

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

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

(a) There is in the Department of Consumer Affairs a California State Board of Pharmacy in which the administration and enforcement of this chapter is vested. The board consists of 13 members.
(b) The Governor shall appoint seven competent pharmacists who reside in different parts of the state to serve as members of the board. The Governor shall appoint four public members, and the Senate Committee on Rules and the Speaker of the Assembly shall each appoint a public member who shall not be a licensee of the board, any other board under this division, or any board referred to in Section 1000 or 3600.

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

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

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

(f) This section shall remain in effect only until January 1, 2017, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2017, deletes or extends that date. Notwithstanding any other provision of law, the repeal of this section renders the board subject to review by the appropriate policy committees of the Legislature.

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

4003. (a) The board, with the approval of the director, may appoint a person exempt from civil service who shall be designated
as an executive officer and who shall exercise the powers and
perform the duties delegated by the board and vested in him or her
by this chapter. The executive officer may or may not be a member
of the board as the board may determine.
(b) The executive officer shall receive the compensation as
established by the board with the approval of the Director of
Finance. The executive officer shall also be entitled to travel and
other expenses necessary in the performance of his or her duties.
(c) The executive officer shall maintain and update in a timely
fashion records containing the names, titles, qualifications, and
places of business of all persons subject to this chapter.
(d) The executive officer shall give receipts for all money
received by him or her and pay it to the department, taking its
receipt therefor. Besides the duties required by this chapter, the
executive officer shall perform other duties pertaining to the office
as may be required of him or her by the board.
(e) This section shall remain in effect only until January 1, 2017,
2021, and as of that date is repealed, unless a later enacted statute,
that is enacted before January 1, 2017, deletes or extends that date.
repealed.
Attachment 2
Assembly Bill 45 would require the California Department of Resources Recycling and Recovery (CalRecycle) to adopt one or more model ordinances for a comprehensive program for the collection of household hazardous waste; would authorize a local jurisdiction that provides for the residential collection and disposal of solid waste that proposes to enact an ordinance for the collection and diversion of household hazardous waste to adopt one of the model ordinances adopted by CalRecycle; and would define “household hazardous waste,” “home-generated pharmaceutical waste” and other terms.

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

**Prior Versions:**

The board’s current position (based on the 4/30/15 text version) is Oppose Unless Amended. The board offered amendments that would require mail-back return of prescription drugs which is consistent with federal law, but the board’s requested amendments were not accepted.

The differences between the prior version and the current version are as follows:

- Removes the intent language that the legislation would establish curbside, door-to-door and residential pickup services as the principal means of collecting waste, as specified [SEC. 1]
• Adds the Article 3.4 Heading “Household Hazardous Waste Collection and Reduction” [SEC. 2]
• Removes the mandate that a local jurisdiction shall increase its baseline collections, as defined, and to report such to CalRecycle; [prior section 47121]
• Removes CalRecycle’s authority to adopt regulations and, instead, requires CalRecycle to consult with affected industries and stakeholders to adopt one or more model ordinances. [new Section 47121]

THIS BILL

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

Section 47120: Establishes various definitions including:
(a) “Comprehensive program for the collection of household hazardous waste” means a local program that includes several components:
   a. Utilization of locally sponsored collection sites
   b. Scheduled and publicly advertised drop off days
   c. Door-to-door collection programs
   d. Mobile collection programs
   e. Dissemination of information about how consumers should dispose of the various types of household hazardous waste
   f. Education programs to promote consumer understanding and use of the location components of a comprehensive program.

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

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

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

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

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

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

EXISTING LAW:

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

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

STAFF COMMENTS:

Prior versions of this bill allowed for curbside pickup of household hazardous waste (including prescription drugs). The bill is silent on safety measures to ensure the security of the home-generated pharmaceutical waste as part of the comprehensive program.

Board staff has conveyed concerns to the sponsors of this measure as well as amendments that would require mail back of prescription drugs, to ensure consistency with federal law – the amendments were not accepted.

As reflected in the Assembly Floor Analysis (recent amendment) the author has stated that state law has loosely regulated household hazardous waste for approximately 25 years. Declarations in the bill cite very low consumer participation in local efforts to collect household hazardous waste. Opponents of the measure cite different ways that household hazardous waste is handled by jurisdictions and the need to ensure that these types of waste be handled appropriately.

1 Medical Waste Management Act administered by the California Department of Public Health
The board may wish to request amendments to remove “home-generated pharmaceutical waste” from the provisions all together and/or to oppose the bill.

**FISCAL IMPACT ON THE BOARD:**

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

**SUPPPORT/OPOSSESSION:** (based on the text version 4/23/15)

<table>
<thead>
<tr>
<th>Support</th>
<th>Opposition</th>
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<tr>
<td>California Healthcare Institute</td>
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<td>TechNet</td>
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<td>BIOCOM</td>
<td>California State Association of Counties</td>
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<td>Biotechnology Industry Association</td>
<td>Solid Waste Association of North America</td>
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<td>California Cable &amp; Telecommunications Association</td>
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<td>California Product Stewardship Council</td>
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<td>Contra Costa Clean Water Program</td>
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<td>Los Angeles County Integrated Waste Management Task Force</td>
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<td>Lincoln Policy Department</td>
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<td>Rocklin Police Department</td>
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<td>Roseville Police Department</td>
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**HISTORY:**

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<tr>
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</tr>
<tr>
<td>01/25/16</td>
<td>Read second time. Ordered to third reading.</td>
</tr>
<tr>
<td>01/21/16</td>
<td>Read second time and amended. Ordered returned to second reading.</td>
</tr>
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<td>01/21/16</td>
<td>From committee: Amend, and do pass as amended. (Ayes 12. Noes 0.) (January 21).</td>
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<td>05/28/15</td>
<td>In committee: Hearing postponed by committee.</td>
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<td>05/20/15</td>
<td>In committee: Set, first hearing. Referred to APPR. suspense file.</td>
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<td>05/04/15</td>
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<td>04/30/15</td>
<td>Read second time and amended.</td>
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<td>04/29/15</td>
<td>From committee: Amend, and do pass as amended and re-refer to Com. on APPR. (Ayes 4. Noes 2.) (April 28).</td>
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<td>Re-referred to Com. on E.S. &amp; T.M.</td>
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<tr>
<td>04/23/15</td>
<td>From committee chair, with author's amendments: Amend, and re-refer to Com. on E.S. &amp; T.M. Read second time and amended.</td>
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<td>04/14/15</td>
<td>Re-referred to Com. on L. GOV.</td>
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<td>04/13/15</td>
<td>From committee chair, with author's amendments: Amend, and re-refer to Com. on L. GOV. Read second time and amended.</td>
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<td>03/23/15</td>
<td>Re-referred to Com. on L. GOV.</td>
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<td>03/19/15</td>
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<td>Referred to Coms. on L. GOV. and E.S. &amp; T.M.</td>
</tr>
<tr>
<td>12/02/14</td>
<td>From printer. May be heard in committee January 1.</td>
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<tr>
<td>12/01/14</td>
<td>Read first time. To print.</td>
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</table>
SECTION 1. The Legislature finds and declares all of the following:

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

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

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

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

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

Article 3.4. Household Hazardous Waste Collection and Reduction

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

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

(1) Utilization of locally sponsored collection sites.

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

(3) Door-to-door collection programs.

(4) Mobile collection programs.

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

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

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

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

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

(3) Household chemicals, including, but not limited to, ammonia, cleaners, strippers, and rust removers.
(4) Paint products, including, but not limited to, paint, caulk, glue, stripper, thinner, and wood preservatives and stain.

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

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

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

(8) Fluorescent tubes and compact fluorescent lamps.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(c) Upon making a determination that an appropriate nonprofit organization exists as set forth in subdivision (a), the department shall post the fact that the department has made this determination on the department’s Internet Web site.
47123. This article is applicable only to local jurisdictions that provide for the residential collection and disposal of solid waste.

47124. If the department does not make the determination that there exists an appropriate nonprofit organization, as specified in subdivision (a) of Section 47122, by December 31, 2018, this article shall be repealed on January 1, 2019.
SUMMARY
Household Hazardous Wastes (HHW) are products individuals use in their daily lives that contain potentially hazardous ingredients. These products require special care when disposed of but more often than not consumers may not have the most convenient mechanisms to do so.

Although it is illegal to dispose of HHW in the trash, down the drain or by abandonment, people may not know the hazardous effects of these products on human health, animals and the environment.

Recent CalRecycle statistics indicate the State’s HHW collection and disposal programs are moribund. Data shows that only 7% of Californians dispose of HHW products properly. This paltry participation rate shows how much improvement the state can make in the future.

CURRENT LAW
State law has loosely regulated Household Hazardous Wastes for approximately 25 years. Generally, HHWs are ubiquitous household products that contain small amounts of hazardous or toxic substances and require more intensive handling, treatment, or disposal than solid waste, but fall outside the State’s hazardous waste laws applicable to industrial and large commercial facilities. HHWs include: paint, pesticides, compact fluorescent lamps (CFLs), batteries, sharps, discarded drugs, and similar products.

SOLUTION
AB 45 aims to coordinate with local governments, producers of HHW products and CalRecycle to adopt model ordinances for a comprehensive program for the collection of household hazardous waste.

Local governments have the option to choose whether or not to use the model ordinances listed by CalRecycle.

In addition, CalRecycle will determine whether or not an appropriate nonprofit organization has been created with the following considerations:

1) has a minimum of 5 million dollars dedicated to assist in educating residents about HHW disposal programs and how to use them (please see attached industry letter)

2) has sufficient funding to allocate grants to local governments throughout the state

3) the board of directors is diverse and experienced to appropriately consider grant applications that will positively impact efforts to improve disposal of HHW

4) has appropriate criteria for considering grant applications

STAFF CONTACT
Elena Santamaria
Elena.Santamaria@asm.ca.gov
916.319.2022
**Bill Analysis**

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

**Affected Sections:** Amend section 150204 of the Health and Safety Code (H&SC)  
**Status:** In Senate Appropriations Committee  

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

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

H&SC Section 150201 provides definitions for purposes of the division including  
- Donor organization as a health and care facilities that donates centrally stored unused medications including: general acute care hospital, acute psychiatric hospital, skilled nursing facility, intermediate care facility, correctional treatment center, psychiatric health facility, chemical dependency recovery hospital, residential care home, and approved mental health rehabilitation center.  
- Eligible Entity which includes a licensed pharmacy as specified  
- Medication as a dangerous drug as defined in B&PC 4022  
- Participating Entity as an entity eligible that operates a repository and distribution program  

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

H&SC 150203 allows for a wholesaler and drug manufacturer to donate unused medication.
H&SC 150204 sets forth the means by which a county may establish a program, the reporting requirements as well as the written procedures that address the following:

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

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

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

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

**THIS BILL WOULD:**

Amend H&SC Section 150204

a. To allow for the transfer of donated medications from one county entity to another county. It would also allow for a transfer of up to 15% of the donated medications received annually unless a transfer is done that is patient and prescription specific.

b. To allow for medications to be repackaged into new, properly labeled containers until dispensed and specify that such a medication cannot be repackaged more than two times. The repackaging could be of a supply of no more than 90 days and would allow for the mixing of lot numbers and expiration dates. Such information would be required to be included on the label.

**STAFF COMMENTS:**

During the previous committee meeting and board meeting, Board staff discussed several concerns with the proposed expansion of this program and the conflicts it created with federal and state law. Last year board staff has spent considerable staff time working with the author’s office and sponsors to highlight these conflicts and secure amendments to remove such conflicts. The recent amendments to this law create new conflicts with federal and state law, including repackaging in entities that are neither pharmacies nor licensed by the State Food and Drug Branch or the FDA. Such repackaging could also be performed without a pharmacist oversight. This repackaging appears to create conflict with Good Manufacturing Practices and is in conflict with USP standards.
Further, board staff continues to question the need to expand the transfer provisions of the current law given that only one county in California is currently operating a program and staff is unaware of any eminent adoption by other counties.

**FISCAL IMPACT ON THE BOARD:**

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

**HISTORY:**

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<td>07/07/2015</td>
<td>July 7 From committee: Do pass and re-refer to Com. on APPR. (Ayes 7. Noes 0.) (July 6). Re-referred to Com. on APPR.</td>
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<td>June 15 In committee: Set, first hearing. Hearing canceled at the request of author.</td>
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<td>05/07/2015</td>
<td>May 7 Read second time. Ordered to third reading.</td>
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<td>05/06/2015</td>
<td>May 6 Read second time and amended. Ordered returned to second reading.</td>
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<td>May 5 From committee: Amend, and do pass as amended. (Ayes 17. Noes 0.) (May 5).</td>
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<td>03/26/2015</td>
<td>Mar. 26 Referred to Com. on HEALTH. From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.</td>
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<td>02/27/2015</td>
<td>Feb. 27 From printer. May be heard in committee March 29.</td>
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<tr>
<td>02/26/2015</td>
<td>Feb. 26 Read first time. To print.</td>
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AB-1069 Prescription drugs: collection and distribution program. (2015-2016)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(1) Dispensed to an eligible patient.

(2) Destroyed.

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

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

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

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

(h) Medication that is donated to the repository and distribution program that does not meet the requirements of this division shall not be distributed or transferred under this program and shall be either destroyed or returned to a reverse distributor. This medication shall not be sold, dispensed, or otherwise transferred to any other entity.
(i) **(1)** Medication donated to the repository and distribution program shall be maintained in the donated packaging units or new, properly labeled containers until dispensed to an eligible patient under this program, who presents a valid prescription. When dispensed to an eligible patient under this program, the medication shall be in a new and properly labeled container, specific to the eligible patient and ensuring the privacy of the individuals for whom the medication was initially dispensed. Expired medication shall not be dispensed. **Donated medication shall not be repackaged more than two times. Nothing in this section requires donated medication to be repackaged two times.**

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

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

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

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

(i) All applicable lot numbers.

(ii) The earliest expiration date.

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

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

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

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

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

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

**Bill Number:**  AB 1386  
**Current Version:**  January 13, 2016  
**Author:**  Low  
**Topic:**  Emergency medical care: epinephrine auto-injectors  
**Board Position:**  

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

**Status:**  Referred to Senate Health  

**SUMMARY:**  
This measure would amend Pharmacy Law and other provisions of the Civil Code and Health and Safety Code to authorize a health care provider to issue a prescription, and a pharmacy to furnish epinephrine auto-injectors to an authorized entity, as defined. The bill calls for specific labeling on any epinephrine auto-injectors dispensed pursuant to the bill’s provisions. Authorized entities include any for-profit, nonprofit, or government entity or organization that employs at least one person or utilizes at least one volunteer or agent that has voluntarily completed a training course, as defined. As is with current law, authorized training providers shall be approved, and the minimum standards for training and the use and administration of epinephrine auto-injectors shall be established and approved by the California Emergency Medical Services Authority (EMSA). A copy of the bill is provided in Attachment 1.

**EXISTING LAW:**  
Authorizes a pharmacy to furnish epinephrine auto-injectors to a school district, county office of education, or charter school, so long as the epinephrine auto-injectors are furnished exclusively for use at a school district site, county office of education or charter school; and requires that a physician and surgeon provides a written order that specifies the quantity of epinephrine auto-injectors to be furnished.

Authorizes a pharmacy to dispense epinephrine auto-injectors to a prehospital emergency medical care person or lay rescuer for the purpose of rendering emergency care, as specified; prescribes labeling for epinephrine auto-injectors dispensed pursuant to this section; and requires the person receiving the epinephrine auto-injectors to make and maintain records, as specified.
Section 1797.197 of the Health and Safety Code specifies various definitions, to include “anaphylaxis,” “epinephrine auto-injector” and others.

Establishes the California Emergency Medical Services (EMS) Authority, and requires the authority to establish and approve the minimum standards for training and the use and administration of epinephrine auto-injectors.

THIS BILL WOULD:

Specific to pharmacy law, this measure would:
Add Section 4119.4 to the Business and Professions Code to authorize a pharmacy to dispense epinephrine auto-injectors to an “authorized entity” under the following conditions
- if it will be used by or in connection with an authorized entity
- is provided pursuant to a prescription written by a health care provider that includes the quantity to be furnished
- is labeled with the name of the person or entity to whom the prescription was issued, the dosage, use and expiration date as well as appropriate designations related to First Aid
- the manufacturer’s product information sheet is provided
- records of acquisition and disposition are maintained

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

Amend the Civil Code to provide civil immunity to an authorized entity’s employees, volunteers, or agents who is a lay rescuer, as defined. This provision does not apply where damages may result from an act or omission that constitutes gross negligence or willful or wanton misconduct connected to the administration of the epinephrine auto-injector.

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

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

Requires authorized entities to submit to the Department of Public Health a report of each incident that involves the administration of an epinephrine auto-injector, as specified.

Requires the Department of Public Health to annually publish a report that summarizes and analyzes all reports submitted to it.
FISCAL IMPACT ON THE BOARD:
Staff does not anticipate any impact to the board or its operations.

**SUPPORT: (1/13/16 version)**
- Two individuals
- American Red Cross
- Allergy & Asthma Network
- San Francisco Bay Area Food Allergy Network
- American Latex Allergy Association
- Mylan, Inc. (sponsor)
- Allergy Station
- California ACEP

**OPPOSITION: None**

**HISTORY:**

<table>
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<tr>
<th>Date</th>
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<tbody>
<tr>
<td>02/04/2016</td>
<td>Feb. 4 Referred to Coms. on HEALTH and JUD.</td>
</tr>
<tr>
<td>01/27/2016</td>
<td>Jan. 27 In Senate. Read first time. To Com. on RLS. for assignment.</td>
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<tr>
<td>01/15/2016</td>
<td>Jan. 15 From committee: Do pass and re-refer to Com. on APPR. (Ayes 9. Noes 0.) (January 15). Re-referred to Com. on APPR.</td>
</tr>
<tr>
<td>01/14/2016</td>
<td>Jan. 14 Re-referred to Com. on JUD.</td>
</tr>
<tr>
<td>01/13/2016</td>
<td>Jan. 13 Read second time and amended.</td>
</tr>
<tr>
<td>01/12/2016</td>
<td>Jan. 12 From committee: Amend, and do pass as amended and re-refer to Com. on JUD. (Ayes 14. Noes 0.) (January 12).</td>
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<tr>
<td>01/07/2016</td>
<td>Jan. 7 Assembly Rule 56 suspended. (Page 3367.) (pending re-refer to Com. on JUD.)</td>
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<tr>
<td>01/06/2016</td>
<td>Jan. 6 Re-referred to Com. on B. &amp; P.</td>
</tr>
<tr>
<td>01/05/2016</td>
<td>Jan. 5 From committee chair, with author's amendments: Amend, and re-refer to Com. on B. &amp; P. Read second time and amended.</td>
</tr>
<tr>
<td>01/04/2016</td>
<td>Jan. 4 From committee chair, with author's amendments: Amend, and re-refer to Com. on B. &amp; P. Read second time and amended. Re-referred to Com. on B. &amp; P.</td>
</tr>
<tr>
<td>04/28/2015</td>
<td>Apr. 28 In committee: Hearing postponed by committee.</td>
</tr>
<tr>
<td>04/23/2015</td>
<td>Apr. 23 From committee: Be re-referred to Coms. on B. &amp; P. and JUD. (Ayes 10. Noes 0.) (April 23). Re-referred to Com. on B. &amp; P.</td>
</tr>
<tr>
<td>04/20/2015</td>
<td>Apr. 20 Re-referred to Com. on B. &amp; P. Re-referred to Com. on RLS. pursuant to Assembly Rule 96.</td>
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<tr>
<td>04/16/2015</td>
<td>Apr. 16 From committee chair, with author's amendments: Amend, and re-refer to Com. on B. &amp; P. Read second time and amended.</td>
</tr>
<tr>
<td>04/06/2015</td>
<td>Apr. 6 Re-referred to Com. on B. &amp; P.</td>
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<tr>
<td>03/26/2015</td>
<td>Mar. 26 Referred to Com. on B. &amp; P. From committee chair, with author's amendments: Amend, and re-refer to Com. on B. &amp; P. Read second time and amended.</td>
</tr>
<tr>
<td>03/02/2015</td>
<td>Mar. 2 Read first time.</td>
</tr>
<tr>
<td>03/01/2015</td>
<td>Mar. 1 From printer. May be heard in committee March 31.</td>
</tr>
<tr>
<td>02/27/2015</td>
<td>Feb. 27 Introduced. To print.</td>
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</table>

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

4119.4. (a) Notwithstanding any other law, a pharmacy may furnish epinephrine auto-injectors to an authorized entity, as defined by Section 1797.197a of the Health and Safety Code, if both of the following requirements are met:

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

(2) An authorized health care provider provides a prescription that specifies the quantity of epinephrine auto-injectors to be furnished.

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

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

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

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

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

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

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

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

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

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

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

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

(2) “Epinephrine auto-injector” means a disposable drug delivery system with a spring-activated concealed needle that is designed for emergency administration of epinephrine to provide rapid, convenient first aid for persons suffering from anaphylaxis.

(b) (1) Any person described in subdivision (b) of Section 1797.197a of the Health and Safety Code who administers an epinephrine auto-injector, in good faith and not for compensation, to another person who appears to be experiencing anaphylaxis at the scene of an emergency situation is not liable for any civil damages resulting from his or her acts or omissions in administering the epinephrine auto-injector, if that person has complied with the requirements and standards of Section 1797.197a of the Health and Safety Code.

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

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

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

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

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

SEC. 3. Section 1797.197a of the Health and Safety Code is amended to read:

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

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

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

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

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

(3) “Epinephrine auto-injector” means a disposable drug delivery system with a spring-activated concealed needle that is designed for emergency administration of epinephrine to provide rapid, convenient first aid for persons suffering from anaphylaxis.

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

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

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

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

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

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

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

(5) The epinephrine auto-injectors obtained by prehospital emergency medical care personnel pursuant to Section 4119.3 of the Business and Professions Code shall be used only when functioning outside the course of the person’s occupational duties, or as a volunteer, pursuant to this section.
(6) The Emergency Medical Services System is activated as soon as practicable when an epinephrine auto-injector is used.

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

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

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

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

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

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

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

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

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

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

(A) Fraud.

(B) Incompetence.

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

(D) Conviction of any crime that is substantially related to the qualifications, functions, or duties of training program directors or instructors. The record of conviction or a certified copy of the record shall be conclusive evidence of the conviction.

(E) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of, or conspiring to violate, any provision of this section or the regulations promulgated by the authority pertaining to the review and approval of training programs in anaphylaxis and the use and administration of epinephrine auto-injectors, as described in this subdivision.

(d) (1) The authority shall assess a fee pursuant to regulation sufficient to cover the reasonable costs incurred by the authority for the ongoing review and approval of training and certification under subdivision (c).

(2) The fees shall be deposited in the Specialized First Aid Training Program Approval Fund, which is hereby created in the State Treasury. All moneys deposited in the fund shall be made available, upon appropriation, to the authority for purposes described in paragraph (1).

(3) The authority may transfer unused portions of the Specialized First Aid Training Program Approval Fund to the Surplus Money Investment Fund. Funds transferred to the Surplus Money Investment Fund shall be placed in a separate trust account, and shall be available for transfer to the Specialized First Aid Training Program Approval Fund, together with the interest earned, when requested by the authority.
(4) The authority shall maintain a reserve balance in the Specialized First Aid Training Program Approval Fund of 5 percent of annual revenues. Any increase in the fees deposited in the Specialized First Aid Training Program Approval Fund shall be effective upon determination by the authority that additional moneys are required to fund expenditures pursuant to subdivision (c).

(e) (1) An authorized health care provider may issue a prescription for an epinephrine auto-injector to a prehospital emergency medical care person or a lay rescuer for the purpose of rendering emergency care to another person upon presentation of a current certification demonstrating that the person is trained and qualified to administer an epinephrine auto-injector pursuant to this section or any other law.

(2) An authorized health care provider may issue a prescription for an epinephrine auto-injector to an authorized entity if the authorized entity submits evidence it employs at least one person, or utilizes at least one volunteer or agent, who is trained and qualified to administer an epinephrine auto-injector pursuant to this section.

(f) An authorized entity that possesses and makes available epinephrine auto-injectors shall do both of the following:

(1) Create and maintain on its premises an operations plan that includes all of the following:

(A) The name and contact number for the authorized health care provider who prescribed the epinephrine auto-injector.

(B) Where and how the epinephrine auto-injector will be stored.

(C) The names of the designated employees or agents who have completed the training program required by this section and who are authorized to administer the epinephrine auto-injector.

(D) How and when the epinephrine auto-injector will be inspected for an expiration date.

(E) The process to replace the expired epinephrine auto-injector, including the proper disposal of the expired epinephrine auto-injector or used epinephrine auto-injector in a sharps container.

(2) Submit to the State Department of Public Health, on a form developed by the State Department of Public Health, a report of each incident on the authorized entity's premises that involves the administration of an epinephrine auto-injector. The State Department of Public Health shall annually publish a report that summarizes and analyzes all reports submitted to it under this subdivision.

(g) This section shall not apply to a school district or county office of education, or its personnel, that provides and utilizes epinephrine auto-injectors to provide emergency medical aid pursuant to Section 49414 of the Education Code.

(h) This section shall not be construed to limit or restrict the ability of prehospital emergency medical care personnel, under any other statute or regulation, to administer epinephrine, including the use of epinephrine auto-injectors, or to require additional training or certification beyond what is already required under the other statute or regulation.

SEC. 4. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.
An act to amend Sections 4073.5 and 4074 of the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL’S DIGEST

AB 2144, as introduced, Rodriguez. Pharmacy: prescriptions.

The Pharmacy Law provides for the licensure and regulation of pharmacists by the California State Board of Pharmacy. That law establishes requirements for the substitution of an alternative biological product when a pharmacist is filling a prescription order for a prescribed biological product. That law requires a pharmacist to inform the patient orally or in writing of harmful effects of a drug dispensed by prescription, if the drug poses substantial risk to the person consuming the drug when taken in combination with alcohol, or if the drug may impair a person’s ability to drive a motor vehicle, whichever is applicable, and the board requires by regulation that warning is to be given.

This bill would make nonsubstantive changes to those substitution and warning provisions.


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

1. SECTION 1. Section 4073.5 of the Business and Professions Code is amended to read:
4073.5. (a) A pharmacist filling a prescription order for a
prescribed biological product may select an alternative biological
product only if all of the following apply:
(1) The alternative biological product is interchangeable.
(2) The prescriber does not personally indicate “Do not
substitute,” or words of similar meaning, in the manner provided
in subdivision (d) (e).
(b) Within five days following the dispensing of a biological
product, a dispensing pharmacist or the pharmacists’ designee
shall make an entry of the specific biological product provided to
the patient, including the name of the biological product and the
manufacturer. The communication shall be conveyed by making
an entry that can be electronically accessed by the prescriber
through one or more of the following electronic records systems:
(1) An interoperable electronic medical records system.
(2) An electronic prescribing technology.
(3) A pharmacy benefit management system.
(4) A pharmacy record.
(c) Entry into an electronic records system as described in
subdivision (b) is presumed to provide notice to the prescriber.
(d) If the pharmacy does not have access to one or more of the
entry systems in subdivision (b), the pharmacist or the pharmacist’s
designee shall communicate the name of the biological product
dispensed to the prescriber using facsimile, telephone, electronic
transmission, or other prevailing means, except that communication
shall not be required in this instance to the prescriber when either
of the following apply:
(1) There is no interchangeable biological product approved by
the federal Food and Drug Administration for the product
prescribed.
(2) A refill prescription is not changed from the product
dispensed on the prior filling of the prescription.
(e) In no case shall a selection shall not be made pursuant to
this section if the prescriber personally indicates, either orally or
in his or her own handwriting, “Do not substitute,” or words of
similar meaning.
(1) This subdivision shall not prohibit a prescriber from checking
a box on a prescription marked “Do not substitute,” provided that
the prescriber personally initials the box or checkmark.
(2) To indicate that a selection shall not be made pursuant to this section for an electronic data transmission prescription, as defined in subdivision (c) of Section 4040, a prescriber may indicate “Do not substitute,” or words of similar meaning, in the prescription as transmitted by electronic data, or may check a box marked on the prescription “Do not substitute.” In either instance, it shall not be required that the prohibition on substitution be manually initialed by the prescriber.

(f) Selection pursuant to this section is within the discretion of the pharmacist, except as provided in subdivision (e). A pharmacist who selects an alternative biological product to be dispensed pursuant to this section shall assume the same responsibility for substituting the biological product as would be incurred in filling a prescription for a biological product prescribed by name. There shall be no liability on the prescriber for an act or omission by a pharmacist in selecting, preparing, or dispensing a biological product pursuant to this section. In no case shall the pharmacist shall not select a biological product that meets the requirements of subdivision (a) unless the cost to the patient of the biological product selected is the same or less than the cost of the prescribed biological product. Cost, “Cost,” as used in this subdivision, includes any professional fee that may be charged by the pharmacist.

(g) This section shall apply to all prescriptions, including those presented by or on behalf of persons receiving assistance from the federal government or pursuant to the Medi-Cal Act set forth in Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code.

(h) When a selection is made pursuant to this section, the substitution of a biological product shall be communicated to the patient.

(i) The board shall maintain on its public Internet Web site a link to the current list, if available, of biological products determined by the federal Food and Drug Administration to be interchangeable.

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

(1) “Biological product” has the same meaning that applies to that term under Section 351 of the federal Public Health Service Act (42 U.S.C. Sec. 262(i)).
"Interchangeable” means a biological product that the federal Food and Drug Administration has determined meets the standards set forth in Section 262(k)(4) of Title 42 of the United States Code, or has been deemed therapeutically equivalent by the federal Food and Drug Administration as set forth in the latest addition or supplement of the Approved Drug Products with Therapeutic Equivalence Evaluations.

(3) “Prescription,” with respect to a biological product, means a prescription for a product that is subject to Section 503(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 353(b)).

(k) This section shall not prohibit the administration of immunizations, as permitted in Sections 4052 and 4052.8.

(l) This section shall not prohibit a disability insurer or health care service plan from requiring prior authorization or imposing other appropriate utilization controls in approving coverage for any biological product.

SEC. 2. Section 4074 of the Business and Professions Code is amended to read:

4074. (a) A pharmacist shall inform a patient orally or in writing of the harmful effects of a drug dispensed by prescription if both of the following apply:

(1) The drug poses substantial risk to the person consuming the drug when taken in combination with alcohol or the drug may impair a person’s ability to drive a motor vehicle, whichever is applicable.

(2) The drug is determined by the board pursuant to subdivision (c) to be a drug or drug type for which this warning shall be given.

(b) In addition to the requirement described in subdivision (a), on and after July 1, 2014, if a pharmacist exercising his or her professional judgment determines that a drug may impair a person’s ability to operate a vehicle or vessel, the 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. The label required by this subdivision may be printed on an auxiliary label that is affixed to the prescription container.

(c) The board, by regulation may require additional information or labeling.

(d) This section shall not apply to a drug furnished to a patient in conjunction with treatment or emergency services provided in
a health facility or, except as provided in subdivision (e), to a drug furnished to a patient pursuant to subdivision (a) of Section 4056. (e) A health facility shall establish and implement a written policy to ensure that each patient shall receive information regarding each drug given at the time of discharge and each drug given pursuant to subdivision (a) of Section 4056. This information shall include the use and storage of each drug, the precautions and relevant warnings, and the importance of compliance with directions. This information shall be given by a pharmacist or registered nurse, unless already provided by a patient’s prescriber, and the written policy shall be developed in collaboration with a physician, a pharmacist, and a registered nurse. The written policy shall be approved by the medical staff. Nothing in this subdivision or any other law shall be construed to require that only a pharmacist provide this consultation.
An act to amend Section 11209 of the Health and Safety Code, relating to prescriptions.

LEGISLATIVE COUNSEL’S DIGEST

AB 2592, as introduced, Cooper. Prescriptions.
Existing law, the California Uniform Controlled Substances Act, classifies controlled substances into 5 designated schedules, with the most restrictive limitations generally placed on controlled substances classified in Schedule I, and the least restrictive limitations generally placed on controlled substances classified in Schedule V. Existing law prohibits the delivery of Schedule II, III, or IV controlled substances to a pharmacy unless a receipt for the merchandise is signed by a pharmacist or authorized receiving personnel. A violation of this provision is a crime.

This bill would make nonsubstantive changes to this provision.


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

SECTION 1. Section 11209 of the Health and Safety Code is amended to read:

(a) No person shall not deliver Schedule II, III, or IV controlled substances to a pharmacy or pharmacy receiving area, nor shall any person receive controlled substances on behalf
of a pharmacy unless, at the time of delivery, a pharmacist or
authorized receiving personnel signs a receipt showing the type
and quantity of the controlled substances received. Any discrepancy
between the receipt and the type or quantity of controlled
substances actually received shall be reported to the delivering
wholesaler or manufacturer by the next business day after delivery
to the pharmacy.
(b) The delivery receipt and any record of discrepancy shall be
maintained by the wholesaler or manufacturer for a period of three
years.
(c) A violation of this section is a misdemeanor.
(d) Nothing in this section shall require a common carrier to
label a package containing controlled substances in a manner
contrary to federal law or regulation.
Bill Number: SB 482
Current Version: As Amended April 30, 2015
Author: Lara
Topic: Controlled Substances: CURES database
Board Position: 

Affected Sections: Add Section 11164.5 to the Health and Safety Code

Status: Held at the Assembly Desk

SUMMARY:
This measure would require a prescriber to access the CURES system under specified conditions, to include checking the system before prescribing a Schedule II or Schedule III medication for the first time and at least annually.

EXISTING LAW:
Existing law classifies certain controlled substances into designated schedules. Further existing law requires the Department of Justice to maintain CURES for the electronic monitoring of the prescribing and dispensing of Schedule II, Schedule III, and Schedule IV controlled substances and requires dispensing pharmacies and clinics to report specified information for each prescription of a Schedule II, Schedule III, or Schedule IV controlled substance to the department.

THIS BILL WOULD:
Add Section 11164.5 to do the following:
1. Require prescribers to access and consult the CURES database to obtain an electronic history of a patient’s controlled substances dispensing history before prescribing a Schedule II or Schedule III drug the first time for a patient as well as at least annually.
2. Specify that a prescriber shall not prescribe an additional controlled substance until the prescriber determines there is a legitimate medical need.
3. Establish that failure to consult the CURES database is cause for disciplinary action and require respective licensing agencies to advise prescribers of this requirement.
4. Provide that a prescriber is not held to these provisions during any period in which the CURES system is not available.
5. Specify that the provisions do not take effect until the DOJ certifies that the CURES database is ready for statewide use.
6. Reference the definition of prescriber in another section of the Health and Safety Code, Section 11150.
STAFF COMMENTS:
As the board continues to educate licensees about the value of the CURES system, it would seem appropriate to support this measure. As pharmacists can be prescribers, this measure would create a new requirement. Staff notes that it would be valuable to place similar requirements on dispensers.

FISCAL IMPACT ON THE BOARD:
Board staff does not anticipate any significant impact and believes that any minor impact could be absorbed within existing resources.

HISTORY:

<table>
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<tr>
<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>05/28/15</td>
<td>In Assembly. Read first time. Held at Desk.</td>
</tr>
<tr>
<td>05/19/15</td>
<td>Read second time. Ordered to third reading.</td>
</tr>
<tr>
<td>05/08/15</td>
<td>Set for hearing May 18.</td>
</tr>
<tr>
<td>04/30/15</td>
<td>Read second time and amended. Re-referred to Com. on APPR.</td>
</tr>
<tr>
<td>04/16/15</td>
<td>From committee with author's amendments. Read second time and amended. Re-referred to Com. on B., P. &amp; E.D.</td>
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<tr>
<td>04/14/15</td>
<td>Set for hearing April 27.</td>
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<tr>
<td>04/13/15</td>
<td>April 20 set for first hearing canceled at the request of author.</td>
</tr>
<tr>
<td>03/24/15</td>
<td>Set for hearing April 20.</td>
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<tr>
<td>03/12/15</td>
<td>Referred to Com. on B., P. &amp; E.D.</td>
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<tr>
<td>02/27/15</td>
<td>From printer. May be acted upon on or after March 29.</td>
</tr>
<tr>
<td>02/26/15</td>
<td>Introduced. Read first time. To Com. on RLS. for assignment. To print.</td>
</tr>
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SECTION 1. Section 11165.4 is added to the Health and Safety Code, to read:

11165.4. (a) A prescriber shall access and consult the CURES database for the electronic history of controlled substances dispensed to a patient under his or her care before prescribing a Schedule II or Schedule III controlled substance for the first time to that patient and at least annually when that prescribed controlled substance remains part of his or her treatment. If the patient has an existing prescription for a Schedule II or Schedule III controlled substance, the prescriber shall not prescribe an additional controlled substance until the prescriber determines that there is a legitimate need for that controlled substance.

(b) Failure to consult a patient’s electronic history as required by subdivision (a) is cause for disciplinary action by the prescriber’s licensing board. The licensing boards of all prescribers authorized to write or issue prescriptions for controlled substances shall notify these licensees of the requirements of this section.

(c) Notwithstanding any other law, a prescriber is not in violation of this section during any period of time in which the CURES database is suspended or not accessible or any period of time in which the Internet is not operational.

(d) This section shall not become operative until the Department of Justice certifies that the CURES database is ready for statewide use.

(e) For purposes of this section, “prescriber” means a health care practitioner who is authorized to write or issue prescriptions under Section 11150, excluding veterinarians.

(f) A violation of this section shall not be subject to the provisions of Section 11374.
BILL ANALYSIS

Bill Number: SB 999

Current Version: As Introduced February 10, 2016

Author: Pavley

Topic: Health Insurance: Contraceptives: Annual Supply

Board Position: 

Affected Sections: Amends Section 4064 of the Business and Professions Code, Section 1367.25 of the Health and Safety Code and Section 10123.5 of the Insurance Code

Status: Hearing scheduled for April 4, 2016, Senate Business, Professions and Economic Development Committee

SUMMARY:
This bill would authorize a pharmacist to dispense prescribed, FDA-approved, self-administered hormonal contraceptives either as prescribed or, at the patient's request, in a 12-month supply, unless the prescriber specifically indicates no change to quantity. The measure would also require a health care service plan or health insurance policy, on or after January 1, 2017, to cover a 12-month supply of a self-administered hormonal contraception dispensed at one time by a prescriber or dispenser.

EXISTING LAW:
Specific to pharmacy law provisions, existing law authorizes a pharmacist to dispense not more than a 90-day supply of a dangerous drug other than a controlled substance pursuant to a valid prescription that specifies an initial quantity of less than a 90-day supply followed by periodic refills of that amount if the patient has met specified requirements, including having completed an initial 30-day supply of the drug. Existing law prohibits a pharmacist from dispensing a greater supply of a dangerous drug if the prescriber indicates "no change to quantity" on the prescription.

THIS BILL WOULD:
1. Make legislative findings including that California has a long history and commitment to expanding access to services that aim to reduce the risk of unintended pregnancies and improving reproductive health outcomes and that studies support that dispensing a 12-month supply of birth control at one time has numerous benefits.
2. Declare it is the intent of the legislature to expand existing contraceptive coverage policy by requiring all health care service plans and health insurance policies to cover a 12-month supply of specified types of hormonal contraception.
3. Amend Section 4064.5 to allow a pharmacist to dispense up to a 12-month supply of an FDA approved self-administered hormonal contraceptive at either the request of the patient or based on the prescription.
4. Make changes to the health and safety code and insurance code to facilitate implementation of the legislative intent.

STAFF COMMENTS:
According to the author’s office, for birth control to be effective, consistency is essential. The fact sheet provided by the author’s office noted that for women, particularly those who are low income or live in rural areas, receiving and 30 or 90 day supply of contraception at one time can impede their ability to use birth control on a consistent basis.

FISCAL IMPACT ON THE BOARD:
Board staff does not anticipate any significant impact and believes that any minor impact could be absorbed within existing resources.

HISTORY:

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<th>Date</th>
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<tr>
<td>03/11/16</td>
<td>Set for hearing April 4.</td>
</tr>
<tr>
<td>02/18/16</td>
<td>Referred to Coms. on B., P. &amp; E.D. and HEALTH.</td>
</tr>
<tr>
<td>02/11/16</td>
<td>From printer. May be acted upon on or after March 12.</td>
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<tr>
<td>02/10/16</td>
<td>Introduced. Read first time. To Com. on RLS. for assignment. To print.</td>
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An act to amend Section 4064.5 of the Business and Professions Code, to amend Section 1367.25 of the Health and Safety Code, and to amend Section 10123.196 of the Insurance Code, relating to contraceptives.

LEGISLATIVE COUNSEL'S DIGEST

SB 999, as introduced, Pavley. Health insurance: contraceptives: annual supply.

Existing law, the Knox-Keene Health Care Service Plan Act of 1975, provides for the licensure and regulation of health care service plans by the Department of Managed Health Care and makes a willful violation of the act a crime. Existing law also provides for the regulation of health insurers by the Department of Insurance. Existing law requires a health care service plan contract or health insurance policy issued, amended, or renewed on or after January 1, 2016, to provide coverage for women for all prescribed and FDA-approved female contraceptive drugs, devices, and products, as well as voluntary sterilization procedures, contraceptive education and counseling, and related followup services.

This bill would require a health care service plan or a health insurance policy issued, amended, or renewed on or after January 1, 2017, to cover
a 12-month supply of FDA-approved, self-administered hormonal contraceptives dispensed at one time by a prescriber, pharmacy, or onsite at a location licensed or authorized to dispense drugs or supplies. Because a willful violation of the bill’s requirements by a health care service plan would be a crime, the bill would impose a state-mandated local program.

Existing law authorizes a pharmacist to dispense not more than a 90-day supply of a dangerous drug other than a controlled substance pursuant to a valid prescription that specifies an initial quantity of less than a 90-day supply followed by periodic refills of that amount if the patient has met specified requirements, including having completed an initial 30-day supply of the drug. Existing law prohibits a pharmacist from dispensing a greater supply of a dangerous drug if the prescriber indicates “no change to quantity” on the prescription.

This bill would authorize a pharmacist to dispense prescribed, FDA-approved, self-administered hormonal contraceptives either as prescribed or, at the patient’s request, in a 12-month supply, unless the prescriber specifically indicates no change to quantity.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement. This bill would provide that no reimbursement is required by this act for a specified reason.


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

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

1. California has a long history of, and commitment to, expanding access to services that aim to reduce the risk of unintended pregnancies and improving reproductive health outcomes.
2. California’s Family Planning, Access, Care, and Treatment (PACT) program, created in 1999, is viewed nationally as the “gold standard” of publicly funded programs providing access to reproductive health care. The program has long recognized the value and importance of providing women with a year’s supply of birth control.
(3) The Affordable Care Act (ACA) and subsequent federal regulations made contraceptive coverage a national policy by requiring most private health insurance plans to provide coverage for a broad range of preventive services without cost-sharing, including FDA-approved prescription contraceptives.

(4) Since the passage of the ACA, many states have passed laws strengthening or expanding this federal contraceptive coverage requirement. In 2014, California passed the Contraceptive Coverage Equity Act of 2014, which requires plans to cover all prescribed FDA-approved contraceptives for women without cost-sharing, and requires plans to cover at least one therapeutic equivalent of a prescribed contraceptive drug, device, or product.

(5) Numerous studies support what California has determined for decades in the Family PACT program: dispensing a 12-month supply of birth control at one time has numerous benefits, including, but not limited to, reducing a woman’s odds of having an unintended pregnancy by 30 percent, increasing contraception continuation rates, and decreasing costs per client to insurers by reducing the number of pregnancy tests and pregnancies.

(6) Access to contraception is a key element in shaping women’s health and well-being. Nearly all women have used contraceptives at some point in their lives, and 62 percent are currently using at least one method.

(7) Several states have mirrored the year-supply requirement for contraceptive coverage in their publicly funded family planning or Medicaid programs, recognizing the health benefits of reducing barriers to continuous and effective use of contraception. Recently, Oregon and Washington D.C. have gone further to require private health care service plans and health insurance policies to also cover a 12-month supply of contraceptives. With California’s history of leadership in establishing public policies that increase access to contraceptives, adopting a similar requirement is a natural progression of our state’s commitment to reducing unintended pregnancy.

(b) It is therefore the intent of the Legislature to expand on California’s existing contraceptive coverage policy by requiring all health care service plans and health insurance policies, including both commercial and Medi-Cal managed care plans, to cover a 12-month supply of a prescribed FDA-approved contraceptive, such as the ring, the patch, and oral contraceptives.
SEC. 2. Section 4064.5 of the Business and Professions Code is amended to read:

4064.5. (a) A pharmacist may dispense not more than a 90-day supply of a dangerous drug other than a controlled substance pursuant to a valid prescription that specifies an initial quantity of less than a 90-day supply followed by periodic refills of that amount if all of the following requirements are satisfied:

(1) The patient has completed an initial 30-day supply of the dangerous drug.

(2) The total quantity of dosage units dispensed does not exceed the total quantity of dosage units authorized by the prescriber on the prescription, including refills.

(3) The prescriber has not specified on the prescription that dispensing the prescription in an initial amount followed by periodic refills is medically necessary.

(4) The pharmacist is exercising his or her professional judgment.

(b) For purposes of this section, if the prescription continues the same medication as previously dispensed in a 90-day supply, the initial 30-day supply under paragraph (1) of subdivision (a) is not required.

(c) A pharmacist dispensing an increased supply of a dangerous drug pursuant to this section shall notify the prescriber of the increase in the quantity of dosage units dispensed.

(d) In no case shall a pharmacist dispense a greater supply of a dangerous drug pursuant to this section if the prescriber personally indicates, either orally or in his or her own handwriting, “No change to quantity,” or words of similar meaning. Nothing in this subdivision shall prohibit a prescriber from checking a box on a prescription marked “No change to quantity,” provided that the prescriber personally initials the box or checkmark. To indicate that an increased supply shall not be dispensed pursuant to this section for an electronic data transmission prescription as defined in subdivision (c) of Section 4040, a prescriber may indicate “No change to quantity,” or words of similar meaning, in the prescription as transmitted by electronic data, or may check a box marked on the prescription “No change to quantity.” In either instance, it shall not be required that the prohibition on an increased supply be manually initialed by the prescriber.
(e) This section shall not apply to psychotropic medication or 
psychotropic drugs as described in subdivision (d) of Section 369.5 
of the Welfare and Institutions Code.

(f) Except for the provisions of subdivision (d), this section does 
not apply to a prescription for FDA-approved, self-administered 
hormonal contraceptives approved by the FDA. A prescription for 
FDA-approved, self-administered hormonal contraceptives shall 
be dispensed either as provided on the prescription or, at the 
patient’s request, up to a 12-month supply.

(g) Nothing in this section shall be construed to require a health 
care service plan, health insurer, workers’ compensation insurance 
plan, pharmacy benefits manager, or any other person or entity, 
including, but not limited to, a state program or state employer, to 
provide coverage for a dangerous drug in a manner inconsistent 
with a beneficiary’s plan benefit.

SEC. 3. Section 1367.25 of the Health and Safety Code is 
amended to read:

1367.25. (a) A group health care service plan contract, except 
for a specialized health care service plan contract, that is issued, 
amended, renewed, or delivered on or after January 1, 2000, 
through December 31, 2015, inclusive, and an individual health 
care service plan contract that is amended, renewed, or delivered 
on or after January 1, 2000, through December 31, 2015, inclusive, 
except for a specialized health care service plan contract, shall 
provide coverage for the following, under general terms and 
conditions applicable to all benefits:

(1) A health care service plan contract that provides coverage 
for outpatient prescription drug benefits shall include coverage for 
a variety of federal Food and Drug Administration (FDA)-approved 
contraceptive methods designated by the plan. In the 
event the patient’s participating provider, acting within his or her 
scope of practice, determines that none of the methods designated 
by the plan is medically appropriate for the patient’s medical or 
personal history, the plan shall also provide coverage for another 
FDA-approved, medically appropriate prescription contraceptive 
method prescribed by the patient’s provider.

(2) Benefits for an enrollee under this subdivision shall be the 
same for an enrollee’s covered spouse and covered nonspouse 
dependents.
(b) (1) A health care service plan contract, except for a specialized health care service plan contract, that is issued, amended, renewed, or delivered on or after January 1, 2016, shall provide coverage for all of the following services and contraceptive methods for women:

(A) Except as provided in subparagraphs (B) and (C) of paragraph (2), all FDA-approved contraceptive drugs, devices, and other products for women, including all FDA-approved contraceptive drugs, devices, and products available over the counter, as prescribed by the enrollee’s provider.

(B) Voluntary sterilization procedures.

(C) Patient education and counseling on contraception.

(D) Followup services related to the drugs, devices, products, and procedures covered under this subdivision, including, but not limited to, management of side effects, counseling for continued adherence, and device insertion and removal.

(2) (A) Except for a grandfathered health plan, a health care service plan subject to this subdivision shall not impose a deductible, coinsurance, copayment, or any other cost-sharing requirement on the coverage provided pursuant to this subdivision. Cost sharing shall not be imposed on any Medi-Cal beneficiary.

(B) If the FDA has approved one or more therapeutic equivalents of a contraceptive drug, device, or product, a health care service plan is not required to cover all of those therapeutically equivalent versions in accordance with this subdivision, as long as at least one is covered without cost sharing in accordance with this subdivision.

(C) If a covered therapeutic equivalent of a drug, device, or product is not available, or is deemed medically inadvisable by the enrollee’s provider, a health care service plan shall provide coverage, subject to a plan’s utilization management procedures, for the prescribed contraceptive drug, device, or product without cost sharing. Any request by a contracting provider shall be responded to by the health care service plan in compliance with the Knox-Keene Health Care Service Plan Act of 1975, as set forth in this chapter and, as applicable, with the plan’s Medi-Cal managed care contract.

(3) Except as otherwise authorized under this section, a health care service plan shall not impose any restrictions or delays on the coverage required under this subdivision.
(4) Benefits for an enrollee under this subdivision shall be the same for an enrollee’s covered spouse and covered nonspouse dependents.

(5) For purposes of paragraphs (2) and (3) of this subdivision, “health care service plan” shall include Medi-Cal managed care plans that contract with the State Department of Health Care Services pursuant to Chapter 7 (commencing with Section 14000) and Chapter 8 (commencing with Section 14200) of Part 3 of Division 9 of the Welfare and Institutions Code.

(c) Notwithstanding any other provision of this section, a religious employer may request a health care service plan contract without coverage for FDA-approved contraceptive methods that are contrary to the religious employer’s religious tenets. If so requested, a health care service plan contract shall be provided without coverage for contraceptive methods.

(1) For purposes of this section, a “religious employer” is an entity for which each of the following is true:

(A) The inculcation of religious values is the purpose of the entity.

(B) The entity primarily employs persons who share the religious tenets of the entity.

(C) The entity serves primarily persons who share the religious tenets of the entity.

(D) The entity is a nonprofit organization as described in Section 6033(a)(3)(A)(i) or (iii) of the Internal Revenue Code of 1986, as amended.

(2) Every religious employer that invokes the exemption provided under this section shall provide written notice to prospective enrollees prior to enrollment with the plan, listing the contraceptive health care services the employer refuses to cover for religious reasons.

(d) (1) Every health care service plan contract that is issued, amended, renewed, or delivered on or after January 1, 2017, shall cover a 12-month supply of FDA-approved, self-administered hormonal contraceptives dispensed by a prescriber or pharmacy at one time to an enrollee.

(2) If a 12-month supply of FDA-approved, self-administered hormonal contraceptives is dispensed onsite at a location licensed or otherwise authorized to dispense drugs or supplies, the health care service plan shall cover the 12-month supply.
(d) This section shall not be construed to exclude coverage for contraceptive supplies as prescribed by a provider, acting within his or her scope of practice, for reasons other than contraceptive purposes, such as decreasing the risk of ovarian cancer or eliminating symptoms of menopause, or for contraception that is necessary to preserve the life or health of an enrollee.

(e) This section shall not be construed to deny or restrict in any way the department’s authority to ensure plan compliance with this chapter when a plan provides coverage for contraceptive drugs, devices, and products.

(f) This section shall not be construed to require an individual or group health care service plan contract to cover experimental or investigational treatments.

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

1. “Grandfathered health plan” has the meaning set forth in Section 1251 of PPACA.
2. “PPACA” means the federal Patient Protection and Affordable Care Act (Public Law 111-148), as amended by the federal Health Care and Education Reconciliation Act of 2010 (Public Law 111-152), and any rules, regulations, or guidance issued thereunder.
3. With respect to health care service plan contracts issued, amended, or renewed on or after January 1, 2016, “provider” means an individual who is certified or licensed pursuant to Division 2 (commencing with Section 500) of the Business and Professions Code, or an initiative act referred to in that division, or Division 2.5 (commencing with Section 1797) of this code.

SEC. 4. Section 10123.196 of the Insurance Code is amended to read:

10123.196. (a) An individual or group policy of disability insurance issued, amended, renewed, or delivered on or after January 1, 2000, through December 31, 2015, inclusive, that provides coverage for hospital, medical, or surgical expenses, shall provide coverage for the following, under the same terms and conditions as applicable to all benefits:
(1) A disability insurance policy that provides coverage for outpatient prescription drug benefits shall include coverage for a variety of federal Food and Drug Administration (FDA)-approved prescription contraceptive methods, as designated by the insurer. If an insured’s health care provider determines that none of the methods designated by the disability insurer is medically appropriate for the insured’s medical or personal history, the insurer shall, in the alternative, provide coverage for some other FDA-approved prescription contraceptive method prescribed by the patient’s health care provider.

(2) Coverage with respect to an insured under this subdivision shall be identical for an insured’s covered spouse and covered nonspouse dependents.

(b) (1) A group or individual policy of disability insurance, except for a specialized health insurance policy, that is issued, amended, renewed, or delivered on or after January 1, 2016, shall provide coverage for all of the following services and contraceptive methods for women:

(A) Except as provided in subparagraphs (B) and (C) of paragraph (2), all FDA-approved contraceptive drugs, devices, and other products for women, including all FDA-approved contraceptive drugs, devices, and products available over the counter, as prescribed by the insured’s provider.

(B) Voluntary sterilization procedures.

(C) Patient education and counseling on contraception.

(D) Followup services related to the drugs, devices, products, and procedures covered under this subdivision, including, but not limited to, management of side effects, counseling for continued adherence, and device insertion and removal.

(2) (A) Except for a grandfathered health plan, a disability insurer subject to this subdivision shall not impose a deductible, coinsurance, copayment, or any other cost-sharing requirement on the coverage provided pursuant to this subdivision.

(B) If the FDA has approved one or more therapeutic equivalents of a contraceptive drug, device, or product, a disability insurer is not required to cover all of those therapeutically equivalent versions in accordance with this subdivision, as long as at least one is covered without cost sharing in accordance with this subdivision.

(C) If a covered therapeutic equivalent of a drug, device, or product is not available, or is deemed medically inadvisable by
the insured’s provider, a disability insurer shall provide coverage,
subject to an insurer’s utilization management procedures, for the
prescribed contraceptive drug, device, or product without cost
sharing. Any request by a contracting provider shall be responded
to by the disability insurer in compliance with Section 10123.191.
(3) Except as otherwise authorized under this section, an insurer
shall not impose any restrictions or delays on the coverage required
under this subdivision.
(4) Coverage with respect to an insured under this subdivision
shall be identical for an insured’s covered spouse and covered
nonspouse dependents.
(c) This section shall not be construed to deny or restrict in any
way any existing right or benefit provided under law or by contract.
(d) This section shall not be construed to require an individual
or group disability insurance policy to cover experimental or
investigational treatments.
(e) Notwithstanding any other provision of this section, a
religious employer may request a disability insurance policy
without coverage for contraceptive methods that are contrary to
the religious employer’s religious tenets. If so requested, a
disability insurance policy shall be provided without coverage for
contraceptive methods.
(1) For purposes of this section, a “religious employer” is an
entity for which each of the following is true:
(A) The inculcation of religious values is the purpose of the
entity.
(B) The entity primarily employs persons who share the religious
tenets of the entity.
(C) The entity serves primarily persons who share the religious
tenets of the entity.
(D) The entity is a nonprofit organization pursuant to Section
6033(a)(3)(A)(i) or (iii) of the Internal Revenue Code of 1986, as
amended.
(2) Every religious employer that invokes the exemption
provided under this section shall provide written notice to any
prospective employee once an offer of employment has been made,
and prior to that person commencing that employment, listing the
contraceptive health care services the employer refuses to cover
for religious reasons.
(f) (1) A group or individual policy of disability insurance, except for a specialized health insurance policy, that is issued, amended, renewed, or delivered on or after January 1, 2017, shall cover a 12-month supply of FDA-approved, self-administered hormonal contraceptives dispensed by a prescriber or pharmacy at one time to an insured.

(2) If a 12-month supply of FDA-approved, self-administered hormonal contraceptives is dispensed onsite at a location licensed or otherwise authorized to dispense drugs or supplies, the insurer shall cover the 12-month supply.

(g) This section shall not be construed to exclude coverage for contraceptive supplies as prescribed by a provider, acting within his or her scope of practice, for reasons other than contraceptive purposes, such as decreasing the risk of ovarian cancer or eliminating symptoms of menopause, or for contraception that is necessary to preserve the life or health of an insured.

(h) This section only applies to disability insurance policies or contracts that are defined as health benefit plans pursuant to subdivision (a) of Section 10198.6, except that for accident only, specified disease, or hospital indemnity coverage, coverage for benefits under this section applies to the extent that the benefits are covered under the general terms and conditions that apply to all other benefits under the policy or contract. This section shall not be construed as imposing a new benefit mandate on accident only, specified disease, or hospital indemnity insurance.

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

(1) “Grandfathered health plan” has the meaning set forth in Section 1251 of PPACA.

(2) “PPACA” means the federal Patient Protection and Affordable Care Act (Public Law 111-148), as amended by the federal Health Care and Education Reconciliation Act of 2010 (Public Law 111-152), and any rules, regulations, or guidance issued thereunder.

(3) With respect to policies of disability insurance issued, amended, or renewed on or after January 1, 2016, “health care provider” means an individual who is certified or licensed pursuant to Division 2 (commencing with Section 500) of the Business and
Professions Code, or an initiative act referred to in that division, or Division 2.5 (commencing with Section 1797) of the Health and Safety Code.

SEC. 5. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.
Legislative Proposal
12-Month Dispensing of Contraception

**Purpose**
This bill would require all health care service plans and health insurers (including Medi-Cal managed care plans) to cover up to 12-months of FDA-approved self-administered hormonal contraceptives (including oral contraceptives, transdermal patches, and vaginal rings) when dispensed at one time.

**The Problem**
For birth control to be effective, consistency is essential. For many women, particularly those who are low income or who live rural areas, receiving only a 30 or 90 day supply of contraception at a time can impede their ability to use birth control on a consistent basis.

**Background**
Studies show that dispensing a 12-month supply of birth control at one time: (1) reduces a woman’s odds of having an unintended pregnancy by 30%, (2) increases contraception continuation rates, and (3) decreases costs per client to insurers by reducing the number of pregnancy tests and pregnancies.¹ Consistent with these findings, the Department of Health Care Services released a draft All Plan Letter (APL) in December 2015 stating that Medi-Cal Managed Care will soon cover up to 12-months of oral contraceptives dispensed at one time in an onsite clinic. While this draft APL marks great progress, California can and should do better.

Several states have adopted a one year-supply requirement in their Medicaid programs. Recently, Oregon and Washington D.C. have gone further to require private health care service plans and health insurance policies to also cover a 12-month supply of contraceptives. With California’s history of leadership in establishing public policies that increase access to contraceptives, adopting a similar requirement is a natural progression of our state’s commitment to reducing unintended pregnancy.

All women in California should have access to best practices when it comes to contraception and the ability to reduce unintended pregnancies. This bill makes dispensing a 12-month supply of birth control a best practice in the commercial and Medi-Cal managed care settings. When a woman has the ability to plan if and when to have children, it is beneficial to both her and to the state of California.

**This Proposal**
This bill would improve women’s access to birth control by requiring health insurance plans to cover the dispensing of a year’s supply of self-administered hormonal contraceptives at one time, as prescribed or requested, rather than requiring her to return every 30 or 90 days.

Contact: Christina Romero / (916) 584-4217 / christina.romero@ppacca.org

¹ Foster, Diana Greene, PhD, Denis Hulett, Mary Bradsberry, Philip Darney, MD, MSc, and Michael Policar, MD, MPH. “Number of Oral Contraceptive Pill Packages Dispensed and Subsequent Unintended Pregnancies.” Obstetrics & Gynecology 117, no. 3 (March 2011): 566-72. See, too, the 2103 Centers for Disease Control and Prevention report entitled “U.S. Selected Practice Recommendations for Contraceptive Use (MMWR 2013 62, no. 5 (June 2013) 25-29), which found that the more pill packs given up to 13 cycles, the higher the continuation rates. Restricting the number of pill packs distributed or prescribed can result in unwanted discontinuation of the method and increased risk for pregnancy.”
Bill Number: SB 1217
Current Version: As Introduced February 18, 2016
Author: Stone
Topic: Healing Arts: Reporting Requirements: Professional Liability
Board Position:

Affected Sections: Amend Sections 800, 801, 801.1, and 802 of the Business and Professions Code.

Status: Hearing scheduled for April 11, 2016, Senate Business, Professions and Economic Development Committee

SUMMARY:
This measure would increase the mandatory reporting limit for licensees and insurers of any judgement or settlement requiring a licensee or insurer to pay to $10,000 in damages.

EXISTING LAW:
Existing law requires each person who holds a license from the board to report judgment or settlement requiring the licensee or the licensee's insurer to pay over $3,000 in damages for any claim that injury or death was proximately caused by the licensee's negligence, error or omission in practice, or rendering unauthorized professional service.

THIS BILL WOULD:
1. Amend Section 800 to require the board to maintain any reports of a judgement or settlement with an award in excess of $10,000 for any claim that injury or death was proximately caused by the licensee’s negligence, error or omission in practice, or by rendering unauthorized professional services.
2. Amend Sections 801. 801.1, and 802 making conforming changes to the reporting amount.

STAFF COMMENTS:
The board currently investigates reports submitted as required by these provisions. Over the last four fiscal years the board received 583 reports. Unfortunately the board’s current computer system does not track the actual amount of the award that resulted from a settlement.

This measure is author sponsored.
According to the author’s office, under existing law there is a disparity in the reporting limits between differing license types, some practitioners must report awards of $3,000 while others must report at or above $10,000. The measure would establish a consistent reporting limit of $10,000.

**FISCAL IMPACT ON THE BOARD:**

As a result of this legislation, the board could realize a reduction in the number of cases it receives because of the increase in the reporting threshold which in turn could result in a very modest reduction in the board’s enforcement costs.

**HISTORY:**

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</table>
An act to amend Sections 800, 801, 801.1, and 802 of the Business and Professions Code, relating to healing arts.

LEGISLATIVE COUNSEL’S DIGEST

SB 1217, as introduced, Stone. Healing arts: reporting requirements: professional liability resulting in death or personal injury.

Existing law establishes within the Department of Consumer Affairs various boards that license and regulate the practice of various professions and vocations, including those relating to the healing arts. Existing law requires each healing arts licensing board to create and maintain a central file containing an individual historical record on each person who holds a license from that board. Existing law requires that the individual historical record contain any reported judgment or settlement requiring the licensee or the licensee’s insurer to pay over $3,000 in damages for any claim that injury or death was proximately caused by the licensee’s negligence, error or omission in practice, or rendering unauthorized professional service.

This bill would instead require the record to contain reported judgments or settlements with damages over $10,000.

Existing law requires an insurer providing professional liability insurance to a physician and surgeon, a governmental agency that self-insures a physician and surgeon or, if uninsured, a physician and surgeon himself or herself, to report to the respective licensing board information concerning settlements over $30,000, arbitration awards in any amount, and judgments in any amount in malpractice actions to the practitioner’s licensing board. Existing law provides that information concerning professional liability settlements, judgments, and arbitration
awards of over $10,000 in damages arising from death or personal injury must be reported to the respective licensing boards of specified healing arts practitioners including, among others, licensed professional clinical counselors, licensed dentists, and licensed veterinarians. Existing law provides that, for other specified healing arts practitioners including, among others, licensed educational psychologists, licensed nurses, and licensed pharmacists, information concerning professional liability settlements, judgments, and arbitration awards of over $3,000 in damages arising from death or personal injury shall be reported to their respective licensing boards.

This bill would raise the minimum dollar amount triggering those reporting requirements from $3,000 to $10,000.


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

SECTION 1. Section 800 of the Business and Professions Code is amended to read:

800. (a) The Medical Board of California, the Board of Psychology, the Dental Board of California, the Dental Hygiene Committee of California, the Osteopathic Medical Board of California, the State Board of Chiropractic Examiners, the Board of Registered Nursing, the Board of Vocational Nursing and Psychiatric Technicians of the State of California, the State Board of Optometry, the Veterinary Medical Board, the Board of Behavioral Sciences, the Physical Therapy Board of California, the California State Board of Pharmacy, the Speech-Language Pathology and Audiology and Hearing Aid Dispensers Board, the California Board of Occupational Therapy, the Acupuncture Board, and the Physician Assistant Board shall each separately create and maintain a central file of the names of all persons who hold a license, certificate, or similar authority from that board. Each central file shall be created and maintained to provide an individual historical record for each licensee with respect to the following information:

(1) Any conviction of a crime in this or any other state that constitutes unprofessional conduct pursuant to the reporting requirements of Section 803.
(2) Any judgment or settlement requiring the licensee or his or her insurer to pay any amount of damages in excess of three thousand dollars ($3,000) ten thousand dollars ($10,000) for any claim that injury or death was proximately caused by the licensee’s negligence, error or omission in practice, or by rendering unauthorized professional services, pursuant to the reporting requirements of Section 801 or 802.

(3) Any public complaints for which provision is made pursuant to subdivision (b).

(4) Disciplinary information reported pursuant to Section 805, including any additional exculpatory or explanatory statements submitted by the licentiate pursuant to subdivision (f) of Section 805. If a court finds, in a final judgment, that the peer review resulting in the 805 report was conducted in bad faith and the licensee who is the subject of the report notifies the board of that finding, the board shall include that finding in the central file. For purposes of this paragraph, “peer review” has the same meaning as defined in Section 805.

(5) Information reported pursuant to Section 805.01, including any explanatory or exculpatory information submitted by the licensee pursuant to subdivision (b) of that section.

(b) (1) Each board shall prescribe and promulgate forms on which members of the public and other licensees or certificate holders may file written complaints to the board alleging any act of misconduct in, or connected with, the performance of professional services by the licensee.

(2) If a board, or division thereof, a committee, or a panel has failed to act upon a complaint or report within five years, or has found that the complaint or report is without merit, the central file shall be purged of information relating to the complaint or report.

(3) Notwithstanding this subdivision, the Board of Psychology, the Board of Behavioral Sciences, and the Respiratory Care Board of California shall maintain complaints or reports as long as each board deems necessary.

(c) (1) The contents of any central file that are not public records under any other provision of law shall be confidential except that the licensee involved, or his or her counsel or representative, shall have the right to inspect and have copies made of his or her complete file except for the provision that may disclose the identity of an information source. For the purposes of
this section, a board may protect an information source by
providing a copy of the material with only those deletions necessary
to protect the identity of the source or by providing a
comprehensive summary of the substance of the material.
Whichever method is used, the board shall ensure that full
disclosure is made to the subject of any personal information that
could reasonably in any way reflect or convey anything detrimental,
disparaging, or threatening to a licensee’s reputation, rights,
benefits, privileges, or qualifications, or be used by a board to
make a determination that would affect a licensee’s rights, benefits,
privileges, or qualifications. The information required to be
disclosed pursuant to Section 803.1 shall not be considered among
the contents of a central file for the purposes of this subdivision.

(2) The licensee may, but is not required to, submit any
additional exculpatory or explanatory statement or other
information that the board shall include in the central file.

(3) Each board may permit any law enforcement or regulatory
agency when required for an investigation of unlawful activity or
have copies made of that licensee’s file, unless the disclosure is
otherwise prohibited by law.

(4) These disclosures shall effect no change in the confidential
status of these records.

SEC. 2. Section 801 of the Business and Professions Code is
amended to read:

801. (a) Except as provided in Section 801.01 and subdivisions
(b), (c), and (d) subdivision (b) of this section, every insurer
providing professional liability insurance to a person who holds a
license, certificate, or similar authority from or under any agency
specified in subdivision (a) of Section 800 shall send a complete
report to that agency as to any settlement or arbitration award over
three thousand dollars ($3,000) ten thousand dollars ($10,000) of
a claim or action for damages for death or personal injury caused
by that person’s negligence, error, or omission in practice, or by
his or her rendering of unauthorized professional services. The
report shall be sent within 30 days after the written settlement
agreement has been reduced to writing and signed by all parties
therein or within 30 days after service of the arbitration award on
the parties.
(b) Every insurer providing professional liability insurance to a person licensed pursuant to Chapter 13 (commencing with Section 4980), Chapter 14 (commencing with Section 4990), or Chapter 16 (commencing with Section 4999.10) shall send a complete report to the Board of Behavioral Sciences as to any settlement or arbitration award over ten thousand dollars ($10,000) of a claim or action for damages for death or personal injury caused by that person's negligence, error, or omission in practice, or by his or her rendering of unauthorized professional services. The report shall be sent within 30 days after the written settlement agreement has been reduced to writing and signed by all parties thereto or within 30 days after service of the arbitration award on the parties.

(c) Every insurer providing professional liability insurance to a dentist licensed pursuant to Chapter 4 (commencing with Section 1600) shall send a complete report to the Dental Board of California as to any settlement or arbitration award over ten thousand dollars ($10,000) of a claim or action for damages for death or personal injury caused by that person's negligence, error, or omission in practice, or rendering of unauthorized professional services. The report shall be sent within 30 days after the written settlement agreement has been reduced to writing and signed by all parties thereto or within 30 days after service of the arbitration award on the parties.

(d) Every insurer providing liability insurance to a veterinarian licensed pursuant to Chapter 11 (commencing with Section 4800) shall send a complete report to the Veterinary Medical Board of any settlement or arbitration award over ten thousand dollars ($10,000) of a claim or action for damages for death or injury caused by that person's negligence, error, or omission in practice, or rendering of unauthorized professional service. The report shall be sent within 30 days after the written settlement agreement has been reduced to writing and signed by all parties thereto or within 30 days after service of the arbitration award on the parties.

(e) The insurer shall notify the claimant, or if the claimant is represented by counsel, the insurer shall notify the claimant's attorney, that the report required by subdivision (a), (b), or (c) (a) has been sent to the agency. If the attorney has not received this...
notice within 45 days after the settlement was reduced to writing
and signed by all of the parties, the arbitration award was served
on the parties, or the date of entry of the civil judgment, the
attorney shall make the report to the agency.

(d) Notwithstanding any other provision of law, no insurer shall
enter into a settlement without the written consent of the insured,
except that this prohibition shall not void any settlement entered
into without that written consent. The requirement of written
consent shall only be waived by both the insured and the insurer.
This section shall only apply to a settlement on a policy of
insurance executed or renewed on or after January 1, 1971.

SEC. 3. Section 801.1 of the Business and Professions Code
is amended to read:

801.1. (a) Every state or local governmental agency that
self-insures a person who holds a license, certificate, or similar
authority from or under any agency specified in subdivision (a) of
Section 800 (except a person licensed pursuant to Chapter 3
(commencing with Section 1200) or Chapter 5 (commencing with
Section 2000) or the Osteopathic Initiative Act) shall send a
complete report to that agency as to any settlement or arbitration
award over three thousand dollars ($3,000) ten thousand dollars
($10,000) of a claim or action for damages for death or personal
injury caused by that person’s negligence, error, or omission in
practice, or rendering of unauthorized professional services. The
report shall be sent within 30 days after the written settlement
agreement has been reduced to writing and signed by all parties
thereto or within 30 days after service of the arbitration award on
the parties.

(b) Every state or local governmental agency that self-insures
a person licensed pursuant to Chapter 13 (commencing with
Section 4980), Chapter 14 (commencing with Section 4990), or
Chapter 16 (commencing with Section 4999.10) shall send a
complete report to the Board of Behavioral Science Examiners as
to any settlement or arbitration award over ten thousand dollars
($10,000) of a claim or action for damages for death or personal
injury caused by that person’s negligence, error, or omission in
practice, or rendering of unauthorized professional services. The
report shall be sent within 30 days after the written settlement
agreement has been reduced to writing and signed by all parties
SEC. 4. Section 802 of the Business and Professions Code is amended to read:

802. (a) Every settlement, judgment, or arbitration award over three thousand dollars ($3,000) ten thousand dollars ($10,000) of a claim or action for damages for death or personal injury caused by negligence, error or omission in practice, or by the unauthorized rendering of professional services, by a person who holds a license, certificate, or other similar authority from an agency specified in subdivision (a) of Section 800 (except a person licensed pursuant to Chapter 3 (commencing with Section 1200) or Chapter 5 (commencing with Section 2000) or the Osteopathic Initiative Act) who does not possess professional liability insurance as to that claim shall, within 30 days after the written settlement agreement has been reduced to writing and signed by all the parties thereto or 30 days after service of the judgment or arbitration award on the parties, be reported to the agency that issued the license, certificate, or similar authority. A complete report shall be made by appropriate means by the person or his or her counsel, with a copy of the communication to be sent to the claimant through his or her counsel if the person is so represented, or directly if he or she is not. If, within 45 days of the conclusion of the written settlement agreement or service of the judgment or arbitration award on the parties, counsel for the claimant (or if the claimant is not represented by counsel, the claimant himself or herself) has not received a copy of the report, he or she shall himself or herself make the complete report. Failure of the licensee or claimant (or, if represented by counsel, their counsel) to comply with this section is a public offense punishable by a fine of not less than fifty dollars ($50) or more than five hundred dollars ($500). Knowing and intentional failure to comply with this section or conspiracy or collusion not to comply with this section, or to hinder or impede any other person in the compliance, is a public offense punishable by a fine of not less than five thousand dollars ($5,000) nor more than fifty thousand dollars ($50,000).

(b) Every settlement, judgment, or arbitration award over ten thousand dollars ($10,000) of a claim or action for damages for death or personal injury caused by negligence, error or omission in practice, or by the unauthorized rendering of professional services, by a person who holds a license, certificate, or other similar authority from an agency specified in subdivision (a) of Section 800 (except a person licensed pursuant to Chapter 3 (commencing with Section 1200) or Chapter 5 (commencing with Section 2000) or the Osteopathic Initiative Act) who does not possess professional liability insurance as to that claim shall, within 30 days after the written settlement agreement has been reduced to writing and signed by all the parties thereto or 30 days after service of the judgment or arbitration award on the parties, be reported to the agency that issued the license, certificate, or similar authority. A complete report shall be made by appropriate means by the person or his or her counsel, with a copy of the communication to be sent to the claimant through his or her counsel if the person is so represented, or directly if he or she is not. If, within 45 days of the conclusion of the written settlement agreement or service of the judgment or arbitration award on the parties, counsel for the claimant (or if the claimant is not represented by counsel, the claimant himself or herself) has not received a copy of the report, he or she shall himself or herself make the complete report. Failure of the licensee or claimant (or, if represented by counsel, their counsel) to comply with this section is a public offense punishable by a fine of not less than fifty dollars ($50) or more than five hundred dollars ($500). Knowing and intentional failure to comply with this section or conspiracy or collusion not to comply with this section, or to hinder or impede any other person in the compliance, is a public offense punishable by a fine of not less than five thousand dollars ($5,000) nor more than fifty thousand dollars ($50,000).
services, by a marriage and family therapist, a clinical social worker, or a professional clinical counselor licensed pursuant to Chapter 13 (commencing with Section 4980), Chapter 14 (commencing with Section 4990), or Chapter 16 (commencing with Section 4999.10), respectively, who does not possess professional liability insurance as to that claim shall within 30 days after the written settlement agreement has been reduced to writing and signed by all the parties thereto or 30 days after service of the judgment or arbitration award on the parties be reported to the agency that issued the license, certificate, or similar authority. A complete report shall be made by appropriate means by the person or his or her counsel, with a copy of the communication to be sent to the claimant through his or her counsel if he or she is so represented, or directly if he or she is not. If, within 45 days of the conclusion of the written settlement agreement or service of the judgment or arbitration award on the parties, counsel for the claimant (or if he or she is not represented by counsel, the claimant himself or herself) has not received a copy of the report, he or she shall himself or herself make a complete report. Failure of the marriage and family therapist, clinical social worker, or professional clinical counselor or claimant (or, if represented by counsel, his or her counsel) to comply with this section is a public offense punishable by a fine of not less than fifty dollars ($50) nor more than five hundred dollars ($500). Knowing and intentional failure to comply with this section, or conspiracy or collusion not to comply with this section or to hinder or impede any other person in that compliance, is a public offense punishable by a fine of not less than five thousand dollars ($5,000) nor more than fifty thousand dollars ($50,000).
SUMMARY
Senate Bill 1229 would require a pharmacy that owns or operates a secure drug take-back bin, as defined, in a publicly accessible location to take reasonable steps to ensure the proper disposal of the pharmaceutical waste contained in the bins. The bill would provide that the owner or operator is not liable for civil damages arising from the use of the secure drug take-back bin if the owner or operator takes reasonable steps, as specified, to ensure the health and safety of consumers and employees and the proper disposal in the waste stream of the pharmaceutical waste contained in the bins.

SB 1229 adds to the Health and Safety Code the definitions “home-generated pharmaceutical waste” and “secure drug take-back bin.”

EXISTING LAW:
Section 4022 of the Business and Professions code defines “Dangerous Drug – Dangerous Device” as that which can be lawfully dispensed pursuant to a prescription.

Section 4025 of the Business and Professions Code defines “drug” to be that which is consistent with the federal Food, Drug and Cosmetic Act; articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals; articles (other than food) intended to affect the structure or any function of the body of humans or other animals; and any component of the aforementioned.

1“Medical waste” is defined in the California Medical Waste Management Act (MWMA) as any biohazardous, pathology, pharmaceutical, or trace chemotherapy waste not regulated by the

1 Health and Safety Code section 117690
federal Resource Conservation and Recovery Act of 1976; ... waste generated from the
consolidation of home-generated sharps, etc. This section incorporates the definition of
“pharmaceutical” to be a prescription or over-the-counter human or veterinary drug,
including, but not limited to, a drug as defined in the federal Food, Drug and Cosmetic Act.
The MWMA generally prohibits a person from transporting, storing, treating, disposing, or
causing the treatment of medical waste in a manner not authorized.

THIS BILL WOULD:
1. State it is the intent of the legislature to encourage good faith participation by
   pharmacies in hosting drug take-back bins as well as its intent to prescribe the
   standards of reasonable care necessary for such pharmacies.
2. Add Section 1714.24 of the Civil Code to provide that such a pharmacy shall not be
   liable for civil damages arising from the use of the take-back bin if the owner takes
   reasonable steps to ensure safety to consumers and employees as well as proper
   disposal.
3. Adds the following definitions to the Medical Waste Management Act:
   - “Home-generated pharmaceutical waste” means a pharmaceutical that is a waste
     generated by a household or households.
   - “Secure drug take-back bin” means a receptacle that can receive home-generated
     pharmaceutical waste, that employs a locking mechanism that requires the
     hazardous waste hauler and the bin owner or operator to use two, non-identical
     keys simultaneously to access the contents of the bin, and that is secured to a
     wall or the ground.

Board Efforts
The board has initiated regulations that would establish requirements for prescription drug
take-back programs. The regulation is in the initial comment phase with regulation hearing
scheduled for April 2016.

Federal Drug Takeback
In 2010 the federal government enacted the Secure and Responsible Drug Disposal Act of 2010.
The act was passed in an effort to curtail prescription drug abuse by authorizing regulations
that outline methods for ultimate users to dispose of their unused or unwanted pharmaceutical
controlled substances.

Federal law allows for current DEA registrants to become authorized collectors of controlled
substances. The Final Rule became operative on October 9, 2014, and authorizes certain DEA
registrants (manufacturers, distributors, reverse distributors, narcotic treatment programs,
retail pharmacies, and hospitals/clinics with an on-site pharmacy) to modify their registration

2 Health and Safety Code section 11747
3 21 U.S.C. Sec. 321(g)(1)
4 Proposal to add Article 9.1, Sections 1776 to 1776.6 to the California Code of Regulations. The 45-day notice for
   public comment was issued February 12, 2016.
5 21 CFR Parts 1300, 1301, 1304, et al. Disposal of Controlled Substances; Final Rule
with the DEA to become authorized collectors. All collectors may operate a collection receptacle at their registered location, and collectors with an on-site means of destruction may operate a mail-back program. Retail pharmacies and hospitals/clinics with an on-site pharmacy may operate collection receptacles at long-term care facilities.

The final rule also establishes 6 regulations related to each element of the disposal process, including the transfer, delivery, collection, destruction, return and recall of pharmaceutical controlled substances, by both registrants and non-registrants.

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6 These regulations are incorporated into 21 C.F.R. part 1317 on disposal.
SENATE BILL No. 1229

Introduced by Senators Jackson and Stone

February 18, 2016

An act to add Section 1714.24 to the Civil Code, and to add Sections 117670.5, 117748, and 118312 to the Health and Safety Code, relating to pharmaceutical waste.

LEGISLATIVE COUNSEL’S DIGEST

SB 1229, as introduced, Jackson. Pharmacies: secure drug take-back bins.

Under existing law, the Medical Waste Management Act, the State Department of Public Health regulates the management and handling of medical waste, including pharmaceutical waste, as defined. The act generally prohibits a person from transporting, storing, treating, disposing, or causing the treatment of medical waste in a manner not authorized by the act. A violation of that provision is a crime.

This bill would require a pharmacy that owns or operates a secure drug take-back bin, as defined, in a publicly accessible location to take reasonable steps to ensure the proper disposal of the pharmaceutical waste contained in the bins. The bill would provide that the owner or operator is not liable for civil damages arising from the use of the secure drug take-back bin if the owner or operator takes reasonable steps, as specified, to ensure the health and safety of consumers and employees and the proper disposal in the waste stream of the pharmaceutical waste contained in the bins. By expanding the application of a crime, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.
This bill would provide that no reimbursement is required by this act for a specified reason.


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

SECTION 1. (a) It is the intent of the Legislature to encourage the good faith participation of pharmacies in hosting secure drug take-back bins on their premises for the convenience and public health and safety of prescription drug consumers and the proper disposal in the waste stream of the pharmaceutical waste contained in the bins.

(b) It is the intent of the Legislature to prescribe the standards of reasonable care necessary for pharmacies that host secure drug take-back bins on their premises.

SEC. 2. Section 1714.24 is added to the Civil Code, to read:

1714.24. Any pharmacy that owns or operates a secure drug take-back bin in a publicly accessible location shall not be liable for civil damages arising from the use of the secure drug take-back bin if the owner or operator takes reasonable steps pursuant to Section 118312 of the Health and Safety Code to ensure the health and safety of consumers and employees and the proper disposal in the waste stream of the pharmaceutical waste contained in the bins.

SEC. 3. Section 117670.5 is added to the Health and Safety Code, to read:

117670.5. “Home-generated pharmaceutical waste” means a pharmaceutical that is a waste generated by a household or households.

SEC. 4. Section 117748 is added to the Health and Safety Code, to read:

117748. “Secure drug take-back bin” means a receptacle that can receive home-generated pharmaceutical waste, that employs a locking mechanism that requires the hazardous waste hauler and the bin owner or operator to use two, nonidentical keys simultaneously to access the contents of the bin, and that is secured to a wall or the ground.

SEC. 5. Section 118312 is added to the Health and Safety Code, to read:
118312. Any pharmacy that owns or operates a secure drug
2 take-back bin in a publicly accessible location shall take reasonable
3 steps to ensure the proper disposal in the waste stream of the
4 pharmaceutical waste contained in the bins.
SEC. 6. No reimbursement is required by this act pursuant to
Section 6 of Article XIII B of the California Constitution because
the only costs that may be incurred by a local agency or school
district will be incurred because this act creates a new crime or
infraction, eliminates a crime or infraction, or changes the penalty
for a crime or infraction, within the meaning of Section 17556 of
the Government Code, or changes the definition of a crime within
the meaning of Section 6 of Article XIII B of the California
Constitution.
BILL ANALYSIS

**Bill Number:** SB 1230

**Current Version:** As Introduced February 18, 2016

**Author:** Stone

**Topic:** Pharmacies: Compounding

**Board Position:**

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**Affected Sections:** Add Section 4126.7 to the Business and Professions Code

**Status:** Hearing scheduled for April 11, 2016, Senate Business, Professions and Economic Development Committee

**SUMMARY:**
This bill would allow a pharmacy to compound nonpatient-specific medications, as specified, to a clinic if a professional compounding services agreement is in place.

**EXISTING LAW:**
Existing law allows for pharmacies to compound medications under specified conditions. Further, existing law allows a pharmacy to compound injectable medications for another pharmacy pursuant to a prescription if a contract is in place and reported to the board (Business and Professions Code Section 4123).

Federal law regulates pharmacy compounding under Section 503A of the Federal Food, Drug and Cosmetic Act. Under these provisions, a pharmacist may compound a product pursuant to a prescription and provide the medication to a physician’s office. Further this section allows a licensed pharmacy, to provided, in limited quantities, compounded medication before receipt of a valid prescription order based on a history and established relationship between the pharmacist and physician.

Further, Section 503B if the Federal Food, Drug and Cosmetic creates a second tier of regulation for sterile compounding in the form of outsourcing facilities.

**THIS BILL WOULD:**
Add section 4126.7 to establish the authority for a pharmacy to provide compounding services to a clinic under the following conditions:

1. The products may be commercially available products that are unique or otherwise unavailable to the clinic.
2. The clinic and pharmacy have entered into a professional compounding agreement.
3. The pharmacy can provide nonpatient-specific compounded medications that cannot be planned for prospectively. Further, the board would be required to develop regulations for establishing professional compounding services agreement.

STAFF COMMENTS:
Over the past several years the board has worked diligently to review its regulations related to compounding and sterile compounding. Board staff is concerned that the proposed measure may create conflict with federal law relating to compounding by pharmacies as well as the compounding regulations recently adopted by the board which will take effect January 1, 2016.

Board staff will work with the author’s office to gain a better understanding of the measure.

FISCAL IMPACT ON THE BOARD:
The board will incur the costs associated with development and promulgation of the required regulation should this measure pass.

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An act to add Section 4126.7 to the Business and Professions Code, relating to pharmacies.

LEGISLATIVE COUNSEL’S DIGEST

SB 1230, as introduced, Stone. Pharmacies: compounding.

Under the Pharmacy Law, a violation of which is a crime, the California State Board of Pharmacy licenses and regulates the practice of pharmacy. That law authorizes a pharmacy to furnish prescription drugs only to certain entities, including specific health care entities, and individual patients either pursuant to prescription or as otherwise authorized by law.

This bill would authorize a pharmacy that provides compounding services to provide to a clinic commercial products that are unique or otherwise unavailable to the clinic, if the compounding pharmacy and the clinic have entered into a professional compounding services agreement to provide nonpatient-specific compounded medications that cannot be planned for prospectively. The bill would require the board to adopt regulations for establishing a professional compounding services agreement.


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

SECTION 1. Section 4126.7 is added to the Business and Professions Code, to read:
4126.7. (a) A pharmacy that provides compounding services may provide to a clinic commercial products that are unique or otherwise unavailable to the clinic, if the compounding pharmacy and the clinic have entered into a professional compounding services agreement, that complies with regulation adopted pursuant to subdivision (b), to provide nonpatient-specific compounded medications that cannot be planned for prospectively. (b) The board shall adopt regulations for establishing a professional compounding services agreement.
Bill Number: SB 1346
Current Version: As Introduced February 19, 2016
Author: Allen
Topic: Pharmacists: Drug Labeling: Medication Guides: Electronic Delivery
Board Position:

Affected Sections: Add Section 4074.5 to the Business and Professions Code

Status: Hearing scheduled for April 4, 2016, Senate Business, Professions and Economic Development Committee

SUMMARY:
This measure would allow a pharmacist to provide medication guides via e-mail at the request of a patient.

EXISTING LAW:
Federal law (21 CFR 208) establishes the requirements for drug manufacturers to produce medication guides for specified products. Further, federal law requires dispensers to provide medication guides for these products unless otherwise directed by the prescriber in which case the dispenser is only required to provide the guide at the request of the patient.

THIS BILL WOULD:
Add section 4074.5 to the Business and Professions Code to allow a pharmacist to provide a medication guideline electronically at the request of the patient. This measure would also provide the board with the authority to exempt a drug from this authorization via regulation.

STAFF COMMENTS:
According to the author’s office, the FDA is currently in the process of studying how to more effectively present information to patients with the intention of creating an online database for Medication Guides. The author’s office notes that many individuals may take the same medication for months or even longer, but still receive a medication guide with each refill. Further, the author’s office also notes that some patients would prefer these guides in an electronic format.

According to the FDA’s website, the FDA refers to Medication Guides as “paper handouts that come with many prescription medications.” Board staff is seeking clarification from the FDA to determine if this is still the position of the FDA. An update will be provided in the meeting if available.
FISCAL IMPACT ON THE BOARD:

The board could incur the costs associated with development and promulgation if it chose to exempt a drug from the provisions of this measure.

HISTORY:

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An act to add Section 4074.5 to the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL’S DIGEST


The Pharmacy Law provides for the licensure and regulation of pharmacists by the California State Board of Pharmacy. Existing law requires a pharmacist to inform a patient orally or in writing of the harmful effects of a drug dispensed by prescription, if the drug poses a substantial risk when taken in combination with alcohol or the drug may impair a person’s ability to drive a motor vehicle, and the board requires that warning by regulation. Existing law also requires a pharmacist to include a written label on the drug container indicating that the drug may impair a person’s ability to operate a vehicle or vessel if the pharmacist, in exercising his or her professional judgment, determines that the drug may impair a person’s ability to operate a vehicle or vessel, as specified. Existing law authorizes the board to require by regulation additional information or labeling. A violation of the Pharmacy Law is a crime.

This bill would authorize a pharmacist to offer to a patient, as an alternative to a printed paper medication guide for a prescription drug as required by the United States Food and Drug Administration, the electronic delivery of the medication guide. The bill would authorize a pharmacist to deliver the medication guide by electronic means if the patient chooses electronic delivery. The bill would authorize the board to exempt a drug from that authorization by regulation.
The people of the State of California do enact as follows:

SECTION 1. Section 4074.5 is added to the Business and Professions Code, to read:

4074.5. (a) Except as provided by regulation pursuant to subdivision (b), a pharmacist may do the following:

(1) Offer to a patient, as an alternative to a printed paper medication guide for a prescription drug as required by the United States Food and Drug Administration, the electronic delivery of the medication guide.

(2) Deliver the medication guide by electronic means if the patient chooses electronic delivery.

(b) The board may by regulation exempt a drug from the authorization established in subdivision (a).
SENATE BILL  No. 1454

Introduced by Senator Stone

February 19, 2016

An act to amend Section 4001 of the Business and Professions Code, relating to healing arts.

LEGISLATIVE COUNSEL’S DIGEST

SB 1454, as introduced, Stone. Pharmacy.

The Pharmacy Law establishes in the Department of Consumer Affairs the California State Board of Pharmacy, which consists of 13 members. This bill would make a nonsubstantive change to these provisions. 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 4001 of the Business and Professions Code is amended to read:

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

(b) The Governor shall appoint seven competent pharmacists who reside in different parts of the state to serve as members of the board. The Governor shall appoint four public members, and the Senate Committee on Rules and the Speaker of the Assembly shall each appoint a public member who shall not be a licensee of the board, any other board under this division, or any board referred to in Section 1000 or 3600.
(c) At least five of the seven pharmacist appointees to the board shall be pharmacists who are actively engaged in the practice of pharmacy. Additionally, the membership of the board shall include at least one pharmacist representative from each of the following practice settings: an acute care hospital, an independent community pharmacy, a chain community pharmacy, and a long-term health care or skilled nursing facility. The pharmacist appointees shall also include a pharmacist who is a member of a labor union that represents pharmacists. For the purposes of this subdivision, a “chain community pharmacy” means a chain of 75 or more stores in California under the same ownership, and an “independent community pharmacy” means a pharmacy owned by a person or entity who owns no more than four pharmacies in California.

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

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

(f) This section shall remain in effect only until January 1, 2017, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2017, deletes or extends that date. Notwithstanding any other provision of law, the repeal of this section renders the board subject to review by the appropriate policy committees of the Legislature.
BILL ANALYSIS

Bill Number: AB 12
Current Version: August 19, 2015 Amended
Author: Cooley
Topic: State Government, Administration
Regulations: Review
Board Position: Oppose (4/22/15 Text Version)

Affected Sections: Adds Chapter 3.6 to Part 1 of Division 3 of Title 2 of the Government Code.

Status: Last location was Senate Appropriations (8/27/15)

SUMMARY:
AB 12 would require state agencies to review, adopt, amend or repeal any regulations that are duplicative, overlapping, and inconsistent or out-of-date by January 1, 2018, and establish reporting requirements.

EXISTING LAW:
The Administrative Procedure Act establishes requirements for the adoption, amendment or repeal of regulations.

THIS BILL WOULD:
Require the board to identify all regulations that are duplicative, overlapping, inconsistent or out of date and ensure that necessary changes are made via the rulemaking process to correct any such identified changes. Further, this measure would require that all actions be completed on or before January 1, 2018.

There are no substantive differences between the April 22 and the August 19 versions of the bill. The board established an oppose position at its June 2015 Board Meeting.

STAFF COMMENTS:
Board staff notes that this measure could have a significant impact to its current operations. Completing the necessary review of its regulations as well as securing the changes within the time allotted (two years) seems extremely challenging. Given the complexity of the board’s regulatory structure, board staff has concerns that the board could achieve compliance with this measure in the timeframe allowed without significantly impacting other areas of board operations.

STAFF RECOMMENDATION:
Maintain Oppose position for the August 19, 2015 amended version.
FISCAL IMPACT ON THE BOARD:

Board staff have identified a significant fiscal impact to this measure to ensure the necessary review of its regulations are conducted and necessary changes secured in conformance with this measure.

SUPPORT / OPPOSITION: (According to the Senate Governmental Organization analysis for the 4/22/15 text version)

SUPPORT
American Federation of State, County and Municipal Employees
Associated Builders and Contractors of California Building Owners and Managers Association of California
California Asian Pacific Chamber of Commerce
California Association of Bed & Breakfast Inns
California Building Industry Association
California Business Properties Association
California Business Roundtable
California Chamber of Commerce
California Construction and Industrial Materials Association
California Grocers Association
California Hotel & Lodging Association
California League of Food Processors
California Manufacturers & Technology Association
California Retailers Association
California Taxpayers Association
Commercial Real Estate Development Association
Consumer Specialty Products Association
Family Business Association
Industrial Environmental Association
International Council of Shopping Centers
National Federation of Independent Business/California
Small Business California
USANA Health Services, Inc.
Western States Petroleum Association

OPPOSITION:
None

HISTORY:

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<td>06/11/15</td>
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<td>06/01/15</td>
<td>Read third time. Passed. Ordered to the Senate. (Ayes 80. Noes 0. Page 1693.)</td>
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<td>Read second time. Ordered to third reading.</td>
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<td>04/22/15</td>
<td>From committee chair, with author's amendments: Amend, and re-refer to Com. on A. &amp; A.R. Read second time and amended.</td>
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<td>03/23/15</td>
<td>In committee: Set, first hearing. Hearing canceled at the request of author.</td>
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<td>01/16/15</td>
<td>Referred to Com. on A. &amp; A.R.</td>
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<td>12/02/14</td>
<td>From printer. May be heard in committee January 1.</td>
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SECTION 1. Chapter 3.6 (commencing with Section 11366) is added to Part 1 of Division 3 of Title 2 of the Government Code, to read:

CHAPTER 3.6. Regulatory Reform

Article 1. Findings and Declarations

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

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

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

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

Article 2. Definitions

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

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

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

Article 3. State Agency Duties

11366.2. On or before January 1, 2018, each state agency shall do all of the following:

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

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

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

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

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

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

(2) The report shall be submitted in compliance with Section 9795 of the Government Code.
11366.3. (a) On or before January 1, 2018, each agency listed in Section 12800 shall notify a department, board, or other unit within that agency of any existing regulations adopted by that department, board, or other unit that the agency has determined may be duplicative, overlapping, or inconsistent with a regulation adopted by another department, board, or other unit within that agency.

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

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

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

Article 4. Chapter Repeal

11366.5. This chapter shall remain in effect only until January 1, 2019, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2019, deletes or extends that date.
ASSEMBLY BILL No. 1939

Introduced by Assembly Member Patterson

February 12, 2016

An act to add Section 312.3 to the Business and Professions Code, relating to professions.

LEGISLATIVE COUNSEL’S DIGEST

AB 1939, as introduced, Patterson. Licensing Requirements.

Under existing law, the Department of Consumer Affairs is comprised of various boards, bureaus, commissions, committees, and similarly constituted agencies that license and regulate the practice of various professions and vocations for the purpose of protecting the people of California. Existing law requires each of these entities to submit annually to the director of the department its methods for ensuring that every licensing examination it administers is subject to periodic evaluation.

This bill would require the director of the department to conduct a study and submit to the Legislature by July 1, 2017, a report identifying, exploring, and addressing occupational licensing requirements that create unnecessary barriers to labor market entry or mobility.


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

SECTION 1. Section 312.3 is added to the Business and Professions Code, to read:

312.3. (a) The director shall conduct a study and submit to the Legislature by July 1, 2017, a report identifying, exploring, and
addressing areas where occupational licensing requirements create
an unnecessary barrier to labor market entry or labor mobility,
particularly for dislocated workers, transitioning service members,
and military spouses.

(b) The report to be submitted pursuant to subdivision (a) shall
be submitted in compliance with Section 9795 of the Government
Code.
Attachment 3
Self-Assessments
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. 01/11) entitled “Community Pharmacy Self-Assessment Hospital Outpatient Pharmacy Self-Assessment” and on Form 17M-14 (Rev. 01/11) 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.

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 and retained in the pharmacy. Do not copy a previous assessment.

Notes: If a hospital pharmacy dispenses prescriptions for outpatient use, a 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. 1/11 02/12).

Each self-assessment must be kept on file in the pharmacy for three years after it is performed.
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13. ___________________________________ TCH # ________________ Exp. Date: _______________

14. ___________________________________ TCH # ________________ Exp. Date: _______________

15. ___________________________________ TCH # ________________ Exp. Date: _______________
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. Additional “Notice to Consumers” in languages other than English may also be posted. (B&PC 4122, CCR 1707.2)

☐ ☐ ☐ 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])

☐ ☐ ☐ 1.9. 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)

☐ ☐ ☐ 1.10. Does the pharmacy compound sterile injectable drugs? (If yes, complete section 24 section 27 – “Compounding.”)
1.11. 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. 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. The pharmacy reports to the board within 14-30 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. 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. For a pharmacy whose owner owns two or more pharmacies, the pharmacy receives the board’s e-mail notifications through the owner’s electronic notice system. (B&PC 4013[c])

    Date Last Notification Received: ________________________________

    E-mail address registered with the board: ________________________________

CORRECTIVE ACTION OR ACTION PLAN: ________________________________________________________________

______________________________________________________________________________________________
2. 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])

CORRECTIVE ACTION OR ACTION PLAN: ________________________________________________________

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: ________________________________________________________
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 of this Self-Assessment.)

4.5. Pharmacist-in-Charge (PIC)

Yes No N/A
☐ ☐ ☐ 4.1.5.1. 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)

Yes No N/A
☐ ☐ ☐ 4.2.5.2. The PIC has adequate authority to assure the pharmacy’s compliance with laws governing the operation of a pharmacy. (CCR 1709.1[b])

☐ ☐ ☐ 4.3.5.3. 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)

☐ ☐ ☐ 4.4.5.4. Is the PIC in charge of another pharmacy?

☐ ☐ ☐ 4.5.5.5. If yes, are the pharmacies within 50 driving miles of each other? (CCR 1709.1[c])
   Name of the other pharmacy ____________________________________________

☐ ☐ ☐ 4.6.5.6. 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)

☐ ☐ ☐ 4.7.5.7. 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. 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: ___________________________________________
5. 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)

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))

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 access 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)
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: ____________________

CORRECTIVE ACTION OR ACTION PLAN: ____________________________________________________________

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. The advance practice pharmacist has received an advance practice pharmacist recognition by the board and may do the following: (B&PC 4016.5, 4210)

☐ 7.2.1 Perform 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 Participate in the evaluation and management of diseases and health conditions in collaboration with other health care providers; (B&PC 4052.6[a])

☐ 7.2.3 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])

☐ 7.2.4 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])

☐ 7.2.5 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])

☐ 7.2.6 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])

6. 8. Duties of an Intern Pharmacist

Yes No N/A

☐ ☐ ☐ 6.1. 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)
6.2. 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)

6.3. The intern hours affidavits are signed by the pharmacist under whom the experience was earned. (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])

CORRECTIVE ACTION OR ACTION PLAN: ____________________________________________________________

7. 9. Duties of a Pharmacy Technician

7.1. Registered pharmacy technicians are performing 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)

7.2. 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])

7.3. A pharmacy technician or pharmacy technician trainee wears identification, in 18-point type, that identifies him or her self as a pharmacy technician or pharmacy technician trainee. (B&PC 680, B&PC 4115.5[e], CCR 1793.7[d])

7.4. 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: ____________________________________________________________

PIC Initials
8. 10. Duties of Non-Licensed Personnel

Yes No N/A

☐ ☐ ☐ 8.1. 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)

☐ ☐ ☐ 8.2. 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: ________________________________________________________

PHARMACY PRACTICE

9. 11. Consultation/Patient Profile/Review of Drug Therapy

Yes No N/A

☐ ☐ ☐ 9.1. 11.1. Pharmacists provide oral consultation: (B&PC 4052[a][7], CCR 1707.2):

☐ 9.1.1. 11.1.1. whenever the prescription drug has not been previously dispensed to the patient;

☐ 9.1.2. 11.1.2. whenever a refill prescription drug is dispensed in a different dosage form, strength, or with new written directions;

☐ 9.1.3. 11.1.3. upon request; and

☐ 9.1.4. 11.1.4. whenever the pharmacist deems it is warranted in the exercise of his or her professional judgment.

☐ ☐ ☐ 9.2. 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)

☐ ☐ ☐ 9.3. 11.3. The pharmacist reviews a patient’s drug therapy and medication record prior to consultation. (CCR 1707.3)

☐ ☐ ☐ 9.4. 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])

☐ ☐ ☐ 9.5. 11.5. Appropriate drug warnings are provided orally or in writing. (B&PC 4074, CCR 1744)

☐ ☐ ☐ 9.6. 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: ________________________________________________________

PIC

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10. 12. Prescription Requirements

Yes No N/A

10.1. 12.1. Prescriptions are complete with all the required information. (B&PC 4040, 4070)

10.2. 12.2. Orally transmitted prescriptions are received and reduced to writing only by a pharmacist or intern pharmacist working under the direction of a pharmacist. (B&PC 4070, CCR 1717)

10.3. 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)

10.4. 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)

10.5. 12.5. The security and confidentiality of electronically transmitted prescriptions are maintained. (B&PC 4070[c], CCR 1717.4[h])

10.6. 12.6. Facsimile prescriptions are received only from a prescriber’s office. (B&PC 4040[c])

10.7. 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])

10.8. 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)

10.9. 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])

CORRECTIVE ACTION OR ACTION PLAN: ____________________________________________________________

11. 13. Prescription Labeling, Furnishing and Dispensing

Yes No N/A

11.1. 13.1. The prescription label contains all the required information. (B&PC 4076)

11.2. 13.2. The prescription label is formatted in accordance with CCR 1707.5.

11.3. 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])
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 13.3.1; (CCR 1707.5[a][2])
- 13.4.3 When applicable, standardized directions for use are utilized. (CCR 1707.5[a][4])

13.4. The pharmacy is exempt from the prescription label requirements in CCR 1707.5.

Exemption approved by board from: ___________ to ________________

13.5. Expiration dates of drugs' effectiveness are consistent with those of the manufacturer if the information is required on the original manufacturer's label. (B&PC 4076)

13.6. 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])

13.7. Generic substitution is communicated to the patient. (B&PC 4073)

13.8. 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. (B&PC 4115, CCR 1793.7, CCR 1712)

13.9. The federal warning label prohibiting transfer of controlled substances is on the prescription container. (21 CFR 290.5)

13.10. 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. (21 USC 1473 section 4[b], 16 CFR 1700.15, CCR 1717)

13.11. Patient package inserts are dispensed with all estrogen medications. (21 CFR 310.515)

13.12. The pharmacy provides patients with Black Box Warning Information in conformance with 21 CFR 201.57[c].

13.13. 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 received drugs, or to another pharmacy of common ownership.

13.14. 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)
11.15. 13.16. Controlled substance prescriptions are not filled or refilled more than six months from the date written. (H&SC 11200)

13.17. The pharmacy dispenses not more than a 90-day supply of a dangerous drug (other than controlled substances, or psychotropic medication or drugs): (B&PC 4064.5)

☐ 13.17.1 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])
   ☐ 13.17.1.1 The prescriber has not indicated “no change to quantity” or words of similar meaning; (B&PC 4064.5[d])
   ☐ 13.17.1.2. 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])
   ☐ 13.17.1.3. The total quantity dispensed does not exceed the total quantity authorized on the prescription, including refills; (B&PC 4064.5[a][2])
   ☐ 13.17.1.4. 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])
   ☐ 13.17.1.5. The pharmacist is exercising his or her professional judgment. (B&PC 4064.5[a][4])

☐ 13.17.2. The pharmacist notifies the prescriber of the increase in quantity dispensed. (B&PC 4064.5[c])

☐ 13.18. 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])

CORRECTIVE ACTION OR ACTION PLAN: ____________________________________________________________


Yes No N/A

☐ ☐ 12.1. 14.1. Refill authorization from the prescriber is obtained before refilling a prescription. (B&PC 4063, 4064)

☐ ☐ 12.2. 14.2. Refills are documented. (CCR 1717)

☐ ☐ 12.3. 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)

☐ ☐ 12.4. 14.4. Refills for Schedule II controlled substances are prohibited. (H&SC 11200)
12.5. 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&S C 11200)

CORRECTIVE ACTION OR ACTION PLAN: ____________________________________________________________

13. 15. Quality Assurance and Medication Errors

13.1. 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)

13.2. 15.2. Pharmacy quality assurance policies and procedures are maintained in the pharmacy and are immediately retrievable. (CCR 1711[c])

13.3. 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])

13.4. 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])

13.5. 15.5. Investigation of pharmacy medication errors is initiated within two business days from the date the medication error is discovered. (CCR 1711[d])

13.6. 15.6. The record for quality assurance review for a medication error contains: (CCR 1711[e])

- 13.6.1. 15.6.1. Date, location, and participants in the quality assurance review;
- 13.6.2. 15.6.2. Pertinent data and other information related to the medication error(s) reviewed;
- 13.6.3. 15.6.3. Findings and determinations; and
- 13.6.4. 15.6.4. Recommended changes to pharmacy policy, procedure, systems or processes, if any.

13.7. 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])

13.8. 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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14. 16. Erroneous or Uncertain Prescriptions / Corresponding Responsibility for Filling Controlled Substance Prescriptions

Yes  No  N/A
☐ ☐ ☐  14.1. 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])

Yes  No  N/A
☐ ☐ ☐  14.2. 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)

☐ ☐ ☐  14.3. 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])

☐ ☐ ☐  16.4. Internet prescriptions are only dispensed on a prescription issued pursuant to a good faith prior examination. (B&PC 4067[a])

☐ ☐ ☐  16.5. 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: ________________________________________________________________

15. 17. Prescription Transfer

Yes  No  N/A
☐ ☐ ☐  15.1. 17.1. Only pharmacists transfer prescriptions from pharmacy to pharmacy, and records of prescription transfers are kept as required. (CCR 1717[e][1-6])

☐ ☐ ☐  15.2. 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

☐ ☐ ☐  15.3. 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])
15.4, 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: ____________________________________________________________

16. 18. Confidentiality of Prescriptions

Yes No N/A
☐ ☐ ☐ 16.1, 18.1. Patient information is maintained to safeguard confidentiality. (Civil Code 56.10 et seq.)
☐ ☐ ☐ 16.2, 18.2. All prescriptions are kept confidential and only disclosed as authorized by law. (CCR 1764)

Yes No N/A
☐ ☐ ☐ 16.3, 18.3. The pharmacy ensures electronically transmitted prescriptions are received, maintained and transmitted in a secure and confidential manner. (CCR 1717.4[h])
☐ ☐ ☐ 16.4, 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])
☐ ☐ ☐ 16.5, 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)
☐ ☐ ☐ 16.6, 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: ____________________________________________________________

17. 19. Record Keeping Requirements

Yes No N/A
☐ ☐ ☐ 17.1, 19.1. A completed biennial pharmacy self-assessment is on file in the pharmacy and maintained for three years. (CCR 1715)
☐ ☐ ☐ 17.2, 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):
☐  17.2.1, 19.2.1. Prescription records (B&PC 4081[a])
☐  17.2.2, 19.2.2. Purchase Invoices for all prescription drugs (B&PC 4081[b])
☐  17.2.3, 19.2.3. Biennial controlled substances inventory (21 CFR 1304.11, CCR 1718)
☐  17.2.4, 19.2.4. U.S. Official Order Forms (DEA Form 222) (21 CFR 1305.13)
17.2.5. **Power of Attorney for completion of DEA 222 forms (21 CFR 1305.07)**

17.2.6. **Theft and Loss Reports (DEA Form 106) (21 CFR 1301.74[c])**

17.2.7. **Record documenting return of drugs to wholesaler or manufacturer (B&PC 4081)**

17.2.8. **Record documenting transfers or sales to other pharmacies, licensees and prescribers (B&PC 4081, 4105, CCR 1718)**

17.3. **Hypodermic needle and syringe sales by a pharmacist to a person without a prescription are limited to:** (B&PC 4140, 4149 4145.5)

17.3.1. **Persons known to the pharmacist and when the pharmacist has previously been provided with a prescription or other proof of legitimate medical need;**

17.3.2. **Use on animals, provided the person is known to the pharmacist or the person’s identity can be properly established.**

17.3.3. **The sale of 10 or fewer 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)**

17.3.4. **For industrial use, as determined by the board. (B&PC 4144.5)**

17.3.5. **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.**

17.4. **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. Records for controlled substances are maintained on the licensed premises for at least two years from the date of dispensing. (CCR 1707, B&PC 4105)**

19.6. The pharmacy dispenses epinephrine auto-injector to 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)

19.6.1. A physician/surgeon provides a written order that specifies the quantity of epinephrine auto-injectors to be dispensed (B&PC 4119.3[a][1])
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])

19.6.3. Each dispensed prescription includes the manufacturer’s product information sheet for epinephrine auto-injectors. (B&PC 4119.3[a][2])

CORRECTIVE ACTION OR ACTION PLAN: ________________________________________________________

18. 20. DEA Controlled Substances Inventory

Inventory:

Yes No N/A

18.1. 20.1. Is completed biennially (every two years).
  Date completed: ____________________________ (21 CFR 1304.11[b])

18.2. 20.2. Schedule II inventory is separate from Schedule III, IV and V. (21 CFR 1304.04[h][1], 1304.04[h][2])

18.3. 20.3. Is available for inspection for three years. (CCR 1718)

18.4. 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])

18.5. 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])

18.6. 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])

18.7. 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)

18.8. 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)

18.9. 20.9. When a pharmacy distributes schedule II controlled substances to a DEA registrant (pharmacies, wholesalers, 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)
18.9. 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)

18.10. 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)

18.11. 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])

18.12. 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.

18.13. 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)

18.14. Do pharmacy staff hand initial prescription records or prescription labels, or

18.15. 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])

18.16. All Schedule II through IV controlled substance dispensing data is successfully transmitted to CURES weekly. (H&SC 11165[d])

18.17. 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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19. 21. Oral/Electronic Transmission and Fractionation of Schedule II Controlled Substance Prescriptions

Yes No N/A

☐ 19.1. 21.1. A faxed prescription for a Schedule II controlled substance is dispensed after the original written prescription is received from the prescriber. (21 CFR 1306.11[a], H&SC 11164)

☐ 19.2. 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: The licensed facility provides the pharmacy with a copy of the prescriber signed order when available. (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.

☐ 19.3. An electronically transmitted order 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 after the pharmacist produces, signs and dates the hard copy prescription on a form of the pharmacy’s design. The licensed facility forwards to the dispensing pharmacist a copy of the order signed by the prescriber when available. (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, 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. 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)
19.8. 21.7. 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])

19.9. 21.8. 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])

19.10. 21.9. 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. 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. 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. 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: ____________________________________________________________

20. 22. Automated Dispensing/Delivery Devices

20.1. 22.1. Does the pharmacy use an automated dispensing/delivery device and/or prescription drop box? (CCR 1713)

20.2. 22.2. 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)

20.3. 22.3. 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:

- 20.3.1. 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])

- 20.3.2. 22.3.2. A pharmacist reviews the order and patient’s profile prior to the drug being removed. (H&SC 1261.6[e][2])
20.3.3. Stocking of the automated drug delivery system is done by a pharmacist. (H&SC 1261.6[f])

Yes No N/A
☐ ☐ ☐

20.4. 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:

☐ 20.4.1. 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])

☐ 20.4.2. Removable pockets or drawers are transported between the pharmacy and the facility in a secure tamper-evident container. (H&SC 1261.6[f][2])

CORRECTIVE ACTION OR ACTION PLAN: ____________________________________________________________

21. Repackaging by the Pharmacy

Yes No N/A
☐ ☐ ☐

21.1. 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)

☐ 21.2. A log is maintained for drugs pre-packed for future dispensing. (CCR 1751.1, 21 CFR Parts 210, 211)

☐ 21.3. Drugs previously dispensed are re-packaged at the patient’s request in compliance with B&PC 4052.7.

CORRECTIVE ACTION OR ACTION PLAN: ____________________________________________________________

22. Refill Pharmacy

Yes No N/A
☐ ☐ ☐

22.1. Pharmacy processes refills for another California licensed pharmacy (CCR 1707.4[a])

If the answer is "yes", name the pharmacy or pharmacies __________________________

☐ 22.2. 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)

☐ 22.3. Some or all pharmacy refill orders are processed by another California licensed pharmacy. (CCR 1707.4[a])

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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.

Yes No N/A

☐ ☐ ☐ 22.4. 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])

☐ ☐ ☐ 22.5. 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])

☐ ☐ ☐ 22.6. 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])

☐ ☐ ☐ 22.7. 24.7. Both pharmacies maintain complete and accurate records of refill. (CCR 1707.4[a][4])

☐ ☐ ☐ 22.8. 24.8. Both pharmacies are responsible for accuracy of the refilled prescription. (CCR 1707.4[a][5])

☐ ☐ ☐ 22.9. 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: __________________________________________________________

25. 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])


23.1. 26.1. There are written policies and procedures in place for:

23.1.1. 26.1.1. The pharmacist’s administration of immunizations by injection pursuant to a prescriber’s order; (B&PC 4052.1[a][3])

23.1.2. 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])
23.1.3. 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])

23.1.4. 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])

23.1.5. 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])

23.1.6. 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])

23.1.7. 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])


23.1.9. Reporting requirements to protect the public; (B&PC 4104)

23.1.10. Preventing the dispensing of a prescription drug that is contrary to the law; (B&PC 733)

23.1.11. 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)

23.1.12. 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)

Yes No N/A

23.2. Does your pharmacy employ the use of a common electronic file?

23.2.1. 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])

☐ 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.

CORRECTIVE ACTION OR ACTION PLAN: ____________________________________________________________

________________________________________________________

COMPOUNDING

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. 04/11– 02/12) (CCR 1735.2[j])
25. 28. **NUCLEAR PHARMACY Nuclear Pharmacy**

Yes No N/A

25.1. 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)

25.2. 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)

25.3. 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. 01/11 02/12.) (CCR 1735.2 et al.)

CORRECTIVE ACTION OR ACTION PLAN: ____________________________________________________________

29. **Pharmacies That Donate Drugs to a Voluntary County-Approved Drug Repository and Distribution Program**

Yes No N/A

29.1. The pharmacy donates medications to a county-approved drug repository and distribution program, and meets the following requirements: (H&SC 150202.5, 150204, B&PC 4169.5)

- 29.1.1. The pharmacy is licensed by and is not on probation with the California State Board of Pharmacy, and (H&SC 150202.5)
- 29.1.2. The pharmacy’s primary or sole type of pharmacy practice is limited to skilled nursing facility, home health care, board and care, or mail order. (H&SC 150202.5)

29.2. If the pharmacy utilizes a surplus medication collection and distribution intermediary, the pharmacy ensures that the intermediary is licensed by the California State Board of Pharmacy. (B&PC 4169.5)

29.3. No controlled substances shall be donated. (H&SC 150204[c][1])

29.4. Drugs that are donated are unused, unexpired and meet the following requirements: (H&SC 150202.5, 150204[c])

- 29.4.1. Have not been adulterated, misbranded, or stored under conditions contrary to standards set by the USP or the product manufacturer. (H&SC 150202.5[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: ________________

☐ ☐ ☐ 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[j])
☐ 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])

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])

Transferring Donated Drugs From One Participating Entity to Another

☐ 30.11. The pharmacy transfers donated medications to another participating county-owned
pharmacy within an adjacent county. (H&SC 150204[g][4])

☐ 30.12. The pharmacy has a written agreement outlining the protocols and procedures for the
transfer of donated medications. (H&SC 150204[g][4][A])

Adjacent counties to which donated medications are transferred:
_________________________________________________________________________

☐ 30.13. Donated medication is not transferred by any participating entity more than once.
(H&SC 150204[g][4][B])

☐ 30.14. When transferring donated medications, documentation accompanies the medication that
identifies the drug name, strength, quantity of medication, and the donating facility from where the
medication originated. (H&SC 150204[g][4][C])

☐ 30.15. When transferring donated medication, documentation includes a statement that the
medication may not be transferred to another participating entity. (H&SC 150204[g][4][C])

Dispensing to Eligible Patients
30.16. Donated medications that are dispensed to an eligible patient that presents a valid prescription are dispensed in a new and properly labeled container, specific to the eligible patient. (H&SC 150204[i])

30.17. The pharmacist adheres to standard pharmacy practices, as required by state and federal law, when dispensing donated medications under this program. (H&SC 150204[f])

PHARMACIST-IN-CHARGE CERTIFICATION:

I, (please print) ________________________________________, RPH # ______________________ hereby certify that I have completed the self-assessment of this pharmacy of which I am the pharmacist-in-charge. Any deficiency identified herein will be corrected. I understand that all responses are subject to verification by the Board of Pharmacy. I further state under penalty of perjury of the laws of the State of California that the information that I have provided in this self-assessment form is true and correct.

Signature __________________________________________ Date __________________________

(Pharmacist-in-Charge)

ACKNOWLEDGEMENT BY PHARMACY OWNER OR HOSPITAL ADMINISTRATOR:

I, (please print) ________________________________________, hereby certify under penalty of perjury of the laws of the State of California that I have read and reviewed this completed self-assessment. I understand that failure to correct any deficiency identified in this self-assessment could result in the revocation of the pharmacy's license issued by the California State Board of Pharmacy.

Signature __________________________________________ Date __________________________
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 websites.

- 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)

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Phone: (916) 319-9062
Fax: (916) 319-9448
http://www.ag.ca.gov/bne

**CURES Patient Activity Report Request Forms:**
http://www.ag.ca.gov/bne/trips.php

**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) 322-3350
Fax: (916) 574-7697
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
2500 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

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:

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

DEA Registration Support (all of CA):
(800) 882-9539

Online DEA 106 Theft/Loss Reporting:
https://www.deadiversion.usdoj.gov/webforms/app106Login.jsp

Online DEA 222 Controlled Substance Ordering System (CSOS):
http://www.deaecom.gov/

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 - 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 – Oakland
1301 Clay Street, Suite 460N
Oakland, CA 94612
Registration: (888) 304-3251
Diversion or Investigation: (510) 637-5600

DEA – Redding
310 Hensted Drive, Suite 310
Redding, CA 96002
Registration: (888) 304-3251 or (415) 436-7900
Diversion or Investigation: (530) 246-5043

DEA – Riverside
4470 Olivewood Avenue
Riverside, CA 92501-6210
Registration: (888) 415-9822 or (213) 621-6960
Diversion or Investigation: (951) 328-6200

DEA - Sacramento
4328 Watt Avenue
Sacramento, CA 95821
Registration: (888) 304-3251 or (415) 436-7900
Diversion or Investigation: (916) 480-7250

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 – San Francisco
450 Golden Gate Avenue, 14th Floor
San Francisco, CA 94102
Registration: (888) 304-3251
Theft Reports or Diversion: (415) 436-7900

DEA – San Jose
One North First Street, Suite 405
San Jose, CA 95113
Registration: (888) 304-3251
Diversion or Investigation: (408) 291-2631

17M-13 (Rev. 01/11 10/14) 33 of 33
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. 04/14 10/14) must be completed also. A hospital that compounds drug products must also complete the Compounding Self-Assessment (17M-39 Rev. 04/14 02/12).

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: Daily Weekdays ________ Sat _________________ Sun. ________________ 24 Hours ___________

PIC: __________________________________________ RPH # ______________ Exp. Date: __________

_______________________ (PIC Initials)
Pharmacy staff (pharmacists, interns, technicians):

APP=Advanced Practice Pharmacist, DEA =Drug Enforcement Administration.

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PIC 17M-14 (Rev. 01/11 10/14) 2 of 24 Initials
17. ______________________________________  TCH # ________________  Exp. Date: _______________

18. ______________________________________  TCH # ________________  Exp. Date: _______________
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 30 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)
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 injectable drugs?
   (If yes, complete section 24 27 – “Compounding Sterile Injectable Drugs”)

1.13. The pharmacy is subscribed to the board’s e-mail notifications. (B&PC 4013)
   Date Last Notification Received: ____________________________
   E-mail address registered with the board: ____________________________

1.14. For a pharmacy whose owner owns two or more pharmacies, the pharmacy receives the board’s e-mail notifications through the owner’s electronic notice system. (B&PC 4013[c])
   Date Last Notification Received: ____________________________
   E-mail address registered with the board: ____________________________

CORRECTIVE ACTION OR ACTION PLAN: ______________________________________________________

2. Nursing Stations

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[j][3]);

CORRECTIVE ACTION OR ACTION PLAN: ______________________________________________________
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])

Yes No N/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])

CORRECTIVE ACTION OR ACTION PLAN: ________________________________________________________

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])
4.4. All unit-dose drugs received from a centralized hospital packaging pharmacy are correctly labeled, are barcoded, and the barcode is readable at the patient’s bedside. (B&PC 4128.4, 4128.5)

4.5. All drugs are maintained in accordance with national standards regarding the storage area and refrigerator or freezer temperature and manufacturer’s guidelines. (B&PC 4119.7[b])

CORRECTIVE ACTION OR ACTION PLAN: ________________________________________________________

5. Pharmacies That Donate Drugs to a Voluntary County-Approved Drug Repository and Distribution Program

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])
   - 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])
5. 6. Pharmacist-in-Charge (PIC)

5.1. 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)

5.2. 6.2. The PIC has adequate authority to assure the pharmacy’s compliance with laws governing the operation of a pharmacy (CCR 1709.2[b]) (CCR 1709.1[b])

5.3. 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 ________________________________

5.4. 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)

5.5. 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: ____________________________________________________________

6. 7. Duties of a Pharmacist

6.1. 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 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)

6.2. 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. (B&PC 4027, 4051, 4052, 4052.2)
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. The advance practice pharmacist has received an advance practice pharmacist recognition by the board and may do the following: (B&PC 4016.5, 4210)

☐ 8.2.1 Perform patient assessments, order and interpret drug therapy-related tests, and refer patients to other health care providers; (B&PC 4052.6[a])

☐ 8.2.2 Participate in the evaluation and management of diseases and health conditions in collaboration with other health care providers; (B&PC 4052.6[a])

☐ 8.2.3 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])

☐ 8.2.4 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])

☐ 8.2.5 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])

☐ 8.2.6 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)

☐ 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])

☐ 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])
7.3. 9.4. The intern hours affidavits are signed by the pharmacist under whom the experience was earned. (B&PC 4209, CCR 1726)

CORRECTIVE ACTION OR ACTION PLAN: ____________________________________________________________

8. 10. Duties of a Pharmacy Technician

Yes No N/A

8.1. 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)

8.2. 10.2. 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, 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])

8.3. 10.3. 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)

8.4. 10.4. A pharmacy technician or pharmacy technician trainee wears identification, in 18-point type that identifies him or her self as a pharmacy technician or pharmacy technician trainee. (B&PC 680, B&PC 4115.5[e], CCR 1793.7[d])

8.5. 10.5. 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)

Yes No N/A

8.6. 10.6. The ratio is no less than one pharmacist to two technicians. (B&PC 4115[g], CCR 1793.7)

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])

8.7. 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)

8.7.1. 10.8.1. Pharmacists are deployed to the inpatient care setting to provide clinical services.

8.7.2. 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.

8.7.3. 10.8.3. The overall operations are the responsibility of the pharmacist-in-charge.
8.7.4. 10.8.4. The pharmacy technician check checking technician program is under the direct supervision of the Pharmacist as specified in the policies and procedures.

8.7.5. 10.8.5. There is an ongoing evaluation of the program that uses specially specialized and advanced trained pharmacy technicians to check the work of other pharmacy technicians.

Yes No N/A

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: ____________________________________________________________

____________________________________________________________________________________________

9. 11. Duties of Non-Licensed Personnel

Yes No N/A

☐ 9.1. 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)

☐ 9.2. 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: ____________________________________________________________

____________________________________________________________________________________________

PHARMACY PRACTICE

10. 12. Pharmaceutical Service Requirements

Yes No N/A

☐ 10.1. 12.1. The pharmacy complies with the requirements of 22 CCR 70263, addressing the following areas in written policies and procedures:

☐ 10.1.1. 12.1.1. Basic information concerning investigational drugs and adverse drug reactions;

☐ 10.1.2. 12.1.2. Repackaging and compounding records;

☐ 10.1.3. 12.1.3. Physician orders;

☐ 10.1.4. 12.1.4. Wards, nursing stations and night stock medications;
☐ 10.1.5, 12.1.5. Drugs brought into the facility by patients for storage or use;
☐ 10.1.6, 12.1.6. Bedside medications;
☐ 10.1.7, 12.1.7. Emergency drug supply;
☐ 10.1.8, 12.1.8. Pass medications;
☐ 10.1.9, 12.1.9. Inspection of ward stock, nursing stations and night lockers no less frequently
than every 30-days\Outdated drugs;
☐ 10.1.10, 12.1.10. Routine distribution of inpatient medications;
☐ 10.1.11, 12.1.11. Preparation, labeling and distribution of IV admixtures and cytotoxic agents;
☐ 10.1.12, 12.1.12. Handling of medication when pharmacist not on duty; and
☐ 10.1.13, 12.1.13. Use of electronic image and data order transmissions.

Yes No N/A
☐☐☐ 10.2, 12.2. The pharmacy complies with the requirements of 22 CCR 70263, addressing the following
areas:
☐ 10.2.1, 12.2.1. Destruction of controlled substances; and
☐ 10.2.2, 12.2.2. Development and maintenance of the hospital’s formulary. (22 CCR 70263,
CCR 1751, CCR 1751.8)

CORRECTIVE ACTION OR ACTION PLAN: ____________________________________________________________

11. 13. Medication/Chart Order

Yes No N/A
☐☐☐ 11.1, 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)
☐☐☐ 11.2, 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])
☐☐☐ 11.3, 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: ____________________________________________________________
12. 14. Labeling and Distribution

Yes No N/A

12.1. 14.1. Unit dose medication and parenteral admixtures 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 1751.2)

12.2. 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]).

12.3. 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: ____________________________________________________________

13. 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: ____________________________________________________________

14. 16. Confidentiality of Chart Orders, Prescriptions and Patient Medical Information

Yes No N/A

14.1. 16.1. Patient information is maintained to safeguard confidentiality. (Civil Code 56 et seq.)

14.2. 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.)

14.3. 16.3. Destruction or disposal of patient records preserves the confidentiality of the information contained therein. (Civil Code 56.101)
14.4. 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)

CORRECTIVE ACTION OR ACTION PLAN: ____________________________________________________________

15.17. Quality Assurance and Medication Errors

15.1. 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)

15.2. 17.2. Pharmacy quality assurance policies and procedures are maintained in the pharmacy and are immediately retrievable. (CCR 1711[c])

15.3. 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])

15.4. 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])

15.5. 17.5. Investigation of pharmacy medication errors is initiated within two business days from the date the medication error is discovered. (CCR 1711[d])

15.6. 17.6. The record for quality assurance review for a medication error contains: (CCR 1711[e]);

15.6.1. 17.6.1. Date, location, and participants in the quality assurance review;

15.6.2. 17.6.2. Pertinent data and other information related to the medication error(s) reviewed;

15.6.3. 17.6.3. Findings and determinations;

15.6.4. 17.6.4. Recommended changes to pharmacy policy, procedure, systems or processes, if any.

15.7. 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])

15.8. 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: ____________________________________________________________
16. 18. Record Keeping Requirements

Yes No N/A

16.1. 18.1. A completed biennial pharmacy self-assessment is on file in the pharmacy and is maintained for three years. (CCR 1715)

16.2. 18.2. All drug acquisition and disposition records (complete accountability) are maintained for at least three years. These records include:

- 16.2.1. 18.2.1. Prescription records (B&PC 4081[a])
- 16.2.2. 18.2.2. Purchase Invoices for all prescription drugs (B&PC 4081[b])
- 16.2.3. 18.2.3. Biennial controlled substances inventory (21 CFR 1304.11)
- 16.2.4. 18.2.4. U.S. Official Order Forms (DEA Form-222) (21 CFR 1305.13)
- 16.2.5. 18.2.5. Power of Attorney for completion of DEA 222 forms (21 CFR 1305.07)
- 16.2.6. 18.2.6. Theft and Loss Reports (DEA Form 106) (21 CFR 1301.74[c])
- 16.2.7. 18.2.7. Record documenting return of drugs to wholesaler or manufacturer (B&PC 4081)
- 16.2.8. 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).

16.3. 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)

16.4. 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)

16.5. 18.5. A controlled substances inventory is completed biennially (every two years).

Date completed: ____________________ (21 CFR 1304.11)

16.6. 18.6. Separate Schedule II records are maintained. This includes triplicate prescriptions, invoices, US official order forms and inventory records. (21 CFR 1304.04)

16.7. 18.7. 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)

16.8. 18.8. DEA Forms 222 are properly executed. (21 CFR 1305.09) 1305.12)

16.9. 18.9. 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 1300.09) 1305.13)

16.10. 18.10. 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)
16.11. 18.11. 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)

16.12. 18.12. Do pharmacy staff hand initial prescription records and prescription labels, OR

16.13. 18.13. 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: ____________________________________________________________

17. 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: ____________________________________________________________

18. 20. Drug Supplies for Use in Medical Emergencies

Yes No N/A

18.1. 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])

18.2. 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])

18.3. 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])

18.4. 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 written policies. Records of the inspection are kept for at least three years. (22 CCR 70263[f][3])

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Initials
19. 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: ____________________________________________________________

20. 22. Emergency Room Dispensing

Yes No N/A

20.1. 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]):

□ 20.1.1. 22.1.1. The hospital pharmacy is closed and there is no pharmacist available in the hospital;

□ 20.1.2. 22.1.2. The dangerous drug is acquired by the hospital pharmacy;

□ 20.1.3. 22.1.3. The dispensing information is recorded and provided to the pharmacy when the pharmacy reopens;

□ 20.1.4. 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;

□ 20.1.5. 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

□ 20.1.6. 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;

Yes No N/A

20.2. 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])

□ 20.3. 22.3. The prescriber shall be responsible for any error or omission related to the drugs dispensed. (B&PC 4068[b])
Yes No N/A

20.4. 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)

20.5. 22.5. Controlled substances are dispensed in prescription containers bearing a federal warning label prohibiting transfer of the drugs. (CFR 290.5)

20.6. 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)

20.7. 22.7. Patient package inserts are dispensed with all estrogen medications (21 CFR 310.515)

CORRECTIVE ACTION OR ACTION PLAN: __________________________________________________________

21. 23. Discharge Medication/Consultation Services

Yes No N/A

21.1. 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)

21.2. 23.2. Prescriptions are transmitted to another pharmacy as required by law. (B&PC 4072, CCR 1717[f], 1717.4)

21.3. 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)

21.4. 23.4. If requested by the patient, the prescription label is printed in 12-point typeface. (CCR 1707.5[a])

21.5. 23.5. The pharmacy is exempt from the prescription label requirements in CCR 1707.5.

Exemption approved by board from: _____________ to ______________

Yes No N/A

21.6. 23.6. Appropriate drug warnings are provided orally or in writing. (B&PC 4074, CCR 1744)

21.7. 23.7. 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)

21.8. 23.8. 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)

21.9. 23.9. 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)

21.10. 23.10. Controlled substances are dispensed in prescription containers bearing a federal warning label prohibiting transfer of the drugs. (21 CFR 290.5)
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)

Patient package inserts are dispensed with all estrogen medications. (21 CFR 310.515)

CORRECTIVE ACTION OR ACTION PLAN: ____________________________________________________________

22. 24. Central Fill - Central Filling of Patient Cassettes For Other Hospital Pharmacies

Yes No N/A

22.1. 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: ___________________________________________

22.2. 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.

22.3. 24.3. Prescription information is electronically transferred between the two pharmacies (CCR 1710[b][6])

22.4. 24.4. Pharmacy has a contract with the ordering hospital pharmacy or has the same owner. (CCR 1710[b][1])

22.5. 24.5. Filled cassettes are delivered directly to the ordering hospital pharmacy. (CCR 1710[b][2])

22.6. 24.6. Each cassette or container meets the requirements of Business and Professions Code section 4076 (CCR 1710[b][3])

22.7. 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 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): ________

25.2. 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 unit dose medications produced by a centralized hospital packaging pharmacy are barcoded and readable at the inpatient’s bedside. The barcode information contains: (B&PC 4128.4)

- 25.3.1. The date the medication was prepared.
- 25.3.2. The components used in the drug product.
- 25.3.3. The lot number or control number.
- 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.

25.4. The 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. (B&PC 4128.5)

25.5. 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: ____________________________________________________________


Yes No N/A

23.1. 26.1. There are written policies and procedures in place for:

- 23.1.1. 26.1.1. The assurance that each patient received information regarding each medication given at the time of discharge.
- 23.1.2. 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])
- 23.1.3. 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])
- 23.1.4. 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])
- 23.1.5. 26.1.5. Reporting to the board within 30 14 days of the receipt or development of information as specified in B&PC 4104[c][1-6].
☐ 23.1.6. 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])

☐ 23.1.7. 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])

☐ 23.1.8. 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])

☐ 23.1.9. 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: ______________________________________________________________________________________

________________________________________________________________________________________

24. 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. 01/11 02/12]. (CCR 1735.2[j])
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 ____________________________
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 Board of Pharmacy**

1625 N. Market Blvd., Suite N219
Sacramento, CA 95834
Phone: (916) 574-7900
Fax: (916) 574-8618
http://www.pharmacy.ca.gov

**Pharmacy Law** may be obtained by contacting:

*LawTech Publishing Co.*

1060 Calle Cordillera, Suite 105
San Clements CA 92673
(800) 498-0911 Ext. 5
http://www.lawtechpublishing.com

**Pharmacist Recovery Program**

(800) 522-9198 (24 hours a day)

**Atlantic Associates, Inc. (CURES)**

Prescription Collection
8030 S. Willow Street, Bldg 3 Unit 3
Manchester, NH 03103
Phone: (888) 492-7341
Fax: (877) 508-6704

CURES
P.O. Box 160447
Sacramento, CA 95816-1089
Phone: (916) 319-9062
Fax: (916) 319-9448
http://www.ag.ca.gov/bne

CURES Patient Activity Report Request Forms:
http://www.ag.ca.gov/bne/trips.php

**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: (877) 729-7789
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: (888) 492-7341
Fax: (916) 574-7697
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

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:
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
DEA Registration Support (all of CA):
(800) 882-9539
Online DEA 106 Theft/Loss Reporting:
https://www.deadiversion.usdoj.gov/webforms/app106Login.jsp
Online DEA 222 Controlled Substance Ordering System (CSOS):
http://www.deaeom.com/

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 - 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 – Oakland
1301 Clay Street, Suite 460N
Oakland, CA 94612
Registration: (888) 304-3251
Diversion or Investigation: (510) 637-5600

DEA – Redding
310 Hensted Drive, Suite 310
Redding, CA 96002
Registration: (888) 304-3251 or (415) 436-7900
Diversion or Investigation: (530) 246-5043

DEA - Riverside
4470 Olivewood Avenue
Riverside, CA 92501-6210
Registration: (888) 415-9822 or (213) 621-6960
Diversion or Investigation: (951) 328-6200

DEA – Sacramento
4328 Watt Avenue
Sacramento, CA 95821
Registration: (888) 304-3251 or (415) 436-7900

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 – San Francisco
450 Golden Gate Avenue, 14th Floor
San Francisco, CA 94102
Registration: (888) 304-3251
Theft Reports or Diversion: (415) 436-7900

DEA – San Jose
One North First Street, Suite 405
San Jose, CA 95113
Registration: (888) 304-3251
Diversion or Investigation: (408) 291-2631
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. 01/11)-(Rev. 10/14) entitled “Wholesaler Dangerous Drugs & Dangerous Devices Self-Assessment” which is hereby incorporated by reference to evaluate compliance with federal and state laws and regulations.

(d) Each self-assessment shall be kept on file in the licensed wholesale 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.

WHOLESALER
DANGEROUS DRUGS & DANGEROUS DEVICES
SELF-ASSESSMENT

All legal references used throughout this self-assessment form are explained on page 18 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 (optional) _____________________________________________

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: Daily Weekdays ______________ Sat ___________ Sun ___________ 24 Hours

Designated representative-in-charge (DRIC) / pharmacist (RPH) _________________________

DRIC License # / RPH License #_________________ Expiration Date______________

Website Address (optional):________________________________________________________
Licensed Wholesaler Staff (designated representative (DR), pharmacist):

1. _________________________ DR#/RPH#_______________ Exp. Date _____________

2. _________________________ DR#/RPH#_______________ Exp. Date _____________

3. _________________________ DR#/RPH#_______________ Exp. Date _____________

4. _________________________ DR#/RPH#_______________ Exp. Date _____________

5. _________________________ DR#/RPH#_______________ Exp. Date _____________

6. _________________________ DR#/RPH#_______________ Exp. Date _____________

7. _________________________ DR#/RPH#_______________ Exp. Date _____________

8. _________________________ DR#/RPH#_______________ Exp. Date _____________

9. _________________________ DR#/RPH#_______________ Exp. Date _____________

10. _________________________ DR#/RPH#_______________ Exp. Date _____________

DRIC/RPH Initials ____________
Please mark the appropriate box for each question. If “NO,” enter an explanation on the “CORRECTIVE ACTION OR ACTION PLAN” lines at the end of the section. If more space is needed, add additional sheets.

1. Ownership/Location

Yes No N/A
☐ ☐ ☐ 1.1. Review the current wholesaler permit for this business. Are the listed owners correct and is the listed address correct? If not, please indicate discrepancy. If either is incorrect, notify the board in writing immediately. (B&PC 4160[a][c][f])
Attach a copy of the notification letter to the board to this document.

☐ ☐ ☐ 1.2. Have you established and do you maintain a list of officers, directors, managers and other persons in charge of drug distribution, handling and storage? The list must contain a summary of the duties and qualifications for each job listed. (CCR 1780[f][3]) Please attach a copy of the list to this document. (This list should be dated.)

Note: Upon request, the owner must provide the board with the names of the owners, managers and employees and a brief statement of the capacity in which they are employed. (B&PC 4082)

CORRECTIVE ACTION OR ACTION PLAN

2. Facility

2.1. Premises, fixtures and equipment:

Yes No N/A
☐ ☐ ☐ 2.1.1. Are clean and orderly
☐ ☐ ☐ 2.1.2. Are well ventilated
☐ ☐ ☐ 2.1.3. Are free from rodents and insects
☐ ☐ ☐ 2.1.4. Are adequately lit
☐ ☐ ☐ 2.1.5. Have plumbing in good repair
☐ ☐ ☐ 2.1.6. Have temperature & humidity monitoring to assure compliance with USP Standards. (The standards for various drugs may differ, see USP 1990 22nd Edition) (CCR 1780[b])

☐ ☐ ☐ 2.2. Is there a quarantine area for outdated, damaged, deteriorated, or misbranded drugs, drugs with the outer or secondary seal broken, partially used containers, or any drug returned under conditions that cast doubt on the drugs safety, identity, strength, quality or purity? (CCR 1780[e])

17M-26 (Rev. 04/14 10/14) Page 3 of 22 DRIC/RPH Initials ________
2.3. Are dangerous drugs and dangerous devices stored in a secured and locked area? (CCR 1780[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):

_____________________________________________________________________________
_____________________________________________________________________________
_____________________________________________________________________________
_____________________________________________________________________________

2.5. Does this business operate only when a designated representative or pharmacist is on the premises? (CCR 1781)

☐ ☐ ☐ 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 (CCR 1780[c][2]).

Explain how your security system complies with these requirements.

_____________________________________________________________________________
_____________________________________________________________________________

2.7. Is this business a “reverse distributor”, that is, does the business act as an agent for pharmacies, drug wholesalers, manufacturers and others, by receiving, inventorizing and managing the disposition of outdated or nonsalable drugs? (B&PC 4040.5)

☐ ☐ ☐ 2.7. Is this business a “reverse distributor”, that is, does the business act as an agent for pharmacies, drug wholesalers, manufacturers and others, by receiving, inventorizing and managing the disposition of outdated or nonsalable drugs? (B&PC 4040.5)

CORRECTIVE ACTION OR ACTION PLAN ______________________________________

_____________________________________________________________________________
2.8. The facility is subscribed to the board’s e-mail notifications.  (B&PC 4013)

Date Last Notification Received: ___________________________

E-mail address registered with the board: ______________________

CORRECTIVE ACTION OR ACTION PLAN ______________________________________

____________________________________________________________________________

2.9. The facility 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 ______________________________________

____________________________________________________________________________

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 11 12 of this document.

3. Designated Representative-in-Charge / Owner Responsibilities

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.
3.5. The designated representative-in-charge who ends his or her employment at a wholesaler, must notify the board within 30 days. (B&PC 4305.5[c], 4101[b]). This notification is in addition to that required of the owner.

CORRECTIVE ACTION OR ACTION PLAN ________________________________________

4. Designated Representative/Pharmacist

Yes No N/A

X X X  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

X X X  5.1. Are drugs ordered only from a business licensed by this board or from a licensed manufacturer? (B&PC 4163[b], 4169)

Yes No N/A

X X X  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)

X X X  5.3. For license verification, the wholesaler may use the licensing information displayed on the board’s Internet web site. (B&PC 4106)

CORRECTIVE ACTION OR ACTION PLAN ________________________________________

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 11 12 of this document.
6. Receipt of Drugs by this Business

Yes No  N/A
☐ ☐ ☐ 6.1. When drugs are received by your business, are they delivered to the licensed wholesale premises, and received by and signed for only by a designated representative or a pharmacist? (B & P 4059.5[a])

☐ ☐ ☐ 6.2. When drugs are received by your business, are the outside containers visibly inspected to identify the drugs and prevent acceptance of contaminated drugs by detecting container damage? (CCR 1780[d][1])

CORRECTIVE ACTION OR ACTION PLAN

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 1112 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)
7.7. When the conditions under which drugs were returned to your premises cast doubt on the drugs’ safety, identity, strength, quality or purity, are the drugs quarantined and either returned to your supplier or destroyed? If testing or investigation proves the drugs meet USP standards, the drugs may be returned to normal stock. (CCR 1780[e], CFR 1307.21)

CORRECTIVE ACTION OR ACTION PLAN

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 11 12 of this document.

8. Sale or Transfer of Drugs by this Business

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:

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])
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.

Yes No N/A
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:

- 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). Commencing on July 1, 2017, an electronic pedigree must accompany all drugs (B&PC 4163), even those for which your business is an authorized distributor.
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)

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)

CORRECTIVE ACTION OR ACTION PLAN

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 11 12 of this document.

9. Donations of Medication to Voluntary Drug Repository and Distribution Programs (H&SC 150200, 150203, 150204)

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))
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])

9.10. Outgoing Shipments of Drugs

- 9.10.1. 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])

- 9.10.2. 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])

- 9.10.3. List the common carriers (shipping or delivery companies) you use.

CORRECTIVE ACTION OR ACTION PLAN

Note: There are specific requirements for wholesaling controlled substances—these additional requirements are in Section 44 12 of this document.

40.11. Delivery of Drugs

- 40.11. 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])
Yes No N/A

☐ ☐ ☐ 10.2. 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[d])

(B&PC 4059.5[d])

☐ ☐ ☐ 10.3. 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])

☐ ☐ ☐ 10.4. 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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41. Controlled Substances

Yes No N/A

☐ ☐ ☐ 11.1. Are there effective controls to prevent theft or diversion of controlled substances? (CFR 1301.71)

☐ ☐ ☐ 11.2. Are DEA requirements for storage of Schedule II controlled substances being met? (specific requirements are listed in CFR 1301.72[a])

☐ ☐ ☐ 11.3. Are DEA requirements for storage of Schedule III, IV and V controlled substances being met? (specific requirements are listed in CFR 1301.72[b])

Yes No N/A

☐ ☐ ☐ 11.4. 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])

☐ ☐ ☐ 11.5. 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])

☐ ☐ ☐ 11.6. Does the biennial inventory record document that the inventory was taken at the “close of business” or “opening of business.” (CFR 1304.11)

☐ ☐ ☐ 11.7. 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)
11.7. 12.7.1. List the individuals at this location authorized by power of attorney to order controlled substances.

Yes No N/A

11.8. 12.8. Does your business follow employee-screening procedures required by DEA to assure the security of controlled substances? (CFR 1301.90)

11.9. 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)

11.10. 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])

11.11. 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])

11.12. 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])

11.13. 12.13. Explain how your business determines an unknown business or individual is appropriately licensed to purchase controlled substances

Yes No N/A

11.14. 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])

11.15. 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])

11.16. 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)
11.17. 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 form? 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])

11.18. 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)

11.19. 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 1309.13[b])

11.20. 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])

11.21. 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)

11.22. 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))

11.23. 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 1305.09[d], CFR 1305.17[c], 1305.17[a][b], and H & S H&SC 11252, 11253, 1304.03)

11.24. Are records of Schedule II controlled substances stored separate from all others? (CFR 1304.04[f][1])

11.25. Are records for Schedule III-V controlled substances stored so that they are easily retrievable? (CFR 1304.04[f][2])

11.26. 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])

11.27. Do you separate records for the sale of carfentanil etorphine hydrochloride and or diprenorphine from all other records? (CFR 1305.16)
11.28. 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])

☐ ☐ ☐

11.29. 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

12. Policies and Procedures

12.1. Does this business maintain and adhere to policies and procedures for the following: (CCR 1780[f])

Yes No N/A

☐ ☐ ☐ 12.1.1. Receipt of drugs?
☐ ☐ ☐ 12.1.2. Security of drugs?
☐ ☐ ☐ 12.1.3. Storage of drugs? (including maintaining records to document proper storage)
☐ ☐ ☐ 12.1.4. Inventory of drugs? (including correcting inaccuracies in inventories)
☐ ☐ ☐ 12.1.5. Distributing drugs?
☐ ☐ ☐ 12.1.6. Identifying, recording and reporting theft or losses?
☐ ☐ ☐ 12.1.7. Correcting errors? errors and inaccuracies in inventories?

Physically quarantining and separating:

☐ ☐ ☐ 12.1.8. returned, damaged, outdated, deteriorated, misbranded or adulterated drugs?
☐ ☐ ☐ 12.1.9. drugs that have been partially used?
☐ ☐ ☐ 12.1.10. drugs where the outer or secondary seals on the container have been broken?
☐ ☐ ☐ 12.1.11. drugs returned to your business, when there is doubt about the safety, identity, strength, quality, or purity of the drug?
☐ ☐ ☐ 12.1.12. drugs where the conditions of return cast doubt on safety, identity, strength, quality or purity? (CCR 1780[e][f])

CORRECTIVE ACTION OR ACTION PLAN
14. Training

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
</table>

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 ____________________________

14. Dialysis Drugs

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
</table>

14.1 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.

14.2 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])

14.3 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])

14.4 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)

14.5 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 ____________________________
15. 16. Record Keeping Requirements

Yes No N/A

☐ ☐ ☐ 15.1. 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])

☐ ☐ ☐ 15.2. 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.

☐ ☐ ☐ 15.3. Are all purchase and sales records retained in a readily retrievable form? (B&PC 4105[a])

☐ ☐ ☐ 15.4. Is a current accurate inventory maintained for all dangerous drugs? (B&PC 4081, 4332, 1718)

☐ ☐ ☐ 15.5. 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])

☐ ☐ ☐ 15.6. Are required records stored off-site only if a board issued written waiver has been granted?

15.7. 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 ________________________________

Yes No N/A

☐ ☐ ☐ 15.8. Is an off-site written waiver in place and is the storage area secure from unauthorized access? (CCR 1707[b][1])

☐ ☐ ☐ 15.9. If an off-site written waiver is in place, are the records stored off-site retrievable within 2 business days? (CCR 1707[b][2])

☐ ☐ ☐ 15.10. 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])

☐ ☐ ☐ 15.11. Are records of training provided to employees to assure compliance with licensing requirements, retained for 3 years? (CCR 1780[f][4])
15.12, 16.12. 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]):

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
</table>

15.13, 16.13. 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)

15.14, 16.14. 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])

15.15, 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 ______________________________________

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 11 12 of this document.

46. 17. Reporting Requirements to the Board

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
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</table>

46.1, 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]).

46.2, 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])

46.3, 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)

46.4, 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])
16.5. 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)

16.6. 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])

16.7. 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])

16.8. 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])

16.9. 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])

16.10. 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)

16.11. 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 ________________________________
47. 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

Board of Registered Nursing
1625 N. Market Blvd., Suite N217
Sacramento, CA 95834
Phone: (916) 322-9198
Fax: (916) 574-8637
http://www.rn.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

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/

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

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
Federal Agencies:

Food and Drug Administration
– Industry Compliance
http://www.fda.gov/oc/industry/centerlinks.html#

The Drug Enforcement Administration may be contacted at:

DEA Website:
http://www.deadiversion.usdoj.gov
Online Registration – New Applicants:
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
Vaccinations
Add and Adopt §1746.4, which is new regulation text as follows:

§1746.4 Pharmacists Initiating and Administering Vaccines.

(a) A pharmacist initiating and/or administering vaccines pursuant to section 4052.8 of the Business and Professions Code shall follow the requirements specified in subdivisions (b) through (f) of this section.

(b) Training: A pharmacist who initiates and/or administers any vaccine shall keep documentation of:

(1) Completion of an approved immunization training program, and
(2) Basic life support certification.

This documentation shall be kept on site and available for inspection.

(c) Continuing Education: Pharmacists must complete one hour of ongoing continuing education focused on immunizations and vaccines from an approved provider once every two years.

(d) Notifications: The pharmacist shall notify the patient’s primary care provider of any vaccines administered to the patient, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by the primary care provider. Primary care provider notification must take place within 14 days of the administration of any vaccine. If the patient does not have a primary care provider, or is unable to provide contact information for his or her primary care provider, the pharmacist shall advise the patient to consult an appropriate health care provider of the patient’s choice. If known, notification to the prenatal care provider of immunizations provided to pregnant women must take place within 14 days of the administration of any vaccine.

(e) Immunization Registry: A pharmacist shall fully report the information described in Section 120440(c) of the Health and Safety Code into one or more state and/or local immunization information systems within 14 days of the administration of any vaccine. The pharmacist shall inform the patient or the patient’s guardian of immunization record sharing preferences, detailed in Section 120440(e) of the Health and Safety Code.

(f) Documentation: For each vaccine administered by a pharmacist, a patient vaccine administration record shall be maintained in an automated data processing or manual record mode such that the required information under title 42, section 300aa-25 of the United States Code is readily retrievable during the pharmacy or facility’s normal operating hours. A pharmacist shall provide the patient with a
vaccine administration record, which fully documents the vaccines administered by the pharmacist. An example of an appropriate vaccine administration record is available on the Board of Pharmacy’s website.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4052 and 4052.8, Business and Professions Code.
Compounded Drug Preparations
1735 et seq.,
1751 et seq.
To Amend § 1735 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1735. Compounding in Licensed Pharmacies.
(a) “Compounding” means any of the following activities occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a prescription:
(1) Altering the dosage form or delivery system of a drug
(2) Altering the strength of a drug
(3) Combining components or active ingredients
(4) Preparing a compounded drug product preparation from chemicals or bulk drug substances
(b) “Compounding” does not include reconstitution of a drug pursuant to a manufacturer’s direction(s) for oral, rectal, topical, or injectable administration, nor does it include the sole act of tablet splitting or crushing, capsule opening, or the addition of flavoring agent(s) to enhance palatability.
(c) “Compounding” does not include, except in small quantities under limited circumstances as justified by a specific, documented, medical need, preparation of a compounded drug product that is commercially available in the marketplace or that is essentially a copy of a drug product that is commercially available in the marketplace
(d) The parameters and requirements stated by this Article 4.5 (Section 1735 et seq.) apply to all compounding practices. Additional parameters and requirements applicable solely to sterile injectable-compounding are stated by Article 7 (Section 1751 et seq.).

To Amend § 1735.1 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1735.1. Compounding Definitions.

(a) “Ante-area” means an area with ISO Class 8 or better air quality where personnel hand hygiene and garbing procedures, staging of components, and other high-particulate-generating activities are performed, that is adjacent to the area designated for sterile compounding. It is a transition area that begins the systematic reduction of particles, prevents large fluctuations in air temperature and pressures in the cleanroom, and maintains air flows from clean to dirty areas. ISO Class 7 or better air quality is required for ante-areas providing air to a negative pressure room.

(b) “Beyond use date” means the date, or date and time, after which administration of a compounded drug preparation shall not begin, the preparation shall not be dispensed, and the preparation shall not be stored (other than for quarantine purposes).

(c) “Biological Safety Cabinet (BSC)” means a ventilated cabinet for compounding sterile drug preparations, having an open front with inward airflow for personnel protection, downward HEPA-filtered laminar airflow for product protection, and HEPA-filtered exhausted air for environmental protection. Where hazardous drugs are prepared, the exhaust air from the biological safety cabinet shall be appropriately removed by properly designed external building ventilation. This external venting should be dedicated to one BSC or CACI.

(d) “Bulk drug substance” means any substance that, when used in the preparation of a compounded drug preparation, processing, or packaging of a drug, is an active ingredient or a finished dosage form of the drug, but the term does not include any intermediate used in the synthesis of such substances.

(e) “Cleanroom or clean area or buffer area” means a room or area with HEPA-filtered air that provides ISO Class 7 or better air quality where the primary engineering control (PEC) is physically located.

(1) For nonhazardous compounding a positive pressure differential of 0.02- to 0.05-inch water column relative to all adjacent spaces is required.
(2) For hazardous compounding at least 30 air changes per hour of HEPA-filtered supply air and a negative pressure of between 0.01 to 0.03 inches of water column relative to all adjacent spaces is required.

(f) “Compounding Aseptic Containment Isolator (CACI)” means a unidirectional HEPA-filtered airflow compounding aseptic isolator (CAI) designed to provide worker protection from exposure to undesirable levels of airborne drug throughout the compounding and material transfer processes and to provide an aseptic environment for compounding sterile preparations. Air exchange with the surrounding environment should not occur unless the air is first passed through a microbial retentive filter (HEPA minimum) system capable of containing airborne concentrations of the physical size and state of the drug being compounded. Where hazardous drugs are prepared, the exhaust air from the isolator shall be appropriately removed by properly designed external building ventilation. This external venting should be dedicated to one BSC or CACI. Air within the CACI shall not be recirculated nor turbulent.

(g) “Compounding Aseptic Isolator (CAI)” means a form of isolator specifically designed for non-hazardous compounding of pharmaceutical ingredients or preparations while bathed with unidirectional HEPA-filtered air. It is designed to maintain an aseptic compounding environment within the isolator throughout the compounding and material transfer processes. Air exchange into the isolator from the surrounding environment should not occur unless the air has first passed through a microbial retentive filter (HEPA minimum) system capable of containing airborne concentrations of the physical size and state of the drug being compounded. Air within the CAI shall not be recirculated nor turbulent.

(h) “Controlled cold temperature” means 2 degrees to 8 degrees C (35 degrees to 46 degrees F).

(i) “Controlled freezer temperature” means -25 degrees to -10 degrees C (-13 degrees to 14 degrees F) or at a range otherwise specified by the pharmaceutical manufacturer(s) for that product.

(j) “Controlled room temperature” means 20 degrees to 25 degrees C (68 degrees to 77 degrees F).

(k) “Copy or essentially a copy” of a commercially available drug product includes all preparations that are comparable in active ingredients to commercially available drug.
products, except that it does not include any preparations in which there has been a change, made for an identified individual patient, which produces for that patient a clinically significant difference, as determined by a prescribing practitioner, between that compounded preparation and the comparable commercially available drug product.

(l) “Daily” means occurring every day the pharmacy is operating, except when daily monitoring of refrigerator and freezer temperature are required, then daily means every 24 hours.

(m) “Displacement airflow method” means a concept which utilizes a low pressure differential, high airflow principle to maintain segregation from the adjacent ante-area by means of specific pressure differentials. This principle of displacement airflow shall require an air velocity of 40 ft per minute or more, from floor to ceiling and wall to wall, from the clean area across the line of demarcation into the ante-area. The displacement concept may not be used to maintain clean area requirements for sterile compounds which originate from any ingredient that was at any time non-sterile, regardless of intervening sterilization of the ingredient, or for hazardous compounds.

(n) “Dosage unit” means a quantity sufficient for one administration to one patient.

(o) “Equipment” means items that must be calibrated, maintained or periodically certified.

(p) “First air” means the air exiting the HEPA filter in a unidirectional air stream that is essentially particle free.

(q) “Gloved fingertip sampling” means a process whereby compounding personnel lightly press each fingertip and thumb of each hand onto appropriate growth media, which are then incubated at a temperature and for a time period conducive to multiplication of microorganisms, and then examined for growth of microorganisms.

(r) “Hazardous” means all anti-neoplastic agents identified by the National Institute for Occupational Safety and Health (NIOSH) as meeting the criteria for a hazardous drug and any other drugs, compounds, or materials identified as hazardous by the pharmacist-in-charge.

(s) “Integrity” means retention of potency until the expiration beyond use date noted provided on the label, so long as the preparation is stored and handled according to the label directions.

(t) “Lot” means one or more compounded drug preparation(s) prepared during one uninterrupted continuous cycle of compounding from one or more common active
ingredient(s).
(u) “Media-fill test” means a test used to measure the efficacy of compounding personnel in aseptic techniques whereby compounding procedures are mimicked using a growth-based media and then the resulting preparation is evaluated for sterility. The media-fill test must mimic the most complex compounding procedures performed by the pharmacy.
(v) “Non-sterile-to-sterile batch” means any compounded drug preparation containing two (2) or more dosage units with any ingredient that was at any time non-sterile, regardless of intervening sterilization of that ingredient.
(w) “Parenteral” means a preparation of drugs administered in a manner other than through the digestive tract. It does not include topical, sublingual, rectal or buccal routes of administration.
(x) “Personal protective equipment” means clothing or devices that protect the employee from exposure to compounding ingredients and/or potential toxins and minimize the contamination of compounded preparations. These include shoe covers, head and facial hair covers, face masks, gowns, and gloves.
(y) “Potency” means active ingredient strength within +/- 10% (or the range specified in USP37-NF32, 37th Revision, Through 2nd Supplement Effective December 1, 2014) of the labeled amount. Sterile injectable products compounded solely from commercially manufactured sterile pharmaceutical products in a health care facility licensed under section 1250 of the Health and Safety Code are exempt from this definition. For those exempt, the range shall be calculated and defined in the master formula.
(z) “Preparation” means a drug or nutrient compounded in a licensed pharmacy; the preparation may or may not be sterile.
(aa) "Prescriber's office" or "prescriber office" means an office or suite of offices in which a prescriber regularly sees patients for outpatient diagnosis and treatment. This definition does not include any hospital, pharmacy, or other facility, whether or not separately licensed, that may be affiliated with, adjacent to, or co-owned by, the prescriber’s practice environment.
(ab) “Primary Engineering Control (PEC)” means a device that provides an ISO Class 5 or better environment through the use of non-turbulent, unidirectional HEPA-filtered first air for
compounding sterile preparations. Examples of PEC devices include, but are not limited to, laminar airflow workbenches, biological safety cabinets, sterile compounding automated robots, compounding aseptic isolators, and compounding aseptic containment isolators.

(ac) “Process validation” means demonstrating that when a process is repeated within specified limits, the process will consistently produce preparations complying with predetermined requirements. If any aspect of the process is changed, the process would need to be revalidated.

(ad) “Product” means a commercially manufactured drug or nutrient evaluated for safety and efficacy by the FDA.

(ae) “Quality” means the absence of harmful levels of contaminants, including filth, putrid, or decomposed substances, and the absence of active ingredients other than those listed on the label, and the absence of inactive ingredients other than those listed on the master formula document.

#af) “Segregated sterile compounding area” means a designated space for sterile-to-sterile compounding where a PEC is located within either a demarcated area (at least three foot perimeter) or in a separate room. Such area or room shall not contain and shall be void of activities and materials that are extraneous to sterile compounding. The segregated sterile compounding area shall not be in a location that has unsealed windows or doors that connect to the outdoors, in a location with high traffic flow, or in a location that is adjacent to construction sites, warehouses, or food preparation. The segregated sterile compounding area shall not have a sink, other than an emergency eye-washing station, located within three feet of a PEC. The segregated sterile compounding area shall be restricted to preparation of sterile-to-sterile compounded preparations.

(1) The BUD of a sterile drug preparation made in a segregated sterile compounding area is limited to 12 hours or less as defined by section 1751.8(d).

(2) When the PEC in the segregated sterile compounding area is a CAI or a CACI and the documentation provided by the manufacturer shows it meets the requirements listed in section 1751.4(f)(1)-(3), the assigned BUD shall comply with section 1751.8(a-b) or (d).

(ag) “Strength” means amount of active ingredient per unit of a compounded drug product.
To Amend § 1735.2 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1735.2. Compounding Limitations and Requirements; Self-Assessment.

(a) Except as specified in (b) and (c), no drug product preparation shall be compounded prior to receipt by a pharmacy of a valid prescription for an individual patient where the prescriber has approved use of a compounded drug product preparation either orally or in writing. Where approval is given orally, that approval shall be noted on the prescription prior to compounding.

(b) A pharmacy may prepare and store a limited quantity of a compounded drug product preparation in advance of receipt of a patient-specific prescription where and solely in such quantity as is necessary to ensure continuity of care for an identified population of patients of the pharmacy based on a documented history of prescriptions for that patient population.

(c) A “reasonable quantity” as used in that may be furnished to a prescriber for office use by the prescriber as authorized by Business and Professions Code section 4052, subdivision (a)(1), means that amount of compounded drug product preparation that:

1. Is ordered by the prescriber or the prescriber’s agent using a purchase order or other documentation received by the pharmacy prior to furnishing that lists the number of patients seen or to be seen in the prescriber’s office for whom the drug is needed or anticipated, and the quantity for each patient that is sufficient for office administration or application to patients in the prescriber’s office, or for distribution of not more than a 72-hour supply to the prescriber’s patients, as estimated by the prescriber; and

2. Is delivered to the prescriber’s office and signed for by the prescriber or the prescriber’s agent; and

3. Is sufficient for administration or application to patients solely in the prescriber’s office, or
for furnishing of not more than a 120-hour supply for veterinary medical practices, solely to the
prescriber’s own veterinary patients seen as part of regular treatment in the prescriber’s office,
as fairly estimated by the prescriber and documented on the purchase order or other
documentation submitted to the pharmacy prior to furnishing; and
(2) That the pharmacist has a credible basis for concluding it is a reasonable quantity for
office use is reasonable considering the intended use of the compounded medication and the
nature of the prescriber’s practice; and
(3) With regard to any individual prescriber to whom the pharmacy furnishes, and with
regard to for all prescribers to whom the pharmacy furnishes, taken as a whole, is an amount
which the pharmacy is capable of compounding in compliance with pharmaceutical standards
for integrity, potency, quality and strength of the compounded drug product preparation; and
(6) Does not exceed an amount the pharmacy can reasonably and safely compound.

(d) No pharmacy or pharmacist shall compound a drug preparation that:
(1) Is classified by the FDA as demonstrably difficult to compound;
(2) Appears on an FDA list of drugs that have been withdrawn or removed from the market
because such drugs or components of such drugs have been found to be unsafe or not
effective; or
(3) Is a copy or essentially a copy of one or more commercially available drug products, unless
that drug product appears on an ASHP (American Society of Health-System Pharmacists) or FDA
list of drugs that are in short supply at the time of compounding and at the time of dispense,
and the compounding of that drug preparation is justified by a specific, documented medical
need made known to the pharmacist prior to compounding. The pharmacy shall retain a copy of
the documentation of the shortage and the specific medical need in the pharmacy records for
three years from the date of receipt of the documentation.

(d)(e) A drug product preparation shall not be compounded until the pharmacy has first
prepared a written master formula record document that includes at least the following
elements:
(1) Active ingredients to be used.
(2) Equipment to be used.
(3) Expiration dating requirements. The maximum allowable beyond use date for the preparation, and the rationale or reference source justifying its determination.

(4) Inactive ingredients to be used.

(5) Process and/or procedure Specific and essential compounding steps used to prepare the drug.

(6) Quality reviews required at each step in preparation of the drug.

(7) Post-compounding process or procedures required, if any.

(8) Instructions for storage and handling of the compounded drug preparation.

(e)(f) Where a pharmacy does not routinely compound a particular drug product preparation, the master formula record for that product preparation may be recorded on the prescription document itself.

(f)(g) The pharmacist performing or supervising compounding is responsible for the integrity, potency, quality, and labeled strength of a compounded drug product preparation until the beyond use date indicated on the label, so long as label instructions for storage and handling are followed after the preparation is dispensed.

(g)(h) All chemicals, bulk drug substances, drug products, and other components used for drug compounding shall be stored and used according to compendial and other applicable requirements to maintain their integrity, potency, quality, and labeled strength.

(h)(i) Every compounded drug product preparation shall be given an expiration beyond use date representing the date or date and time beyond which the compounded drug preparation should not be used, stored, transported or administered, and determined based on the professional judgment of the pharmacist performing or supervising the compounding. In the professional judgment of the pharmacist performing or supervising the compounding, it should not be used.

(1) For non-sterile compounded drug preparation(s), the beyond use date of the compounded drug product shall not exceed any of the following: 180 days from preparation or:

(A) the shortest expiration date or beyond use date of any component ingredient in the compounded drug product preparation.
(B) the chemical stability of any one ingredient in the compounded drug preparation;
(C) the chemical stability of the combination of all ingredients in the compounded drug preparation,
(D) 180 days for non-aqueous formulations,
(E) 14 days for water-containing oral formulations, and
(F) 30 days for water-containing topical/dermal and mucosal liquid and semisolid formulations.

(2) For sterile compounded drug preparations, the beyond use date shall not exceed any of the following:
(A) The shortest expiration date or beyond use date of any ingredient in the sterile compounded drug product preparation,
(B) The chemical stability of any one ingredient in the sterile compounded drug preparation,
(C) The chemical stability of the combination of all ingredients in the sterile compounded drug preparation,
(D) The beyond use date assigned for sterility in section 1751.8.

(3) Extension of a beyond use date is only allowable when supported by the following:
(A) Method Suitability Test,
(B) Container closure Integrity Test, and
(C) Stability Studies

unless a longer later date is supported by stability studies of.

(4) In addition to the requirements of paragraph three (3), the finished drugs or compounded drug products preparations tested and studied shall be using the same identical components in ingredients, specific and essential compounding steps, quality reviews, and packaging as the finished drug or compounded drug preparation.

(5) Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.

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

(1) Packages of ingredients, both active and inactive, that lack a supplier’s expiration date are subject to the following limitations:

(1) such ingredients cannot be used for any non-sterile compounded drug preparation more than three (3) years after the date of receipt by the pharmacy.

(2) such ingredients cannot be used for any sterile compounded drug preparation more than one (1) year after the date of receipt by the pharmacy.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code, Sections 1735, 1735.1, 1735.8, and 1751.1-1751.8 of Title 16, Division 17, of the California Code of Regulations.
To Amend § 1735.3 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1735.3. Records Recordkeeping of for Compounded Drug Products Preparations.
(a) For each compounded drug product preparation, the pharmacy records shall include:
(1) The master formula record document.
(2) A compounding log consisting of a single document containing all of the following:
   (A) Name and Strength of the compounded drug preparation.
   (B) The date the drug product preparation was compounded.
(3) The identity of the any pharmacy personnel who compounded the engaged in compounding the drug product preparation.
(4) The identity of the pharmacist reviewing the final drug product preparation.
(5) The quantity of each component ingredient used in compounding the drug product preparation.
(6) The manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted.
   If the manufacturer does not supply an expiration date for any component, the records shall include the date of receipt of the component in the pharmacy, and the limitations of section 1735.2, subdivision (l) shall apply.
(j) Exempt from the requirements in this paragraph (1735.3(a)(2)(F)) are sterile products preparations compounded on a one-time basis in a single lot for administration within seventy-two (72) hours to a patient in a health care facility licensed under section 1250 of the Health and Safety Code and stored in accordance with standards for “Redispensed CSPs” found in Chapter 797 of the United States Pharmacopeia – National Formulary (USP37-NF32) Through 2nd Supplement (35 37th Revision, Effective May December 1, 2012-2014), hereby incorporated by reference, to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.
(7) A pharmacy-assigned unique reference or lot number for the compounded drug product preparation.
(8)(H) The expiration beyond use date or beyond use date and time of the final compounded drug product preparation, expressed in the compounding record document in a standard date and time format.
(9)(I) The final quantity or amount of drug product preparation compounded for dispensing.
(J) Documentation of quality reviews and required post-compounding process and procedures.
(b) Pharmacies shall maintain records of the proper acquisition, storage, and destruction of chemicals, bulk drug substances, drug products, and components used in compounding.
(c) Active ingredients shall be obtained from a supplier registered with the Food and Drug Administration (FDA). All other chemicals, bulk drug substances, and drug products, and components used to compound drug products preparations shall be obtained, whenever possible, from reliable FDA-registered suppliers. The pharmacy shall acquire and retain any available certificates of purity or analysis, either written in English or translated into English, for chemicals, bulk drug substances, and drug products, and components used in compounding. Certificates of purity or analysis are not required for drug products that are approved by the FDA. Any certificates of purity or analysis acquired by the pharmacy shall be matched to the corresponding chemical, bulk drug substance, or drug products received.
(d) Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was created last in effect. If only recorded and stored electronically, on magnetic media, or in any other computerized form, the records shall be maintained as specified by Business and Professions Code section 4070 subsection (c).

Authority cited: Sections 4005, 4127, and 4169, Business and Professions Code.
Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.
To Amend § 1735.4 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1735.4. Labeling of Compounded Drug Products Preparations.
(a) Each compounded drug preparation shall be affixed with a container label prior to dispensing that contains at least:
(1) Name of the compounding pharmacy and dispensing pharmacy (if different);
(2) Name (brand or generic) and strength, volume, or weight of each active ingredient. For admixed IV solutions, the intravenous solution utilized shall be included;
(3) Instructions for storage, handling, and administration. For admixed IV solutions, the rate of infusion shall be included;
(4) The beyond use date for the drug preparation;
(5) The date compounded; and
(6) The lot number or pharmacy reference number.

In addition to the labeling information required under Business and Professions Code section 4076 and under California Code of Regulations section 1707.5, the label of a compounded drug product preparation shall contain the generic or brand name(s) of the principal all active ingredient(s).
(b) Any compounded drug preparation dispensed to a patient or readied for dispensing to a patient shall also include on the label the information required under Business and Professions Code section 4076 and California Code of Regulations, title 16, section 1707.5. A statement that the drug has been compounded by the pharmacy shall be included on the container or on the receipt provided to the patient.
(c) Any compounded drug preparation dispensed to a patient or readied for dispensing to a patient shall also include, on the container label or on a receipt provided to the patient, a statement that the drug has been compounded by the pharmacy. Drug products compounded into unit-dose containers that are too small or otherwise impractical for full compliance with subdivisions (a) and (b) shall be labeled with at least the name(s) of the active ingredient(s), concentration or strength, volume or weight of the...
preparation, pharmacy reference or lot number, and expiration date.

(d) Prior to dispensing drug preparations compounded into unit-dose containers that are too small or otherwise impractical for full compliance with subdivisions (a), (b), and (c) shall be labeled with at least the name of the compounding pharmacy and dispensing pharmacy, if different, the name(s) of the active ingredient(s), strength, volume or weight of the preparation, pharmacy reference or lot number, and beyond use date, and shall not be subject to minimum font size requirements. Once dispensed, outer packaging must comply with 1735.4(a) – (c).

(e) All hazardous agents shall bear a special label which states “Chemotherapy - Dispose of Properly” or “Hazardous – Dispose of Properly.”

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4076 and 4127, Business and Professions Code.

To Amend § 1735.5 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1735.5. Compounding Policies and Procedures.

(a) Any pharmacy engaged in compounding shall maintain a written policies and procedures manual for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding. Any material failure to follow the pharmacy’s written policies and procedures shall constitute a basis for disciplinary action.

(b) The policies and procedures manual shall be reviewed and such review shall be documented on an annual basis by the pharmacist-in-charge. The policies and procedures manual shall be updated whenever changes in policies and procedures processes are implemented.

(c) The policies and procedures manual shall include at least the following:
(1) Procedures for notifying staff assigned to compounding duties of any changes in processes or to the policies or procedures manual.

(2) Documentation of a written plan for recall of a dispensed compounded drug product preparation where subsequent verification information demonstrates the potential for adverse effects with continued use of a compounded drug product. The plan shall ensure that all affected doses can be accounted for during the recall and shall provide steps to identify which patients received the affected lot or compounded drug preparation(s).

(3) Procedures for maintaining, storing, calibrating, cleaning, and disinfecting equipment used in compounding, and for training on these procedures as part of the staff training and competency evaluation process.

(4) Procedures for evaluating, maintaining, certifying, cleaning, and disinfecting the facility (physical plant) used for compounding, and for training on these procedures as part of the staff training and competency evaluation process.

(45) Documentation of the methodology used to test validate integrity, potency, quality, and labeled strength of compounded drug products preparations. The methodology must be appropriate to compounded drug preparations.

(56) Documentation of the methodology and rationale or reference source used to determine appropriate expiration beyond use dates for compounded drug products preparations.

(7) Dates and signatures reflecting all annual reviews of the policies and procedures by the pharmacist-in-charge.

(8) Dates and signatures accompanying any revisions to the policies and procedures approved by the pharmacist-in-charge.

(9) Policies and procedures for storage of compounded drug preparations in the pharmacy and daily documentation of all room, refrigerator, and freezer temperatures within the pharmacy.

(10) Policies and procedures regarding ensuring appropriate functioning of refrigeration devices, monitoring refrigeration device temperatures, and actions to take regarding any out of range temperature variations within the pharmacy.

(11) Policies and procedures for proper garbing when compounding with hazardous products. This shall include when to utilize double shoe covers.

To Amend § 1735.6 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1735.6. Compounding Facilities and Equipment.

(a) Any pharmacy engaged in compounding shall maintain written documentation regarding the facilities and equipment necessary for safe and accurate compounding of compounded drug products preparations. This shall include records of maintenance and cleaning of the facilities and equipment. Where applicable, this shall also include records of certification(s) of facilities or equipment.

(b) Any equipment used to compound drug products preparations shall be stored, used, and maintained, and cleaned in accordance with manufacturers' specifications.

(c) Any equipment that weighs, measures, or transfers ingredients used to compound drug products preparations for which calibration or adjustment is appropriate shall be calibrated prior to use, on a schedule and by a method determined by the manufacturer's specifications, to ensure accuracy. Documentation of each such calibration shall be recorded in writing in a form which is not alterable and these records of calibration shall be maintained and retained in the pharmacy.

(d) Any pharmacy engaged in any hazardous drug compounding shall maintain written documentation regarding appropriate cleaning of facilities and equipment to prevent cross-contamination with non-hazardous drugs.

(e) Hazardous drug compounding shall be completed in an externally vented physically separate room with the following requirements:

(1) Minimum of 30 air changes per hour except that 12 air changes per hour are acceptable for segregated compounding areas with a BSC or CACI when products are assigned a BUD of 12 hrs or less or when non sterile products are compounded; and
(2) Maintained at a negative pressure of 0.01 to 0.03 inches of water column relative to all adjacent spaces (rooms, above ceiling, and corridors); and

(3) Each PEC in the room shall also be externally vented; and

(4) All surfaces within the room shall be smooth, seamless, impervious, and non-shedding.

(f) Where compliance with the January 1, 2017 amendments to Article 4.5 or Article 7, requires physical construction or alteration to a facility or physical environment, the board or its designee may grant a waiver of such compliance for a period of time to permit such physical change(s). Application for any waiver shall be made by the licensee in writing, and the request shall identify the provision(s) requiring physical construction or alteration, and the timeline for any such change(s). The board or its designee may grant the waiver when, in its discretion, good cause is demonstrated for such waiver.

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code.
Reference: Sections 4005, 4036, 4037, 4051, 4052 and 4127, Business and Professions Code.

To Amend § 1735.7 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1735.7. Training of Compounding Staff.
(a) A pharmacy engaged in compounding shall maintain documentation demonstrating that personnel involved in compounding have the skills and training required to properly and accurately perform their assigned responsibilities and documentation demonstrating that all personnel involved in compounding are trained in all aspects of policies and procedures. This training shall include but is not limited to support personnel (e.g. institutional environmental services, housekeeping), maintenance staff, supervising pharmacist and all others whose jobs are related to the compounding process. Any pharmacy engaged in compounding shall maintain written documentation sufficient to demonstrate that pharmacy personnel have the skills and training required to properly and accurately perform their assigned responsibilities relating to compounding.
(b) The pharmacy shall develop and maintain an ongoing competency evaluation process for pharmacy personnel involved in compounding, and shall maintain documentation of any and all training related to compounding undertaken by pharmacy personnel.

(c) Pharmacy personnel assigned to compounding duties shall demonstrate knowledge about processes and procedures used in compounding prior to compounding any drug product preparation.

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052 and 4127, Business and Professions Code.

To Amend § 1735.8 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:


(a) Any pharmacy engaged in compounding shall maintain, as part of its written policies and procedures, a written quality assurance plan designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug products preparations.

(b) The quality assurance plan shall include written procedures for verification, monitoring, and review of the adequacy of the compounding processes and shall also include written documentation of review of those processes by qualified pharmacy personnel.

(c) The quality assurance plan shall include written standards for qualitative and quantitative analysis of compounded drug preparations to ensure integrity, potency, quality, and labeled strength, including the frequency of testing analysis of compounded drug products. All qualitative and quantitative analysis reports for compounded drug products preparations shall be retained by the pharmacy and collated maintained along with the compounding log record and master formula document. The quality assurance plan shall include a schedule for routine testing and analysis of specified compounded drug preparations to ensure integrity, potency, quality, and labeled strength, on at least an annual basis.

(d) The quality assurance plan shall include a written procedure for scheduled action in the
event any compounded drug product preparation is ever discovered to be below outside minimum standards for integrity, potency, quality, or labeled strength.

(e) The quality assurance plan shall include a written procedure for responding to out-of-range temperature variations within the pharmacy and within patient care areas of a hospital where furnished drug is returned for redispensing.

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052 and 4127, Business and Professions Code.

To Amend § 1751 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

Article 7. Sterile Injectable Compounding

1751. Sterile Injectable Compounding; Compounding Area; Self-Assessment.

(a) Any pharmacy engaged in compounding sterile injectable drug products preparations shall conform to the parameters and requirements stated by Article 4.5 (Section 1735 et seq.), applicable to all compounding, and shall also conform to the parameters and requirements stated by this Article 7 (Section 1751 et seq.), applicable solely to sterile injectable compounding.

(b) Any pharmacy compounding sterile injectable drug products preparations shall have a designated compounding area designated for the preparation of sterile injectable drug products preparations that is in a restricted location where traffic has no impact on the performance of the PEC(s). The cleanroom, including the walls, ceilings, and floors, shall be constructed in accordance with Section 1250.4 of Title 24, Part 2, Chapter 12, of the California Code of Regulations. The pharmacy shall be ventilated in a manner in accordance with Section 505.5 of Title 24, Part 4, Chapter 5 of the California Code of Regulations, which shall meet the following standards: The environments within the pharmacy shall meet the following standards:

1. Clean Room and Work Station Requirements, shall be in accordance with Section 1250 of Title 24, Part 2, Chapter 12, of the California Code of Regulations.

2. Walls, ceilings and floors shall be constructed in accordance with Section 1250 of Title 24, Part 2, Chapter 12, of the California Code of Regulations.
(3) Be ventilated in a manner in accordance with Section 505.12 of Title 24, Chapter 5 of the California Code of Regulations.

(4) Each ISO environment shall be certified annually at least every six months by a qualified technician who is familiar with the methods and procedures for certifying laminar air flow hoods and clean room requirements, in accordance with standards adopted by the United States General Services Administration in accordance with Section 1751.4. Certification records must be retained for at least 3 years in the pharmacy.

(5) The pharmacy shall be arranged in accordance with Section 1250 of Title 24, Part 2, Chapter 12 of the California Code of Regulations. Items related to the compounding of sterile injectable drug products preparations within the compounding area shall be stored in such a way as to maintain the integrity of an aseptic environment.

(6) A sink shall be included in accordance with Section 1250.4 of Title 24, Part 2, Chapter 12 of the California Code of Regulations. Sinks and drains shall not be present in any ISO Class 7 or better cleanroom, nor in a segregated sterile compounding area within three feet of an ISO Class 5 or better PEC, with the exception of emergency eye-rinsing stations. A sink may be located in an ante-area. When the PEC in the segregated sterile compounding area is a CAI or CACI and the documentation provided by the manufacturer shows it meets the requirements listed in 1751.4(f)(1)-(3) the sterile compounding area is exempt from the room requirement listed in 1751(b)(3).

(7) There shall be 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 to ensure continuity of available compounded drug preparations in the event of a power outage.

(8) Any pharmacy compounding a sterile injectable drug product preparation from one or more non-sterile ingredients shall comply with Business and Professions Code section 4127.7.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127 and 4127.7, Business and Professions Code; Sections 1735, 1735.1-1735.8, and 1751.1-1751.8 of Title 16, Division 17, of the California Code of
To Amend § 1751.1 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1751.1. Sterile Injectable Compounding Recordkeeping Requirements.
(a) Pharmacies compounding sterile injectable products for future use pursuant to section 1735.2 shall, in addition to those records required by section 1735.3, make and keep records indicating the name, lot number, amount, and date on which the products were provided to a prescriber.
(b) In addition to the records required by section 1735.3 and subdivision (a), any pharmacy engaged in any compounding of sterile drug products compounded from one or more non-sterile ingredients, shall maintain the following records, which must be made and kept by readily retrievable, within the pharmacy:

1. The Documents evidencing training and competency evaluations of employees in sterile product drug preparation policies and procedures.
2. Results of hand hygiene and garbing assessments with integrated gloved fingertip testing.
3. Results of assessments of personnel for aseptic techniques including results of media-fill tests and gloved fingertip testing performed in association with media-fill tests.
4. Results of viable air and surface sampling.
5. Video of smoke studies in all ISO certified spaces.
6. Documents indicating daily documentation of room, refrigerator, and freezer temperatures appropriate for sterile compounded drug preparations consistent with the temperatures listed in section 1735.1 for:
   A. Controlled room temperature.
   B. Controlled cold temperature.
   C. Controlled freezer temperature.
7. Certification(s) of the sterile compounding environment(s).
8. Documents indicating daily documentation of air pressure differentials or air velocity...
measurements between all adjoining ISO rooms or areas, including those associated with compounding aseptic (containment) isolators, and air pressure differentials or air velocity measurements between all rooms or spaces with an immediate entry or opening to ISO rooms or areas.

(9) Other facility quality control logs records specific to the pharmacy’s policies and procedures (e.g., cleaning logs for facilities and equipment).

(10) Logs or other documentation of inspections for expired or recalled pharmaceutical products or raw ingredients chemicals, bulk drug substances, drug products, or other ingredients.

(11) Preparation records including the master formula document work sheet, the preparation compounding log work sheet, and records of end-product evaluation testing and results.

(b) Pharmacies compounding sterile drug preparations for future use pursuant to section 1735.2 shall, in addition to those records required by section 1735.3, make and keep records indicating the name, lot number, and amount of any drug preparation compounded for future use, the date on which any preparation was provided to a prescriber, and the name, address, license type and number of the prescriber.

(c) Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was created. If only recorded and stored electronically, on magnetic media, or in any other computerized form, the records shall be maintained as specified by Business and Professions Code section 4070 subsection (c).

To Amend § 1751.2 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1751.2. Sterile Injectable Compounding Labeling Requirements.
In addition to the labeling information required under Business and Professions Code section 4076 and California Code of Regulations, title 16, sections 1707.5 and 1735.4, a pharmacy which that compounds sterile injectable drug products preparations shall include the following information on the labels for each such those products preparation:
(a) The telephone number of the pharmacy, except the telephone number is not required on the label for sterile injectable drug products preparations dispensed administered for to inpatients of within the hospital pharmacy.
(b) Name and concentration of ingredients contained in the sterile injectable drug product.
(c) Instructions for storage, and handling, and administration.
(d) All cytotoxic hazardous agents shall bear a special label which states “Chemotherapy - Dispose of Properly” or “Cytotoxic Hazardous – Dispose of Properly.”


To Amend § 1751.3 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

(a) Any pharmacy engaged in compounding sterile drug preparations shall maintain written policies and procedures for compounding. Any material failure to follow the pharmacy’s written policies and procedures shall constitute a basis for disciplinary action. In addition to the elements required by section 1735.5, there shall be written policies and procedures regarding the following:
(1) Action levels for colony-forming units (CFUs) detected during viable surface sampling, glove
fingertip, and viable air sampling and actions to be taken when the levels are exceeded.

(2) Airflow considerations and pressure differential monitoring.

(3) An environmental sampling plan and procedures specific to viable air, surface and gloved fingertip sampling as well as nonviable particle sampling.

(4) Cleaning and maintenance of ISO environments and segregated compounding areas.

(5) Compounded sterile drug preparation stability and beyond use dating.

(6) Compounding, filling, and labeling of sterile drug preparations.

(7) Daily and monthly cleaning and disinfection schedule for the controlled areas and any equipment in the controlled area as specified in section 1751.4.

(8) Depyrogenation of glassware (if applicable)

(9) Facility management including certification and maintenance of controlled environments and related equipment.

(10) For compounding aseptic isolators and compounding aseptic containment isolators, documentation of the manufacturer’s recommended purge time.

(11) Hand hygiene and garbing.

(12) Labeling of the sterile compounded drug preparations based on the intended route of administration and recommended rate of administration.

(13) Methods by which the supervising pharmacist will fulfill his or her responsibility to ensure the quality of compounded drug preparations.

(14) Orientation, training, and competency evaluation of staff in all aspects of the preparation of sterile drug preparations including didactic training and knowledge/competency assessments that include at minimum: hand hygiene and garbing; decontamination (where applicable); cleaning and disinfection of controlled compounding areas; and proper aseptic technique, demonstrated through the use of a media-fill test performed by applicable personnel; and aseptic area practices.

(15) Preparing sterile compounded drug preparations from non-sterile components (if applicable). This shall include sterilization method suitability testing for each master formula document.

(16) Procedures for handling, compounding and disposal of hazardous agents. The written
policies and procedures shall describe the pharmacy protocols for cleanups and spills in
conformity with local health jurisdiction standards.
(17) Procedures for handling, compounding and disposal of infectious materials. The written
policies and procedures shall describe the pharmacy protocols for cleanups and spills in
conformity with local health jurisdiction standards.
(18) Proper use of equipment and supplies.
(19) Quality assurance program compliant with sections 1711, 1735.8 and 1751.7.
(20) Record keeping requirements.
(21) Temperature monitoring in compounding and controlled storage areas.
(22) The determination and approval by a pharmacist of ingredients and the compounding
process for each preparation before compounding begins.
(23) Use of automated compounding devices (if applicable).
(24) Visual inspection and other final quality checks of sterile drug preparations.
(a) Any pharmacy engaged in compounding sterile injectable drug products shall maintain a
written policy and procedures manual for compounding that includes, in addition to the
elements required by section 1735.5, written policies and procedures regarding the following:
(1) Compounding, filling, and labeling of sterile injectable compounds.
(2) Labeling of the sterile injectable product-compounded drug preparations based on the
intended route of administration and recommended rate of administration.
(3) Equipment and supplies.
(4) Training of staff in the preparation of sterile injectable products.
(5) Procedures for handling cytotoxic agents.
(6) Quality assurance program.
(7) Record keeping requirements.
(b) The ingredients and the compounding process for each preparation must be determined in
writing before compounding begins and must be reviewed by a pharmacist.
(c) Pharmacies compounding sterile injectable drug products-preparations shall have written
policies and procedures for the disposal of infectious materials and/or materials containing
cytotoxic hazardous residues. The written policies and procedures shall describe the pharmacy
protocols for cleanups and spills in conformity with local health jurisdiction standards.

(b) For lot compounding, the pharmacy shall maintain written policies and procedures that includes, in addition to the elements required by section 1735.5 and 1751.3(a), written policies and procedures regarding the following:

1. Use of master formula documents and compounding logs.
2. Appropriate documentation.
3. Appropriate sterility and potency testing.

(c) For non-sterile-to-sterile batch compounding, the pharmacy shall maintain written policies and procedures for compounding that includes, in addition to the elements required by section 1735.5, 1751.3(a), and 1751.7(e), written policies and procedures regarding the following:

1. Process validation for chosen sterilization methods.
2. End-product evaluation, quantitative, and qualitative testing.

(d)(1) All written policies and procedures shall be immediately available to all personnel involved in these compounding activities and to board inspectors.

(d)(2) All personnel involved must read the policies and procedures before compounding sterile injectable products, and any additions, revisions, and deletions to the written policies and procedures must be communicated to all personnel involved in sterile compounding. Each review must be documented by a signature and date.

3. Policies and procedures must address at least the following:
   A. Competency evaluation.
   B. Storage and handling of products and supplies.
   C. Storage and delivery of final products.
   D. Process validation.
   E. Personnel access and movement of materials into and near the controlled area.
   F. Use and maintenance of environmental control devices used to create the critical direct compounding area for manipulation of sterile products (e.g., laminar airflow workstations, biological safety cabinets, class 100 cleanrooms, and barrier isolator...
workstations).

(G) Regular cleaning schedule for the controlled areas and any equipment in the controlled area and the alternation of disinfectants. Pharmacies subject to an institutional infection control policy may follow that policy as it relates to cleaning schedules and the alternation of disinfectants in lieu of complying with this subdivision.

(H) Disposal of packaging materials, used syringes, containers, and needles to enhance sanitation and avoid accumulation in the controlled area.


To Amend § 1751.4 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1751.4. Facility and Equipment Standards for Sterile Injectable Compounding.

(a) No sterile injectable drug product preparation shall be compounded if it is known, or reasonably should be known, that the compounding environment fails to meet criteria specified in the pharmacy’s written policies and procedures for the safe compounding of sterile injectable drug products preparations.

(b) During the compounding of preparation of sterile injectable drug products preparations, access to the areas designated area or cleanroom for compounding must be limited to those individuals who are properly attired.

(c) All equipment used in the areas designated area or cleanroom for compounding must be made of a material that can be easily cleaned and disinfected.

(d) Cleaning shall be done using a germicidal detergent and sterile water. The use of a sporicidal agent is required to be used at least monthly.

(1) All ISO Class 5 surfaces, work table surfaces, carts, counters, and the cleanroom floor shall be cleaned at least daily. After each cleaning, disinfection using a suitable sterile agent shall occur on all ISO Class 5 surfaces, work table surfaces, carts, and counters.
(2) Walls, ceilings, storage shelving, tables, stools, and all other items in the ISO Class 7 or ISO Class 8 environment shall be cleaned at least monthly.

(3) Cleaning shall also occur after any unanticipated event that could increase the risk of contamination.

(4) All cleaning materials, such as wipers, sponges, and mops, shall be non-shedding and dedicated to use in the cleanroom, or ante-area, and segregated sterile compounding areas and shall not be removed from these areas except for disposal.

(e) Disinfection, using a suitable sterile agent, shall also occur on all surfaces in the ISO Class 5 PEC frequently, including:

(1) At the beginning of each shift;

(2) At least every 30 minutes when compounding involving human staff is occurring or before each lot;

(3) After each spill; and

(4) When surface contamination is known or suspected.

(d) Exterior workbench surfaces and other hard surfaces in the designated area, such as walls, floors, ceilings, shelves, tables, and stools, must be disinfected weekly and after any unanticipated event that could increase the risk of contamination.

(f) Pharmacies preparing sterile compounded preparations require the use of a PEC that provides ISO Class 5 air or better air quality. Certification and testing of primary and secondary engineering controls shall be performed no less than every six months and whenever the device or area designated for compounding is relocated, altered or a service to the facility is performed that would impact the device or area. Certification must be completed by a qualified technician who is familiar with certification methods and procedures in accordance with CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006-13, Revised May 20, 2015).

Certification records must be retained for at least 3 years. Unidirectional compounding aseptic isolators or compounding aseptic containment isolators may be used outside of an ISO Class 7 cleanroom if the isolator is certified to meet the following criteria:

(1) Particle counts sampled approximately 6-12 inches upstream of the critical exposure site shall maintain ISO Class 5 levels during compounding operations.
(2) Not more than 3520 particles (0.5 um and larger) per cubic meter shall be counted during material transfer, with the particle counter probe located as near to the transfer door as possible without obstructing transfer.

(3) Recovery time to achieve ISO Class 5 air quality shall be documented and internal procedures developed to ensure that adequate recovery time is allowed after material transfer before and during compounding operations.

Compounding aseptic isolators that do not meet the requirements as outlined in this subdivision or are not located within an ISO Class 7 cleanroom may only be used to compound preparations that meet the criteria specified in accordance with subdivision (d) of Section 1751.8 of Title 16, Division 17, of the California Code of Regulations.

(g) Pharmacies preparing parenteral cytotoxic sterile hazardous agents shall do so in accordance with Section 505.125.1 of Title 24, Chapter 5, of the California Code of Regulations, requiring a laminar air flow hood negative pressure PEC. Additionally, each PEC used to compound hazardous agents shall be externally vented. The hood negative pressure PEC must be certified annually every six months by a qualified technician who is familiar with CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006-13, Revised May 20, 2015). The methods and procedures for certifying laminar air flow hoods and cleanroom requirements, in accordance with National Sanitation Foundation Standard 49 for Class II (Laminar Flow) Biohazard Cabinetry, as revised May, 1983 (available from the National Sanitation Foundation, 3475 Plymouth Road, P.O. Box 1468, Ann Arbor, Michigan 48106, phone number (313) 769-8010) or manufacturer's specifications. Certification records must be retained for at least 3 years. Any drug preparation that is compounded in a PEC where hazardous drugs are prepared must be labeled as hazardous, regardless of whether the drug ingredients are considered hazardous.

(1) During the hazardous drug compounding that is performed in a compounding aseptic containment isolator, full hand hygiene and garbing must occur. Garbing shall include hair cover, facemask, beard cover (if applicable), polypropylene or low shedding gown that closes in the back, shoe covers, and two pairs of sterile ASTM D6978-05 standard gloves.

(h) If a compounding aseptic isolator is certified by the manufacturer to maintain ISO Class 5
air quality during dynamic operation conditions during compounding as well as during the
transfer of ingredients into and out of the compounding aseptic isolator, then it may be placed
into a non-ISO classified room. Individuals that use compounding aseptic isolators in this
manner must ensure appropriate garbing, which consists of donning sterile gloves over the
isolator gloves immediately before non-hazardous compounding. These sterile gloves must be
changed by each individual whenever continuous compounding is ceased and before
compounding starts again.
(i) Compounding aseptic isolator and compounding aseptic containment isolator used in the
compounding of sterile drug preparations shall use non-turbulent unidirectional air flow
patterns. A smoke patterned test shall be used to determine air flow patterns.
(j) Viable surface sampling shall be done at least every six months for all sterile-to-sterile
compounding and quarterly for all non-sterile-to-sterile compounding. Viable air sampling shall
be done by volumetric air sampling procedures which test a sufficient volume of air (400 to
1,000 liters) at each location and shall be done at least once every six months. Viable surface
and viable air sampling shall be performed by a qualified individual who is familiar with the
methods and procedures for surface testing and air sampling. Viable air sampling is to be
performed under dynamic conditions that simulate actual production. Viable surface sampling
is to be performed under dynamic conditions of actual compounding. When the environmental
monitoring action levels are exceeded, the pharmacy shall identify the CFUs at least to the
genus level in addition to conducting an investigation pursuant to its policies and procedures.
Remediation shall include, at minimum, an immediate investigation of cleaning and
compounding operations and facility management.
(k) The sterile compounding area in the pharmacy shall have a comfortable and well-lighted
working environment, which includes a room temperature of 20-24 degrees Celsius (68-75
degrees Fahrenheit) or cooler to maintain comfortable conditions for compounding
personnel when attired in the required compounding garb.
(l) A licensee may request a waiver of these provisions as provided in section 1735.6(f).
Note: Authority Cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052 and 4127, Business and Professions Code; and Section 18944, Health and Safety Code.

To Amend § 1751.5 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1751.5. Sterile Injectable Compounding Attire.

(a) When preparing cytotoxic agents, gowns and gloves shall be worn.
(b) (a) When compounding sterile drug products preparations from one or more non-sterile ingredients the following standards must be met:

(1) Cleanroom garb Personal protective equipment consisting of a low non-shedding coverall gown, head cover, face mask, facial hair covers (if applicable), and shoe covers must be worn inside the designated area at all times. For hazardous compounding double shoe covers are required.

(2) Cleanroom garb Personal protective equipment must be donned and removed outside the designated area in an ante-area or immediately outside the segregated compounding area.

(3) Personnel shall don personal protective equipment in an order that proceeds from those activities considered the dirtiest to those considered the cleanest. The following order is to be followed unless the pharmacy has a procedure in place that documents a method equivalent to or superior to the method described here: The donning of shoe covers or dedicated shoes, head and facial hair covers and face masks shall be followed by the washing of hands and forearms up to the elbows for 30 seconds with soap and water, drying hands, and then the donning of a non-shedding gown.

(3)-(4) Compounding personnel shall not wear any wrist, hand, finger, and or wrist other visible jewelry must be eliminated jewelry, piercing, headphones, earbuds, or personal electronic device. If jewelry cannot be removed then it must be thoroughly cleaned and covered with a sterile glove.

(4) Head and facial hair must be kept out of the critical area or be covered.
(5) Gloves made of low-shedding materials are required. Sterile gloves that have been tested for compatibility with disinfection with isopropyl alcohol are required. Hand cleansing with a persistently active alcohol-based product followed by the donning of sterile gloves may occur within the ante or cleanroom. Gloves are to be routinely disinfected with sterile 70 percent isopropyl alcohol before entering or re-entering the PEC and after contact with non-sterile objects. Gloves shall also be routinely inspected for holes, punctures, or tears and replaced immediately if such are detected.

(6) Individuals experiencing exposed rashes, sunburn, weeping sores, conjunctivitis, active respiratory infections or other communicable disease, or those wearing cosmetics, nail polish, or artificial nails shall be excluded from the ISO Class 5 and ISO Class 7 compounding areas until their conditions are remedied.

(c) The requirements of subdivision (b) do not apply if a barrier isolator is used to compound sterile injectable products from one or more non-sterile ingredients.

(b) When preparing hazardous agents, appropriate gowns and personal protective equipment shall be worn regardless of the PECs used (e.g., biological safety cabinet and compounding aseptic containment isolator).


To Amend § 1751.6 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1751.6 Training of Sterile Injectable Compounding Staff, Patient, and Caregiver. Sterile Compounding Consultation; Training of Sterile Compounding Staff.

(a) Consultation shall be available to the patient and/or primary caregiver concerning proper use, storage, handling, and disposal of sterile injectable drug products preparations and related supplies furnished by the pharmacy.

(b) The pharmacist-in-charge shall be responsible to ensure that all pharmacy personnel
engaging in compounding sterile injectable drug products preparations shall have training and demonstrated competence in the safe handling and compounding of sterile injectable drug products preparations, including cytotoxic hazardous agents if the pharmacy compounds products with cytotoxic hazardous agents.

(c) Records of training and demonstrated competence shall be available for each individual and shall be retained for three years beyond the period of employment.

(d) The pharmacist-in-charge shall be responsible to ensure the continuing competence of pharmacy personnel engaged in compounding sterile injectable drug products preparations.

(e) Pharmacies that compound sterile drug products from one or more non-sterile ingredients preparations must comply with the following training requirements:

(1) The pharmacy must establish and follow a written program of training and performance evaluation designed to ensure that each person working in the designated area has the knowledge and skills necessary to perform their assigned tasks properly. This program of training and performance evaluation must address at least the following:

(A) Aseptic technique.

(B) Pharmaceutical calculations and terminology.

(C) Sterile product preparation compounding documentation.

(D) Quality assurance procedures.

(E) Aseptic preparation procedures.

(F) Proper hand hygiene, gowning and gloving technique.

(G) General conduct in the controlled area (aseptic area practices).

(H) Cleaning, sanitizing, and maintaining of the equipment and used in the controlled area.

(I) Sterilization techniques for compounding sterile drug preparations from one or more non-sterile ingredients.

(J) Container, equipment, and closure system selection.

(2) Each person assigned to the controlled area engaged in sterile compounding must successfully complete practical skills training in aseptic technique and aseptic area practices, using models that are comparable to the most complex manipulations to be performed by the individual. Each pharmacist responsible for, or directly supervising and controlling, aseptic
techniques or practices, must demonstrate the skills needed to ensure the sterility of compounded drug preparations. Evaluation must include written testing and a written protocol of periodic routine performance checks involving adherence to aseptic area policies and procedures. Each person’s proficiency and continuing training needs must be reassessed at least every 12 months. Results of these assessments must be documented and retained in the pharmacy for three years.


To Amend § 1751.7 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1751.7. Sterile Injectable Compounding Quality Assurance and Process Validation.

(a) Any pharmacy engaged in compounding sterile injectable drug products shall maintain, as part of its written policies and procedures, a written quality assurance plan including, in addition to the elements required by section 1735.8, a documented, ongoing quality assurance program that monitors personnel performance, equipment, and facilities. The end product shall be examined on a periodic sampling basis as determined by the pharmacist-in-charge to assure that it meets required specifications. The quality assurance program shall include at least the following:

(1) Procedures for cleaning and sanitization of the parenteral medication sterile preparation area.

(2) The storage of compounded sterile injectable products in the pharmacy and periodic documentation of refrigerator temperature.

(3) Actions to be taken in the event of a drug recall.

(4) Written justification of expiration dates for compounded sterile injectable drug products.

(b) The pharmacy and each individual involved in the compounding of sterile drug...
preparations must successfully demonstrate competency on aseptic technique and aseptic area practices before being allowed to prepare sterile drug preparations. The validation process shall be carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation. The validation process shall be representative of the types of manipulations, products and batch sizes the individual is expected to prepare and include a media-fill test. The validation process shall be as complicated as the most complex manipulations performed by staff and contain the same amount or greater amount of volume transferred during the compounding process. The same personnel, procedures, equipment, and materials must be used in the testing. Media used must have demonstrated the ability to support and promote growth. Completed medium samples must be incubated in a manner consistent with the manufacturer’s recommendations. If microbial growth is detected, then each individual’s sterile preparation process must be evaluated, corrective action taken and documented, and the validation process repeated.

(2) Each individual’s competency must be revalidated at least every twelve months for sterile to sterile compounding and at least every six months for individuals compounding sterile preparations from non-sterile ingredients.

(3) The pharmacy’s validation process on aseptic technique and aseptic area practices must be revalidated whenever:

(A) the quality assurance program yields an unacceptable result,

(B) there is any change in the compounding process, the Primary Engineering Control (PEC), or the compounding environment. For purposes of this subsection, a change includes, but is not limited to, when the PEC is moved, repaired or replaced, when the facility is modified in a manner that affects airflow or traffic patterns, or when improper aseptic techniques are observed.

(4) The pharmacy must document the validation and revalidation process.

Each individual involved in the preparation of sterile injectable drug products preparations must first successfully demonstrate competency by successfully performing aseptic media-fill tests complete a validation process on technique before being allowed to prepare sterile-
injectable drug products preparations. The validation process shall be carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation. The validation process shall be representative of all types of manipulations, products and batch sizes the individual is expected to prepare. The media-fill testing process shall be as complicated as the most complex manipulations performed by staff and contain the same amount or greater of volume transferred during the compounding process. The same personnel, procedures, equipment, and materials must be involved. Media used must have demonstrated the ability to support and promote growth. Completed medium samples must be incubated in a manner consistent with the manufacturer’s recommendations. If microbial growth is detected, then the employee’s sterile preparation process must be evaluated, corrective action taken and documented, and the validation process media-fill testing repeated. Personnel competency must be revalidated at least every twelve months for sterile to sterile compounding and at least every six months for individuals compounding sterile products from non-sterile ingredients. Aseptic work practice assessments via media-fill tests must be revalidated, as appropriate to the circumstance or personnel found to be deficient, whenever the quality assurance program yields an unacceptable result, when the compounding process changes, equipment used in the compounding of sterile injectable drug products preparations is repaired or replaced, the facility is modified in a manner that affects airflow or traffic patterns, or whenever improper aseptic techniques are observed. Revalidation must be documented.

(c) All sterile compounding personnel must successfully complete an initial competency evaluation. In addition, immediately following the initial hand hygiene and garbing procedure, each individual who may be required to do so in practice must successfully complete a gloved fingertip (all fingers on both hands) sampling procedure (zero colony forming units for both hands) at least three times before initially being allowed to compound sterile drug preparations.

(d) Re-evaluation of garbing and gloving competency shall occur at least every 12 months for personnel compounding products made from sterile ingredients and at least every six months for personnel compounding products from non-sterile ingredients.
(e)-(e)(1) Batch-produced sterile drug preparations compounded from one or more non-sterile ingredients, except as provided in paragraph (2), shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens. Sterility testing shall be USP chapter 71 compliant and pyrogens testing shall confirm acceptable levels of pyrogens per USP chapter 85 limits, before dispensing. This requirement of end product testing confirming sterility and acceptable levels of pyrogens prior to dispensing shall apply regardless of any sterility or pyrogen testing that may have been conducted on any ingredient or combination of ingredients that were previously non-sterile. Exempt from pyrogen testing are topical ophthalmic and inhalation preparations.

(2) The following non-sterile-to-sterile batch drug preparations do not require end product testing for sterility and pyrogens:

(A) Preparations for self-administered ophthalmic drops in a quantity sufficient for administration to a single patient for 30 days or less pursuant to a prescription.

(B) Preparations for self-administered inhalation in a quantity sufficient for administration to a single patient for 5 days or less pursuant to a prescription.

Batch-produced sterile injectable drug products compounded from one or more non-sterile ingredients shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens.

(d) Batch-produced sterile to sterile transfers shall be subject to periodic testing through process validation for sterility as determined by the pharmacist-in-charge and described in the written policies and procedures.

To Amend § 1751.8 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1751.8. Beyond Use Dating for Sterile Compounded Drug Preparations.

In conformity with and in addition to the requirements and limitations of section 1735.2, subdivision (h), every sterile compounded drug preparation shall be given and labeled with a beyond use date that does not exceed the shortest expiration date or beyond use date of any ingredient in sterile compounded drug preparation, nor the chemical stability of any one ingredient in the sterile compounded drug preparation, nor the chemical stability of the combination of all ingredients in the sterile compounded drug preparation, and that, in the absence of passing a sterility test in accordance with standards for sterility testing found in Chapter 797 of the United States Pharmacopeia – National Formulary (USP37-NF32) Through 2nd Supplement (37th Revision, Effective December 1, 2014), hereby incorporated by reference, that would justify an extended beyond use date, conforms to the following limitations:

(a) The beyond use date shall specify that storage and exposure periods cannot exceed 48 hours at controlled room temperature, 14 days at controlled cold temperature, and 45 days in solid frozen state, where the sterile compounded drug preparation is compounded solely with aseptic manipulations and all of the following apply:

(1) The preparation is compounded entirely within an ISO Class 5 PEC located in an ISO Class 7 cleanroom with an ante-area or compounded entirely within a CAI which meets the requirements in 1751.4(f)(1)-(3), using only sterile ingredients, products, components, and devices; and

(2) The compounding process involves transferring, measuring, and mixing manipulations using not more than three commercially manufactured packages of sterile preparations and not more than two entries into any one sterile container or package of sterile preparations or administration containers/devices to prepare the drug preparation; and

(3) Compounding manipulations are limited to aseptically opening ampules, penetrating disinfected stoppers on vials with sterile needles and syringes or spiked transfer devices, and transferring sterile liquids in sterile syringes to sterile administration devices, package
containers of other sterile preparations, and containers for storage dispensing.

(b) The beyond use date shall specify that storage and exposure periods cannot exceed 30 hours at controlled room temperature, 9 days at controlled cold temperature, and 45 days in solid frozen state, where the sterile compounded drug preparation is compounded solely with aseptic manipulations and all of the following apply:

(1) The preparation is compounded entirely within an ISO Class 5 PEC located in an ISO Class 7 cleanroom with an ante-area or compounded entirely within a CAI which meets the requirements in 1751.4(f)(1)-(3), using multiple individual or small doses of sterile preparations combined or pooled to prepare a compounded sterile preparation that will be administered either to multiple patients or to one patient on multiple occasions; and

(2) The compounding process involves complex aseptic manipulations other than the single-volume transfer; and

(3) The compounding process requires unusually long duration such as that required to complete dissolution or homogenous mixing.

(c) The beyond use date shall specify that storage and exposure periods cannot exceed 24 hours at controlled room temperature, 3 days at controlled cold temperature, and 45 days in solid frozen state, where the sterile compounded drug preparation is compounded solely with aseptic manipulations using non-sterile ingredients, regardless of intervening sterilization of that ingredient and the following applies:

(1) The preparation is compounded entirely within an ISO Class 5 PEC located in an ISO Class 7 cleanroom with an ante-area or compounded entirely within a CAI which meets the requirements in 1751.4(f)(1)-(3).

(d) The beyond use date shall specify that storage and exposure periods cannot exceed 12 hours where the sterile compounded drug preparation is compounded solely with aseptic manipulations and all of the following apply:

(1) The preparation was compounded entirely within an ISO Class 5 PEC that is located in a segregated sterile compounding area and restricted to sterile compounding activities, using only sterile ingredients, components, and devices, by personnel properly cleansed and garbed; and
(2) The compounding process involves simple transfer of not more than three commercially manufactured packages of sterile nonhazardous preparations or diagnostic radiopharmaceutical preparations from the manufacturer’s original containers; and

(3) The compounding process involves not more than two entries into any one container or package (e.g., bag, vial) of sterile infusion solution or administration container/device.

(e) Where any sterile compounded drug preparation was compounded either outside of an ISO class 5 PEC or under conditions that do not meet all of the requirements for any of subdivisions (a) through (d), the sterile compounded drug preparation shall be labeled “for immediate use only” and administration shall begin no later than one hour following the start of the compounding process. Unless the “immediate use” preparation is immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, the preparation shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the compounded sterile preparation, and the exact one-hour beyond use date and time. If administration has not begun within one hour following the start of the compounding process, the compounded sterile preparation shall be promptly, properly, entirely, and safely discarded. This provision does not preclude the use of a PEC to compound an “immediate use” preparation. A PEC used solely to compound ‘immediate use’ preparations need not be placed within an ISO Class 7 cleanroom, with an ante-area. Such “immediate use” preparations shall be compounded only in those limited situations where there is a need for immediate administration of a sterile preparation compounded outside of an ISO class 5 environment and where failure to administer could result in loss of life or intense suffering. Any such compounding shall be only in such quantity as is necessary to meet the immediate need and the circumstance causing the immediate need shall be documented in accordance with policies and procedures.

(f) The beyond use date for any compounded allergen extracts shall be the earliest manufacturer expiration date of the individual allergen extracts.

To Add § 1751.9 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1751.9 Single-Dose and Multi-Dose Containers; Limitations on Use

(a) Single-dose ampules are for immediate use only, and once opened shall not be stored for any time period.

(b) Unless otherwise specified by the manufacturer, any single-dose container of a compounded sterile drug preparation other than an ampule, such as a bag, bottle, syringe or vial, shall be used in its entirety or its remaining contents shall be labeled with a beyond use date and discarded within the following time limit, depending on the environment:

(1) When needle-punctured in an environment with air quality worse than ISO Class 5, within one (1) hour;

(2) When needle-punctured in an environment with ISO Class 5 or better air quality, within six (6) hours. A container must remain within the ISO Class 5 or better air quality to be used for the full six hours, unless otherwise specified by the manufacturer.

(3) If the puncture time is not noted on the container, the container must immediately be discarded.

(c) Unless otherwise specified by the manufacturer, a multi-dose container stored according to the manufacturer’s specifications shall be used in its entirety or its remaining contents shall be labeled with a beyond use date and discarded within twenty eight (28) days from initial opening or puncture. Any multi-dose container not stored according to the manufacturer’s specifications shall be discarded immediately upon identification of such storage circumstance. If any open container is not labeled with a beyond use date or the beyond use date is not correct, the container must immediately be discarded.
To Amend § 1751.10 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:


In any pharmacy engaged in compounding sterile injectable drug products preparations, there shall be current and appropriate reference materials regarding the compounding of sterile injectable drug products preparations located in or immediately available to the pharmacy.

To Add Article 7.5 of Division 17 of Title 16 of the California Code of Regulations to read as follow

Article 7.5  Furnishing for Home Administration

To Amend § 1751.10 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1751.10. 1752. Furnishing to Parenteral Patient at Home.

Subject to all provisions of this article, a pharmacist may carry and furnish to a patient at home dangerous drugs, other than controlled substances, and devices for parenteral therapy when the dangerous drug or device is one currently prescribed for the patient.

To Amend § 1751.11 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1751.11. Furnishing to Home Health Agencies and Licensed Hospices.

Subject to the following conditions, a licensed pharmacy may furnish to a home health agency licensed under provisions of Chapter 8 (commencing with section 1725 of Division 2 of the Health and Safety Code) or to a hospice licensed under provisions of Chapter 8.5 (commencing with section 1745 of Division 2 of the Health and Safety Code) dangerous drugs for parenteral therapy other than controlled substances, in a portable container for furnishing to patients at home for emergency treatment or adjustment of parenteral drug therapy by the home health agency or licensed hospice.

(a) The pharmacy, having ownership and responsibility for the portable containers, shall ensure that each portable container is:
(1) furnished by a registered pharmacist;
(2) sealed in such a manner that a tamper-proof seal must be broken to gain access to the drugs;
(3) under the effective control of a registered nurse, pharmacist or delivery person at all times when not in the pharmacy;
(4) labeled on the outside of the container with a list of the contents;
(5) maintained at an appropriate temperature according to United States Pharmacopeia Standards (1995, 23rd Revision), and protected at all times from extreme temperatures that could damage the contents.

(b) The portable container may contain up to:
(1) 1000mL of 0.9% sodium chloride intravenous infusion in containers of a size determined by the pharmacy;
(2) 1000mL of 5% dextrose in water injection in containers of a size determined by the
(3) two vials of urokinase 5000 units;

(4) Each of the following items shall be in sealed, unused containers; the furnishing pharmacy may select any or all of these dangerous drugs in up to five dosage units for inclusion in the sealed, portable container:

(A) heparin sodium lock flush 100 units/mL;
(B) heparin sodium lock flush 10 units/mL;
(C) epinephrine HCl solution 1:1,000;
(D) epinephrine HCl solution 1:10,000;
(E) diphenhydramine HCl 50mg/mL;
(F) methylprednisolone 125mg/2mL;
(G) normal saline, preserved, up to 30 mL vials;
(H) naloxone 1mg/mL 2 mL;
(I) droperidol 5mg/2mL;
(J) prochlorperazine 10mg/2mL;
(K) promethazine 25mg/mL;
(L) dextrose 25gms/50mL;
(M) glucagon 1mg/mL;
(N) insulin (human) 100 units/mL;
(O) bumetamide 0.5mg/2mL;
(P) furosemide 10mg/mL;
(Q) EMLA Cream 5 gm tube;
(R) Lidocaine 1 percent 30mL vials.

(5) The pharmacy shall ensure that the specific dangerous drugs and quantities to be included in the portable container are listed in the home health agency's or licensed hospice's policies and procedures.

(c) The pharmacy shall not supply a portable container to a home health agency or licensed hospice which does not:

(1) implement and maintain policies and procedures for:
(A) the storage, temperature stability and transportation of the portable container;
(B) the furnishing of dangerous drugs from the portable container upon the written or oral
authorization of a prescriber; and
(C) a specific treatment protocol for the administration of each medication contained in the
portable container.

(2) have the policies, procedures and protocols reviewed and revised (as needed) annually by a
group of professional personnel including a physician and surgeon, a pharmacist and a
registered nurse.

(d) A copy of these policies, procedures and protocols shall be maintained by the furnishing
pharmacy from each home health agency or licensed hospice for which the pharmacy furnishes
portable containers.

(e) In cases where a drug has been administered to a patient pursuant to the oral order of a
licensed prescriber, the pharmacy shall ensure that the oral order is immediately written down
by the registered nurse or pharmacist and communicated by copy or fax within 24 hours to the
furnishing pharmacy, with a copy of the prescriber-signed document forwarded to the
dispensing pharmacy within 20 days.

(f) The pharmacy shall ensure that within seven days (168 hours) after the seal has been
broken on the portable container, the home health agency’s director of nursing service or a
registered nurse employed by the home health agency or licensed hospice returns the
container to the furnishing pharmacy. The furnishing pharmacy shall then perform an
inventory of the drugs used from the container, and if the container will be reused, must
restock and reseal the container before it is again furnished to the home health agency or
licensed hospice.

(g) The furnishing pharmacy shall have written policies and procedures for the contents,
packaging, inventory monitoring, labeling and storage instructions of the portable container.

(h) The furnishing pharmacy shall ensure that the home health agency or licensed hospice
returns the portable containers to the furnishing pharmacy at least every 60 days for
verification of product quality, quantity, integrity and expiration dates, or within seven days
(168 hours) after the seal has been broken.
(i) The furnishing pharmacy shall maintain a current inventory and record of all items placed into and furnished from the portable container.


To Amend § 1751.12 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1751.12. Obligations of a Pharmacy Furnishing Portable Containers.

(a) A licensed pharmacy shall not issue portable containers to any home health agency or licensed hospice unless the home health agency or licensed hospice complies with provisions of section 1751.11-1753.

(b) A licensed pharmacy shall cease to furnish portable containers to a home health agency or licensed hospice if the home health agency or licensed hospice does not comply with provisions of section 1751.11-1753.

Attachment 4
Advanced Practice Pharmacist – 1730, 1730.1, 1749
Title 16. BOARD OF PHARMACY  
Second Modified Text

Changes made to the originally proposed language are shown by double strikethrough for deleted language and bold and dashed underline for added language. (Additionally, the modified text is listed in red for color printers.)

Changes made to the modified proposed language are shown by double strikethrough and bold underline for deleted language and bold and double underline for added language. (Additionally, the modified text is listed in blue for color printers.)

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

Article 3.5. Advanced Practice Pharmacist

Proposal to 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(a)(2)(A).

Note: Authority cited: Section 4005, 4210 and 4400, Business and Professions Code. Reference: Sections 4052.6, 4210 and 4400, Business and Professions Code.

Proposal to 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

For purposes of Business and Professions Code section 4210 an applicant for advanced practice pharmacist licensure must satisfy two of the following subdivisions.

(a) Demonstrate possession of a current certification as specified in Business and Professions Code section 4210(a)(2)(A), an applicant shall provide either:

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

(2) A letter from the certification program confirming the award of the certification that includes the name of the applicant pharmacist, the area of specialty and the date of completion.
(b) Demonstrate completion of a postgraduate residency earned in the United States through an accredited postgraduate institution as specified in Business and Professions Code section 4210(a)(2)(B), an applicant shall provide either:

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

(2) A letter of completion of a postgraduate residency signed by the dean or residency program director of the postgraduate institution and sent directly to the board from the postgraduate institution that lists the name of the applicant pharmacist, the dates of participation and completion, and area(s) of specialty. For an applicant that cannot satisfy this document requirement, the board may, for good cause shown, grant a waiver for this subsection (2).

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

(1) A written statement from the applicant attesting under penalty of perjury that he or she has:
   (A) Earned the clinical experience within the required time frame;
   (B) Completed the required number of hours of clinical services to patients, as specified in this subdivision and in Business and Professions Code section 4210 (a)(2)(C), which includes initiating, adjusting, modifying or and discontinuing drug therapy of patients; and
   (i) The applicant shall provide a copy of the collaborative practice agreement or protocol.
   (ii) If a copy of the collaborative practice agreement or protocol is not available, the applicant shall provide a description of the collaborative practice agreement or protocol, including examples of the clinical services the applicant provided to patients.

(2) A written statement from the supervising practitioner, program director or health facility administrator attesting under penalty of perjury that the applicant has completed at least one year of experience providing clinical services to patients. For an applicant that cannot satisfy this document requirement, the board may, for good cause shown, grant a waiver for this subsection (2).
Proposal to 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) 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) The fee for the biennial renewal of a pharmacist's license is one hundred ninety-five dollars ($195) two hundred seventy dollars ($270). The penalty fee for failure to renew is ninety-seven dollars fifty cents ($97.50).

(h) 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.

(i) 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).

(j) 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).

(k) 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).

(l) 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.
Advanced Practice Pharmacist – Certification Programs 1730.2
Proposal to add Section 1730.2 of Article 3.5 of Division 17 of Title 16 of the California Code of Regulations as follows:

§ 1730.2 Certification Programs

(a) For purposes of Business and Professions Code section 4210, subdivision (a)(2)(A), general clinical pharmacy practice is among the relevant areas of practice for which certification may be earned.

(b) For a pharmacist seeking to demonstrate certification in general clinical pharmacy as a criterion for advanced practice pharmacist licensure by the board, the certification may be earned from an organization recognized as a continuing education provider by the Accreditation Council for Pharmacy Education or accredited by the National Commission for Certifying Agencies as a certification provider, so long as:

(1) The certification program includes specified learning objectives in at least five sequentially-ordered education modules, covering the following topics: performing patient assessments; ordering and interpreting drug therapy-related tests; referring patients to other health care providers; participating in the evaluation and management of diseases and health conditions in collaboration with other health care providers; and initiating, adjusting, modifying or discontinuing drug therapy;

(2) The certification program requires assessment after completion of each of the education modules in an examination format or by other assessment methodology that confirms the participant’s understanding, knowledge, and application of the specified learning objectives for the module, where any failure to successfully complete the assessment in any module prevents advancement to the next module;

(3) The certification program requires that instruction and assessments in each of the modules are developed and provided by either:
   (A) An advanced practice pharmacist licensed by the board or
   (B) An expert with experience in the respective area(s) of focus specified in subparagraph (1), where “expert” means a person who qualifies to teach at a school of pharmacy recognized by the board.

(4) The certification program requires that, upon successful completion of all modules and their respective assessments, each participant shall earn a passing score on a final overall assessment before being awarded certification. The assessment shall be either a final written examination or an objective structured clinical examination developed and administered in collaboration with an accredited school of pharmacy recognized by the board; and

(5) The certification program require(s) a minimum of ten hours of continuing education on the topics identified in (b)(1) every two years to maintain certification.

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

1760
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)
Additional copies of these disciplinary guidelines may be downloaded from the board’s website.
# BOARD OF PHARMACY

## DISCIPLINARY GUIDELINES

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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 about their drug therapy 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 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 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, 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.
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, 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 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 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
Article 10. Pharmacy Corporations

1. Licensure Requirements
2. Corporate Name Requirements
3. Shareholder Income While Disqualified
4. Unprofessional Conduct by Corporation

Article 11. Wholesalers and Manufacturers

1. Nonresident Wholesaler: When License Required; Application
2. Issuance or Renewal of Wholesaler License; Surety Bond
3. Unauthorized Furnishing by Manufacturer or Wholesaler
4. Sale or Transfer of Dangerous Drug or Device Into State: Furnishing Records to Authorized Officer on Demand; Citation for Non-compliance
5. Shipping of Dangerous Drugs or Devices — Wholesaler or Distributor
6. Wholesaler: Bar on Obtaining Dangerous Drugs or Devices It Cannot Maintain on Licensed Premises

Article 13. Non-Profit or Free Clinics

1. Purchase of Drugs at Wholesale Only with License: Eligible Clinics
2. License Requirements; Policies and Procedures; Who May Dispense
3. Duties of Professional Director; Consulting Pharmacist Required
4. No Professional-Dispensing Fee
5. Dispensing Schedule II Substance Prohibited
6. Automated Drug Delivery Systems

Article 14. Surgical Clinics

1. Purchase of Drugs at Wholesale: Permitted Uses of Drugs; Required Records and Policies; License Required
2. Compliance with Department of Health Services Requirements; Who May Dispense Drugs
3. Duties of Professional Director; Providing Information to Board
4. Clinic Not Eligible for Professional-Dispensing Fee; Ban on Offering Drugs for Sale
5. Dispensing of Schedule II Substance by Clinic Prohibited; Physician May Dispense; Administration Authorized in Clinic

Article 15. Veterinary Food-Animal Drug Retailers

1. License Required; Temporary License on Transfer of Ownership; Persons Authorized in Storage Area
2. Minimum Standards: Security; Sanitation; Board Regulations; Waivers
3. 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
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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 Oral or Electronic Prescriptions for Schedule 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
11225 to
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 an 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
Only Pharmacist or Intern Authorized to Fill Prescription
Delivery and Receiving Requirements for Schedule II, III, and IV Substances; Violation
Possession of Specified Controlled Substance
Unlawful Possession of Specified Substance
CURES Transmission
Surplus Medication Collection and Distribution Program

CODE OF FEDERAL REGULATIONS, TITLE 21

Persons required to keep records and file reports.
Maintenance of records and inventories.
Inventory requirements.
General requirements for continuing records.
Records for manufacturers.
Special procedure for filling certain orders.
Procedure for filling DEA Forms 222.
Purpose of issue of prescription.
Persons entitled to fill prescriptions.
Administering or dispensing of narcotic drugs.
Requirement of prescription.
Refilling prescription.
Partial filling of prescriptions.
Requirement of prescription.
Refilling of prescriptions.
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 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
Voided License: Knowing Failure to Arrange for Disposition of Stock as Misdemeanor

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**

Resale of Preferentially Priced Drugs: Prohibition; Exceptions

**CALIFORNIA CODE OF REGULATIONS, TITLE 16**

Waiver Requirements for Off-Site Storage of Records

Current Inventory Defined

Erroneous or Uncertain Prescriptions

Posting of Notice of Suspension

Disciplinary Condition of Suspension

Disciplinary Conditions of Probation of Pharmacist

Disciplinary Conditions of Probation of Permit

**HEALTH AND SAFETY CODE**

Providing Chemical for Illicit Manufacturing; Evasion of Reporting Requirements; Penalties

False Statement in Report

Persons Authorized to Write or Issue a Prescription

Responsibility for Legitimacy of Prescription; Corresponding Responsibility of Pharmacist; Knowing Violation

Wholesaler or Manufacturer Furnishing Controlled Substance Other Than for Legitimate Medical Purpose; Knowing Violation; Factors in Assessing Legitimacy

No False or Fictitious Prescriptions

Counterfeiting or Possession of Counterfeit Triplicate Prescription Blank; Penalty

Fraud, Deceit, Misrepresentation or False Statement; False Representation; False Label

Prohibition on Providing False Name or Address in Connection with Prescription, etc.

Possession or Purchase for Sale of Specified Controlled Substance

Forged or Altered Prescriptions

Possession for Sale or Selling Specified Substance

Possession for Sale

Using or Being Under Influence of Controlled Substance

Pharmacy Generated Prescription for Schedule II Controlled Substances in a Skilled Nursing Facility

Manufacturing, Selling, or Offering for Sale an Adulterated Drug or Device

Unlawful to Adulterate a Drug

Unlawful to Receive in Commerce an Adulterated Drug

Unlawful Manufacturer, Selling a Misbranded Drug

Unlawful for a Person to Misbrand

Unlawful to Receive into Commerce a Drug that is Misbranded
CATEGORY IV

Penalty: Revocation

Category IV discipline (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 (Health 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.

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 LICENSEEES (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, 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
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
14.15. Tolling of Probation License Practice Requirement – Tolling Extension of Probation
15.16. Violation of Probation
16.17. Completion of Probation

OPTIONAL CONDITIONS
17.18. Suspension
19.20. Restricted Practice
20.21. Pharmacist Examination
21.22. Mental Health Examination Clinical Diagnostic Evaluation
22.23. Pharmacist’s Recovery Program (PRP)
23.24. Medical Evaluation
24.25. Random Drug Screening Drug and Alcohol Testing
25. Notification of Departure
25.26. Abstain from Drugs and Alcohol Use
26.27. Prescription Coordination and Monitoring of Prescription Use
27.28. Facilitated Group Recovery and/or Support Meetings
28.29. Attend Substance Abuse Recovery Relapse Prevention and Support Groups
29.30. Work Site Monitor
30.31. Community Service Program
31.32. Restitution
32.33. Remedial Education
33. Ethics Course
34. Pharmacy Self-Assessment Mechanism (PSAM)
34.35. Intern Pharmacist Experience
35.36. Supervised Practice
36.37. No Supervision of Ancillary Personnel
37.38. No Ownership or Management of Licensed Premises
38.39. Separate File of Controlled Substances Records
39.40. Report of Controlled Substances
40.41. No Access to Controlled Substances
41.42. Criminal Probation/Parole Reports
42.43. Consultant for Owner or Pharmacist-In-Charge
43.44. Tolling of Suspension
44.
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 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 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.

78. 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 Facilities²
(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 responsibilities shall be considered a violation of probation.

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 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 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 approval shall be 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.

### 89. 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.

### 910. 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.

### 4911. 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.

### 11.2. 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 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 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.


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 the minimum number of _______ hours in any calendar month, for any reason (including vacation), respondent shall 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. 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 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 pharmacy 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 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
48.17. 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 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 suspension shall be considered a violation of probation.

Option 4: 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.

48.19.18. 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 shall submit to the board or its designee on writing, satisfactory proof 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 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 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 resumed.

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. The 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.

49.21. **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.
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 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. 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 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 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.

24.23. 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 resume 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 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. 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 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.

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 quarterly reporting thereby on the quarterly reports, 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.) (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.
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 Services 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. 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 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. 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. 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 [insert 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
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**

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 Pharmacists 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 Pharmacists 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 11055-11058 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 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

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

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

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

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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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

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 contendere 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 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 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 least 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 an 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 to 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).

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 W arnings; 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
Chart Order Exemption for Clinic Patient; Maintaining Record for Seven Years

Exception to Triplicate Prescription Requirement

Emergency Dispensing of Schedule II Substance: Circumstances and Requirements

Oral or Electronic Prescriptions for Schedule II Controlled Substance for Specified Inpatients, Residents, and Home Hospice Patients; Requirements

Prescribing, etc. Controlled Substance Only as Authorized

Antedating or Postdating Prescription Prohibited

Prohibition on Obtaining or Possessing Nonconforming Prescription; Prohibition on Obtaining Controlled Substance by Nonconforming Prescription

Prohibition on Controlled Substance Obtained or Possessed by Nonconforming Prescription

Restrictions on Dispensing or Refilling; Refill of Schedule II Prescription Barred

Emergency Refill of Schedule III, IV, or V Prescription; Circumstances; Requirements

Maintenance and Retention of Records in Separate File

Required Information on Prescription

Delivery and Receiving Requirements for Schedule II, III, and IV Substances; Violation

Issuing Prescription: By Whom; For What Purpose; Quantity to Be Prescribed

Authorized Retail Sale by Pharmacists to Physicians, etc.; Required Order Form

Authorized Wholesale Sale by Pharmacists

Preservation of Federally Required Forms

Duration of Retention

Actions Constituting Sale

Required Report of Order By or Sale to Out-of-State Wholesaler or Manufacturer

Adulterated or Misbranded Drugs or Devices

CODE OF FEDERAL REGULATIONS, TITLE 21

Application for registration; time for application; expiration date; registration for independent activities; application forms, fees, contents and signature; coincident activities.

Filing of application; acceptance for filing; defective applications.

Security requirements generally.

Physical security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs; storage areas.

Physical security controls for non-practitioners; compounders for narcotic treatment programs; manufacturing and compounding areas.

Other security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs.

Security controls for freight forwarding facilities.

Employee screening procedures.

Employee responsibility to report drug diversion.

Illicit activities by employees.

Symbol required; exceptions.

Location and size of symbol on label and labeling.

Effective dates of labeling requirements.

Sealing of controlled substances.

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

Article 6. General Requirements

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 7. Pharmacies

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 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)
Discipline of Corporate Licensee for Conduct of Officer, Director, Shareholder

Nonresident Pharmacy: Grounds for Discipline

Out-of-state Distributor: Authority to Discipline

Disciplinary Grounds: Failure of Pharmacy, Pharmacist to Notify Board of Termination of Pharmacist in Charge; Continuing to Operate Without Pharmacist

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

Violation of Professional Corporation Act as Unprofessional Conduct

Misuse of Education, etc. by Pharmacist Outside Course of Practice of Pharmacy as Unprofessional Conduct

Article 20. Prohibitions and Offenses

Misdemeanor: Obtaining Needle or Syringe by Fraud, etc.; Unlawful Use of Needle or Syringe Obtained from Another

Misdemeanor: Permitting Compounding, Dispensing, or Furnishing by Non-pharmacist

Misdemeanor: Non-pharmacist Owner Failing to Place Pharmacist in Charge, Dispensing or Compounding Except by Pharmacist, Interfering with Pharmacist in Charge

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

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

Unlawful Advertising by Nonresident Pharmacy Not Registered with Board

Article 22. Unfair Trade Practices

Resale of Preferentially Priced Drugs; Prohibition; Exceptions

Board May Audit Sales to Walk-in Customers

CALIFORNIA CODE OF REGULATIONS, TITLE 16

Duty to Maintain Medication Profiles (Patient Medication Records)

Notice to Consumers and Duty to Consult

Duty to Review Drug Therapy and Patient Medication Record Prior to Deliver

Designation of Pharmacist in Charge

Pharmacy Operation During Temporary Absence of a Pharmacist

Self Assessment of a Pharmacy by the Pharmacist in Charge

Implementation of Electronic Monitoring of Schedule II Prescriptions

Compounding Unapproved Drugs for Prescriber Office Use

Record Requirements—Compounding for Future Furnishing

Notice of Electronic Prescription Files

Preprinted, Multiple Checkoff Prescription Blanks

Confidentiality of Examination Questions

Partial Filling of Schedule II Prescriptions

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
Prohibition on Providing False Name or Address in Connection with Prescription, etc.

Possession or Purchase for Sale of Specified Controlled Substance
Forged or Altered Prescriptions
Possession for Sale or Selling Specified Substance
Possession for Sale
Using or Being Under Influence of Controlled Substance
Manufacturing, Selling or Offering for Sale an Adulterated Drug or Device
Unlawful to Adulterate a Drug
Unlawful to Receive in Commerce an Adulterated Drug
Unlawful Manufacturer, selling a misbranded Drug
Unlawful for a Person to Misbrand
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 (Health 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 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

Importing, Selling, Furnishing Controlled Substance
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 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 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 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

For the purposes of these terms and conditions, “respondent” shall refer to [insert name], and 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.

4.2. 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 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 $ [amount]. Respondent owner shall make said payments as follows: [schedule]. 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)
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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 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 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.

40 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 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, 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.


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

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.

18. Community Services 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.

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.

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.

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.

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

§1746.5 Pharmacists Furnishing Travel Medications.

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

(1) For a condition that is both self-diagnosable and recognized as self-treatable by the federal Center for Disease Control and Prevention’s (CDC) Health Information for International Travel (commonly called the Yellow Book), or

(2) A prophylactic.

(b) A pharmacist furnishing prescription medications not requiring a diagnosis that are recommended by the CDC for individuals traveling outside the 50 states and the District of Columbia pursuant to section 4052(a)(10) of the Business and Professions Code shall follow the requirements of this section.

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

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

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

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

(4) Current basic life support certification.

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

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

(f) Notifications: The pharmacist shall notify the patient’s primary care provider of any drugs and/or devices furnished to the patient within 30 days of the date of furnishing, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by the primary care provider. If the patient does not have a primary care provider, or is unable to provide contact information for his or her primary care provider, the pharmacist shall provide the patient with written record of the drugs and/or devices furnished and advise the patient to consult a physician of the patient’s choice.

(g) Documentation: For each travel medication furnished by a pharmacist, a patient medication record shall be maintained and securely stored in physical or electronic manner such that the information required by title 42, section 300aa-25 of the United States Code and title 16, sections 1707.1 and 1717 of the California Code of Regulations is readily retrievable during the pharmacy or facility’s normal operating hours. A pharmacist shall provide the patient with a progress note, which fully documents the clinical assessment and travel medication plan. An example of an appropriate and comprehensive progress note is available on the Board’s website.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Section 4052 and 4052.8, Business and Professions Code.
Attachment 5
Drug Warnings

1744
To Amend Section 1744 of Article 5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1744. Drug Warnings

Pursuant to Business and Professions Code Section 4074, a pharmacist shall inform the patient or his or her representative of the harmful effects of certain drugs dispensed by prescription.

(a) Because the following classes of drugs may impair a person’s ability to drive or operate a motor vehicle or vessel, operate machinery when taken alone or in combination with alcohol, a pharmacist shall include a written label on the drug container indicating that the drug may impair a person’s ability to operate a vehicle or vessel:

(1) Muscle relaxants.
(2) Analgesics with central nervous system depressant effects.
(3) Antipsychotic drugs with central nervous system depressant effects including phenothiazines
(4) Antidepressants with central nervous system depressant effects.
(5) Antihistamines, motion sickness agents, antipruritics, antinauseants, anticonvulsants and antihypertensive agents with central nervous system depressant effects.
(6) All Schedule II, III, IV and V agents with central nervous system depressant effects, or narcotic controlled substances as set forth in Health and Safety Code at Section 11055 et seq, prescribed in doses which could have an adverse effect on a person’s ability to operate a motor vehicle.
(7) Anticholinergic agents and other drugs which may impair vision.
(7) Any other drug which, based on the pharmacist’s professional judgment, may impair a patient’s ability to operate a vehicle or vessel.

(b) Because the following are examples of 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 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) Monoamine 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.

Patient-Centered
Labels: Requirements
1707.5
Title 16. Board of Pharmacy
Proposed Regulations

To Amend Section 1707.5 of Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1707.5. Patient-Centered Labels for Prescription Drug Containers; Requirements.
(a) Labels on drug containers dispensed to patients in California shall conform to the following format:
   (1) Each of the following items, and only these four items, shall be clustered into one area of the label that comprises at least 50 percent of the label. Each item shall be printed in at least a 12-point sans serif typeface, and listed in the following order:
      (A) Name of the patient
      (B) Name of the drug and strength of the drug. For the purposes of this section, “name of the drug” means either the manufacturer’s trade name of the drug, or the generic name and the statement “generic for _____” where the brand name is inserted into the parentheses. If it has been at least five years since the expiration of the brand name’s patent or, if in the professional judgment of the pharmacist, the brand name is no longer widely used, the label may list only the generic name of the drug and outside of the patient centered area, the name of the manufacturer.
      (C) The directions for the use of the drug.
      (D) The condition or purpose for which the drug was prescribed if the condition or purpose is indicated on the prescription.
   (2) For added emphasis, the label shall also highlight in bold typeface or color, or use blank space to set off the items listed in subdivision (a)(1).
   (3) The remaining required elements for the label specified in section 4076 of the Business and Professions Code, as well as any other items of information appearing on the label or the container, shall be printed so as not to interfere with the legibility or emphasis of the primary elements specified in paragraph (1) of subdivision (a). These additional elements may appear in any style, font, and size typeface.
   (4) When applicable, directions for use shall use one of the following phrases:
      (A) Take 1 [insert appropriate dosage form] at bedtime
      (B) Take 2 [insert appropriate dosage form] at bedtime
      (C) Take 3 [insert appropriate dosage form] at bedtime
      (D) Take 1 [insert appropriate dosage form] in the morning
      (E) Take 2 [insert appropriate dosage form] in the morning
      (F) Take 3 [insert appropriate dosage form] in the morning
      (G) Take 1 [insert appropriate dosage form] in the morning, and Take 1 [insert appropriate dosage form] at bedtime
      (H) Take 2 [insert appropriate dosage form] in the morning, and Take 2 [insert appropriate dosage form] at bedtime
(I) Take 3 [insert appropriate dosage form] in the morning, and Take 3 [insert appropriate dosage form] at bedtime

(J) Take 1 [insert appropriate dosage form] in the morning, 1 [insert appropriate dosage form] at noon, and 1 [insert appropriate dosage form] in the evening

(K) Take 2 [insert appropriate dosage form] in the morning, 2 [insert appropriate dosage form] at noon, and 2 [insert appropriate dosage form] in the evening

(L) Take 3 [insert appropriate dosage form] in the morning, 3 [insert appropriate dosage form] at noon, and 3 [insert appropriate dosage form] in the evening

(M) Take 1 [insert appropriate dosage form] in the morning, 1 [insert appropriate dosage form] at noon, 1 [insert appropriate dosage form] in the evening, and 1 [insert appropriate dosage form] at bedtime

(N) Take 2 [insert appropriate dosage form] in the morning, 2 [insert appropriate dosage form] at noon, 2 [insert appropriate dosage form] in the evening, and 2 [insert appropriate dosage form] at bedtime

(O) Take 3 [insert appropriate dosage form] in the morning, 3 [insert appropriate dosage form] at noon, 3 [insert appropriate dosage form] in the evening, and 3 [insert appropriate dosage form] at bedtime

(P) If you have pain, take __ [insert appropriate dosage form] at a time. Wait at least __ hours before taking again. Do not take more than __ [appropriate dosage form] in one day

(b) By October 2011, and updated as necessary, the board shall publish on its Web site translation of the directions for use listed in subdivision (a)(4) into at least five languages other than English, to facilitate the use thereof by California pharmacies.

(c) The board shall collect and publish on its Web site examples of labels conforming to these requirements, to aid pharmacies in label design and compliance.

(d) The pharmacy shall have policies and procedures in place to help patients with limited or no English proficiency understand the information on the label as specified in subdivision (a) in the patient's language. The pharmacy's policies and procedures shall be specified in writing and shall include, at minimum, the selected means to identify the patient's language and to provide interpretive services and translation services in the patient's language. The pharmacy shall, at minimum, provide interpretive services in the patient's language, if interpretive services in such language are available, during all hours that the pharmacy is open, either in person by pharmacy staff or by use of a third-party interpretive service available by telephone at or adjacent to the pharmacy counter.

(e) The board shall re-evaluate the requirements of this section by December 2013 to ensure optimal conformance with Business and Professions Code section 4076.5.

(f) (e) As used in this section, “appropriate dosage form” includes pill, caplet, capsule or tablet.

Note: Authority cited: Sections 4005 and 4076.5, Business and Professions Code. Reference: Sections 4005, 4076 and 4076.5, Business and Professions Code.
Reconciliation and Inventory of Controlled Substances - 1715.65
Adopt section 1715.65 in Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

**1715.65. Reconciliation and Inventory Report of Controlled Substances**

(a) Every pharmacy, and every clinic licensed under sections 4180 or 4190, shall perform reconciliation and inventory functions to prevent the loss of controlled substances.

(b) The pharmacist-in-charge of a pharmacy or consultant pharmacist for a clinic shall review all reconciliations and inventories taken, and establish and maintain secure methods to prevent losses of controlled drugs. Written policies and procedures shall be developed for performing the reconciliation and inventory reports required by this section.

(c) Perform a Periodic Inventory: A pharmacy or clinic shall compile an Inventory Report of specific controlled substances at least every three months. The compilation of this Inventory Report shall require a physical count, not an estimate, of all quantities of federal Schedule II controlled substances and at least one additional controlled substance which may be specified by the board each year as based upon loss reports made to the board in the prior year. The Inventory Report shall be dated and signed by the individual(s) performing the inventory, and countersigned by the pharmacist-in-charge or consultant pharmacist.

(1) The original or copy of the signed controlled substances Inventory Report shall be kept in the pharmacy or clinic and be readily retrievable for three years.

(2) The biennial inventory of controlled substances required by federal law may serve as one of the mandated inventories under this section in the year where the federal biennial inventory is performed, provided:

   (A) A physical count of all controlled substances is performed, not an estimated count of how much medication is in a container.

   (B) The federal Drug Enforcement Administration biennial inventory was taken no more than three months from the last inventory required by this section.

(d) A new pharmacist-in-charge of the pharmacy shall complete an inventory as required by subdivision (c) within 30 days of becoming pharmacist-in-charge. Whenever possible an outgoing pharmacist-in-charge should complete an inventory as required in subdivision (c).

(e) Reconciliation with Inventory Report: The pharmacy or clinic shall review all acquisitions and dispositions of controlled substances as part of the inventory process to determine the expected stock of each controlled substance on hand, based on the prior Inventory Report. Records used to compile each reconciliation shall be maintained in the pharmacy or clinic for at least three years in a readily retrievable form.

(1) Losses shall be identified in writing and reported to the board and, when appropriate, to the Drug Enforcement Administration.

(2) Likely causes of overages shall be identified in writing and retained.
(3) Should the reconciliation identify controlled substances which had been in the inventory of the pharmacy or clinic during the prior six-month period, but for which there is no stock at the time of the physical count, the pharmacist-in-charge or consultant pharmacist shall determine there has been a loss of these controlled substances. These losses shall be reported in the manner specified by paragraph 1.

(f) Adjustments to the Inventory Report shall be made following reconciliation, only after the reporting and documenting of any losses or accounting made for overages.

(1) Each adjustment to the Inventory Report made to correct the stock on hand count shall be annotated to show any adjustment in the number of controlled substances on hand in the pharmacy or clinic, and who made the annotation, and the date.

(2) The pharmacist-in-charge or consultant pharmacist shall countersign the adjusted Inventory Report.

(3) The original Inventory Report and amended Inventory Report following reconciliation shall be readily retrievable in the pharmacy or clinic for three years.

(g) The pharmacist-in-charge of a hospital pharmacy or of a pharmacy servicing skilled nursing homes where an automated drug delivery system is in use shall review at least once each month all controlled substances removed from or added into each automated drug delivery machine operated by the pharmacy. Any discrepancy or unusual access identified shall be investigated. Controlled drugs inappropriately accessed or removed from the automated delivery shall be reported to the board within 14 days.

(h) A pharmacy or clinic identifying losses of controlled drugs but unable to identify the cause within 30 days shall take additional steps to identify the origin of the losses, including installation of cameras, relocation of the controlled drugs to a more secure location within the pharmacy, or daily inventory counts of the drugs where shortages are continuing.

Board Accredited
Continuing Education -
1732.02, 1732.02,
and 1732.5
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.

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.

Proposal to amend § 1732.5 of Article 4 of Division 17 of Title 16 of the California Code of Regulations to read:

§1732.5  Renewal Requirements for Pharmacists

(a) Except as provided in Section 4234 of the Business and Professions Code and Section 1732.6 of this Division, each applicant for renewal of a pharmacist license shall submit proof satisfactory to the board, that the applicant has completed 30 hours of continuing education in the prior 24 months.

(b) At least six (6) of the thirty (30) hours required for pharmacist license renewal shall be completed in one or more of the following subject areas:

1. Emergency/Disaster Response
2. Patient Consultation
3. Maintaining Control of a Pharmacy’s Drug Inventory
4. Ethics
5. Substance Abuse, Including Indications of Red Flags and a Pharmacist’s Corresponding Responsibility
6. Compounding

Pharmacists renewing their licenses which expire on or after July 1, 2018, shall be subject to the requirements of this subdivision.

(b)-(c) All pharmacists shall retain their certificates of completion for four (4) years following completion of a continuing education course.

Attachment 6
Self-Administered Hormonal Contraception
Adopt §1746.1 of Article 5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1746.1 Protocol for Pharmacists Furnishing Self-Administered Hormonal Contraception.

(a) A pharmacist furnishing self-administered hormonal contraception pursuant to Section 4052.3 of the Business and Professions Code shall follow the protocol specified in subdivision (b) of this section.

(b) Protocol for Pharmacists Furnishing Self-Administered Hormonal Contraception

(1) Authority: Section 4052.3(a)(1) of the California Business and Professions Code authorizes a pharmacist to furnish self-administered hormonal contraceptives in accordance with a protocol approved by the California State Board of Pharmacy and the Medical Board of California. Use of the protocol in this section satisfies that requirement.

(2) Purpose: To provide timely access to self-administered hormonal contraception medication and to ensure that the patient receives adequate information to successfully comply with therapy.

(3) Definition of Self-Administered Hormonal Contraception: Hormonal contraception products with the following routes of administration are considered self-administered:

(A) Oral;
(B) Transdermal;
(C) Vaginal;
(D) Depot Injection.

(4) Procedure: When a patient requests self-administered hormonal contraception, the pharmacist shall complete the following steps:

(A) Ask the patient to use and complete the self-screening tool;
(B) Review the self-screening answers and clarify responses if needed;
(C) Measure and record the patient’s seated blood pressure if combined hormonal contraceptives are requested or recommended.
(D) Before furnishing self-administered hormonal contraception, the pharmacist shall ensure that the patient is appropriately trained in
administration of the requested or recommended contraceptive medication.

(E) When a self-administered hormonal contraceptive is furnished, the patient shall be provided with appropriate counseling and information on the product furnished, including:

(i) Dosage;
(ii) Effectiveness;
(iii) Potential side effects;
(iv) Safety;
(v) The importance of receiving recommended preventative health screenings;
(vi) That self-administered hormonal contraception does not protect against sexually transmitted infections (STIs).

(5) Self-Screening Tool: The pharmacist shall provide the patient with a self-screening tool containing the list of questions specified in this protocol. The patient shall complete the self-screening tool, and the pharmacist shall use the answers to screen for all Category 3 and 4 conditions and characteristics for self-administered hormonal contraception from the current United States Medical Eligibility Criteria for Contraceptive Use (USMEC) developed by the federal Centers for Disease Control and Prevention (CDC). The patient shall complete the self-screening tool annually, or whenever the patient indicates a major health change.

A copy of the most recently completed self-screening tool shall be securely stored within the originating pharmacy or health care facility for a period of at least three years from the date of dispense.

This self-screening tool should be made available in alternate languages for patients whose primary language is not English.

(6) Fact Sheet: The pharmacist shall provide the patient with the FDA-required patient product information leaflet included in all self-administered hormonal contraception products, as required by the Business and Professions Code Section 4052.3(c). The pharmacist shall answer any questions the patient may have regarding self-administered hormonal contraception.

Pharmacists should provide the patient with a copy of a current consumer-friendly comprehensive birth control guide such as that created by the FDA, and a copy of an administration-specific factsheet; examples of appropriate guides and factsheets are available on the Board of Pharmacy’s website.

(7) Follow-Up Care: Upon furnishing a self-administered hormonal contraceptive, or if is determined that use of a self-administered hormonal contraceptive is not recommended, the pharmacist shall refer the patient for appropriate follow-up care to the patient’s primary care provider or, if the patient does not have a primary care
provider, to nearby clinics. A patient who is determined not to be an appropriate candidate for self-administered hormonal contraception shall be advised of the potential risk and referred to an appropriate health care provider for further evaluation.

(8) Notifications: The pharmacist shall notify the patient’s primary care provider of any drug(s) or device(s) furnished to the patient, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by that primary care provider. If the patient does not have a primary care provider, or is unable to provide contact information for his or her primary care provider, the pharmacist shall provide the patient with a written record of the drug(s) or device(s) furnished and advise the patient to consult an appropriate health care professional of the patient’s choice.

(9) Referrals and Supplies: If self-administered hormonal contraception services are not immediately available or the pharmacist declines to furnish pursuant to a conscience clause, the pharmacist shall refer the patient to another appropriate health care provider.

The pharmacist also shall comply with all state mandatory reporting laws, including sexual abuse laws.

(10) Product Selection: The pharmacist, in consultation with the patient, may select any hormonal contraceptive listed in the current version of the USMEC for individuals identified as Category 1 or 2, based on the information reported in the self-screening tool and the blood pressure (if recorded by the pharmacist). The USMEC shall be kept current and maintained in the pharmacy or health care facility, and shall be available on the Board of Pharmacy’s website.

Generic equivalent products may be furnished.

(11) Documentation: Each self-administered hormonal contraceptive furnished by a pharmacist pursuant to this protocol shall be documented in a patient medication record and securely stored within the originating pharmacy or health care facility for a period of at least three years from the date of dispense. A patient medication record shall be maintained in an automated data processing or manual record mode such that the required information under title 16, sections 1717 and 1707.1 of the California Code of Regulations is readily retrievable during the pharmacy or facility’s normal operating hours.

(12) Training: Prior to furnishing self-administered hormonal contraception, pharmacists who participate in this protocol must have completed a minimum of one hour of a board-approved continuing education program specific to self-administered hormonal contraception, application of the USMEC, and other CDC guidance on contraception. An equivalent curriculum-based training program
completed on or after the year 2014 in an accredited California school of pharmacy is also sufficient training to participate in this protocol.

(13) Patient Privacy: All pharmacists furnishing self-administered hormonal contraception in a pharmacy or health care facility shall operate under the pharmacy or facility’s policies and procedures to ensure that patient confidentiality and privacy are maintained.

(14) Self-Screening Tool Questions

<table>
<thead>
<tr>
<th></th>
<th>HORMONAL CONTRACEPTION SELF-ScreenING TOOL QUESTIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>What was the first date of your last menstrual period?</td>
</tr>
<tr>
<td>2a</td>
<td>Have you ever taken birth control pills, or used a birth control patch, ring, or shot/injection? (If no, go to question 3)</td>
</tr>
<tr>
<td>2b</td>
<td>Did you ever experience a bad reaction to using hormonal birth control?</td>
</tr>
<tr>
<td>2c</td>
<td>Are you currently using birth control pills, or a birth control patch, ring, or shot/injection?</td>
</tr>
<tr>
<td>3</td>
<td>Have you ever been told by a medical professional not to take hormones?</td>
</tr>
<tr>
<td>4</td>
<td>Do you smoke cigarettes?</td>
</tr>
<tr>
<td>5</td>
<td>Do you think you might be pregnant now?</td>
</tr>
<tr>
<td>6</td>
<td>Have you given birth within the past 6 weeks?</td>
</tr>
<tr>
<td>7</td>
<td>Are you currently breastfeeding an infant who is less than 1 month of age?</td>
</tr>
<tr>
<td>8</td>
<td>Do you have diabetes?</td>
</tr>
<tr>
<td>9</td>
<td>Do you get migraine headaches, or headaches so bad that you feel sick to your stomach, you lose the ability to see, it makes it hard to be in light, or it involves numbness?</td>
</tr>
<tr>
<td>10</td>
<td>Do you have high blood pressure, hypertension, or high cholesterol?</td>
</tr>
<tr>
<td>11</td>
<td>Have you ever had a heart attack or stroke, or been told you had any heart disease?</td>
</tr>
<tr>
<td>12</td>
<td>Have you ever had a blood clot in your leg or in your lung?</td>
</tr>
<tr>
<td>13</td>
<td>Have you ever been told by a medical professional that you are at a high risk of developing a blood clot in your leg or in your lung?</td>
</tr>
<tr>
<td>14</td>
<td>Have you had bariatric surgery or stomach reduction surgery?</td>
</tr>
<tr>
<td>15</td>
<td>Have you had recent major surgery or are you planning to have surgery in the next 4 weeks?</td>
</tr>
<tr>
<td>16</td>
<td>Do you have or have you ever had breast cancer?</td>
</tr>
<tr>
<td>17</td>
<td>Do you have or have you ever had hepatitis, liver disease, liver cancer, or gall bladder disease, or do you have jaundice (yellow skin or eyes)?</td>
</tr>
<tr>
<td>18</td>
<td>Do you have lupus, rheumatoid arthritis, or any blood disorders?</td>
</tr>
<tr>
<td>19a</td>
<td>Do you take medication for seizures, tuberculosis (TB), fungal infections, or human immunodeficiency virus (HIV)?</td>
</tr>
<tr>
<td>19b</td>
<td>If yes, list them here:</td>
</tr>
<tr>
<td>20</td>
<td>Do you have any other medical problems or take regular medication?</td>
</tr>
<tr>
<td>----</td>
<td>----------------------------------------------------------</td>
</tr>
<tr>
<td></td>
<td>If yes, list them here:</td>
</tr>
</tbody>
</table>

Authority: Sections 4005, 4052, and 4052.3, Business and Professions Code. Reference: Sections 4022, 4052, 4052.3, 4052.9, 4081, 4103, 4105, 4231, and 4232 Business & Professions Code.
Attachment 7
Section 100
Requirements
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.
Renewal Requirements
Board of Pharmacy

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

1702. Pharmacist Renewal Requirements
(a) A pharmacist applicant for renewal who has not previously submitted fingerprints as a condition of licensure or for whom an electronic record of the licensee’s fingerprints does not exist in the Department of Justice’s criminal offender record identification database shall successfully complete a state and federal level criminal offender record information search conducted through the Department of Justice by the licensee’s or registrant’s renewal date that occurs on or after December 7, 2010.

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

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

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

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

(b) As a condition of renewal, a pharmacist applicant shall disclose on the renewal form whether he or she has been convicted, as defined in Section 490 of the Business and Professions Code, of any violation of the law in this or any other state, the United States, or other country, since his or her last renewal. 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 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, 2014.

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

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

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

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

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

(c) As a condition of renewal, a pharmacy technician applicant shall disclose on the renewal form any disciplinary action against any license issued to the applicant by a government agency. For the purposes of this section, “disciplinary action” means an adverse licensure or certification action that resulted in a restriction or penalty against the license or certification such as revocation, suspension, probation or public reprimand or 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, 2014.

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

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

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

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

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

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

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

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

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

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

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

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

Authority: Section 4005, Business and Professions Code. Reference: Sections 4112, 4161, 4300, and 4301, Business and Professions Code
Third Party Logistics Providers
Article 10. Wholesalers-Dangerous Drug Distributors

1780. Minimum Standards for **Wholesalers**
The following minimum standards shall apply to all wholesale and third-party logistics provider establishments for which permits have been issued by the Board:

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

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

(c) Entry into areas where prescription drugs are held shall be limited to authorized personnel.
   (1) All facilities shall be equipped with an alarm system to detect entry after hours.
   (2) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.
   (3) The outside perimeter of the wholesaler premises shall be well-lighted.

(d) All materials must be examined upon receipt or before shipment.
   (1) Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated prescription drugs or prescription drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.
   (2) Each outgoing shipment shall be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have been damaged in storage or held under improper conditions.

(e) The following procedures must be followed for handling returned, damaged and outdated prescription drugs.
   (1) Prescription drugs that are outdated, damaged, deteriorated, misbranded or adulterated shall be placed in a quarantine area and physically separated from other drugs until they are destroyed or returned to their supplier.
   (2) Any prescription drugs whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be placed in a quarantine area and physically separated from other prescription drugs until they are either destroyed or returned to the supplier.
   (3) If the conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality or purity, the drug shall be destroyed or returned to the supplier unless testing or other investigation proves that the drug meets appropriate United States Pharmacopeia Standards (1990, 22nd Revision).

(f) Policies and procedures must be written and made available upon request by the board.
   (1) Wholesale and third-party logistics provider drug distributors shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory and distribution of prescription drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, for correcting all errors and inaccuracies in inventories, and for maintaining records to document proper storage.
(2) The records required by paragraph (1) shall be in accordance with Title 21, Code of Federal Regulations, Section 205.50(g). These records shall be maintained for three years after disposition of the drugs.

(3) Wholesale and third-party logistics provider drug distributors shall establish and maintain lists of officers, directors, managers and other persons in charge of wholesale drug distribution, storage and handling, including a description of their duties and a summary of their qualifications.

(4) Each wholesaler and third-party logistics provider shall provide adequate training and experience to assure compliance with licensing requirements by all personnel.

(g) The board shall require an applicant for a licensed premise or for renewal of that license to certify that it meets the requirements of this section at the time of licensure or renewal.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4043, 4051, 4053, 4054, 4059, 4120, 4160, 4161 and 4304, Business and Professions Code.


Not relevant to third-party logistics providers

1781. Exemption Certificate.

A registered pharmacist, or a 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.

1782. Reporting Sales of Drugs Subject to Abuse.

All manufacturers, and wholesalers and third-party logistics providers shall report to the Board or its designee, up to twelve (12) times a year, all sales of dangerous drugs subject to abuse as designated by the Board for reporting, in excess of amounts to be determined by the Board from time to time. Reports shall be made within thirty (30) days of the request in the form specified by the Board.

Authority cited: Section 4005, Business and Professions Code; and Section 26692, Health and Safety Code. Reference: Sections 4081 and 4332, Business and Professions Code; and Section 26692, Health and Safety Code.

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 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 if (1) the identity and authorization of the recipient is properly established and (2) this method of receipt is employed only to meet the immediate needs of a particular patient of the authorized person. Dangerous drugs or devices may be furnished to a hospital pharmacy receiving area provided that a pharmacist or authorized receiving personnel signs, at the time of delivery, a receipt showing the type and quantity of the dangerous drugs or devices so received. Any discrepancy between the receipt and the type and quantity of dangerous drugs and devices actually received shall be reported to the delivering manufacturer, or wholesaler or third-party logistics provider by the next business day after the delivery to the pharmacy receiving area.

(d) A manufacturer, or wholesaler or third-party logistics provider shall not accept payment for or allow the use of an entity's credit to establish an account for the purchase of dangerous drugs or devices from any person other than: (1) the owner(s) of record, chief executive officer, or chief financial officer listed on the permit for the authorized person; and (2) on an account bearing the name of the permittee.

(e) All records of dangerous drugs or devices furnished by a manufacturer, or wholesaler or third-party logistics provider to an authorized person shall be preserved by the authorized person for at least three years from the date of making and shall, at all times during business hours, be open to inspection by authorized officers of the law at the licensed premises. The manufacturer, or wholesaler or third-party logistics provider shall also maintain all records of dangerous drugs or devices furnished pursuant to this section for at least three years from the date of making and shall, at all times during business hours, keep them open to inspection by authorized officers of the law at the premises from which the dangerous drugs or devices were furnished.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4043, 4059, 4059.5, 4080, 4081, 4120, 4160, 4161, 4163 and 4304, Business and Professions Code; and Section 11209, Health and Safety Code.

1784. Self-Assessment of a Wholesaler by the Designated Representative-in-Charge.

This section will be modified to also establish a self assessment process for the third-party logistics provider by the responsible manager. The changes have not been incorporated below

(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. 01/11) 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 cited: Section 4005, Business and Professions Code. Reference: Sections 4022.5, 4043, 4053, 4059, 4120, 4160, 4161, 4201, 4301 and 4305.5, Business and Professions Code.