



## LEGISLATION AND REGULATION COMMITTEE

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

### LEGISLATION AND REGULATION COMMITTEE REPORT

The Legislation and Regulation Committee met on March 24, 2016. The minutes of the meeting are provided in **Attachment 1**.

#### **Part 1: LEGISLATION REPORT**

##### **a. Board Sponsored Legislation**

###### SB 1193 (Hill) California State Board of Pharmacy: Executive Officer

Version: April 13, 2016 - Amended  
Location: Senate Appropriations  
Status: Passed from Senate Business Professions and Economic Development  
(April 18, 2016)

As introduced, the 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.

Recently, the bill has been amended to incorporate additional provisions that would

- Establish the regulatory framework for the licensure of resident and nonresident outsourcing facilities (board-sponsored provisions)
- Require the issuance of a clinic license within 30 days of a completed application, as specified,
- Add licensed pharmacists as one of the individuals that are authorized to be in a professional medical corporation
- Authorize the board to issue a cease and desist order for unlicensed activity, as specified, and
- Require a health facility to register the use of the automated drug delivery system with the board, as specified.

A copy of the bill and a staff analysis are provided in **Attachment 2**.

Committee recommendation: Support Senate Bill 1193 (Introduced version)

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

Copies of each bill and related documents are provided in **Attachment 3**.

1. AB 45 (Mullin) Household Hazardous Waste

Version: January 21, 2016 Amended

Location: Senate Environmental Quality Committee

Position: Oppose Unless Amended (Ver: 4/30/15)

The bill adds Article 3.4 "Household Hazardous Waste Collection and Reduction" to the Public Resources Code and 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 (to include home-generated pharmaceutical 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."

AB 45 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.

Committee Recommendation: Maintain position of Oppose Unless Amended for the January 21, 2016 version.

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

Version: July 1, 2015 Amended

Location: Senate Appropriations Committee (July 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.

The committee concurred with comments from proponents that believe Advanced Practice Pharmacists would be well positioned to furnish the auto-injectors, thereby expanding access to those who need them.

Committee Recommendation: Support AB 1386, and offer amendments to allow pharmacists to provide the auto-injectors

4. AB 1977 (Wood) Health Coverage: Abuse-Deterrent Opioid Analgesic

Version: As Amended April 13, 2016

Location: Assembly Health

As amended, AB 1977 makes declarations regarding the abuse and misuse of opioids. The bill would create the Opioid Abuse Task Force that would require health care service plans and health insurer representatives, in collaboration with advocates, experts, health care professionals, and other entities and stakeholders to convene a task force, develop recommendations regarding the abuse and misuse of opioids, as specified, and

requires the task force to report its findings to the Governor and specified Legislators and committees on or before December 31, 2017.

5. AB 2144 (Rodriguez) Pharmacy: Prescriptions

Version: March 18, 2016

Location: Assembly Health

AB 2144 would amend section 4074 of the Business and Professions Code to specify that a health facility shall require each patient to acknowledge in writing that a patient has received specified drug warning, storage and other specified information at the time of discharge.

Committee Recommendation: Support AB 2144

6. AB 2592 (Cooper) Prescriptions

Version: April 11, 2016 Amended

Location: Assembly Appropriations

The author's office has advised that this bill is a spot bill. As amended this measure will require the Department of Public Health, if funding is available, to create a pilot program to award grants to combat opioid abuse through the safe prescribing of opioids. The measure would specify that a pharmacy that applies for and receives a grant shall offer all patients who are prescribed an opioid with a medicine locking closure package if a patient consents. The bill defines a medicine locking closure package as one that can only be unlocked with a user generated, resettable alphanumeric code. This measure requires CDPH to evaluate the effectiveness of the pilot program and report its findings to the Legislature no later than December 31, 2019.

The committee reviewed the prior amended version, but did not recommend a position.

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

Version: As Amended April 7, 2016

Location: Assembly Rules Committee

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.

This measure was amended after the committee meeting. Recent amendments to this measure include additional conditions under which the provisions to check the systems do not apply. Such conditions include specifying that a prescriber is not required to check the system if it is not available, if the patient is in hospice and if the prescription is for use as part of a medical procedure.

Committee Recommendation: Support SB 482.

8. SB 1217 (Stone) Healing Arts: Reporting Requirements: Professional Liability

Version: April 12, 2016

Location: Senate Business, Professions and Economic Development

Status: This measure failed in committee on April 18, 2016. Reconsideration was granted.

As initially introduced this measure would have increased 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.

This measure was recently amended and now only applies to the Board of Pharmacy.

Committee Recommendation: None

9. SB 1229 (Senator Jackson and Assembly Member Stone) Home-Generated Pharmaceutical Waste: Secure Drug Take-Back Bins

Version: Amended March 28, 2016

Location: Senate Floor

Hearing: Do Pass From Senate Environmental Quality

The bill in its current form includes legislative findings and declarations and findings surrounding the disposal of unused medications, including controlled substances and actions taken by the Drug Enforcement Agency. Further this measure provided legislative intent to encourage good faith participation in drug take-back programs and provides the liability protections for specified entities that that provide drug take-back bins on its premises if the entity under specified conditions. The provisions apply to pharmaceutical products including prescription and over-the-counter human and veterinary drugs.

Committee Recommendation: The committee does not have a recommendation on this measure as the (3/28) amendments were not yet available.

10. SB 1230 (Stone) Pharmacies: Compounding

Version: February 18, 2016 Introduced

Location: Senate Business, Professions and Economic Development

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. Board staff has been advised that this measure was held in committee at request of the author's office.

11. SB 1346 (Allen) Pharmacists: Drug Labeling: Medication Guides: Electronic Delivery

Board staff was advised by the author's office that this measure will not be moving as it was determined that legislation isn't necessary. The author's office requested that the board complete some education of our licensees about this issue.

Given that this measure is not moving neither a bill nor analysis is provided.

12. SB 1454 (Stone) Pharmacy

This measure was amended March 31, 2016 and now relates to pharmacy benefit management. As such neither the bill nor analysis is provided.

**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.

Committee recommendation: Maintain Oppose position

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

Version: As Amended March 28, 2016

Location: Senate Appropriations

Hearing: April 25, 2016

This bill would require every board within the Department of Consumer Affairs to grant a fee waiver for the application and for the issuance of an initial license to an individual who is an honorably discharged veteran.

Committee Recommendation: The committee did not discuss this matter.

3. SB 1195 (Hill) Professions and Vocations: Board Actions: Competitive Impact

Version: As Amended April 6, 2016

Location: Senate Business, Professions and Economic Development

Hearing: April 18, 2016

This bill would grant authority to the DCA director to review a decision or other action, except as specified, of a board within the DCA to determine whether it unreasonably restrains trade and to approve, disapprove, or modify the board decision or action, as specified. It clarifies when a judgment or settlement for treble damages antitrust award would be granted for a member of a regulatory board; and provides for an additional standard for the Office of Administrative Law to follow when reviewing regulatory actions of state boards.

**d. Legislative Items for Future Meeting**

## **Part 2: Regulation Report**

### **a. Newly Effective Regulation**

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

On April 8, 2016, the Office of Administrative Law approved the board's rulemaking to add Section 1746.1 to Title 16 of the CCR related to Self-Administered Hormonal Contraception. The regulation went into effect on April 8, 2016. Board staff issued a subscriber alert and press release announcing the approval and effective date of the regulation. The board's Executive Officer has participated in a number of media interviews on the subject.

A copy of the approved regulation language and the subscriber alert is provided in **Attachment 4**.

### **b. Board Approved – Submitted for Administrative Review by the Department of Consumer Affairs or the Office of Administrative Law**

#### **1. Proposed Regulations to Amend Title 16 CCR sections 1715 and 1784 to Update Self-Assessment Forms 17M-13, 17M-14, and 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. OAL has 30 working days to review and submit it to the Secretary of State for filing or disapprove the regulation (April 22, 2016). An update will be provided at the Board meeting. A copy of the approved regulation language is provided in **Attachment 5**.

#### **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 CCR 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 on January 29, 2016 for final review. A copy of the approved regulation language is provided in **Attachment 5**.

**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 5**.

**4. Proposed Regulations to Add Title 16 CCR sections 1730 and 1730.1 related to Advanced Practice Pharmacist**

In July 2015, the board initiated a formal rulemaking to add Section 1730 to Title 16 of the CCR related to the licensing requirements for advanced practice pharmacist. On February 25, 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 18, 2016. A copy of the approved regulation language is provided in **Attachment 5**.

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

In November 2015, the board initiated a formal rulemaking to add Section 1730.2 of Title 16 of the CCR, establishing the certification program criteria for advanced practice pharmacist. On February 25, 2016, following the completion of a 45-day comment period, the board adopted the final regulation text. The final rulemaking file was submitted to the Department of Consumer Affairs for final review on March 21, 2016. A copy of the approved regulation language is provided in **Attachment 5**.

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

**1. 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 initiate a formal rulemaking to amend the text of 16 CCR Sections 1732.05, 1732.2, and 1732.5 expanding the continuing education criteria. At the October 2014 board meeting, the board 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 voted to add “Including Indicated of Red Flags and a Pharmacist’s Corresponding Responsibility” to area five “Substance Abuse”. During the February 25, 2016 board meeting, based on comments received during the 45-day comment period and regulation hearing, 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 6**.

**d. Board Approved – Awaiting Notice**

**1. Proposed Regulations to Amend Title 16 CCR section 1703 (Title 1, CCR, Section 100 changes and Approval of Waivers Submitted Pursuant to Business and Professions Code Section 4076.5)**

At the October 2013 Board Meeting, the board approved proposed text to amend Section 1703 of Title 16 of the CCR 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 Title 16 CCR sections 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 CCR 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 related to Third-Party Logistics Providers**

At the July 2015 Board Meeting, the board approved proposed text to amend Sections 1780 et seq. to Title 16 of the CCR to add Third-Party Logistics Providers. Board staff is preparing the required notice documents and anticipates initiating the rulemaking process during the next several weeks.

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

# **Attachment 1**



**California State Board of Pharmacy**

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

**STATE BOARD OF PHARMACY  
DEPARTMENT OF CONSUMER AFFAIRS  
LEGISLATION AND REGULATION COMMITTEE MEETING  
MINUTES**

**DATE:** March 24, 2016

**LOCATION:** Department of Consumer Affairs  
1625 North Market Blvd., First Floor Hearing Room  
Sacramento, CA 95834

**STAFF  
PRESENT:** Virginia Herold, Executive Officer  
Anne Sodergren, Assistant Executive Officer  
Laura Freedman, DCA Staff Counsel  
Lori Martinez, Staff Manager  
Laura Hendricks, Staff Analyst

**BOARD MEMBERS  
PRESENT:** Gregory Lippe, Chairperson  
Albert Wong, PharmD  
Deborah Veale, RPh  
Ramon Castellblanch, PhD., Public Member  
Lavanza Butler, RPh

**BOARD MEMBERS  
NOT PRESENT:**

**Thursday, March 24, 2016**

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

Chairperson Lippe called the meeting to order at 8:30 a.m.

Board members present: Gregory Lippe, Ramon Castellblanch, Lavanza Butler and Deborah Veale.

Note: Albert Wong arrived at 8:40 a.m.

**II. Public Comments on Items Not on the Agenda**

Pat Whalen, representing NHA, asked if the committee would be discussing SB 952. Ms. Sodergren explained that SB 952 would be discussed at the March 30, Licensing Committee meeting.

**III. 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

Chairperson Lippe explained that 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.

Ms. Herold stated that this is the board’s Sunset bill and asked the committee to support the bill.

Steve Gray, representing Kaiser, offered his support of the bill. Mr. Gray asked if there was a hearing scheduled for the bill. Ms. Herold stated that there was no hearing scheduled yet.

Mr. Gray asked how the public could find out what concerns that the Senate Business Professions and Economic Development committee had with the board’s Sunset Report. Ms. Sodergren explained that this information could be found in the Senate Business Professions and Economic Development Committee Report.

Mr. Castellblanch asked how many terms a member could be appointed for. Ms. Herold explained that a member could serve two full terms. She added that if a member takes over for someone who left their position before their term ended, they could serve the remainder of that term and two full additional terms.

**Motion:** Support SB 1193

**M/S:** Veale/Butler

**Support:** 5

**Oppose:** 0

**Abstain:** 0

| Name          | Support | Oppose | Abstain | Not Present |
|---------------|---------|--------|---------|-------------|
| Butler        | x       |        |         |             |
| Castellblanch | x       |        |         |             |
| Lippe         | x       |        |         |             |

|       |   |  |  |  |
|-------|---|--|--|--|
| Veale | x |  |  |  |
| Wong  | x |  |  |  |

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

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)

Chairperson Lippe stated that 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.

Chairperson Lippe explained that 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.”

Chairperson Lippe reported that 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.

Chairperson Lippe added that 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.

Ms. Herold reported that staff has made appointments with the author’s office to discuss the bill, but their staff has been unavailable. Ms. Herold recommended keeping the board’s position on the prior version of the bill (oppose unless amended).

Dr. Wong stated that pharmacies are taking steps to create take-back programs for their customers. He referenced a recent news article that Walgreens will be adding take-back receptacles at many of their locations.

Dr. Gray, from Kaiser, asked for clarification on the mail back requirement in the bill.

Ms. Sodergren explained that this bill is not specific to pharmaceutical products; it applies to all household hazardous waste. She explained that the board would want mail back for prescription drugs.

Dr. Gray asked if this bill is intended to preempt local ordinances. Ms. Sodergren stated that the bill is not intended to preempt local ordinances. Ms. Herold noted that many local ordinances are opposed to this AB 45.

**Motion:** Oppose AB 45 unless amended.

**M/S:** Veale/Butler

**Support:** 5

**Oppose:** 0

**Abstain:** 0

| Name          | Support | Oppose | Abstain | Not Present |
|---------------|---------|--------|---------|-------------|
| Butler        | x       |        |         |             |
| Castellblanch | x       |        |         |             |
| Lippe         | x       |        |         |             |
| Veale         | x       |        |         |             |
| Wong          | x       |        |         |             |

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

Chairperson Lippe explained that 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.

Chairperson Lippe reported that 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.

Chairperson Lippe concluded that staff continues to reach out to the author’s office.

There were no comments from the committee or from the public.

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

Chairperson Lippe reported that 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. Chairperson Lippe clarified that 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.

Chairperson Lippe explained that 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.

Brian Warren, representing CPHA, stated they support the bill. He added that in the future they would like to see pharmacists being able to furnish these without a doctor needing to be involved. The committee agreed that Advanced Practice Pharmacists would be well positioned to furnish the auto-injectors thus expanding access to those who need them.

Dr. Gray, representing CSHP offered their support of the bill. He noted that CSHP would work with the author to see if they will amend the bill to allow pharmacists to furnish the auto-injectors.

**Motion:** Support AB 1386. Offer amendments allowing pharmacists to furnish the auto-injectors.

**M/S:** Veale/Butler

**Support:** 5

**Oppose:** 0

**Abstain:** 0

| Name          | Support | Oppose | Abstain | Not Present |
|---------------|---------|--------|---------|-------------|
| Butler        | x       |        |         |             |
| Castellblanch | x       |        |         |             |
| Lippe         | x       |        |         |             |
| Veale         | x       |        |         |             |
| Wong          | x       |        |         |             |

Ms. Veale stated that if this bill does not pass or passes without allowing pharmacists to furnish the auto-injectors the board should sponsor legislation next year.

4. AB 1977 (Wood) Health Coverage: Abuse-Deterrent Opioid Analgesics

Version: February 16, 2016 Introduced

Location: Referred to Assembly Health

Chairperson Lippe explained that 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.

Chairperson Lippe stated that 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. He concluded that board staff will continue to monitor this measure and will bring it to the full board during the April Board Meeting if appropriate.

There were no comments from the committee or from the public.

5. AB 2144 (Rodriguez) Pharmacy: Prescriptions

Version: February 17, 2016 Introduced

Amended March 18, 2016 in Assembly Health

Chairperson Lippe reported that as amended this measure would amend Section 4074 of the Business and Professions Code to specify that a health facility shall require each patient to acknowledge in writing that a patient has received specified drug warning, storage and other specified information at the time of discharge.

Dr. Castellblanch stated that he supports this bill as it promotes patient's knowledge of their medication. Chairperson Lippe stated he also supports this bill.

Dr. Gray, representing Kaiser, stated that there could be some technical issues with this bill, for example if the patient cannot sign the acknowledgement who can sign on their behalf.

Ms. Herold stated that currently many patients don't get any information on their medication when they are discharged from the hospital.

Mr. Warren representing CPHA reminded the committee that this is a spot bill.

**Motion:** Support AB 2144.

**M/S:** Castellblanch/Veale

**Support:** 5

**Oppose:** 0

**Abstain:** 0

| Name          | Support | Oppose | Abstain | Not Present |
|---------------|---------|--------|---------|-------------|
| Butler        | x       |        |         |             |
| Castellblanch | x       |        |         |             |
| Lippe         | x       |        |         |             |
| Veale         | x       |        |         |             |
| Wong          | x       |        |         |             |

6. AB 2592 (Cooper) Prescriptions

Version: February 19, 2016 Introduced  
Amended March 18, 2016 in Assembly Health

Chairperson Lippe reported that as amended this measure will require the Department of Public Health, if funding is available, to create an Opioid Abuse Prevention Pilot Program to award grants. Further, this measure would specify that a pharmacy that applies for and receives a grant shall offer all patients who are prescribed an opioid with a medicine locking closure package if a patient consents. Further, this section defines a medicine locking closure package as one that can only be unlocked with a user generated, resettable alphanumeric code. This measure includes a sunset date for this pilot project.

Note: Dr. Castellblanch recused himself from the discussion.

The committee briefly discussed the bill, but took no position.

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

Version: April 30, 2015  
Location: Held at Assembly Desk (5/28/15)

Chairperson Lippe explained that 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.

The committee expressed their support of this bill stating that prescribers should be checking CURES to ensure that patients are not doctor shopping.

Ms. Sodergren asked the committee if pharmacists should be required to use the CURES system in a mandated fashion similar to those in SB 482. The committee did not feel that at this time pharmacists should have the same mandated requirements as prescribers.

Dr. Gray stated that this bill is premature as there are still problems with the CURES system. Ms. Sodergren stated that the DOJ must certify that the CURES system has the capability to handle the workload that would be created by the bill.

**Motion:** Support SB 482.

**M/S:** Veale/ Castellblanch

**Support: 5**

**Oppose: 0**

**Abstain: 0**

| Name          | Support | Oppose | Abstain | Not Present |
|---------------|---------|--------|---------|-------------|
| Butler        | x       |        |         |             |
| Castellblanch | x       |        |         |             |
| Lippe         | x       |        |         |             |
| Veale         | x       |        |         |             |
| Wong          | x       |        |         |             |

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

Chairperson Lippe reported that 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.

The committee did not take a position on this bill as the board has no jurisdiction of insurance requirements.

Ms. Sodergren asked the committee if they would like staff to continue tracking the bill. Chairperson Lippe responded that staff did not need to track this bill.

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

Chairperson Lippe reported that 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.

Ms. Herold explained that the board currently receives reports on settlements of \$3,000 or more, which staff then uses to open investigations on the pharmacist. She reported that over the past four years the board has opened 562 cases based on these reports. Ms. Herold added that other healthcare professionals have higher thresholds for reporting settlements to their regulatory agency.

Dr. Gray explained that because pharmacists have a lower threshold for reporting settlements (for example doctors are mandated to report settlements of \$10,000 or more) healthcare teams hesitate to include pharmacists. Dr. Gray asked the committee to support the bill as it will encourage pharmacists to be included in healthcare teams.

Chairperson Lippe stated that he was unclear if this bill would benefit or harm consumers.

Ms. Veale expressed her concern that raising the threshold would prevent the board from finding out about claims where patients were harmed.

Ms. Butler stated that the board should support the bill as it would encourage pharmacists to be included on healthcare teams.

**Motion:** Support SB 1217.

**M/S:** Butler/Wong

**Support: 2    Oppose: 2    Abstain: 1**

| Name          | Support | Oppose | Abstain | Not Present |
|---------------|---------|--------|---------|-------------|
| Butler        | x       |        |         |             |
| Castellblanch |         |        | x       |             |
| Lippe         |         | x      |         |             |
| Veale         |         | x      |         |             |
| Wong          | x       |        |         |             |

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

Chairperson Lippe explained that 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.

Chairperson Lippe reported that 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. Ms. Sodergren noted that the amendments are not available yet.

The committee opted not to take a position on the bill until the amendments are available for review.

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.

Anne staff has been working with the author's office to find out what the intent of the bill is as the current draft creates a discrepancy between state and federal law. She added that additional information would be provided at the April 2016, Board meeting.

Dr. Gray noted that there is currently conflict between state and federal compounding law and the author of this bill intends to clarify the states authority regarding compounding.

The committee did not take a position on the bill.

12. SB 1346 (Allen) Pharmacists: Drug Labeling: Medication Guides: Electronic Delivery

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.

Dr. Castellblanch stated that when patients get their medication they receive multiple medication guides from various sources, he asked which information would be provided electronically.

Staff agreed that there are different medication guides provided to patients and stated that they would contact the author to clarify which one this bill applies to.

Members of the public stated that the FDA has always required medication handouts be provided in hard copy. Ms. Sodergren noted that she had been in contact with the FDA and it seems that they may have changed this requirement to allow information to be provided to patients electronically.

The committee expresses support of patients having the option to receive information electronically. They asked board staff to clarify which medication information the bill would apply to and to contact the FDA to ensure that the bill would not create a conflict between state and federal law.

**Motion:** Support SB 1346 as long as it complies with the FDA medication guide requirements.

**M/S:** Veale/Butler

**Support:** 5                      **Oppose:** 0                      **Abstain:** 0

| Name          | Support | Oppose | Abstain | Not Present |
|---------------|---------|--------|---------|-------------|
| Butler        | x       |        |         |             |
| Castellblanch | x       |        |         |             |
| Lippe         | x       |        |         |             |
| Veale         | x       |        |         |             |
| Wong          | x       |        |         |             |

13. SB 1454 (Stone) Pharmacy

Version: February 19, 2016 Introduced  
Location: Senate Rules

Chairperson Lippe reported that 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.

There were no comments from the committee or from the public.

**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)

Chairperson Lippe explained that 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.

Ms. Sodergren stated that staff recommends the board maintain its oppose position.

**Motion:** Oppose AB 12.

**M/S:** Veale/Castellblanch

**Support:** 4      **Oppose:** 0      **Abstain:** 1

| Name          | Support | Oppose | Abstain | Not Present |
|---------------|---------|--------|---------|-------------|
| Butler        | x       |        |         |             |
| Castellblanch | x       |        |         |             |
| Lippe         | x       |        |         |             |
| Veale         | x       |        |         |             |
| Wong          |         |        | x       |             |

2. AB 1939 (Patterson) Licensing Requirements

Version: February 12, 2016 Introduced

Location: Assembly Business & Professions

Chairperson Lippe stated that 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 at the April Board meeting.

There were no comments from the committee or from the public.

**IV. 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)

Chairperson Lippe reported that 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).

Chairperson Lippe stated that 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.

There were no comments from the committee or from the public.

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

Chairperson Lippe stated that 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.

Chairperson Lippe noted that 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.

There were no comments from the committee or from the public.

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

Chairperson Lippe stated that on May 8, 2015, the board initiated a formal rulemaking related to compounded drug preparations. He added that 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.

There were no comments from the committee or the public.

**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

Chairperson Lippe reported that 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.

Staff noted that the final rulemaking package had been submitted for administrative review by the Department of Consumer Affairs and the Office of Administrative Law on March 19.

There were no comments from the committee or from the public.

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

Chairperson Lippe reported that 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.

Chairperson Lippe explained that at the February 2016 board meeting, the board adopted the final regulation text.

Staff noted that the final rulemaking package had been submitted for administrative review by the Department of Consumer Affairs and the Office of Administrative Law on March 19.

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

Chairperson Lippe stated that 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.

Chairperson Lippe concluded that 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.

There were no comments from the committee or from the public.

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

Chairperson Lippe explained that 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.

Staff manager Lori Martinez explained that legal counsel had concerns with the use of the word "certification" in the regulation language. The DCA legal office recommended the board look at the language again and consider changing the word "certification" to "certificate." Ms. Martinez stated that this regulation will be discussed during the March 28, 2016 teleconference meeting and at that time the board could decide if the language should be modified.

**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

Chairperson Lippe reported that 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.

Chairperson Lippe concluded that that the comments are pending review by the full Board at the April 2016 board meeting.

There were no comments from the board or from the public.

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

Chairperson Lippe stated that 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.

There were no comments from the committee or from the public.

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

Chairperson Lippe stated that 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 2016.

There were no comments from the committee or from the public.

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

Chairperson Lippe reported that in 2013, the board approved a proposal to initiate 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”.

Chairperson Lippe explained that 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.

There were no comments from the committee or from the public.

**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

Chairperson Lippe reported that 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.

Chairperson Lippe explained that 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. He added that the comment period closes on March 24, 2016 and the comments would be reviewed at the April 2016 board meeting.

There were no comments from the board or from the public.

**e. Board Approved – Awaiting Notice**

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

Chairperson Lippe reported that 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.

Chairperson Lippe concluded that Board staff is preparing the required notice documents and anticipates initiating the rulemaking process in April 2016.

There were no comments from the board or from the public.

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

Chairperson Lippe explained that 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.

Chairperson Lippe stated that this regulatory change is currently pending and board staff anticipates initiating the rulemaking process in May 2016.

There were no comments from the committee or from the public.

3. Proposed Regulations to Amend and/or Add Title 16 CCR sections 1780 – 1786, et seq., related to Third Party Logistics Providers

Chairperson Lippe reported that 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.

Chairperson Lippe concluded that board staff is preparing the required notice documents and anticipates initiating the rulemaking process in April 2016.

There were no comments from the committee or from the public.

Ms. Herold thanked Lori Martinez and Debbie Damoth for their work on getting pending regulations finalized and submitted for the required reviews by various control agencies.

Chairperson Lippe adjourned the meeting at 10:15 a.m.

# **Attachment 2**



|                                      |   |
|--------------------------------------|---|
| <b>Bill Number:</b>                  | <b>SB 1193</b>  |
| <b>Current Version:</b>              | <b>As Amended April 13, 2016</b>                                      |
| <b>Author:</b>                       | <b>Hill</b>   |
| <b>Topic:</b>                        | <b>California State Board of Pharmacy;<br/>Outsourcing Facilities</b> |
| <b>Committee<br/>Recommendation:</b> | <b>Support as Amended</b>   |

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

**Status:** Do pass from Senate Business, Professions, and Economic Development Committee (4/18/16)

**Location:** Senate Appropriations

**SUMMARY:**

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

Recent amendments incorporate board sponsored "outsourcing" provisions – language that was previously contained in Senate Bill 619 (Morrell).

**EXISTING LAW:**

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

Emergency Pharmaceutical Supplies Container

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

Clinic Licensure

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

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

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<sup>1</sup> Business and Professions Code section 4119

### Professional Corporations

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

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

### **THIS BILL WOULD:**

#### Sunset Provisions

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

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

#### Emergency Pharmaceutical Supplies Container

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

#### Clinic Applications

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

#### Cease and Desist / Facilities

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

#### Professional Medical Corporations

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

#### Outsourcing Facility Provisions

Add Section 4034 to define "outsourcing facility."

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

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

**STAFF COMMENTS:**

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

As part of the Sunset review process, the board will have the opportunity to also provide written responses to all of the issues identified by the joint oversight committee. The committee will again discuss the board's sunset on April 18, 2016.

**COMMITTEE DISCUSSION:**

The committee briefly discussion this measure and recommend a support position for the introduced version of the bill. The committee did not discuss the amended version, which incorporates board-sponsored "outsourcing facility" provisions, and other amendments as noted in the analysis.

**FISCAL IMPACT ON THE BOARD:**

With respect to the sunset provisions, board staff does not anticipate any fiscal impact.

**HISTORY:**

| Date     | Action  |
|----------|---|
| 04/13/16 | From committee with author's amendments. Read second time and amended. Re-referred to Com. on B., P. & E.D. |
| 03/29/16 | Set for hearing April 18.   |
| 03/03/16 | Referred to Com. on B., P. & E.D.   |
| 02/19/16 | From printer. May be acted upon on or after March 20.   |
| 02/18/16 | Introduced. Read first time. To Com. on RLS. for assignment. To print.                                      |



**SB-1193 Pharmacy: outsourcing facilities.** (2015-2016)

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

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

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

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

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

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

(f) This section shall remain in effect only until January 1, ~~2017, 2021~~, and as of that date is ~~repealed, unless a later enacted statute, that is enacted before January 1, 2017, deletes or extends that date.~~ *repealed.* Notwithstanding any other ~~provision of~~ law, the repeal of this section renders the board subject to review by the appropriate policy committees of the Legislature.

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

**4003.** (a) The board, with the approval of the director, may appoint a person exempt from civil service who shall be designated as an executive officer and who shall exercise the powers and perform the duties delegated by the board and vested in him or her by this chapter. The executive officer may or may not be a member of the board as the board may determine.

(b) The executive officer shall receive the compensation as established by the board with the approval of the Director of Finance. The executive officer shall also be entitled to travel and other expenses necessary in the performance of his or her duties.

(c) The executive officer shall maintain and update in a timely fashion records containing the names, titles, qualifications, and places of business of all persons subject to this chapter.

(d) The executive officer shall give receipts for all money received by him or her and pay it to the department, taking its receipt therefor. Besides the duties required by this chapter, the executive officer shall perform other duties pertaining to the office as may be required of him or her by the board.

(e) This section shall remain in effect only until January 1, ~~2017, 2021~~, and as of that date is ~~repealed, unless a later enacted statute, that is enacted before January 1, 2017, deletes or extends that date.~~ *repealed.*

**SEC. 3.** *Section 4034 is added to the Business and Professions Code, to read:*

**4034.** "Outsourcing facility" means a facility that meets all of the following:

(a) Is located within the United States of America at one address that is engaged in the compounding of sterile drugs and nonsterile drugs.

(b) Has registered as an outsourcing facility with the federal Food and Drug Administration under Section 503B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 353b).

(c) Is doing business within or into California.

(d) Is licensed with the board as an outsourcing facility pursuant to Article 7.7 (commencing with Section 4129).

**SEC. 4.** Section 4119.1 of the Business and Professions Code is amended to read:

**4119.1.** (a) A pharmacy may provide pharmacy services to a health facility licensed pursuant to subdivision (c), (d), or both, of Section 1250 of the Health and Safety Code, through the use of an automated drug delivery system that need not be located at the same location as the pharmacy.

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

(c) (1) The pharmacy shall maintain records of the acquisition and disposition of dangerous drugs and dangerous devices stored in the automated drug delivery system separate from other pharmacy records.

(2) The pharmacy shall own and operate the automated drug delivery system.

(3) The pharmacy shall provide training regarding the operation and use of the automated drug delivery system to both pharmacy and health facility personnel using the system.

(4) The pharmacy shall operate the automated drug delivery system in compliance with Section 1261.6 of the Health and Safety Code.

(d) The operation of the automated drug delivery system shall be under the supervision of a licensed pharmacist. To qualify as a supervisor for an automated drug delivery system, the pharmacist need not be physically present at the site of the automated drug delivery system and may supervise the system electronically.

(e) *The pharmacy shall register use of an automated drug delivery system with the board, including the address and location of use.*

~~(e)~~ (f) ~~Nothing in this~~ This section shall *not* be construed to revise or limit the use of automated drug delivery systems as permitted by the board in any licensed health facility other than a facility defined in subdivision (c) or (d), or both, of Section 1250 of the Health and Safety Code.

**SEC. 5.** Article 7.7 (commencing with Section 4129) is added to Chapter 9 of Division 2 of the Business and Professions Code, to read:

**Article 7.7. Outsourcing Facilities**

**4129.** (a) A facility licensed as an outsourcing facility with the federal Food and Drug Administration (FDA) shall be concurrently licensed with the board as an outsourcing facility if it compounds sterile medication or nonsterile medication for nonpatient-specific distribution within or into California.

(b) A facility premises licensed with the board as a sterile compounding pharmacy shall not be concurrently licensed with the board as an outsourcing facility at the same location.

(c) The board may adopt regulations in accordance with the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code) to establish policies, guidelines, and procedures to implement this article.

(d) The board shall review any formal requirements or guidance documents developed by the FDA regarding outsourcing facilities within 90 days after their release in order to determine whether revisions are necessary for any regulations promulgated by the board.

*(e) An outsourcing facility licensed by the board shall not perform the duties of a pharmacy, such as filling individual prescriptions for individual patients.*

**4129.1.** *(a) An outsourcing facility that is licensed with the federal Food and Drug Administration (FDA) and with an address in this state shall also be licensed by the board as an outsourcing facility before doing business within this state. The license shall be renewed annually and is not transferable.*

*(b) An outsourcing facility shall compound all sterile products and nonsterile products in compliance with regulations issued by the board and with federal current good manufacturing practices applicable to outsourcing facilities.*

*(c) An outsourcing facility license shall not be issued or renewed until the location is inspected by the board and found in compliance with this article and regulations adopted by the board.*

*(d) An outsourcing facility license shall not be issued or renewed until the board does all of the following:*

*(1) Prior to inspection, reviews a current copy of the outsourcing facility's policies and procedures for sterile compounding and nonsterile compounding.*

*(2) Is provided with copies of all federal and state regulatory agency inspection reports, as well as accreditation reports, and certification reports of facilities or equipment of the outsourcing facility's premises conducted in the prior 12 months.*

*(3) Prior to inspection, receives a list of all sterile drugs and nonsterile drugs compounded by the outsourcing facility as reported to the FDA in the last 12 months.*

*(e) An outsourcing facility licensed pursuant to this section shall provide the board with all of the following:*

*(1) A copy of any disciplinary or other action taken by another state or the FDA within 10 days of the action.*

*(2) Notice within 24 hours of any recall notice issued by the outsourcing facility.*

*(3) A copy of any clinically related complaint it receives involving an outsourcing facility's compounded products from or involving any provider, pharmacy, or patient in California within 72 hours of receipt.*

*(4) Notice within 24 hours after learning of adverse effects reported or potentially attributable to the outsourcing facility's products.*

**4129.2.** *(a) An outsourcing facility that is licensed with the federal Food and Drug Administration (FDA) as an outsourcing facility and has an address outside of this state but in the United States of America is a nonresident outsourcing facility. A nonresident outsourcing facility shall not compound sterile drug products or nonsterile drug products for distribution or use into this state without an outsourcing license issued by the board pursuant to this section. The license shall be renewed annually and shall not be transferable.*

*(b) A nonresident outsourcing facility shall compound all sterile products and nonsterile products to be distributed or used in this state in compliance with regulations of the board and with federal current good manufacturing practices applicable to outsourcing facilities.*

*(c) A license for a nonresident outsourcing facility shall not be issued or renewed until the location is inspected by the board and found in compliance with this article and any regulations adopted by the board. The nonresident outsourcing facility shall reimburse the board for all actual and necessary costs incurred by the board in conducting an inspection of the nonresident outsourcing facility at least once annually pursuant to subdivision (x) of Section 4400.*

*(d) A license for a nonresident outsourcing facility shall not be issued or renewed until the board:*

*(1) Prior to inspection, reviews a current copy of the nonresident outsourcing facility's policies and procedures for sterile compounding and nonsterile compounding.*

*(2) Is provided with copies of all federal and state regulatory agency inspection reports, as well as accreditation reports, and certification reports of facilities or equipment of the nonresident outsourcing facility's premises conducted in the prior 12 months.*

*(3) Prior to inspection, receives a list of all sterile drug products and nonsterile drug products compounded by the pharmacy as reported to the FDA within the prior 12 months.*

*(e) A nonresident outsourcing facility licensed pursuant to this section shall provide the board with all of the following:*

*(1) A copy of any disciplinary or other action taken by another state or the FDA within 10 days of the action.*

*(2) Notice within 24 hours of any recall notice issued by the nonresident outsourcing facility.*

*(3) A copy of any complaint it receives involving an outsourcing facility's compounded products from or involving any provider, pharmacy, or patient in California within 72 hours of receipt.*

*(4) Notice within 24 hours after learning of adverse effects reported or potentially attributable to a nonresident outsourcing facility's products.*

**4129.3.** *(a) On or before January 1, 2018, the board shall provide a report to the Legislature regarding the regulation of nonresident outsourcing facilities. The report shall be submitted to the Legislature in the manner required pursuant to Section 9795 of the Government Code. At a minimum, the report shall address all of the following:*

*(1) A detailed description of board activities related to the inspection and licensure of nonresident outsourcing facilities.*

*(2) Whether fee revenue collected pursuant to subdivision (x) of Section 4400 and travel cost reimbursements collected pursuant to subdivision (c) of Section 4129.2 provide revenue in an amount sufficient to support the board's activities related to the inspection and licensure of nonresident outsourcing facilities.*

*(3) The status of proposed changes to federal law that are under serious consideration and that would govern outsourcing facilities and compounding pharmacies, including, but not limited to, legislation pending before Congress, administrative rules, regulations or orders under consideration by the FDA or other appropriate federal agency, and cases pending before the courts.*

*(4) If applicable, recommended modifications to the board's statutory duties related to nonresident outsourcing facilities as a result of changes to federal law or any additional modifications necessary to protect the health and safety of the public.*

*(b) The requirement for submitting a report imposed under subdivision (a) is inoperative on January 1, 2022, pursuant to Section 10231.5 of the Government Code.*

**4129.4.** *(a) Whenever the board has a reasonable belief, based on information obtained during an inspection or investigation by the board, that an outsourcing facility compounding sterile drug products or nonsterile drug products poses an immediate threat to the public health or safety, the executive officer of the board may issue an order to the outsourcing facility to immediately cease and desist compounding sterile drug products or nonsterile drug products. The cease and desist order shall remain in effect for no more than 30 days or the date of a hearing seeking an interim suspension order, whichever is earlier.*

*(b) Whenever the board issues a cease and desist order pursuant to subdivision (a), the board shall immediately issue a notice to the owner setting forth the acts or omissions with which the owner is charged, specifying the pertinent code section or sections and any regulations.*

*(c) The cease and desist order shall state that the owner, within 15 days of receipt of the notice, may request a hearing before the president of the board to contest the cease and desist order. Consideration of the owner's contest of the cease and desist order shall comply with the requirements of Section 11425.10 of the Government Code. The hearing shall be held no later than five days after the date the request of the owner is received by the board. The president shall render a written decision within five days after the hearing. In the absence of the president of the board, the vice president of the board may conduct the hearing permitted by this subdivision. Review of the decision may be sought by the owner or person in possession or control of the outsourcing facility pursuant to Section 1094.5 of the Code of Civil Procedure.*

*(d) Failure to comply with a cease and desist order issued pursuant to this section shall be unprofessional conduct.*

**4129.5.** *Notwithstanding any other law, a violation of this article, or regulation adopted pursuant thereto, may subject the person or entity that committed the violation to a fine of up to five thousand dollars (\$5,000) per occurrence pursuant to a citation issued by the board.*

**4129.6.** *For purposes of this article, "sterile compounded products" means compounded preparations for injection, administration into the eye, or inhalation.*

**4129.8.** *The board, at its discretion, may issue a temporary license to an outsourcing facility when the ownership of the outsourcing facility is transferred from one person to another, upon the conditions and for any periods of time as the board determines to be in the public interest. A temporary license fee shall be required as specified in subdivision (w) of Section 4400. When needed to protect public safety, a temporary license may be issued for a period not to exceed 180 days, and may be issued subject to terms and conditions the board deems necessary. If the board determines a temporary license was issued by mistake or denies the application for a permanent license, the temporary license shall terminate upon the earlier of personal service of the notice of termination upon the licensee or service by certified mail with return receipt requested at the licensee's address of record with the board. The temporary licensee shall not be deemed to have a vested property right or interest in the license for purposes of retaining a temporary license or for purposes of any disciplinary or license denial proceeding before the board.*

**4129.9.** *(a) An outsourcing facility licensed pursuant to Section 4129.1 or 4129.2 that issues a recall notice for a sterile drug or nonsterile drug compounded by the outsourcing facility, in addition to any other duties, shall contact the recipient pharmacy, prescriber, or patient of the recalled drug and the board as soon as possible within 24 hours of the recall notice if both of the following apply:*

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

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

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

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

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

**SEC. 6.** *Section 4203.5 is added to the Business and Professions Code, to read:*

**4203.5.** *(a) Notwithstanding any other law, when a clinic applicant submits either type of application described in subdivision (b), the board shall issue a license or incorporate the reported changes, as appropriate, within 30 days of receipt of a completed application and payment of any prescribed fees.*

*(b) This section applies to the following types of applications:*

*(1) A new clinic license application filed under Section 4180.*

*(2) Applications to report changes to an existing site licensed under Section 4180, including, but not limited to, changes in professional director, clinic administrator, corporate officers, change of location, or change of address.*

*(c) This section shall not be construed to limit the board's authority to conduct an investigation to determine whether applicants and the premises for which an application is made qualify for a license.*

**SEC. 7.** *Section 4316 is added to the Business and Professions Code, to read:*

**4316.** *(a) The board is authorized to issue a cease and desist order for operating any facility under this chapter that requires licensure or for practicing any activity under this chapter that requires licensure.*

*(b) Whenever the board issues a cease and desist order pursuant to subdivision (a), the board shall immediately issue the facility a notice setting forth the acts or omissions with which it is charged, specifying the pertinent code section or sections and any regulations.*

*(c) The order shall provide that the facility, within 15 days of receipt of the notice, may request a hearing before the president of the board to contest the cease and desist order. Consideration of the facility's contest of the cease and desist order shall comply with the requirements of Section 11425.10 of the Government Code. The hearing shall be held no later than five days from the date the request of the owner is received by the board. The president shall render a written decision within five days of the hearing. In the absence of the president of the board, the vice president of the board may conduct the hearing permitted by this subdivision. Review of the decision of the president of the board may be sought by the owner or person in possession or control of the pharmacy pursuant to Section 1094.5 of the Code of Civil Procedure.*

**SEC. 8.** *Section 4400 of the Business and Professions Code is amended to read:*

**4400.** The amount of fees and penalties prescribed by this chapter, except as otherwise provided, is that fixed by the board according to the following schedule:

(a) The fee for a nongovernmental pharmacy license shall be four hundred dollars (\$400) and may be increased to five hundred twenty dollars (\$520). The fee for the issuance of a temporary nongovernmental pharmacy permit shall be two hundred fifty dollars (\$250) and may be increased to three hundred twenty-five dollars (\$325).

(b) The fee for a nongovernmental pharmacy license annual renewal shall be two hundred fifty dollars (\$250) and may be increased to three hundred twenty-five dollars (\$325).

(c) The fee for the pharmacist application and examination shall be two hundred dollars (\$200) and may be increased to two hundred sixty dollars (\$260).

(d) The fee for regrading an examination shall be ninety dollars (\$90) and may be increased to one hundred fifteen dollars (\$115). If an error in grading is found and the applicant passes the examination, the regrading fee shall be refunded.

(e) The fee for a pharmacist license and biennial renewal shall be one hundred fifty dollars (\$150) and may be increased to one hundred ninety-five dollars (\$195).

(f) The fee for a nongovernmental wholesaler or third-party logistics provider license and annual renewal shall be seven hundred eighty dollars (\$780) and may be decreased to no less than six hundred dollars (\$600). The application fee for any additional location after licensure of the first 20 locations shall be three hundred dollars (\$300) and may be decreased to no less than two hundred twenty-five dollars (\$225). A temporary license fee shall be seven hundred fifteen dollars (\$715) and may be decreased to no less than five hundred fifty dollars (\$550).

(g) The fee for a hypodermic license and renewal shall be one hundred twenty-five dollars (\$125) and may be increased to one hundred sixty-five dollars (\$165).

(h) (1) The fee for application, investigation, and issuance of a license as a designated representative pursuant to Section 4053, or as a designated representative-3PL pursuant to Section 4053.1, shall be three hundred thirty dollars (\$330) and may be decreased to no less than two hundred fifty-five dollars (\$255).

(2) The fee for the annual renewal of a license as a designated representative or designated representative-3PL shall be one hundred ninety-five dollars (\$195) and may be decreased to no less than one hundred fifty dollars (\$150).

(i) (1) The fee for the application, investigation, and issuance of a license as a designated representative for a veterinary food-animal drug retailer pursuant to Section 4053 shall be three hundred thirty dollars (\$330) and may be decreased to no less than two hundred fifty-five dollars (\$255).

(2) The fee for the annual renewal of a license as a designated representative for a veterinary food-animal drug retailer shall be one hundred ninety-five dollars (\$195) and may be decreased to no less than one hundred fifty dollars (\$150).

(j) (1) The application fee for a nonresident wholesaler or third-party logistics provider license issued pursuant to Section 4161 shall be seven hundred eighty dollars (\$780) and may be decreased to no less than six hundred dollars (\$600).

(2) For nonresident wholesalers or third-party logistics providers that have 21 or more facilities operating nationwide the application fees for the first 20 locations shall be seven hundred eighty dollars (\$780) and may be decreased to no less than six hundred dollars (\$600). The application fee for any additional location after licensure of the first 20 locations shall be three hundred dollars (\$300) and may be decreased to no less than two hundred twenty-five dollars (\$225). A temporary license fee shall be seven hundred fifteen dollars (\$715) and may be decreased to no less than five hundred fifty dollars (\$550).

(3) The annual renewal fee for a nonresident wholesaler license or third-party logistics provider license issued pursuant to Section 4161 shall be seven hundred eighty dollars (\$780) and may be decreased to no less than six hundred dollars (\$600).

(k) The fee for evaluation of continuing education courses for accreditation shall be set by the board at an amount not to exceed forty dollars (\$40) per course hour.

(l) The fee for an intern pharmacist license shall be ninety dollars (\$90) and may be increased to one hundred fifteen dollars (\$115). The fee for transfer of intern hours or verification of licensure to another state shall be twenty-five dollars (\$25) and may be increased to thirty dollars (\$30).

(m) The board may waive or refund the additional fee for the issuance of a license where the license is issued less than 45 days before the next regular renewal date.

(n) The fee for the reissuance of any license, or renewal thereof, that has been lost or destroyed or reissued due to a name change shall be thirty-five dollars (\$35) and may be increased to forty-five dollars (\$45).

(o) The fee for the reissuance of any license, or renewal thereof, that must be reissued because of a change in the information, shall be one hundred dollars (\$100) and may be increased to one hundred thirty dollars (\$130).

(p) It is the intent of the Legislature that, in setting fees pursuant to this section, the board shall seek to maintain a reserve in the Pharmacy Board Contingent Fund equal to approximately one year's operating expenditures.

(q) The fee for any applicant for a nongovernmental clinic license shall be four hundred dollars (\$400) and may be increased to five hundred twenty dollars (\$520) for each license. The annual fee for renewal of the license shall be two hundred fifty dollars (\$250) and may be increased to three hundred twenty-five dollars (\$325) for each license.

(r) The fee for the issuance of a pharmacy technician license shall be eighty dollars (\$80) and may be increased to one hundred five dollars (\$105). The fee for renewal of a pharmacy technician license shall be one hundred dollars (\$100) and may be increased to one hundred thirty dollars (\$130).

(s) The fee for a veterinary food-animal drug retailer license shall be four hundred five dollars (\$405) and may be increased to four hundred twenty-five dollars (\$425). The annual renewal fee for a veterinary food-animal drug retailer license shall be two hundred fifty dollars (\$250) and may be increased to three hundred twenty-five dollars (\$325).

(t) The fee for issuance of a retired license pursuant to Section 4200.5 shall be thirty-five dollars (\$35) and may be increased to forty-five dollars (\$45).

(u) The fee for issuance or renewal of a nongovernmental sterile compounding pharmacy license shall be six hundred dollars (\$600) and may be increased to seven hundred eighty dollars (\$780). The fee for a temporary license shall be five hundred fifty dollars (\$550) and may be increased to seven hundred fifteen dollars (\$715).

(v) The fee for the issuance or renewal of a nonresident sterile compounding pharmacy license shall be seven hundred eighty dollars (\$780). In addition to paying that application fee, the nonresident sterile compounding pharmacy shall deposit, when submitting the application, a reasonable amount, as determined by the board, necessary to cover the board's estimated cost of performing the inspection required by Section 4127.2. If the required deposit is not submitted with the application, the application shall be deemed to be incomplete. If the actual cost of the inspection exceeds the amount deposited, the board shall provide to the applicant a written invoice for the remaining amount and shall not take action on the application until the full amount has been paid to the board. If the amount deposited exceeds the amount of actual and necessary costs incurred, the board shall remit the difference to the applicant.

(w) ~~This section shall become operative on July 1, 2014.~~ *The fee for the issuance or renewal of an outsourcing facility license shall be seven hundred eighty dollars (\$780). The fee for a temporary outsourcing facility license shall be seven hundred fifteen dollars (\$715).*

*(x) The fee for the issuance or renewal of a nonresident outsourcing facility license shall be seven hundred eighty dollars (\$780). In addition to paying that application fee, the nonresident outsourcing facility shall deposit, when submitting the application, a reasonable amount, as determined by the board, necessary to cover the board's estimated cost of performing the inspection required by Section 4129.2. If the required deposit is not submitted with the application, the application shall be deemed to be incomplete. If the actual cost of the inspection exceeds the amount deposited, the board shall provide to the applicant a written invoice for the remaining amount and shall not take action on the application until the full amount has been paid to the board. If the amount deposited exceeds the amount of actual and necessary costs incurred, the board shall remit the difference to the applicant.*

**SEC. 9.** *Section 13401.5 of the Corporations Code is amended to read:*

**13401.5.** Notwithstanding subdivision (d) of Section 13401 and any other provision of law, the following licensed persons may be shareholders, officers, directors, or professional employees of the professional corporations designated in this section so long as the sum of all shares owned by those licensed persons does not exceed 49 percent of the total number of shares of the professional corporation so designated herein, and so long as the number of those licensed persons owning shares in the professional corporation so designated herein does not exceed the number of persons licensed by the governmental agency regulating the designated professional corporation. This section does not limit employment by a professional corporation designated in this section to only those licensed professionals listed under each subdivision. Any person duly licensed under Division 2 (commencing with Section 500) of the Business and Professions Code, the Chiropractic Act, or the Osteopathic Act may be employed to render professional services by a professional corporation designated in this section.

(a) Medical corporation.

- (1) Licensed doctors of podiatric medicine.
- (2) Licensed psychologists.
- (3) Registered nurses.
- (4) Licensed optometrists.
- (5) Licensed marriage and family therapists.
- (6) Licensed clinical social workers.
- (7) Licensed physician assistants.
- (8) Licensed chiropractors.
- (9) Licensed acupuncturists.
- (10) Naturopathic doctors.
- (11) Licensed professional clinical counselors.
- (12) Licensed physical therapists.

**(13) Licensed pharmacists.**

(b) Podiatric medical corporation.

- (1) Licensed physicians and surgeons.
- (2) Licensed psychologists.
- (3) Registered nurses.
- (4) Licensed optometrists.
- (5) Licensed chiropractors.
- (6) Licensed acupuncturists.
- (7) Naturopathic doctors.
- (8) Licensed physical therapists.

(c) Psychological corporation.

- (1) Licensed physicians and surgeons.
- (2) Licensed doctors of podiatric medicine.
- (3) Registered nurses.
- (4) Licensed optometrists.
- (5) Licensed marriage and family therapists.

- (6) Licensed clinical social workers.
- (7) Licensed chiropractors.
- (8) Licensed acupuncturists.
- (9) Naturopathic doctors.
- (10) Licensed professional clinical counselors.
- (d) Speech-language pathology corporation.
- (1) Licensed audiologists.
- (e) Audiology corporation.
- (1) Licensed speech-language pathologists.
- (f) Nursing corporation.
- (1) Licensed physicians and surgeons.
- (2) Licensed doctors of podiatric medicine.
- (3) Licensed psychologists.
- (4) Licensed optometrists.
- (5) Licensed marriage and family therapists.
- (6) Licensed clinical social workers.
- (7) Licensed physician assistants.
- (8) Licensed chiropractors.
- (9) Licensed acupuncturists.
- (10) Naturopathic doctors.
- (11) Licensed professional clinical counselors.
- (g) Marriage and family therapist corporation.
- (1) Licensed physicians and surgeons.
- (2) Licensed psychologists.
- (3) Licensed clinical social workers.
- (4) Registered nurses.
- (5) Licensed chiropractors.
- (6) Licensed acupuncturists.
- (7) Naturopathic doctors.
- (8) Licensed professional clinical counselors.
- (h) Licensed clinical social worker corporation.
- (1) Licensed physicians and surgeons.
- (2) Licensed psychologists.
- (3) Licensed marriage and family therapists.
- (4) Registered nurses.
- (5) Licensed chiropractors.

- (6) Licensed acupuncturists.
- (7) Naturopathic doctors.
- (8) Licensed professional clinical counselors.
- (i) Physician assistants corporation.
- (1) Licensed physicians and surgeons.
- (2) Registered nurses.
- (3) Licensed acupuncturists.
- (4) Naturopathic doctors.
- (j) Optometric corporation.
- (1) Licensed physicians and surgeons.
- (2) Licensed doctors of podiatric medicine.
- (3) Licensed psychologists.
- (4) Registered nurses.
- (5) Licensed chiropractors.
- (6) Licensed acupuncturists.
- (7) Naturopathic doctors.
- (k) Chiropractic corporation.
- (1) Licensed physicians and surgeons.
- (2) Licensed doctors of podiatric medicine.
- (3) Licensed psychologists.
- (4) Registered nurses.
- (5) Licensed optometrists.
- (6) Licensed marriage and family therapists.
- (7) Licensed clinical social workers.
- (8) Licensed acupuncturists.
- (9) Naturopathic doctors.
- (10) Licensed professional clinical counselors.
- (l) Acupuncture corporation.
- (1) Licensed physicians and surgeons.
- (2) Licensed doctors of podiatric medicine.
- (3) Licensed psychologists.
- (4) Registered nurses.
- (5) Licensed optometrists.
- (6) Licensed marriage and family therapists.
- (7) Licensed clinical social workers.
- (8) Licensed physician assistants.

- (9) Licensed chiropractors.
- (10) Naturopathic doctors.
- (11) Licensed professional clinical counselors.
- (m) Naturopathic doctor corporation.
- (1) Licensed physicians and surgeons.
- (2) Licensed psychologists.
- (3) Registered nurses.
- (4) Licensed physician assistants.
- (5) Licensed chiropractors.
- (6) Licensed acupuncturists.
- (7) Licensed physical therapists.
- (8) Licensed doctors of podiatric medicine.
- (9) Licensed marriage and family therapists.
- (10) Licensed clinical social workers.
- (11) Licensed optometrists.
- (12) Licensed professional clinical counselors.
- (n) Dental corporation.
- (1) Licensed physicians and surgeons.
- (2) Dental assistants.
- (3) Registered dental assistants.
- (4) Registered dental assistants in extended functions.
- (5) Registered dental hygienists.
- (6) Registered dental hygienists in extended functions.
- (7) Registered dental hygienists in alternative practice.
- (o) Professional clinical counselor corporation.
- (1) Licensed physicians and surgeons.
- (2) Licensed psychologists.
- (3) Licensed clinical social workers.
- (4) Licensed marriage and family therapists.
- (5) Registered nurses.
- (6) Licensed chiropractors.
- (7) Licensed acupuncturists.
- (8) Naturopathic doctors.
- (p) Physical therapy corporation.
- (1) Licensed physicians and surgeons.
- (2) Licensed doctors of podiatric medicine.

- (3) Licensed acupuncturists.
- (4) Naturopathic doctors.
- (5) Licensed occupational therapists.
- (6) Licensed speech-language therapists.
- (7) Licensed audiologists.
- (8) Registered nurses.
- (9) Licensed psychologists.
- (10) Licensed physician assistants.
- (q) Registered dental hygienist in alternative practice corporation.
- (1) Registered dental assistants.
- (2) Licensed dentists.
- (3) Registered dental hygienists.
- (4) Registered dental hygienists in extended functions.

***SEC. 10. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.***

# **Attachment 3**



**Bill Number:** AB 45  
**Current Version:** January 21, 2016 - Amended  
**Authors:** Mullin  
**Topic:** Household Hazardous Waste  
**Board Position:** Oppose Unless Amended (Ver: 4/30/15)  
**Committee**  
**Recommendation:** Oppose Unless Amended (Ver: 1/21/16)

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**Affected Section(s):**

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

**Status:** Referred to Senate Environmental Quality

**SUMMARY:**

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

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

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

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

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

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

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

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

#### **EXISTING LAW:**

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

<sup>1</sup>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 conveyed the board’s concerns to the sponsors of this measure with the April 2015 version, and offered amendments that would require mail back of prescription drugs, to ensure consistency with federal law – the amendments were not accepted. Board staff have also made attempts to schedule discussions with the author’s office.

As reflected in the Assembly Floor Analysis (1/21/16 amendment) the author has stated that state law has loosely regulated household hazardous waste for approximately 25 years.

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<sup>1</sup> Medical Waste Management Act administered by the California Department of Public Health

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.

**COMMITTEE RECOMMENDATION:**

The committee recommends that the board maintain its Oppose Unless Amended position (for the 1/21/16 version) that that amendments to require that take-back of prescription drugs be done in a manner consistent with federal law (i.e., mail-back).

**FISCAL IMPACT ON THE BOARD:**

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

**SUPPORT/OPPOSITION:** (based on the text version 4/23/15)

Support

California Healthcare Institute  
 TechNet  
 BIOCUM  
 Biotechnology Industry Association  
 California Cable & Telecommunications Association

Opposition

City of Lakewood  
 County of San Bernardino  
 California State Association of Counties  
 Solid Waste Association of North America  
 City of Torrance  
 County of Placer  
 County of Monterey  
 California Product Stewardship Council

County of Sacramento  
 City of Thousand Oaks  
 County of Santa Clara  
 City of Santa Monica  
 San Mateo County  
 City of Roseville  
 City of Duarte  
 Western Placer Waste Management Authority  
 Stanislaus County  
 Tulare County  
 Contra Costa Clean Water Program  
 Los Angeles County Integrated Waste Management Task Force  
 City of La Verne  
 City of Diamondbar  
 City of Lomita  
 Lincoln Policy Department  
 Rocklin Police Department  
 Roseville Police Department

**HISTORY:**

| Date     | Action   |
|----------|--|
| 02/04/16 | Referred to Com. on E.Q.   |
| 01/27/16 | In Senate. Read first time. To Com. on RLS. for assignment.  |
| 01/27/16 | Read third time. Passed. Ordered to the Senate. (Ayes 50. Noes 18. Page 3507.)   |
| 01/25/16 | Read second time. Ordered to third reading.  |
| 01/21/16 | Read second time and amended. Ordered returned to second reading.  |
| 01/21/16 | From committee: Amend, and do pass as amended. (Ayes 12. Noes 0.) (January 21).  |
| 05/28/15 | In committee: Hearing postponed by committee.  |
| 05/20/15 | In committee: Set, first hearing. Referred to APPR. suspense file.   |
| 05/04/15 | Re-referred to Com. on APPR.   |
| 04/30/15 | Read second time and amended.  |
| 04/29/15 | From committee: Amend, and do pass as amended and re-refer to Com. on APPR. (Ayes 4. Noes 2.) (April 28).                    |
| 04/27/15 | Re-referred to Com. on E.S. & T.M.   |
| 04/23/15 | From committee chair, with author's amendments: Amend, and re-refer to Com. on E.S. & T.M. Read second time and amended.     |
| 04/23/15 | From committee: Do pass and re-refer to Com. on E.S. & T.M. (Ayes 6. Noes 3.) (April 22). Re-referred to Com. on E.S. & T.M. |
| 04/14/15 | Re-referred to Com. on L. GOV.   |
| 04/13/15 | From committee chair, with author's amendments: Amend, and re-refer to Com. on L. GOV. Read second time and amended.         |
| 03/23/15 | Re-referred to Com. on L. GOV.   |
| 03/19/15 | From committee chair, with author's amendments: Amend, and re-refer to Com. on L. GOV. Read second time and amended.         |
| 03/19/15 | Referred to Coms. on L. GOV. and E.S. & T.M.   |
| 12/02/14 | From printer. May be heard in committee January 1.   |
| 12/01/14 | Read first time. To print.   |



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

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

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

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

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

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

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

**Article 3.4. Household Hazardous Waste Collection and Reduction**

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

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

*(1) Utilization of locally sponsored collection sites.*

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

*(3) Door-to-door collection programs.*

*(4) Mobile collection programs.*

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



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

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**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
- Develop a formulary of medications appropriate for the program
- Ensure proper safety and management of any medication collected and maintained
- Ensure the privacy of individuals for whom the medication was originally prescribed

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

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

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

**THIS BILL WOULD:**

Amend H&SC Section 150204

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

**STAFF COMMENTS:**

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.

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

**SUPPORT**

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

**OPPOSE**

Board of Pharmacy

**HISTORY:**

| Date       | Action   |
|------------|--|
| 07/07/2015 | July 7 From committee: Do pass and re-refer to Com. on APPR. (Ayes 7. Noes 0.) (July 6). Re-referred to Com. on APPR.  |
| 07/01/2015 | July 1 From committee chair, with author's amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. on B., P. & E.D. |
| 06/15/2015 | June 15 In committee: Set, first hearing. Hearing canceled at the request of author.   |
| 06/11/2015 | June 11 Referred to Com. on B., P. & E.D.  |
| 06/01/2015 | June 1 In Senate. Read first time. To Com. on RLS. for assignment.   |
| 06/01/2015 | June 1 Read third time. Passed. Ordered to the Senate. (Ayes 80. Noes 0. Page 1685.)   |
| 05/07/2015 | May 7 Read second time. Ordered to third reading.  |
| 05/06/2015 | May 6 Read second time and amended. Ordered returned to second reading.  |
| 05/05/2015 | May 5 From committee: Amend, and do pass as amended. (Ayes 17. Noes 0.) (May 5).   |
| 04/21/2015 | Apr. 21 In committee: Hearing postponed by committee.  |
| 04/06/2015 | Apr. 6 Re-referred to Com. on HEALTH.  |
| 03/26/2015 | 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.     |
| 02/27/2015 | Feb. 27 From printer. May be heard in committee March 29.  |
| 02/26/2015 | Feb. 26 Read first time. To print.   |



**California State Board of Pharmacy**

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

July 1, 2015

The Honorable Richard Gordon  
California State Assembly  
State Capitol, Room 3013  
Sacramento, CA 95814

**RE: Assembly Bill 1069 (As proposed to be amended) – Oppose Unless Amended**

Dear Assembly Member Gordon:

Late yesterday the board received proposed amendments that will be introduced during the Senate Business, Professions and Economic Development Committee Meeting scheduled for July 6, 2015. I regret to inform you that the Board of Pharmacy continues to have an "oppose unless amended" position on your Assembly Bill 1069. The amendments proposed would create conflicts with other areas of state and federal law, and also create several policy concerns impacting patient safety for the board.

The board is grateful for your public acknowledgment to work with the board. Over the prior few months board staff has spent considerable time working with your office and the sponsors to educate them about legal requirements of pharmaceutical practice as well as discuss various aspects of the redistribution program in support of their intent to expand some elements of the program. Regrettably, the recently proposed amendments are not a reflection of the collaboration we have worked so hard to achieve, and go far beyond what the board could agree to.

Specifically, the proposed amendments would:

1. remove a pharmacist from the several aspects of the redistribution program of prescription drugs
2. allow a participating entity to transfer drugs like a distributor without appropriate licensure and control
3. Permit what is currently unlawful repackaging of and co-mingling of previously dispensed medications, including donated medications from various sources.

This is all to the detriment of the patient.

We understand the sponsor's intent to address the needs of indigent patients to secure access to medications; however, AB 1069 will eliminate existing patient protections established in state and federal law that are afforded to all Californians. The elimination of important patient safety safeguards for a specific population of Californians -- indigent patients-- is contrary to the board's consumer protection mandate. You are welcome to contact Anne Sodergren at (916) 574-7910 if you have any questions.

Sincerely,

A handwritten signature in black ink that reads "Virginia Herold". The signature is written in a cursive, flowing style.

VIRGINIA HEROLD  
Executive Officer

cc: Department of Consumer Affairs  
Senate Business, Professions and Economic Development Committee



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(1) Dispensed to an eligible patient.

(2) Destroyed.

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

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

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

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

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

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

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

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

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

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

*(i) All applicable lot numbers.*

*(ii) The earliest expiration date.*

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

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

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

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

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

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



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**Bill Number:** AB 1386

**Current Version:** January 13, 2016

**Author:** Low

**Topic:** Emergency medical care: epinephrine auto-injectors

**Board Position:**

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**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

**Committee Recommendation:** SUPPORT AB 1386, and offer amendments allowing pharmacists to furnish the auto injectors.

**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.

The committee discussed APPs being well positioned to furnish the auto-injectors to further expand access to these live-saving injectors.

#### **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:**

| Date                       | Action   |
|----------------------------|--|
| 02/04/2016                 | Feb. 4 Referred to Coms. on HEALTH and JUD.  |
| 01/27/2016                 | Jan. 27 In Senate. Read first time. To Com. on RLS. for assignment.  |
| 01/27/2016                 | Jan. 27 Read third time. Passed. Ordered to the Senate. (Ayes 78. Noes 0. Page 3510.)  |
| 01/21/2016                 | Jan. 21 From committee: Do pass. To Consent Calendar. (Ayes 17. Noes 0.) (January 21). Read second time. Ordered to Consent Calendar.                      |
| 01/15/2016                 | 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.                                 |
| 01/14/2016                 | Jan. 14 Re-referred to Com. on JUD.  |
| 01/13/2016                 | Jan. 13 Read second time and amended.  |
| 01/12/2016                 | Jan. 12 From committee: Amend, and do pass as amended and re-refer to Com. on JUD. (Ayes 14. Noes 0.) (January 12).  |
| 01/07/2016                 | Jan. 7 Assembly Rule 56 suspended. (Page 3367.) (pending re-refer to Com. on JUD.)   |
| 01/06/2016                 | Jan. 6 Re-referred to Com. on B. & P.  |
| 01/05/2016                 | Jan. 5 From committee chair, with author's amendments: Amend, and re-refer to Com. on B. & P. Read second time and amended.                                |
| 01/04/2016                 | Jan. 4 From committee chair, with author's amendments: Amend, and re-refer to Com. on B. & P. Read second time and amended. Re-referred to Com. on B. & P. |
| 04/28/2015                 | Apr. 28 In committee: Hearing postponed by committee.  |
| 04/23/2015 –<br>03/02/2015 | Content removed  |
| 02/27/2015                 | Feb. 27 Introduced. To print.  |



## OFFICE OF ASSEMBLYMEMBER

**Evan Low**

TWENTY-EIGHTH ASSEMBLY DISTRICT

### Assembly Bill 1386: Epinephrine Entity Access

#### SUMMARY

Assembly Bill (AB) 1386 will allow businesses, organizations and entities to voluntarily obtain a prescription and to stock epinephrine auto-injectors for use in an emergency if the business, organization or entity has employees, agents or others who are trained in recognition of anaphylaxis and administration of epinephrine auto-injectors.

#### BACKGROUND

Anaphylaxis is a serious, potentially life-threatening allergic response that can lead to swelling, hives, lowered blood pressure, respiratory distress and dilated blood vessels. In severe cases, a person will go into shock. If anaphylactic shock isn't treated immediately, it can be fatal.

Often caused by an allergy to food, latex, insect sting or medication, anaphylaxis is a large and growing public health problem. Statistics for food allergy alone are on the rise, affecting an estimated one out of 13 children and 1 out of 20 adults in the U.S.

Anaphylaxis is unpredictable. First-time anaphylactic reactions can be serious and cause death. Similarly, it can affect individuals whose allergic reactions were mild in the past.

#### PROBLEM

47 States, including California, currently have laws to allow or mandate schools to stock epinephrine auto-injectors but schools are not the only place where children can come into contact with allergens capable of causing anaphylaxis. Greater access is needed to allow businesses, organization and other entities to stock epinephrine auto-injectors and allow for trained employees, agents and others to use those auto-injectors in an emergency.

Failure to administer epinephrine early in the course of treatment has been repeatedly implicated in anaphylaxis fatalities. The more rapid anaphylaxis develops, the more likely the reaction will be severe and potentially life-threatening.

While existing law allows trained individuals to administer epinephrine auto-injectors to others in an emergency and provides liability protection for these individuals, current law does not allow the business, group or entity that the individual is employed by or associated with to obtain a prescription for an epinephrine auto-injector or to have liability protection if the epinephrine auto-injector is used on the entity's premises.

#### SOLUTION

AB 1386 would make epinephrine auto-injectors more readily available in places where individuals could come into contact with potentially life-threatening allergens and would allow for quicker administration in the event of an emergency.

AB 1386 also provides liability protection to the business, organization or entity that obtained the epinephrine auto-injector and allows use by a trained employee, agent or other individual under certain circumstances.

#### SUPPORT

Allergy & Asthma Network  
American Latex Allergy Association  
American Red Cross  
California ACEP  
Mylan  
SF Bay Area Food Allergy Network  
The Allergy Station



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

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

**4119.4.** (a) *Notwithstanding any other law, a pharmacy may furnish epinephrine auto-injectors to an authorized entity, 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).*

~~(2)~~ (3) "Epinephrine auto-injector" means a disposable drug delivery system with a spring-activated concealed needle that is designed for emergency administration of epinephrine to provide rapid, convenient first aid for persons suffering from anaphylaxis.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(A) Fraud.

(B) Incompetence.

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

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

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

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

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

(3) The authority may transfer unused portions of the Specialized First Aid Training Program Approval Fund to the Surplus Money Investment Fund. Funds transferred to the Surplus Money Investment Fund shall be placed in a separate trust account, and shall be available for transfer to the Specialized First Aid Training Program Approval Fund, together with the interest earned, when requested by the authority.

(4) The authority shall maintain a reserve balance in the Specialized First Aid Training Program Approval Fund of 5 percent of annual revenues. Any increase in the fees deposited in the Specialized First Aid Training Program Approval Fund shall be effective upon determination by the authority that additional moneys are required to fund expenditures pursuant to subdivision (c).

*(e) (1) An authorized health care provider may issue a prescription for an epinephrine auto-injector to a prehospital emergency medical care person or a lay rescuer for the purpose of rendering emergency care to another person upon presentation of a current 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.*

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

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

**SEC. 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.*



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**Bill Number:** AB 1977

**Current Version:** April 13, 2016 Amended

**Authors:** Members Wood and Waldron

**Topic:** Opioid Abuse Task Force

**Board Position:**

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**Affected Section(s):**

Adds section 11999.30 to the Health & Safety Code

**Status:** Re-referred to Assembly Committee on Health

**Committee Recommendation:**

None

NOTE: The committee considered the prior amendment of the bill (3/30/13) and did not recommend a position on the measure.

**SUMMARY:**

As recently amended, AB 1977 makes declarations regarding the abuse and misuse of opioids. The bill would create the Opioid Abuse Task Force that would require health care service plans and health insurer representatives, in collaboration with advocates, experts, health care professionals, and other entities and stakeholders to convene a task force, develop recommendations regarding the abuse and misuse of opioids, as specified, and requires the task force to report its findings to the Governor and specified Legislators and committees on or before December 31, 2017.

The prior version of the bill specified limits for the prescribing of a first prescription by physician and surgeon, as specified; amended provisions related to individual or group health care service plans' coverage of non-abuse-deterrent as well as abuse-deterrent opioid analgesic drug products; and required pharmacists to inform a patient on the proper storage and disposal of an opioid analgesic drug product when dispensed – and to require the board to adopt regulations to implement this provision.

**EXISTING LAW:**

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 that act a crime. Existing law also provides for the regulation of health insurers by the Department of Insurance.

Section 4005 of the Business and Professions Code provides the board with the statutory authority to adopt rules and regulations to implement provisions of pharmacy law, as specified.

Title 16 Section 1707.2 specifies a pharmacist's duty to consult. As part of the oral consultation requirements, the pharmacist must provide the patient with the directions for use and storage; the importance of complying with the directions for use; precautions and relevant warnings; and common severe side or adverse effects or interactions that may be encountered. The regulation provides additional information that the pharmacist is to convey whenever the pharmacist deems it warranted in the exercise of his or her professional judgment.

**THIS BILL WOULD:**

1. Makes legislative findings about the abuse and misuse of opioids that affect the health, social and economic welfare of the state.
2. Add Section 11999.30 to the Health and Safety Code to
  - a. Require health care service plans and health insurer representatives, in collaboration with advocates, experts, health care professionals and other entities and stakeholders to convene an Opioid Abuse Task Force.
  - b. The task force would be required to develop recommendations regarding the abuse and misuse of opioids as a serious problem that affects the health, social welfare, and economic welfare of persons in the state.
  - c. Require the task force to address all of the following and, on or before December 31, 2017, submit a report detailing its findings and recommendations to the Governor, the President pro Tempore of the Senate, the Speaker of the Assembly, and to the Senate and Assembly Committees on Health.
    - Interventions that have been scientifically validated and have demonstrated clinical efficacy.
    - Interventions that have measurable treatment outcomes.
    - Collaborative, evidence-based approaches to resolving opioid abuse and misuse that incorporate both the provider and the patient into the solution.
    - Education that engages and encourages providers to be prudent in prescribing opioids and to be proactive in defining care plans that include a plan to taper and stop opioid use.
    - Review and consideration of medication coverage policies and formulary management and development of an interdisciplinary case management program that addresses quality, fraud, waste and abuse.

**FISCAL IMPACT ON THE BOARD:**

None

**PRIOR LEGISLATION:**

In 2015, the author sponsored AB 623 containing provisions that would require pharmacists to inform a patient on the proper storage and disposal of an opioid analgesic drug product when dispensed, and further require the board to adopt regulations to implement that provision. The board stated its opposition because it felt that the bill would result in brand name drugs remaining on drug formularies after generic versions of the drug were available. AB 623 died on the ASM Appropriations suspense file.

**HISTORY:**

| Date    | Action  |
|---------|---|
| 4/13/16 | From committee chair, with author's amendments: Amend, and re-refer to Com o HEALTH. Read second time and amended.  |
| 4/12/16 | In committee: Set, first hearing. Hearing canceled at the request of author.  |
| 3/31/16 | Re-referred to Com on HEALTH  |
| 3/30/16 | From committee chair, with author's amendments: Amend, and re-refer to Com on HEALTH. Read second time and amended. |
| 2/25/16 | Referred to Com on HEALTH   |
| 2/17/16 | From printer. May be heard in committee March 18.   |
| 2/16/16 | Read first time. To Print.  |



**AB-1977 Opioid Abuse Task Force.** (2015-2016)

**SECTION 1.** *The Legislature finds and declares as follows:*

- (a) *Abuse and misuse of opioids is a serious problem that affects the health, social, and economic welfare of the state.*
- (b) *After alcohol, prescription drugs are the most commonly abused substances by Americans over 12 years of age.*
- (c) *Almost 2,000,000 people in the United States suffer from substance use disorders related to prescription opioid pain relievers.*
- (d) *Nonmedical use of prescription opioid pain relievers can be particularly dangerous when the products are manipulated for snorting, injection, or combination with other drugs.*
- (e) *Deaths involving prescription opioid pain relievers represent the largest proportion of drug overdose deaths, greater than the number of overdose deaths involving heroin or cocaine.*
- (f) *The number of unintentional overdose deaths involving prescription opioid pain relievers has more than quadrupled since 1999.*

**SEC. 2.** *Division 10.10 (commencing with Section 11999.30) is added to the Health and Safety Code, to read:*

**DIVISION 10.10. Opioid Abuse Task Force**

**11999.30.** (a) *On or before February 1, 2017, health care service plans and health insurer representatives, in collaboration with advocates, experts, health care professionals, and other entities and stakeholders that they deem appropriate, shall convene an Opioid Abuse Task Force. The task force shall develop recommendations regarding the abuse and misuse of opioids as a serious problem that affects the health, social welfare, and economic welfare of persons in the state. The task force shall address all of the following:*

- (1) *Interventions that have been scientifically validated and have demonstrated clinical efficacy.*
  - (2) *Interventions that have measurable treatment outcomes.*
  - (3) *Collaborative, evidence-based approaches to resolving opioid abuse and misuse that incorporate both the provider and the patient into the solution.*
  - (4) *Education that engages and encourages providers to be prudent in prescribing opioids and to be proactive in defining care plans that include a plan to taper and stop opioid use.*
  - (5) *Review and consideration of medication coverage policies and formulary management and development of an interdisciplinary case management program that addresses quality, fraud, waste, and abuse.*
- (b) *On or before December 31, 2017, the task force shall submit a report detailing its findings and recommendations to the Governor, the President pro Tempore of the Senate, the Speaker of the Assembly, the Senate Committee on Health, and the Assembly Committee on Health.*
- (c) *The task force shall be dissolved and shall cease to exist on June 1, 2018.*
- (d) *A violation of this section is not subject to Section 1390.*

**11999.31.** *This division 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.*



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**Bill Number:** AB 2144  
**Current Version:** March 18, 2016 Amended  
**Authors:** Assembly Member Rodriguez  
**Topic:** Pharmacy  
**Board Position:**

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**Affected Section(s):**

Amend sections 4073.5 and 4074 of the Business and Professions Code

**Status:** Referred to ASM Health

**Committee Recommendation:**

Support AB 2144

Note: Following the Legislation and Regulation Committee meeting held March 24, 2016, staff confirmed with the author's office that there are no plans for the bill anytime in the near future and that it is a "spot" bill.

**SUMMARY:**

AB 2144 would amend Section 4074 of the Business and Professions Code to specify that a health facility shall require each patient *to acknowledge in writing* that a patient has received specified drug warning, storage and other specified information at the time of discharge. The amendments to section 4073.5 are nonsubstantive.

**EXISTING LAW:**

Section 4074 of the Business and Professions code requires a pharmacy, as specified, to inform a patient orally or in writing of the harmful effects of a drug that is dispensed; requires specified labeling if in the pharmacist's professional judgment, the drug may impair a person's ability to operate a vehicle or vessel; and requires a health facility to establish and implement a written policy to ensure that each patient receives information regarding drugs received at the time of discharge to include the use and storage of each drug, precautions and relevant warnings, and the importance of compliance with directions

**COMMITTEE DISCUSSION:**

The committee heard comments in support of the provisions. While it is required that patients receive information regarding their medication at discharge, the provisions would ensure that the patient has this knowledge and require that the patient sign an acknowledgement. Public comment noted that AB 2144 is a spot bill.

**THIS BILL WOULD:**

1. Make very minor nonsubstantive amendments to section 4073.5.
2. Amend section 4073.5 to specify that a health facility require each patient to *acknowledge in writing* that he or she has received the information required by section 4074 regarding the drugs the patient receives at discharge.

**FISCAL IMPACT ON THE BOARD:**

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

**HISTORY:**

| Date    | Action  |
|---------|---|
| 3/28/16 | Re-referred to Com on HEALTH  |
| 3/18/16 | From committee chair, with author’s amendments: Amend, and re-refer to Com on HEALTH. Read second time and amended. |
| 3/17/16 | Referred to Coms on HEALTH and B & P  |
| 2/18/16 | From printer. May be heard in committee March 19.   |
| 2/17/16 | Read first time. To Print.  |

# AB 2144 (Rodriguez) Pharmacy: prescriptions.

**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:~~ *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 pharmacist’s 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~~ *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~~ *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)).

(2) “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 may by regulation~~ *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. *The health facility shall require each patient to acknowledge in writing that the patient has received this information.* 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.

*SEC. 3. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.*



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|                                  |  |
|----------------------------------|--|
| <b>Bill Number:</b>              | <b>SB 482</b>                                |
| <b>Current Version:</b>          | <b>As Amended April 7, 2016</b>              |
| <b>Author:</b>                   | <b>Lara</b>                                  |
| <b>Topic:</b>                    | <b>Controlled Substances: CURES database</b> |
| <b>Committee Recommendation:</b> | <b>Support</b>                               |

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

**Status:** Assembly Rules Committee

**SUMMARY:**

This measure would require a prescriber to access the CURES system under specified conditions, to include checking the system before prescribing a Schedule II 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. Specify that a prescriber will not be liable in a civil action solely for failing to consult the CURES system as required
5. Specify that the requirements do not apply in the following conditions
  - a. if the CURES system is suspended or inaccessible, the internet is not operational, the data in the CURES system is inaccurate or incomplete, or it is not possible to query the system in a timely manner based on an emergency

- b. the patient is in hospice
  - c. the medication is prescribed as part of a surgical procedure that has or will occur in a licensed health care facility and the medication is nonrefillable
  - d. the medication is administered directly to the patient by the prescriber or other person authorized to prescribe a controlled substance
6. The provisions do not take effect until the DOJ certifies that the CURES database is ready for statewide use. Notification is required to the Secretary of State and the Office of Legislative Counsel of the date of the certification.
  7. Reference the definition of prescriber in another section of the Health and Safety Code, Section 11150.
  8. Specify that all provisions of privacy law govern the duties of this section.
  9. Specify that the provisions of this section are severable. If a section is deemed invalid, the remainder of the requirements remains in place.

**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.

**COMMITTEE DISCUSSION:**

During the committee meeting, the members discussed the value of the CURES system and the role it plays in identifying. The committee is recommending that the board take a support position on this bill.

**FISCAL IMPACT ON THE BOARD:**

Board staff does not anticipate any significant impact and believes that any minor impact could be absorbed within existing resources.

**HISTORY:**

| Date     | Action   |
|----------|--|
| 04/07/16 | From committee with author's amendments. Read second time and amended. Re-referred to Com. on RLS. |
| 04/07/16 | Referred to Com. on RLS.   |
| 05/28/15 | In Assembly. Read first time. Held at Desk.  |
| 05/28/15 | Read third time. Passed. (Ayes 28. Noes 11. Page 1116.) Ordered to the Assembly.                   |
| 05/19/15 | Read second time. Ordered to third reading.  |
| 05/18/15 | From committee: Do pass. (Ayes 5. Noes 2. Page 1033.) (May 18).                                    |
| 05/08/15 | Set for hearing May 18.  |
| 04/30/15 | Read second time and amended. Re-referred to Com. on APPR.   |

| Date     | Action  |
|----------|---|
| 04/29/15 | From committee: Do pass as amended and re-refer to Com. on APPR. (Ayes 7. Noes 1. Page 794.) (April 27).    |
| 04/16/15 | From committee with author's amendments. Read second time and amended. Re-referred to Com. on B., P. & E.D. |
| 04/14/15 | Set for hearing April 27.   |
| 04/13/15 | April 20 set for first hearing canceled at the request of author.   |
| 03/24/15 | Set for hearing April 20.   |
| 03/12/15 | Referred to Com. on B., P. & E.D.   |
| 02/27/15 | From printer. May be acted upon on or after March 29.   |
| 02/26/15 | Introduced. Read first time. To Com. on RLS. for assignment. To print.                                      |



**SB-482 Controlled substances: CURES database.** (2015-2016)

**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) *A prescriber is not liable in a civil action solely for failing to consult the CURES database as required pursuant to subdivision (a).*

(d) *The requirement in subdivision (a) does not apply, and a prescriber is not in violation of this section, if any of the following conditions are met:*

(1) *The CURES database is suspended or inaccessible, the Internet is not operational, the data in the CURES database is inaccurate or incomplete, or it is not possible to query the CURES database in a timely manner because of an emergency.*

(2) *The controlled substance is prescribed to a patient receiving hospice care.*

(3) *The controlled substance is prescribed to a patient as a part of a surgical procedure that has or will occur in a licensed health care facility and the prescription is nonrefillable.*

(4) *The controlled substance is directly administered to the patient by the prescriber or another person authorized to prescribe a controlled substance.*

(e) *This section shall not become operative until the Department of Justice certifies that the CURES database is ready for statewide use. The department shall notify the Secretary of State and the Office of Legislative Counsel of the date of that certification.*

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

(g) *A violation of this section shall not be subject to the provisions of Section 11374.*

(h) *All applicable state and federal privacy laws govern the duties required by this section.*

(i) *The provisions of this section are severable. If any provision of this section or its application is held invalid, that invalidity shall not affect other provisions or applications that can be given effect without the invalid provision or application.*



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**Bill Number:** AB 2592

**Current Version:** April 11, 2016 Amended

**Authors:** Assembly Member Cooper

**Topic:** Controlled Substances: medicine locking  
closure packages: grant program

**Board Position:**

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**Affected Section(s):**

Add and repeal section 11209.3 of the Health and Safety Code

**Location:** Assembly Appropriations

**SUMMARY:**

AB 2592 would require the California Department of Public Health (CDPH) to establish a pilot program until January 1, 2020, to combat opioid abuse in targeted areas by awarding grants to individual pharmacies that choose to participate. These pharmacies would be required to offer all patients who are prescribed an opioid, a medicine locking closure package, as defined.

AB 2592 would require the CDPH to evaluate the effectiveness of the program and to report its findings to the Legislature no later than December 31, 2019.

**EXISTING LAW:**

Pharmacy Law governs the practice of pharmacy. Pharmacies dispense dangerous drugs in a manner consistent with state and federal law, to include specified labeling, packaging, drug warnings, consultation, etc.

Opioids are a controlled substance and are defined and scheduled in the California Health and Safety Code. Controlled substance<sup>1</sup> prescriptions are valid for six months. A container dispensing a controlled substance must have a<sup>2</sup> federal warning label prohibiting transfer of the controlled substance. <sup>3</sup>Refills for Schedule II controlled substances are prohibited.

Prescriptions must be dispensed in a<sup>4</sup> 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.

**THIS BILL WOULD:**

Establish a pilot program by which the CDPH would until January 1, 2020, award grants to individual pharmacies that choose to participate. These pharmacies would be required to offer

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<sup>1</sup> Health and Safety Code section 11164

<sup>2</sup> 21 CFR 290.5

<sup>3</sup> Health and Safety Code section 11200

<sup>4</sup> 16 CFR 1700.15, and 16 CCR 1717

all patients who are prescribed an opioid, a medicine locking closure package, as defined. AB 2592 would require the CDPDH to evaluate the effectiveness of the program and to report its findings to the Legislature no later than December 31, 2019.

**FISCAL IMPACT ON THE BOARD:**

None.

**COMMITTEE COMMENTS:**

The committee only briefly discussed the prior amended version of the bill but did not make a recommendation. The prior amended version (3/28) and the current version have only minor changes.

**STAFF COMMENTS:**

The bill is sponsored by Gatekeeper Innovation, Inc., a Sacramento-based company that provides portable containers for securing prescription medications.

**HISTORY:**

| Date    | Action  |
|---------|---|
| 4/19/16 | Do pass as amended. (Ayes. 13 Noes. 0). Re-referred to Appropriations.  |
| 4/12/16 | Re-referred to Com on B&P   |
| 4/11/16 | Read second time and amended.   |
| 4/7/16  | From committee: Amend, and do pass as amended and re-refer to Com on B & P (Ayes 19. Noes0.) (April 5)              |
| 3/28/16 | Re-referred to Com on HEALTH  |
| 3/18/16 | From committee chair, with author's amendments: Amend, and re-refer to Com on HEALTH. Read second time and amended. |
| 3/17/16 | Referred to Coms on HEALTH and B & P  |
| 2/18/16 | From printer. May be heard in committee March 19.   |
| 2/17/16 | Read first time. To Print.  |



*California*  
LEGISLATIVE INFORMATION

**AB-2592 Controlled substances: medicine locking closure packages: grant program.** (2015-2016)

AS AMENDED 4/11/2016

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

- (a) More than 4,300 people died from drug poisoning in California in 2013.*
- (b) Most drug poisonings stem from prescription medications, and opioids are the most commonly prescribed.*
- (c) Recent research by the federal Centers for Disease Control and Prevention finds that 98 percent of all sources for abused prescription drugs originate within the home. Only 3 percent of homes lock up their medications.*
- (d) The State Department of Public Health recently received a new grant of more than \$3.7 million to improve the safe prescribing of opioid painkillers.*

**SEC. 2.** *Section 11209.3 is added to the Health and Safety Code, to read:*

**11209.3.** *(a) The State Department of Public Health shall, to the extent funding is available, establish a pilot program to award grants to combat opioid abuse through the safe prescribing of opioids. Grants, in an amount determined by the department, shall be awarded to individual pharmacies that choose to participate in the program. Grants shall target areas where the prevalence of prescription drug abuse is high as determined by data that have been collected by the department and the California Health Care Foundation.*

*(b) A pharmacy that applies for and receives a grant pursuant to this section shall offer all patients who are prescribed an opioid a medicine locking closure package. A patient shall not receive a medicine locking closure package unless he or she consents either orally or in writing. Every medicine locking closure package shall be dispensed with instructions for patient use unless the patient indicates orally or in writing that instructions are not needed.*

*(c) The State Department of Public Health shall not expend General Fund moneys on this program unless those moneys are specifically appropriated for this purpose. The department may seek funds from private entities, including foundations and nonprofit organizations, and may apply for federal or other grants, to fund the grant program.*

*(d) For purposes of this section, "medicine locking closure package" means a locking closure container, unlocked only with a user-generated code, that only allows the person with the prescription to access the medicine. A medicine locking closure package includes, but is not limited to, an amber prescription container combined with a resettable alphanumeric code.*

*(e) The department shall evaluate the effectiveness of the pilot program to combat prescription drug abuse in targeted areas and report its findings to the Legislature no later than December 31, 2019. The report shall be submitted in compliance with Section 9795 of the Government Code.*

*(f) This section shall remain in effect only until January 1, 2020, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2020, deletes or extends that date.*



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|--------------------------------------|---|
| <b>Bill Number:</b>                  | <b>SB 1217</b>  |
| <b>Current Version:</b>              | <b>As Amended April 12, 2016</b>  |
| <b>Author:</b>                       | <b>Stone</b>  |
| <b>Topic:</b>                        | <b>Healing Arts: Reporting Requirements:<br/>Professional Liability</b> |
| <b>Committee<br/>Recommendation:</b> | <b>None</b>   |

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

**Location:** Senate Business, Professions and Economic Development Committee

**Status:** Failed passage in committee (2-3). Reconsideration granted. (4/18/16)

**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 completed 583 investigations initiated by such reports and substantiated violations of pharmacy law in about 83% of the cases. 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.

As initially introduced, this measure would have applied to several boards with the DCA. At that time, 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 have established a consistent reporting limit of \$10,000.

**COMMITTEE DISCUSSION:**

The committee discussed this measure and heard public comment but ultimately did not recommend a position on the measure.

**FISCAL IMPACT ON THE BOARD:**

As a result of this legislation, the board could realize a reduction in the number of complaints 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:**

| Date     | Action  |
|----------|---|
| 04/18/16 | April 18 set for second hearing. Failed passage in committee. (Ayes 2. Noes 3.) Reconsideration granted.    |
| 04/12/16 | From committee with author's amendments. Read second time and amended. Re-referred to Com. on B., P. & E.D. |
| 04/08/16 | Set for hearing April 18.   |
| 04/07/16 | April 11 set for first hearing canceled at the request of author.   |
| 03/11/16 | Set for hearing April 11.   |
| 03/03/16 | Referred to Com. on B., P. & E.D.   |
| 02/19/16 | From printer. May be acted upon on or after March 20.   |
| 02/18/16 | Introduced. Read first time. To Com. on RLS. for assignment. To print.                                      |



**SB-1217 Healing arts: reporting requirements: professional liability resulting in death or personal injury.** (2015-2016)

**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) (A) 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) 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.

*(B) Notwithstanding subparagraph (A), any judgment or settlement requiring a person licensed pursuant to Chapter 9 (commencing with Section 4000) or his or her insurer to pay any amount of damages in excess of 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 for licensing, certification, or regulatory purposes to inspect and 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), ~~(d)~~, and ~~(e)~~ 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) 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.

(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~~, 4991), 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) Every insurer providing liability insurance to a person licensed pursuant to Chapter 9 (commencing with Section 4000) shall send a complete report to the California State Board of Pharmacy 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)~~ (f) 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.

~~(f)~~ (g) 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) 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~~, 4991), 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 thereto or within 30 days after service of the arbitration award on the parties.

*(c) Every state or local governmental agency that self-insures a person licensed pursuant to Chapter 9 (commencing with Section 4000) shall send a complete report to the California State Board of Pharmacy 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.*

**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) 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 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~~, 4991), 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).

*(c) 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 licensed pursuant to Chapter 9 (commencing with Section 4000) 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 California State Board of Pharmacy. 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 person licensed pursuant to Chapter 9 (commencing with Section 4000) (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).*



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**Bill Number:** SB 1229

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

**Authors:** Senator Jackson  
Assembly Member Stone

**Topic:** Pharmacies: secure drug take-back bins

**Board Position:**

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**Affected Section(s):**

Add Civil Code section 1714.24

Add Health & Safety Code sections 117670.5, 117748 and 118312

**Status:** Referred to Senate Environmental Quality and to Senate Judiciary

**Hearing:** April 6, 2016 Senate Environmental Quality

**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.

<sup>1</sup>“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

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<sup>1</sup> 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 <sup>2</sup>“pharmaceutical” to be a prescription or over-the-counter human or veterinary drug, including, but not limited to, a drug as <sup>3</sup>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, nonidentical 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 <sup>4</sup>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 <sup>5</sup>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

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<sup>2</sup> Health and Safety Code section 11747

<sup>3</sup> 21 U.S.C. Sec. 321(g)(1)

<sup>4</sup> 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.

<sup>5</sup> 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 <sup>6</sup>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.

**HISTORY:**

| Date       | Action   |
|------------|--|
| 03/15/2016 | Mar. 15 Set for hearing April 6.   |
| 03/03/2016 | Mar. 3 Referred to Coms. on E.Q. and JUD.                                      |
| 02/19/2016 | Feb. 19 From printer. May be acted upon on or after March 20.                  |
| 02/18/2016 | Feb. 18 Introduced. Read first time. To Com. on RLS. for assignment. To print. |

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<sup>6</sup> These regulations are incorporated into 21 C.F.R. part 1317 on disposal.

AMENDED IN SENATE MARCH 28, 2016

**SENATE BILL**

**No. 1229**

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**Introduced by Senators Jackson and Stone**

February 18, 2016

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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 amended, Jackson. ~~Pharmacies:—Home-generated pharmaceutical waste:~~ 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~~ 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.~~

*Under existing law, everyone is generally responsible, not only for the result of his or her willful acts, but also for an injury occasioned to another by his or her want of ordinary care or skill in the management of his or her property or person, except so far as the latter, has willfully or by want of ordinary care, brought the injury upon himself or herself.*

*This bill would provide that a collector, as defined, is not liable for civil damages, or subject to criminal prosecution, for maintaining a secure drug take-back bin on its premises if the collector, in good faith and not for compensation, takes specified steps, including that the collector regularly inspects the area surrounding the secure drug take-back bin for potential tampering or diversion, to ensure the health and safety of consumers and employees and the proper disposal in the waste stream of home-generated pharmaceutical waste, as defined, contained in the bins.*

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

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

1 SECTION 1. (a) *The Legislature finds and declares the*  
 2 *following:*  
 3 *(1) On October 12, 2010, the federal Secure and Responsible*  
 4 *Drug Disposal Act of 2010 (Public Law 111-273; hereafter*  
 5 *referred to as the Disposal Act) was enacted. Before the Disposal*  
 6 *Act, individuals who wanted to dispose of unused, unwanted, or*  
 7 *expired pharmaceutical controlled substances had limited disposal*  
 8 *options. The federal Controlled Substances Act (21 U.S.C. Sec.*  
 9 *801 et seq.; hereafter referred to as CSA) only permitted*  
 10 *individuals to destroy those substances themselves (e.g., by flushing*  
 11 *or discarding), surrender them to law enforcement, or seek*  
 12 *assistance from the federal Drug Enforcement Agency (DEA).*  
 13 *These restrictions resulted in the accumulation of pharmaceutical*  
 14 *controlled substances in household medicine cabinets that were*  
 15 *available for abuse, misuse, diversion, and accidental ingestion.*  
 16 *The Disposal Act amended the CSA to authorize specified*

1 individuals, referred to as “ultimate users,” to deliver their  
2 pharmaceutical controlled substances to another person for the  
3 purpose of disposal in accordance with regulations promulgated  
4 by the United States Attorney General.

5 (2) On September 9, 2014, the DEA issued its final rule  
6 governing the secure disposal of controlled substances by  
7 registrants and ultimate users. Those regulations implement the  
8 Disposal Act by expanding the options available to collect  
9 controlled substances from ultimate users for the purpose of  
10 disposal, including take-back events, mail-back programs, and  
11 collection receptacle locations. Those regulations, among other  
12 things, allow authorized manufacturers, distributors, reverse  
13 distributors, narcotic treatment programs, hospitals/clinics with  
14 an on-site pharmacy, and retail pharmacies to voluntarily  
15 administer mail-back programs and maintain collection  
16 receptacles.

17 (b) It is the intent of the Legislature, with the enactment of this  
18 act, to do both of the following:

19 (1) To encourage the good faith participation of  
20 federally-authorized entities to maintain secure drug take-back  
21 bins on their premises for the convenience and public health and  
22 safety of prescription drug consumers and the proper disposal in  
23 the waste stream of the pharmaceutical waste contained in the  
24 bins.

25 (2) To limit the civil and criminal liability of participating  
26 entities that meet certain minimum standards and take reasonable  
27 care to ensure the health and safety of consumers and employees  
28 when maintaining secure drug take-back bins on their premises.

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

30 1714.24. (a) For purposes of this section, the following  
31 definitions shall apply:

32 (1) “Collector” includes only those entities authorized by and  
33 registered with the federal Drug Enforcement Agency to receive  
34 a controlled substance for the purpose of destruction, if the entity  
35 is in good standing with any applicable licensing authority.

36 (2) “Compensation” means reimbursement or funds received  
37 from a customer to compensate for the cost incurred in obtaining,  
38 installing, or maintaining a secure drug take-back bin.  
39 Compensation does not include reimbursement or funds received  
40 from any other person or entity, other than a customer, to

1 *compensate for the costs incurred in obtaining, installing, or*  
2 *maintaining a secure drug take-back bin.*

3 (3) *“Home-generated pharmaceutical waste” means a*  
4 *pharmaceutical that is no longer wanted or needed by the consumer*  
5 *and includes any delivery system, such as pills, liquids, and*  
6 *inhalers.*

7 (4) *“Maintains” includes owning, leasing, operating, or*  
8 *otherwise hosting a secure drug-take back bin on the collector’s*  
9 *premises.*

10 (5) *“Pharmaceutical” means a prescription or over-the-counter*  
11 *human or veterinary drug, including, but not limited to, a drug as*  
12 *defined in Section 109925 of the Health and Safety Code and*  
13 *Section 321(g)(1) of Title 21 of the United States Code.*  
14 *“Pharmaceutical” includes controlled substances included in*  
15 *Schedule II, III, IV, or V of the Uniform Controlled Substances*  
16 *Act (Division 10 (commencing with Section 11000) of the Health*  
17 *and Safety Code), but does not include a controlled substance*  
18 *included in Schedule I.*

19 (6) *“Secure drug take-back bin” means a collection receptacle*  
20 *as described in Section 1317.75 of Title 21 of the Code of Federal*  
21 *Regulations.*

22 (b) *Any collector that maintains a secure drug take-back bin,*  
23 *in good faith and not for compensation, shall not be liable in a*  
24 *civil action, or be subject to criminal prosecution, for maintaining*  
25 *a secure drug take-back bin on its premises if the collector takes*  
26 *all of the following steps to ensure the health and safety of*  
27 *consumers and employees and the proper disposal in the waste*  
28 *stream of the home-generated pharmaceutical waste contained in*  
29 *a secure drug take-back bin:*

30 (1) *Complies with all applicable state and federal laws and*  
31 *regulations relating to the collection of home-generated*  
32 *pharmaceutical waste for disposal in secure drug take-back bins,*  
33 *including, but not limited to the federal Secure and Responsible*  
34 *Drug Disposal Act of 2010 (Public Law 111-273).*

35 (2) *Notifies local law enforcement and any local environmental*  
36 *health department as to the existence and location of any secure*  
37 *drug-take back bin on the collector’s premises and the status of*  
38 *the collector’s registration as a collector with the federal Drug*  
39 *Enforcement Agency.*

1 (3) Ensures that the secure drug take-back bin is placed in a  
2 location that is regularly monitored by employees of the registered  
3 collector.

4 (4) Ensures that conspicuous signage is posted on the secure  
5 drug take-back bin that clearly notifies customers as to what  
6 controlled and non-controlled substances are and are not  
7 acceptable for deposit into the bin, as well as the hours during  
8 which collection is allowed.

9 (5) Ensures that public access to the secure drug take-back bin  
10 is limited to hours wherein employees of the registered collector  
11 are present and able to monitor the operation of the secure drug  
12 take-back bin.

13 (6) Regularly inspects the area surrounding the secure drug  
14 take-back bin for potential tampering or diversion. Record logs  
15 of those inspections shall be maintained and retained for four  
16 years, reflecting the date and time of the inspection, and the initials  
17 of the employee inspecting the area. Other records or reports  
18 mandated by federal or state regulations shall also be retained  
19 for a minimum of four years unless regulations mandate a longer  
20 period.

21 (7) Notifies local law enforcement authorities of any suspected  
22 or known tampering, theft, or significant loss of controlled  
23 substances, within one business day of discovery. If the collector  
24 maintains daily business hours, this notification shall be made  
25 within one calendar day.

26 (8) Notify local law enforcement as to any decision to  
27 discontinue its voluntary collection of controlled substances and  
28 provide documentation of its written notification to the federal  
29 Drug Enforcement Agency's Registration Unit as otherwise  
30 required under federal laws and regulations.

31 (c) The protection specified in subdivision (b) shall not apply  
32 in a case of personal injury or wrongful death that results from  
33 the collector's gross negligence or willful or wanton misconduct  
34 in maintaining a secure drug take-back bin.

35 (d) Nothing in this section shall be construed to require entities  
36 that may qualify as a collector to acquire, maintain, or make  
37 available to the public a secure drug take-back bin on its premises.

38 ~~SECTION 1. (a) It is the intent of the Legislature to encourage~~  
39 ~~the good faith participation of pharmacies in hosting secure drug~~  
40 ~~take-back bins on their premises for the convenience and public~~

1 health and safety of prescription drug consumers and the proper  
2 disposal in the waste stream of the pharmaceutical waste contained  
3 in the bins.

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

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

8 1714.24. Any pharmacy that owns or operates a secure drug  
9 take-back bin in a publicly accessible location shall not be liable  
10 for civil damages arising from the use of the secure drug take-back  
11 bin if the owner or operator takes reasonable steps pursuant to  
12 Section 118312 of the Health and Safety Code to ensure the health  
13 and safety of consumers and employees and the proper disposal  
14 in the waste stream of the pharmaceutical waste contained in the  
15 bins.

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

18 117670.5. “Home-generated pharmaceutical waste” means a  
19 pharmaceutical that is a waste generated by a household or  
20 households.

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

23 117748. “Secure drug take-back bin” means a receptacle that  
24 can receive home-generated pharmaceutical waste, that employs  
25 a locking mechanism that requires the hazardous waste hauler and  
26 the bin owner or operator to use two, nonidentical keys  
27 simultaneously to access the contents of the bin, and that is secured  
28 to a wall or the ground.

29 SEC. 5. Section 118312 is added to the Health and Safety Code,  
30 to read:

31 118312. Any pharmacy that owns or operates a secure drug  
32 take-back bin in a publicly accessible location shall take reasonable  
33 steps to ensure the proper disposal in the waste stream of the  
34 pharmaceutical waste contained in the bins.

35 SEC. 6. No reimbursement is required by this act pursuant to  
36 Section 6 of Article XIII B of the California Constitution because  
37 the only costs that may be incurred by a local agency or school  
38 district will be incurred because this act creates a new crime or  
39 infraction, eliminates a crime or infraction, or changes the penalty  
40 for a crime or infraction, within the meaning of Section 17556 of

1 ~~the Government Code, or changes the definition of a crime within~~  
2 ~~the meaning of Section 6 of Article XIII B of the California~~  
3 ~~Constitution.~~

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|-------------------------|--|
| <b>Bill Number:</b>     | <b>SB 1230</b>                         |
| <b>Current Version:</b> | <b>As Introduced February 18, 2016</b> |
| <b>Author:</b>          | <b>Stone</b>                           |
| <b>Topic:</b>           | <b>Pharmacies: Compounding</b>         |
| <b>Board Position:</b>  |  |

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

**Location:** 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 of the Federal Food, Drug and Cosmetic Act 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.

**HISTORY:**

| Date     | Action   |
|----------|--|
| 04/13/16 | April 18 set for second hearing canceled at the request of author.     |
| 04/07/16 | Set for hearing April 18.  |
| 04/06/16 | April 11 set for first hearing canceled at the request of author.      |
| 03/11/16 | Set for hearing April 11.  |
| 03/03/16 | Referred to Com. on B., P. & E.D.                                      |
| 02/19/16 | From printer. May be acted upon on or after March 20.                  |
| 02/18/16 | Introduced. Read first time. To Com. on RLS. for assignment. To print. |

**Introduced by Senator Stone**

February 18, 2016

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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.

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

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

- 1 SECTION 1. Section 4126.7 is added to the Business and
- 2 Professions Code, to read:

1 4126.7. (a) A pharmacy that provides compounding services  
2 may provide to a clinic commercial products that are unique or  
3 otherwise unavailable to the clinic, if the compounding pharmacy  
4 and the clinic have entered into a professional compounding  
5 services agreement, that complies with regulation adopted pursuant  
6 to subdivision (b), to provide nonpatient-specific compounded  
7 medications that cannot be planned for prospectively.  
8 (b) The board shall adopt regulations for establishing a  
9 professional compounding services agreement.

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

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**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)

**Committee Recommendation:** Maintain Oppose for the 8/19/16 text version.

**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 were no substantive differences between the April 22 version (board opposed, June 2015) and the August 19 versions of the bill.

**STAFF COMMENTS:**

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

**FISCAL IMPACT ON THE BOARD:**

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

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

**SUPPORT**

- American Federation of State, County and Municipal Employees
- 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:**

| Date     | Action   |
|----------|--|
| 07/14/15 | From committee: Do pass and re-refer to Com. on APPR. (Ayes 13. Noes 0.) (July 14). Re-referred to Com. on APPR. |
| 06/11/15 | Referred to Com. on G.O.   |
| 06/01/15 | In Senate. Read first time. To Com. on RLS. for assignment.  |
| 06/01/15 | Read third time. Passed. Ordered to the Senate. (Ayes 80. Noes 0. Page 1693.)                                    |

| Date     | Action   |
|----------|--|
| 05/28/15 | Read second time. Ordered to third reading.  |
| 05/28/15 | From committee: Do pass. (Ayes 17. Noes 0.) (May 28).  |
| 05/13/15 | In committee: Set, first hearing. Referred to APPR. suspense file.   |
| 04/29/15 | From committee: Do pass and re-refer to Com. on APPR. (Ayes 9. Noes 0.) (April 29). Re-referred to Com. on APPR.       |
| 04/23/15 | Re-referred to Com. on A. & A.R.   |
| 04/22/15 | From committee chair, with author's amendments: Amend, and re-refer to Com. on A. & A.R. Read second time and amended. |
| 03/23/15 | In committee: Set, first hearing. Hearing canceled at the request of author.   |
| 01/16/15 | Referred to Com. on A. & A.R.  |
| 12/02/14 | From printer. May be heard in committee January 1.   |
| 12/01/14 | Read first time. To print.   |

## AB 12 (Cooley)

### Regulatory Review and Major Regulation Economic Impact Reporting

#### Bill Summary

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AB 12 strengthens the accountability and transparency of the regulatory process by requiring that state agencies complete a top-to-bottom review by January 1, 2018, of all current and new regulations to ensure that they are not duplicative, overlapping, inconsistent, or outdated.

#### Problem

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Numerous economists and business leaders agree that one of the greatest obstacles to California job growth is the "thicket" of government regulations that constrain business owners. Duplicative and inconsistent regulations leave business owners confused and often times out of compliance despite their best efforts. In addition, the burdensome regulatory scheme often discourages innovation and new business ventures.

#### Solution

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California's regulatory system needs careful review and accountability. To that end, AB 12 requires that each state agency initiate a top-to-bottom review of current and new regulations looking for duplicative, inconsistent, overlapping, or outdated regulations. Agencies will have two years to complete this review so that it can be completed in a comprehensive and timely manner.

#### Background

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Under the Administrative Procedures Act (APA), state agencies which wish to promulgate a regulation must first have it reviewed by the OAL and have public notice and input. Additionally, AB 1111 (1979) and SB 1754 (1980) mandated the Office of Administrative Law (OAL) to

oversee an orderly review by each state agency of all the regulations they administered with the purpose of reducing the number of regulations and simplifying and improving quality. Since that time, top-to-bottom reviews of state agencies' regulations have been few and far between, leading to outdated, duplicative or overlapping regulations that are not automatically purged or updated upon the passage of new regulations. The last top-to-bottom review of regulations was in 1995 initiated by Governor Pete Wilson.

#### Support

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California Chamber of Commerce  
California Manufacturer's and Technology Association  
California Association of Independent Business AFSCME  
California Asian Pacific Chamber of Commerce  
California Association of Bed and Breakfast Inns  
California Building Industry Association  
California Construction and Industrial Materials Association  
California Business Roundtable  
California Hotel and Lodging Association  
California League of Food Processors  
California Retailers Association  
Consumer Specialty Products Association  
Industrial Environmental Association  
National Federation of Independent Businesses-California  
Small Business California  
USANA Health Sciences, Inc.  
Western States Petroleum Association

#### For More Information

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**AB-12 State government: administrative regulations: review.** (2015-2016)

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

**CHAPTER 3.6. Regulatory Reform**  
**Article 1. Findings and Declarations**

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

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

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

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

**Article 2. Definitions**

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

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

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

**Article 3. State Agency Duties**

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

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

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

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

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

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

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

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

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

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

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

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

**Article 4. Chapter Repeal**

**11366.5.** This chapter shall remain in effect only until January 1, 2019, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2019, deletes or extends that date.



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|                         |  |
|-------------------------|--|
| <b>Bill Number:</b>     | <b>SB 1155</b>                               |
| <b>Current Version:</b> | <b>As Amended March 28, 2016</b>             |
| <b>Author:</b>          | <b>Morrell</b>                               |
| <b>Topic:</b>           | <b>Professions and Vocations: Fee Waiver</b> |
| <b>Committee</b>        | <b>None</b>                                  |
| <b>Recommendation:</b>  |  |

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**Affected Sections:** Add section 114.6 to the Business and Professions Code

**Status:** Hearing scheduled for April 25, 2016, Senate Appropriations

**SUMMARY:**

This measure would allow a veteran who is honorably discharged who served as an active duty member of the California National Guard or the United States Armed Forces to have one fee waiver for the application for an issuance of one license by one of the boards within the Department of Consumer Affairs.

**EXISTING LAW:**

Existing Pharmacy Law provides for the licensure of five (5) personal licenses, as follows:

- Pharmacist
- Pharmacist Intern
- Pharmacy Technician
- Designated Representative
- Designated Representative-3PL

The board currently expedites the review of applications from those who are active duty military, honorably discharged veterans, or spouses or partners of active duty military. In fiscal year 2015/16 and for a five-month period, the board received 26 requests for expedite – 23 were for pharmacist applications, and 3 were for designated representative applications.

**THIS BILL WOULD:**

Add section 114.6 to the Business and professions code to allow a veteran who is honorably discharged who served as an active duty member of the California National Guard or the United States Armed Forces to have one fee waiver for the application for an issuance of one license from any board within the Department of Consumer Affairs.

The provisions specify that only one waiver shall be granted to a veteran, as specified.

**STAFF COMMENTS:**

Because the waiver provisions apply to one application across all DCA boards, the board would need to determine how to determine if an applicant has already taken advantage of the one waiver allowance.

**COMMITTEE DISCUSSION:**

The committee did not discuss the bill.

**FISCAL IMPACT ON THE BOARD:**

Using the expedite statistics provided (five-month period), the license fees that may have been waived are as follows:

| Category                  | Fee   | No. | Total          |
|---------------------------|-------|-----|----------------|
| Pharmacist Exam           | \$260 | 23  | \$5,980        |
| Designated Representative | \$330 | 3   | \$900          |
|                           |       |     | <b>\$6,880</b> |

**HISTORY:**

| Date     | Action   |
|----------|--|
| 04/13/16 | From committee: Do pass and re-refer to Com. on APPR. (Ayes 5. Noes 0.) (April 12). Re-referred to Com. on APPR.         |
| 04/06/16 | Set for hearing April 12.  |
| 04/05/16 | From committee: Do pass and re-refer to Com. on V.A. (Ayes 9. Noes 0. Page 3377.) (April 4). Re-referred to Com. on V.A. |
| 03/28/16 | From committee with author's amendments. Read second time and amended. Re-referred to Com. on B., P. & E.D.              |
| 03/11/16 | Set for hearing April 4.   |
| 03/03/16 | Referred to Coms. on B., P. & E.D. and V.A.  |
| 02/19/16 | From printer. May be acted upon on or after March 20.  |
| 02/18/16 | Introduced. Read first time. To Com. on RLS. for assignment. To print.   |



# Senate California Legislature

**Mike Morrell**

Senator, Twenty-Third District

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## SB 1155 – Veterans’ Occupational Licensure Fee Waiver

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### BILL SUMMARY

This bill will waive initial application and license fees for honorably discharged veterans entering an occupation requiring licensure in California. Only one fee of each waiver may be granted in a veteran’s lifetime.

For all licensing boards within the Department of Consumer Affairs, the bill specifies:

- If a board requires an application fee, the board shall waive the fee;
- If a board requires a fee for the issuance of a license, the board shall waive the fee;
- Only one fee waiver shall be granted to a veteran. If the veteran applies for a second license or a second time for a denied license, the veteran will be deemed to have used his or her one-time fee waiver;
- Fee waivers will not be granted for license renewals;
- The fee waiver will only apply to individual veterans and not to businesses or other entities.

### BACKGROUND

Initial application and occupational license fees can act as barriers of entry to the workforce for the 240,000 to 360,000 veterans who separate from the military each year. Many either already reside in or intend to make California their home, adding to the 1.9 million veterans currently residing in the state.

Veterans often gain valuable job skills during military service which can be used upon entering the civilian workforce. Despite this fact, young veterans have an unemployment rate of 16.2 percent.

California also has upwards of 11,000 veterans living on the streets, the most of any state.

Wisconsin, Florida, and Texas have passed legislation granting fee waivers for the initial issuance of occupational licenses to honorably discharged veterans. Ohio is currently considering similar legislation.

### PROBLEM

Boards within the California Department of Consumer Affairs often charge a fee for the application and issuance of a license. These fees vary by board.

Current California statute does not provide waived fees for the application and issuance of a license for honorably discharged veterans.

### SOLUTION

Require boards within the Department of Consumer Affairs to grant one-time fee waivers for the application and issuance of licenses to honorably discharged veterans.

Eliminating these fees will bring more veterans into the workforce, growing the skilled labor market in California, and taking a step to alleviate the growing problem of veteran homelessness.

### BILL STATUS

**Referred to the Senate Appropriations Committee  
(4/12/16)**

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Updated: 4/13/2016



**SB-1155 Professions and vocations: licenses: military service.** (2015-2016)

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

**114.6.** *Notwithstanding any other provision of law, every board within the department shall grant a fee waiver for the application for and issuance of a license to an individual who is an honorably discharged veteran who served as an active duty member of the California National Guard or the United States Armed Forces. Under this program, all of the following apply:*

*(a) A veteran shall be granted only one fee waiver.*

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

*(c) A waiver shall not be issued for a renewal of a license or for the application for and issuance of a license other than one initial license.*



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**Bill Number:** SB 1195

**Current Version:** As Amended April 6, 2016

**Author:** Hill

**Topic:** Business and Professions: Board Actions:  
Competitive Impact

**Committee  
Recommendation:**

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**Affected Sections:** Amend several sections within Division 1 of the Business and Professions Code related to the Department of Consumer Affairs, such as B&PC §109, §116, §153 and others

**Location:** Senate Appropriations

**SUMMARY:**

This bill would grant authority to the DCA director to review a decision or other action, except as specified, of a board within the DCA to determine whether it unreasonably restrains trade and to approve, disapprove, or modify the board decision or action, as specified. It clarifies when a judgment or settlement for treble damages antitrust award would be granted for a member of a regulatory board; and provides for an additional standard for the Office of Administrative Law to follow when reviewing regulatory actions of state boards.

This bill makes additional changes related to the Board of Registered Nursing and also is the sunset bill for the Veterinary Medical Board.

**EXISTING LAW:**

Section 108 of the Business and Professions Code specifies that each board within the Department of Consumer Affairs and has the functions of setting standards, holding meetings, preparing and conducting examinations, passing upon applicants, conducting investigations of violations of laws under its jurisdiction, issuing citations and holding hearings for the revocation of licenses, and the imposing of penalties following those hearings.

The Pharmacy Law, Section 4000, et seq. of the Business and Professions Code, provides for the licensure and regulation of various professionals and entities under the board's jurisdiction, and authorizes the board to adopt regulations to enforce the laws under its jurisdiction.

Existing law allows the director to audit and review inquiries and complaints regarding licensees, dismissals of disciplinary cases, the opening, conduct, or closure of investigations; informal conferences, and discipline short of formal accusation by the allied health professional

boards; and allows the director to make recommendations for changes to the disciplinary system to the appropriate board, the Legislature or both. Any such findings are to be reported to the chairpersons of the Senate BP&ED and Assembly Health committees annually. (BPC §108)

Existing law defines the scope under which the Director of the DCA may intervene, audit or review. Currently, decisions of the board pertaining to setting standards, conducting examinations, passing candidates, and revoking licenses are not subject to review the Director of the DCA. (BPC § 109)

Section 313.1 as well as provisions in the Government Code (the Administrative Procedure Act) governs the procedure for the adoption, amendment or repeal of regulations by the board, to include review by the director of the DCA. The Government Code further mandates that the Office of Administrative Law review proposed regulations to ensure they comply with specified standards and either approve or disapprove regulatory actions.

**THIS BILL WOULD:**

Amend section 109 of the Business and Professions Code to

1. Remove language that specifies that the decisions of the board with respect to setting standards, conducting examinations, passing candidates, and revoking licenses, are not subject to review by the director, but are final within the limits provided by the Business and Professions Code, as is applicable to Pharmacy Law, except as otherwise provided in this section.
2. Authorize the DCA director to, upon his or her own initiative, and required upon the request of a consumer or licensee, to review any board decision or other action to determine whether it unreasonably restrains trade.

These reviews shall proceed as follows:

- a. The director shall assess whether a board action or decision reflects a clearly articulated and affirmatively expressed state law. If it does not, the director shall disapprove the board action or decision and it shall not go into effect.
- b. If the board action or decision is a reflection of clearly articulated and affirmatively expressed state law, the director shall assess whether the action or decision was the result of the board's exercise of ministerial or discretionary judgment. If the director finds no exercise of discretionary judgment, but merely the direct application of statutory or constitutional provisions, the director shall close the investigation and review the board action or decision.
- c. Based on the aforementioned, if the director concludes that the board exercised discretionary judgment, the director shall review the board action or decision as follows:
  - i. The director shall conduct a full review of the board action or decision using all relevant facts, data, market conditions, public comment, studies, or other documentary evidence pertaining to the market impacted by the board's action or decision and determine whether the anticompetitive effects of the action or decision are clearly outweighed by the benefit to the public.

- ii. If the board action or decision was not previously subject to a public comment period, the director shall release the subject matter of his or her investigation for a 30-day public comment period and shall consider all comments received.
  - iii. If the director determines that the action or decision furthers the public protection mission of the board and the impact on competition is justified, the director may approve the action or decision.
  - iv. If the director determines that the action or decision does not further the public protection mission of the board or finds that the action or decision is not justified, the director shall either refuse to approve it or shall modify the action or decision to ensure that any restraints of trade are related to, and advance, clearly articulated state law or public policy.
  - v. The director shall issue, and post on the department's Internet Web site, his or her final written decision approving, modifying, or disapproving the action or decision with an explanation of the reasons and rationale behind the director's decision within 90 days from the receipt of the request from a consumer or licensee. Notwithstanding any other law, the decision of the director shall be final, except if the state or federal constitution requires an appeal of the director's decision.
- d. The review set forth above, shall not apply when an individual seeks review of disciplinary or other action pertaining solely to that individual.
  - e. The director shall report to the Chairs of the Senate Business, Professions, and Economic Development Committee and the Assembly Business and Professions Committee annually, commencing March 1, 2017, regarding his or her disapprovals, modifications, or findings from any audit, review, or monitoring and evaluation conducted pursuant to this section. A report submitted shall comply with section 9795 of the Government Code.
  - f. If the director has already reviewed a board action or decision pursuant to this section or Section 313.1, the director shall not review that action or decision again.
  - g. The section shall not be construed to affect, impede, or delay any disciplinary actions of any board.

**COMMITTEE DISCUSSION:**

The committee did not discuss this measure.

**HISTORY:**

| Date     | Action  |
|----------|---|
| 04/19/16 | From committee: Do pass and re-refer to Com on APPR (Ayes 6. Noes 0.) (April 18) Re-referred to Com on APPR |
| 04/06/16 | From committee with author's amendments. Read second time and amended. Re-referred to Com. on B., P. & E.D. |
| 03/29/16 | Set for hearing April 18.   |
| 03/03/16 | Referred to Com. on B., P. & E.D.   |
| 02/19/16 | From printer. May be acted upon on or after March 20.   |
| 02/18/16 | Introduced. Read first time. To Com. on RLS. for assignment. To print.                                      |



**SB-1195 Professions and vocations: board actions: competitive impact.** (2015-2016)

**SECTION 1.** *Section 109 of the Business and Professions Code is amended to read:*

~~109.~~

~~(a) The decisions of any of the boards comprising the department with respect to setting standards, conducting examinations, passing candidates, and revoking licenses, are not subject to review by the director, but are final within the limits provided by this code which are applicable to the particular board, except as provided in this section.~~

~~(b)~~

~~109. (a) The decisions of any of the boards comprising the department with respect to setting standards, conducting examinations, passing candidates, and revoking licenses, are not subject to review by the director, but are final within the limits provided by this code which are applicable to the particular board, except as provided in this section.~~

~~(b)~~ (a) The director may initiate an investigation of any allegations of misconduct in the preparation, administration, or scoring of an examination which is administered by a board, or in the review of qualifications which are a part of the licensing process of any board. A request for investigation shall be made by the director to the Division of Investigation through the chief of the division or to any law enforcement agency in the jurisdiction where the alleged misconduct occurred.

~~(c)~~ (b) (1) The director may intervene in any matter of any board where an investigation by the Division of Investigation discloses probable cause to believe that the conduct or activity of a board, or its members or employees constitutes a violation of criminal law.

(2) The term "intervene," as used in paragraph ~~(c) of this section~~ (1) may include, but is not limited to, an application for a restraining order or injunctive relief as specified in Section 123.5, or a referral or request for criminal prosecution. For purposes of this section, the director shall be deemed to have standing under Section 123.5 and shall seek representation of the Attorney General, or other appropriate counsel in the event of a conflict in pursuing that action.

(c) *The director may, upon his or her own initiative, and shall, upon request by a consumer or licensee, review any board decision or other action to determine whether it unreasonably restrains trade. Such a review shall proceed as follows:*

*(1) The director shall assess whether the action or decision reflects a clearly articulated and affirmatively expressed state law. If the director determines that the action or decision does not reflect a clearly articulated and affirmatively expressed state law, the director shall disapprove the board action or decision and it shall not go into effect.*

*(2) If the action or decision is a reflection of clearly articulated and affirmatively expressed state law, the director shall assess whether the action or decision was the result of the board's exercise of ministerial or discretionary judgment. If the director finds no exercise of discretionary judgment, but merely the direct application of statutory or constitutional provisions, the director shall close the investigation and review of the board action or decision.*

*(3) If the director concludes under paragraph (2) that the board exercised discretionary judgment, the director shall review the board action or decision as follows:*

*(A) The director shall conduct a full review of the board action or decision using all relevant facts, data, market conditions, public comment, studies, or other documentary evidence pertaining to the market impacted by the board's action or decision and determine whether the anticompetitive effects of the action or decision are clearly outweighed by the benefit to the public. The director may seek, designate, employ, or contract for the services*

of independent antitrust or economic experts pursuant to Section 307. These experts shall not be active participants in the market affected by the board action or decision.

(B) If the board action or decision was not previously subject to a public comment period, the director shall release the subject matter of his or her investigation for a 30-day public comment period and shall consider all comments received.

(C) If the director determines that the action or decision furthers the public protection mission of the board and the impact on competition is justified, the director may approve the action or decision.

(D) If the director determines that the action furthers the public protection mission of the board and the impact on competition is justified, the director may approve the action or decision. If the director finds the action or decision does not further the public protection mission of the board or finds that the action or decision is not justified, the director shall either refuse to approve it or shall modify the action or decision to ensure that any restraints of trade are related to, and advance, clearly articulated state law or public policy.

(4) The director shall issue, and post on the department's Internet Web site, his or her final written decision approving, modifying, or disapproving the action or decision with an explanation of the reasons and rationale behind the director's decision within 90 days from receipt of the request from a consumer or licensee. Notwithstanding any other law, the decision of the director shall be final, except if the state or federal constitution requires an appeal of the director's decision.

(d) The review set forth in paragraph (3) of subdivision (c) shall not apply when an individual seeks review of disciplinary or other action pertaining solely to that individual.

(e) The director shall report to the Chairs of the Senate Business, Professions, and Economic Development Committee and the Assembly Business and Professions Committee annually, commencing March 1, 2017, regarding his or her disapprovals, modifications, or findings from any audit, review, or monitoring and evaluation conducted pursuant to this section. That report shall be submitted in compliance with Section 9795 of the Government Code.

(f) If the director has already reviewed a board action or decision pursuant to this section or Section 313.1, the director shall not review that action or decision again.

(g) This section shall not be construed to affect, impede, or delay any disciplinary actions of any board.

**SEC. 2.** Section 116 of the Business and Professions Code is amended to read:

**116.** (a) The director may audit and review, upon his or her own initiative, or upon the request of a consumer or licensee, inquiries and complaints regarding licensees, dismissals of disciplinary cases, the opening, conduct, or closure of investigations, informal conferences, and discipline short of formal accusation by ~~the Medical Board of California, the allied health professional boards, and the California Board of Podiatric Medicine. The director may make recommendations for changes to the disciplinary system to the appropriate board, the Legislature, or both.~~ any board or bureau within the department.

(b) The director shall report to the ~~Chairpersons~~ Chairs of the Senate ~~Business and Professions~~ Business, Professions, and Economic Development Committee and the Assembly ~~Health Business and Professions~~ Committee annually, commencing March 1, ~~1995,~~ 2017, regarding his or her findings from any audit, review, or monitoring and evaluation conducted pursuant to this section. *This report shall be submitted in compliance with Section 9795 of the Government Code.*

**SEC. 3.** Section 153 of the Business and Professions Code is amended to read:

**153.** The director may investigate the work of the several boards in his department and may obtain a copy of all records and full and complete data in all official matters in possession of the boards, their members, officers, or ~~employees, other than examination questions prior to submission to applicants at scheduled examinations.~~ employees.

**SEC. 4.** Section 307 of the Business and Professions Code is amended to read:

**307.** The director may contract for the services of experts and consultants where necessary to carry out ~~the provisions of~~ this chapter and may provide compensation and reimbursement of expenses for ~~such~~ those experts and consultants in accordance with state law.

**SEC. 5.** Section 313.1 of the Business and Professions Code is amended to read:

**313.1.** (a) Notwithstanding any other ~~provision of~~ law to the contrary, no rule or ~~regulation, except those relating to examinations and qualifications for licensure, and~~ *regulation and* no fee change proposed or promulgated by any of the boards, commissions, or committees within the department, shall take effect pending compliance with this section.

(b) The director shall be formally notified of and shall ~~be provided a full opportunity to~~ review, in accordance with the requirements of Article 5 (commencing with Section 11346) of Chapter 3.5 of Part 1 of Division 3 of Title 2 of the Government Code, *the requirements in subdivision (c) of Section 109,* and this section, all of the following:

(1) All notices of proposed action, any modifications and supplements thereto, and the text of proposed regulations.

(2) Any notices of sufficiently related changes to regulations previously noticed to the public, and the text of proposed regulations showing modifications to the text.

(3) Final rulemaking records.

*(4) All relevant facts, data, public comments, market conditions, studies, or other documentary evidence pertaining to the market impacted by the proposed regulation. This information shall be included in the written decision of the director required under paragraph (4) of subdivision (c) of Section 109.*

(c) The submission of all notices and final rulemaking records to the director and the ~~completion of the director's review,~~ *director's approval,* as authorized by this section, shall be a precondition to the filing of any rule or regulation with the Office of Administrative Law. The Office of Administrative Law shall have no jurisdiction to review a rule or regulation subject to this section until after the ~~completion of the~~ director's review and ~~only then if the director has not disapproved it.~~ *approval.* The filing of any document with the Office of Administrative Law shall be accompanied by a certification that the board, commission, or committee has complied with the requirements of this section.

(d) Following the receipt of any final rulemaking record subject to subdivision (a), the director shall have the authority for a period of 30 days to *approve a proposed rule or regulation or* disapprove a proposed rule or regulation on the ground that it is injurious to the public health, safety, or ~~welfare.~~ *welfare, or has an impermissible anticompetitive effect. The director may modify a rule or regulation as a condition of approval. Any modifications to regulations by the director shall be subject to a 30-day public comment period before the director issues a final decision regarding the modified regulation. If the director does not approve the rule or regulation within the 30-day period, the rule or regulation shall not be submitted to the Office of Administrative Law and the rule or regulation shall have no effect.*

(e) Final rulemaking records shall be filed with the director within the one-year notice period specified in Section 11346.4 of the Government Code. If necessary for compliance with this section, the one-year notice period may be extended, as specified by this subdivision.

(1) In the event that the one-year notice period lapses during the director's 30-day review period, or within 60 days following the notice of the director's disapproval, it may be extended for a maximum of 90 days.

(2) If the director approves the final rulemaking ~~record or declines to take action on it within 30 days,~~ *record,* the board, commission, or committee shall have five days from the receipt of the record from the director within which to file it with the Office of Administrative Law.

(3) If the director disapproves a rule or regulation, it shall have no force or effect unless, within 60 days of the notice of disapproval, (A) the disapproval is overridden by a unanimous vote of the members of the board, commission, or committee, and (B) the board, commission, or committee files the final rulemaking record with the Office of Administrative Law in compliance with this section and the procedures required by Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code. *This paragraph shall not apply to any decision disapproved by the director under subdivision (c) of Section 109.*

~~(f) (f) This Nothing in this~~ section shall *not* be construed to prohibit the director from affirmatively approving a proposed rule, regulation, or fee change at any time within the 30-day period after it has been submitted to him or her, in which event it shall become effective upon compliance with this section and the procedures required by Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code.

**SEC. 6.** *Section 2708 of the Business and Professions Code is amended to read:*

**2708.** (a) The board shall appoint an executive officer who shall perform the duties delegated by the board and who shall be responsible to it for the accomplishment of those duties.

(b) The executive officer shall *not* be a ~~nurse currently licensed~~ *licensee* under this chapter and shall possess other qualifications as determined by the board.

(c) The executive officer shall not be a member of the board.

(d) This section shall remain in effect only until January 1, 2018, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2018, deletes or extends that date.

~~SECTION 4.~~**SEC. 7.** Section 4800 of the Business and Professions Code is amended to read:

**4800.** (a) There is in the Department of Consumer Affairs a Veterinary Medical Board in which the administration of this chapter is vested. The board consists of the following members:

(1) Four licensed veterinarians.

(2) One registered veterinary technician.

(3) Three public members.

(b) This section shall remain in effect only until January 1, ~~2017, 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.*

(c) Notwithstanding any other law, the repeal of this section renders the board subject to review by the appropriate policy committees of the Legislature. However, the review of the board shall be limited to those issues identified by the appropriate policy committees of the Legislature and shall not involve the preparation or submission of a sunset review document or evaluative questionnaire.

~~SEC. 2.~~**SEC. 8.** Section 4804.5 of the Business and Professions Code is amended to read:

**4804.5.** (a) The board may appoint a person exempt from civil service who shall be designated as an executive officer and who shall exercise the powers and perform the duties delegated by the board and vested in him or her by this chapter.

(b) This section shall remain in effect only until January 1, ~~2017, 2021~~, and as of that date is ~~repealed, unless a later enacted statute, that is enacted before January 1, 2017, deletes or extends that date.~~ *repealed.*

**SEC. 9.** *Section 4825.1 of the Business and Professions Code is amended to read:*

**4825.1.** These definitions shall govern the construction of this chapter as it applies to veterinary medicine.

(a) "Diagnosis" means the act or process of identifying or determining the health status of an animal through examination and the opinion derived from that examination.

(b) "Animal" means any member of the animal kingdom other than humans, and includes fowl, fish, and reptiles, wild or domestic, whether living or dead.

(c) "Food animal" means any animal that is raised for the production of an edible product intended for consumption by humans. The edible product includes, but is not limited to, milk, meat, and eggs. Food animal includes, but is not limited to, cattle (beef or dairy), swine, sheep, poultry, fish, and amphibian species.

(d) "Livestock" includes all animals, poultry, aquatic and amphibian species that are raised, kept, or used for profit. It does not include those species that are usually kept as pets such as dogs, cats, and pet birds, or companion animals, including equines.

(e) *"Compounding," for the purposes of veterinary medicine, shall have the same meaning given in Section 1735 of Title 16 of the California Code of Regulations, except that every reference therein to "pharmacy" and "pharmacist" shall be replaced with "veterinary premises" and "veterinarian," and except that only a licensed veterinarian or a licensed registered veterinarian technician under direct supervision of a veterinarian may perform compounding and shall not delegate to or supervise any part of the performance of compounding by any other person.*

**SEC. 10.** *Section 4826.3 is added to the Business and Professions Code, to read:*

**4826.3.** (a) Notwithstanding Section 4051, a veterinarian or registered veterinarian technician under the direct supervision of a veterinarian with a current and active license may compound a drug for anesthesia, the prevention, cure, or relief of a wound, fracture, bodily injury, or disease of an animal in a premises currently and actively registered with the board and only under the following conditions:

(1) Where there is no FDA-approved animal or human drug that can be used as labeled or in an appropriate extralabel manner to properly treat the disease, symptom, or condition for which the drug is being prescribed.

(2) Where the compounded drug is not available from a compounding pharmacy, outsourcing facility, or other compounding supplier in a dosage form and concentration to appropriately treat the disease, symptom, or condition for which the drug is being prescribed.

(3) Where the need and prescription for the compounded medication has arisen within an established veterinarian-client-patient relationship as a means to treat a specific occurrence of a disease, symptom, or condition observed and diagnosed by the veterinarian in a specific animal that threatens the health of the animal or will cause suffering or death if left untreated.

(4) Where the quantity compounded does not exceed a quantity demonstrably needed to treat a patient with which the veterinarian has a current veterinarian-client-patient relationship.

(5) Except as specified in subdivision (c), where the compound is prepared only with commercially available FDA-approved animal or human drugs as active ingredients.

(b) A compounded veterinary drug may be prepared from an FDA-approved animal or human drug for extralabel use only when there is no approved animal or human drug that, when used as labeled or in an appropriate extralabel manner will, in the available dosage form and concentration, treat the disease, symptom, or condition. Compounding from an approved human drug for use in food-producing animals is not permitted if an approved animal drug can be used for compounding.

(c) A compounded veterinary drug may be prepared from bulk drug substances only when:

(1) The drug is compounded and dispensed by the veterinarian to treat an individually identified animal patient under his or her care.

(2) The drug is not intended for use in food-producing animals.

(3) If the drug contains a bulk drug substance that is a component of any marketed FDA-approved animal or human drug, there is a change between the compounded drug and the comparable marketed drug made for an individually identified animal patient that produces a clinical difference for that individually identified animal patient, as determined by the veterinarian prescribing the compounded drug for his or her patient.

(4) There are no FDA-approved animal or human drugs that can be used as labeled or in an appropriate extralabel manner to properly treat the disease, symptom, or condition for which the drug is being prescribed.

(5) All bulk drug substances used in compounding are manufactured by an establishment registered under Section 360 of Title 21 of the United States Code and are accompanied by a valid certificate of analysis.

(6) The drug is not sold or transferred by the veterinarian compounding the drug, except that the veterinarian shall be permitted to administer the drug to a patient under his or her care or dispense it to the owner or caretaker of an animal under his or her care.

(7) Within 15 days of becoming aware of any product defect or serious adverse event associated with any drug compounded by the veterinarian from bulk drug substances, the veterinarian shall report it to the federal Food and Drug Administration on Form FDA 1932a.

(8) In addition to any other requirements, the label of any veterinary drug compounded from bulk drug substances shall indicate the species of the intended animal patient, the name of the animal patient, and the name of the owner or caretaker of the patient.

(d) Each compounded veterinary drug preparation shall meet the labeling requirements of Section 4076 and Sections 1707.5 and 1735.4 of Title 16 of the California Code of Regulations, except that every reference therein to "pharmacy" and "pharmacist" shall be replaced by "veterinary premises" and "veterinarian," and any reference to "patient" shall be understood to refer to the animal patient. In addition, each label on a compounded veterinary drug preparation shall include withdrawal and holding times, if needed, and the disease, symptom, or condition for which the drug is being prescribed. Any compounded veterinary drug preparation

*that is intended to be sterile, including for injection, administration into the eye, or inhalation, shall in addition meet the labeling requirements of Section 1751.2 of Title 16 of the California Code of Regulations, except that every reference therein to "pharmacy" and "pharmacist" shall be replaced by "veterinary premises" and "veterinarian," and any reference to "patient" shall be understood to refer to the animal patient.*

*(e) Any veterinarian, registered veterinarian technician who is under the direct supervision of a veterinarian, and veterinary premises engaged in compounding shall meet the compounding requirements for pharmacies and pharmacists stated by the provisions of Article 4.5 (commencing with Section 1735) of Title 16 of the California Code of Regulations, except that every reference therein to "pharmacy" and "pharmacist" shall be replaced by "veterinary premises" and "veterinarian," and any reference to "patient" shall be understood to refer to the animal patient:*

*(1) Section 1735.1 of Title 16 of the California Code of Regulations.*

*(2) Subdivisions (d),(e), (f), (g), (h), (i), (j), (k), and (l) of Section 1735.2 of Title 16 of the California Code of Regulations.*

*(3) Section 1735.3 of Title 16 of the California Code of Regulations, except that only a licensed veterinarian or registered veterinarian technician may perform compounding and shall not delegate to or supervise any part of the performance of compounding by any other person.*

*(4) Section 1735.4 of Title 16 of the California Code of Regulations.*

*(5) Section 1735.5 of Title 16 of the California Code of Regulations.*

*(6) Section 1735.6 of Title 16 of the California Code of Regulations.*

*(7) Section 1735.7 of Title 16 of the California Code of Regulations.*

*(8) Section 1735.8 of Title 16 of the California Code of Regulations.*

*(f) Any veterinarian, registered veterinarian technician under the direct supervision of a veterinarian, and veterinary premises engaged in sterile compounding shall meet the sterile compounding requirements for pharmacies and pharmacists under Article 7 (commencing with Section 1751) of Title 16 of the California Code of Regulations, except that every reference therein to "pharmacy" and "pharmacist" shall be replaced by "veterinary premises" and "veterinarian," and any reference to "patient" shall be understood to refer to the animal patient.*

*(g) The California State Board of Pharmacy shall have authority with the board to ensure compliance with this section and shall have the right to inspect any veterinary premises engaged in compounding, along with or separate from the board, to ensure compliance with this section. The board is specifically charged with enforcing this section with regard to its licensees.*

**SEC. 11.** *Section 4826.5 is added to the Business and Professions Code, to read:*

**4826.5.** *Failure by a licensed veterinarian, registered veterinarian technician, or veterinary premises to comply with the provisions of this article shall be deemed unprofessional conduct and constitute grounds for discipline.*

**SEC. 12.** *Section 4826.7 is added to the Business and Professions Code, to read:*

**4826.7.** *The board may adopt regulations to implement the provisions of this article.*

**SEC. 13.** *Section 4830 of the Business and Professions Code is amended to read:*

**4830.** (a) This chapter does not apply to:

(1) Veterinarians while serving in any armed branch of the military service of the United States or the United States Department of Agriculture while actually engaged and employed in their official capacity.

(2) Regularly licensed veterinarians in actual consultation from other states.

(3) Regularly licensed veterinarians actually called from other states to attend cases in this state, but who do not open an office or appoint a place to do business within this state.

~~(4) Veterinarians employed by the University of California while engaged in the performance of duties in connection with the College of Agriculture, the Agricultural Experiment Station, the School of Veterinary~~

~~Medicine, or the agricultural extension work of the university or employed by the Western University of Health Sciences while engaged in the performance of duties in connection with the College of Veterinary Medicine or the agricultural extension work of the university.~~

~~(5)~~ (4) Students in the School of Veterinary Medicine of the University of California or the College of Veterinary Medicine of the Western University of Health Sciences who participate in diagnosis and treatment as part of their educational experience, including those in off-campus educational programs under the direct supervision of a licensed veterinarian in good standing, as defined in paragraph (1) of subdivision (b) of Section 4848, appointed by the University of California, Davis, or the Western University of Health Sciences.

~~(6)~~ (5) A veterinarian who is employed by the Meat and Poultry Inspection Branch of the California Department of Food and Agriculture while actually engaged and employed in his or her official capacity. A person exempt under this paragraph shall not otherwise engage in the practice of veterinary medicine unless he or she is issued a license by the board.

~~(7)~~ (6) Unlicensed personnel employed by the Department of Food and Agriculture or the United States Department of Agriculture when in the course of their duties they are directed by a veterinarian supervisor to conduct an examination, obtain biological specimens, apply biological tests, or administer medications or biological products as part of government disease or condition monitoring, investigation, control, or eradication activities.

(b) (1) For purposes of paragraph (3) of subdivision (a), a regularly licensed veterinarian in good standing who is called from another state by a law enforcement agency or animal control agency, as defined in Section 31606 of the Food and Agricultural Code, to attend to cases that are a part of an investigation of an alleged violation of federal or state animal fighting or animal cruelty laws within a single geographic location shall be exempt from the licensing requirements of this chapter if the law enforcement agency or animal control agency determines that it is necessary to call the veterinarian in order for the agency or officer to conduct the investigation in a timely, efficient, and effective manner. In determining whether it is necessary to call a veterinarian from another state, consideration shall be given to the availability of veterinarians in this state to attend to these cases. An agency, department, or officer that calls a veterinarian pursuant to this subdivision shall notify the board of the investigation.

(2) Notwithstanding any other provision of this chapter, a regularly licensed veterinarian in good standing who is called from another state to attend to cases that are a part of an investigation described in paragraph (1) may provide veterinary medical care for animals that are affected by the investigation with a temporary shelter facility, and the temporary shelter facility shall be exempt from the registration requirement of Section 4853 if all of the following conditions are met:

(A) The temporary shelter facility is established only for the purpose of the investigation.

(B) The temporary shelter facility provides veterinary medical care, shelter, food, and water only to animals that are affected by the investigation.

(C) The temporary shelter facility complies with Section 4854.

(D) The temporary shelter facility exists for not more than 60 days, unless the law enforcement agency or animal control agency determines that a longer period of time is necessary to complete the investigation.

(E) Within 30 calendar days upon completion of the provision of veterinary health care services at a temporary shelter facility established pursuant to this section, the veterinarian called from another state by a law enforcement agency or animal control agency to attend to a case shall file a report with the board. The report shall contain the date, place, type, and general description of the care provided, along with a listing of the veterinary health care practitioners who participated in providing that care.

(c) For purposes of paragraph (3) of subdivision (a), the board may inspect temporary facilities established pursuant to this section.

**SEC. 14.** *Section 4846.5 of the Business and Professions Code is amended to read:*

**4846.5.** (a) Except as provided in this section, the board shall issue renewal licenses only to those applicants that have completed a minimum of 36 hours of continuing education in the preceding two years.

(b) (1) Notwithstanding any other law, continuing education hours shall be earned by attending courses relevant to veterinary medicine and sponsored or cosponsored by any of the following:

- (A) American Veterinary Medical Association (AVMA) accredited veterinary medical colleges.
  - (B) Accredited colleges or universities offering programs relevant to veterinary medicine.
  - (C) The American Veterinary Medical Association.
  - (D) American Veterinary Medical Association recognized specialty or affiliated allied groups.
  - (E) American Veterinary Medical Association's affiliated state veterinary medical associations.
  - (F) Nonprofit annual conferences established in conjunction with state veterinary medical associations.
  - (G) Educational organizations affiliated with the American Veterinary Medical Association or its state affiliated veterinary medical associations.
  - (H) Local veterinary medical associations affiliated with the California Veterinary Medical Association.
  - (I) Federal, state, or local government agencies.
  - (J) Providers accredited by the Accreditation Council for Continuing Medical Education (ACCME) or approved by the American Medical Association (AMA), providers recognized by the American Dental Association Continuing Education Recognition Program (ADA CERP), and AMA or ADA affiliated state, local, and specialty organizations.
- (2) Continuing education credits shall be granted to those veterinarians taking self-study courses, which may include, but are not limited to, reading journals, viewing video recordings, or listening to audio recordings. The taking of these courses shall be limited to no more than six hours biennially.
- (3) The board may approve other continuing veterinary medical education providers not specified in paragraph (1).
- (A) The board has the authority to recognize national continuing education approval bodies for the purpose of approving continuing education providers not specified in paragraph (1).
- (B) Applicants seeking continuing education provider approval shall have the option of applying to the board or to a board-recognized national approval body.
- (4) For good cause, the board may adopt an order specifying, on a prospective basis, that a provider of continuing veterinary medical education authorized pursuant to paragraph (1) or (3) is no longer an acceptable provider.
- (5) Continuing education hours earned by attending courses sponsored or cosponsored by those entities listed in paragraph (1) between January 1, 2000, and January 1, 2001, shall be credited toward a veterinarian's continuing education requirement under this section.
- (c) Every person renewing his or her license issued pursuant to Section 4846.4, or any person applying for relicensure or for reinstatement of his or her license to active status, shall submit proof of compliance with this section to the board certifying that he or she is in compliance with this section. Any false statement submitted pursuant to this section shall be a violation subject to Section 4831.
- (d) This section shall not apply to a veterinarian's first license renewal. This section shall apply only to second and subsequent license renewals granted on or after January 1, 2002.
- (e) The board shall have the right to audit the records of all applicants to verify the completion of the continuing education requirement. Applicants shall maintain records of completion of required continuing education coursework for a period of four years and shall make these records available to the board for auditing purposes upon request. If the board, during this audit, questions whether any course reported by the veterinarian satisfies the continuing education requirement, the veterinarian shall provide information to the board concerning the content of the course; the name of its sponsor and cosponsor, if any; and specify the specific curricula that was of benefit to the veterinarian.
- (f) A veterinarian desiring an inactive license or to restore an inactive license under Section 701 shall submit an application on a form provided by the board. In order to restore an inactive license to active status, the veterinarian shall have completed a minimum of 36 hours of continuing education within the last two years preceding application. The inactive license status of a veterinarian shall not deprive the board of its authority to institute or continue a disciplinary action against a licensee.

(g) Knowing misrepresentation of compliance with this article by a veterinarian constitutes unprofessional conduct and grounds for disciplinary action or for the issuance of a citation and the imposition of a civil penalty pursuant to Section 4883.

(h) The board, in its discretion, may exempt from the continuing education requirement any veterinarian who for reasons of health, military service, or undue hardship cannot meet those requirements. Applications for waivers shall be submitted on a form provided by the board.

(i) The administration of this section may be funded through professional license and continuing education provider fees. The fees related to the administration of this section shall not exceed the costs of administering the corresponding provisions of this section.

(j) For those continuing education providers not listed in paragraph (1) of subdivision (b), the board or its recognized national approval agent shall establish criteria by which a provider of continuing education shall be approved. The board shall initially review and approve these criteria and may review the criteria as needed. The board or its recognized agent shall monitor, maintain, and manage related records and data. The board may impose an application fee, not to exceed two hundred dollars (\$200) biennially, for continuing education providers not listed in paragraph (1) of subdivision (b).

(k) (1) ~~On or after~~ *Beginning* January 1, 2018, a licensed veterinarian who renews his or her license shall complete a minimum of one credit hour of continuing education on the judicious use of medically important antimicrobial drugs every four years as part of his or her continuing education requirements.

(2) For purposes of this subdivision, "medically important antimicrobial drug" means an antimicrobial drug listed in Appendix A of the federal Food and Drug Administration's Guidance for Industry #152, including critically important, highly important, and important antimicrobial drugs, as that appendix may be amended.

**SEC. 15.** *Section 4848.1 is added to the Business and Professions Code, to read:*

**4848.1.** *(a) A veterinarian engaged in the practice of veterinary medicine, as defined in Section 4826, employed by the University of California while engaged in the performance of duties in connection with the School of Veterinary Medicine or employed by the Western University of Health Sciences while engaged in the performance of duties in connection with the College of Veterinary Medicine shall be licensed in California or shall hold a university license issued by the board.*

*(b) An applicant is eligible to hold a university license if all of the following are satisfied:*

*(1) The applicant is currently employed by the University of California or Western University of Health Sciences as defined in subdivision (a).*

*(2) Passes an examination concerning the statutes and regulations of the Veterinary Medicine Practice Act, administered by the board, pursuant to subparagraph (C) of paragraph (2) of subdivision (a) of Section 4848.*

*(3) Successfully completes the approved educational curriculum described in paragraph (5) of subdivision (b) of Section 4848 on regionally specific and important diseases and conditions.*

*(c) A university license:*

*(1) Shall be numbered as described in Section 4847.*

*(2) Shall cease to be valid upon termination of employment by the University of California or by the Western University of Health Sciences.*

*(3) Shall be subject to the license renewal provisions in Section 4846.4.*

*(4) Shall be subject to denial, revocation, or suspension pursuant to Sections 4875 and 4883.*

*(d) An individual who holds a University License is exempt from satisfying the license renewal requirements of Section 4846.5.*

**SEC. 16.** *Section 4853.7 is added to the Business and Professions Code, to read:*

**4853.7.** *A premise registration that is not renewed within five years after its expiration may not be renewed and shall not be restored, reissued, or reinstated thereafter. However, an application for a new premise registration may be submitted and obtained if both of the following conditions are met:*

*(a) No fact, circumstance, or condition exists that, if the premise registration was issued, would justify its revocation or suspension.*

*(b) All of the fees that would be required for the initial premise registration are paid at the time of application.*

**SEC. 17.** *Section 825 of the Government Code is amended to read:*

**825.** (a) Except as otherwise provided in this section, if an employee or former employee of a public entity requests the public entity to defend him or her against any claim or action against him or her for an injury arising out of an act or omission occurring within the scope of his or her employment as an employee of the public entity and the request is made in writing not less than 10 days before the day of trial, and the employee or former employee reasonably cooperates in good faith in the defense of the claim or action, the public entity shall pay any judgment based thereon or any compromise or settlement of the claim or action to which the public entity has agreed.

If the public entity conducts the defense of an employee or former employee against any claim or action with his or her reasonable good-faith cooperation, the public entity shall pay any judgment based thereon or any compromise or settlement of the claim or action to which the public entity has agreed. However, where the public entity conducted the defense pursuant to an agreement with the employee or former employee reserving the rights of the public entity not to pay the judgment, compromise, or settlement until it is established that the injury arose out of an act or omission occurring within the scope of his or her employment as an employee of the public entity, the public entity is required to pay the judgment, compromise, or settlement only if it is established that the injury arose out of an act or omission occurring in the scope of his or her employment as an employee of the public entity.

Nothing in this section authorizes a public entity to pay that part of a claim or judgment that is for punitive or exemplary damages.

(b) Notwithstanding subdivision (a) or any other provision of law, a public entity is authorized to pay that part of a judgment that is for punitive or exemplary damages if the governing body of that public entity, acting in its sole discretion except in cases involving an entity of the state government, finds all of the following:

- (1) The judgment is based on an act or omission of an employee or former employee acting within the course and scope of his or her employment as an employee of the public entity.
- (2) At the time of the act giving rise to the liability, the employee or former employee acted, or failed to act, in good faith, without actual malice and in the apparent best interests of the public entity.
- (3) Payment of the claim or judgment would be in the best interests of the public entity.

As used in this subdivision with respect to an entity of state government, "a decision of the governing body" means the approval of the Legislature for payment of that part of a judgment that is for punitive damages or exemplary damages, upon recommendation of the appointing power of the employee or former employee, based upon the finding by the Legislature and the appointing authority of the existence of the three conditions for payment of a punitive or exemplary damages claim. The provisions of subdivision (a) of Section 965.6 shall apply to the payment of any claim pursuant to this subdivision.

The discovery of the assets of a public entity and the introduction of evidence of the assets of a public entity shall not be permitted in an action in which it is alleged that a public employee is liable for punitive or exemplary damages.

The possibility that a public entity may pay that part of a judgment that is for punitive damages shall not be disclosed in any trial in which it is alleged that a public employee is liable for punitive or exemplary damages, and that disclosure shall be grounds for a mistrial.

(c) Except as provided in subdivision (d), if the provisions of this section are in conflict with the provisions of a memorandum of understanding reached pursuant to Chapter 10 (commencing with Section 3500) of Division 4 of Title 1, the memorandum of understanding shall be controlling without further legislative action, except that if those provisions of a memorandum of understanding require the expenditure of funds, the provisions shall not become effective unless approved by the Legislature in the annual Budget Act.

(d) The subject of payment of punitive damages pursuant to this section or any other provision of law shall not be a subject of meet and confer under the provisions of Chapter 10 (commencing with Section 3500) of Division 4 of Title 1, or pursuant to any other law or authority.

(e) Nothing in this section shall affect the provisions of Section 818 prohibiting the award of punitive damages against a public entity. This section shall not be construed as a waiver of a public entity's immunity from liability for punitive damages under Section 1981, 1983, or 1985 of Title 42 of the United States Code.

(f) (1) Except as provided in paragraph (2), a public entity shall not pay a judgment, compromise, or settlement arising from a claim or action against an elected official, if the claim or action is based on conduct by the elected official by way of tortiously intervening or attempting to intervene in, or by way of tortiously influencing or attempting to influence the outcome of, any judicial action or proceeding for the benefit of a particular party by contacting the trial judge or any commissioner, court-appointed arbitrator, court-appointed mediator, or court-appointed special referee assigned to the matter, or the court clerk, bailiff, or marshal after an action has been filed, unless he or she was counsel of record acting lawfully within the scope of his or her employment on behalf of that party. Notwithstanding Section 825.6, if a public entity conducted the defense of an elected official against such a claim or action and the elected official is found liable by the trier of fact, the court shall order the elected official to pay to the public entity the cost of that defense.

(2) If an elected official is held liable for monetary damages in the action, the plaintiff shall first seek recovery of the judgment against the assets of the elected official. If the elected official's assets are insufficient to satisfy the total judgment, as determined by the court, the public entity may pay the deficiency if the public entity is authorized by law to pay that judgment.

(3) To the extent the public entity pays any portion of the judgment or is entitled to reimbursement of defense costs pursuant to paragraph (1), the public entity shall pursue all available creditor's remedies against the elected official, including garnishment, until that party has fully reimbursed the public entity.

(4) This subdivision shall not apply to any criminal or civil enforcement action brought in the name of the people of the State of California by an elected district attorney, city attorney, or attorney general.

*(g) Notwithstanding subdivision (a), a public entity shall pay for a judgment or settlement for treble damage antitrust awards against a member of a regulatory board for an act or omission occurring within the scope of his or her employment as a member of a regulatory board.*

**SEC. 18.** *Section 11346.5 of the Government Code is amended to read:*

**11346.5.** (a) The notice of proposed adoption, amendment, or repeal of a regulation shall include the following:

(1) A statement of the time, place, and nature of proceedings for adoption, amendment, or repeal of the regulation.

(2) Reference to the authority under which the regulation is proposed and a reference to the particular code sections or other provisions of law that are being implemented, interpreted, or made specific.

(3) An informative digest drafted in plain English in a format similar to the Legislative Counsel's digest on legislative bills. The informative digest shall include the following:

(A) A concise and clear summary of existing laws and regulations, if any, related directly to the proposed action and of the effect of the proposed action.

(B) If the proposed action differs substantially from an existing comparable federal regulation or statute, a brief description of the significant differences and the full citation of the federal regulations or statutes.

(C) A policy statement overview explaining the broad objectives of the regulation and the specific benefits anticipated by the proposed adoption, amendment, or repeal of a regulation, including, to the extent applicable, nonmonetary benefits such as the protection of public health and safety, worker safety, or the environment, the prevention of discrimination, the promotion of fairness or social equity, and the increase in openness and transparency in business and government, among other things.

(D) An evaluation of whether the proposed regulation is inconsistent or incompatible with existing state regulations.

(4) Any other matters as are prescribed by statute applicable to the specific state agency or to any specific regulation or class of regulations.

(5) A determination as to whether the regulation imposes a mandate on local agencies or school districts and, if so, whether the mandate requires state reimbursement pursuant to Part 7 (commencing with Section 17500) of Division 4.

(6) An estimate, prepared in accordance with instructions adopted by the Department of Finance, of the cost or savings to any state agency, the cost to any local agency or school district that is required to be reimbursed under Part 7 (commencing with Section 17500) of Division 4, other nondiscretionary cost or savings imposed on local agencies, and the cost or savings in federal funding to the state.

For purposes of this paragraph, "cost or savings" means additional costs or savings, both direct and indirect, that a public agency necessarily incurs in reasonable compliance with regulations.

(7) If a state agency, in proposing to adopt, amend, or repeal any administrative regulation, makes an initial determination that the action may have a significant, statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states, it shall include the following information in the notice of proposed action:

(A) Identification of the types of businesses that would be affected.

(B) A description of the projected reporting, recordkeeping, and other compliance requirements that would result from the proposed action.

(C) The following statement: "The (name of agency) has made an initial determination that the (adoption/amendment/repeal) of this regulation may have a significant, statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states. The (name of agency) (has/has not) considered proposed alternatives that would lessen any adverse economic impact on business and invites you to submit proposals. Submissions may include the following considerations:

(i) The establishment of differing compliance or reporting requirements or timetables that take into account the resources available to businesses.

(ii) Consolidation or simplification of compliance and reporting requirements for businesses.

(iii) The use of performance standards rather than prescriptive standards.

(iv) Exemption or partial exemption from the regulatory requirements for businesses."

(8) If a state agency, in adopting, amending, or repealing any administrative regulation, makes an initial determination that the action will not have a significant, statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states, it shall make a declaration to that effect in the notice of proposed action. In making this declaration, the agency shall provide in the record facts, evidence, documents, testimony, or other evidence upon which the agency relies to support its initial determination.

An agency's initial determination and declaration that a proposed adoption, amendment, or repeal of a regulation may have or will not have a significant, adverse impact on businesses, including the ability of California businesses to compete with businesses in other states, shall not be grounds for the office to refuse to publish the notice of proposed action.

(9) A description of all cost impacts, known to the agency at the time the notice of proposed action is submitted to the office, that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

If no cost impacts are known to the agency, it shall state the following:

"The agency is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action."

(10) A statement of the results of the economic impact assessment required by subdivision (b) of Section 11346.3 or the standardized regulatory impact analysis if required by subdivision (c) of Section 11346.3, a summary of any comments submitted to the agency pursuant to subdivision (f) of Section 11346.3 and the agency's response to those comments.

(11) The finding prescribed by subdivision (d) of Section 11346.3, if required.

(12) (A) A statement that the action would have a significant effect on housing costs, if a state agency, in adopting, amending, or repealing any administrative regulation, makes an initial determination that the action would have that effect.

(B) The agency officer designated in paragraph ~~(14)~~ (15) shall make available to the public, upon request, the agency's evaluation, if any, of the effect of the proposed regulatory action on housing costs.

(C) The statement described in subparagraph (A) shall also include the estimated costs of compliance and potential benefits of a building standard, if any, that were included in the initial statement of reasons.

(D) For purposes of model codes adopted pursuant to Section 18928 of the Health and Safety Code, the agency shall comply with the requirements of this paragraph only if an interested party has made a request to the agency to examine a specific section for purposes of estimating the costs of compliance and potential benefits for that section, as described in Section 11346.2.

*(13) If the regulatory action is submitted by a state board on which a controlling number of decisionmakers are active market participants in the market the board regulates, a statement that the adopting agency has evaluated the impact of the proposed regulation on competition, and that the proposed regulation furthers a clearly articulated and affirmatively expressed state law to restrain competition.*

~~(13)~~ (14) A statement that the adopting agency must determine that no reasonable alternative considered by the agency or that has otherwise been identified and brought to the attention of the agency would be more effective in carrying out the purpose for which the action is proposed, would be as effective and less burdensome to affected private persons than the proposed action, or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law. For a major regulation, as defined by Section 11342.548, proposed on or after November 1, 2013, the statement shall be based, in part, upon the standardized regulatory impact analysis of the proposed regulation, as required by Section 11346.3, as well as upon the benefits of the proposed regulation identified pursuant to subparagraph (C) of paragraph (3).

~~(14)~~ (15) The name and telephone number of the agency representative and designated backup contact person to whom inquiries concerning the proposed administrative action may be directed.

~~(15)~~ (16) The date by which comments submitted in writing must be received to present statements, arguments, or contentions in writing relating to the proposed action in order for them to be considered by the state agency before it adopts, amends, or repeals a regulation.

~~(16)~~ (17) Reference to the fact that the agency proposing the action has prepared a statement of the reasons for the proposed action, has available all the information upon which its proposal is based, and has available the express terms of the proposed action, pursuant to subdivision (b).

~~(17)~~ (18) A statement that if a public hearing is not scheduled, any interested person or his or her duly authorized representative may request, no later than 15 days prior to the close of the written comment period, a public hearing pursuant to Section 11346.8.

~~(18)~~ (19) A statement indicating that the full text of a regulation changed pursuant to Section 11346.8 will be available for at least 15 days prior to the date on which the agency adopts, amends, or repeals the resulting regulation.

~~(19)~~ (20) A statement explaining how to obtain a copy of the final statement of reasons once it has been prepared pursuant to subdivision (a) of Section 11346.9.

~~(20)~~ (21) If the agency maintains an Internet Web site or other similar forum for the electronic publication or distribution of written material, a statement explaining how materials published or distributed through that forum can be accessed.

~~(21)~~ (22) If the proposed regulation is subject to Section 11346.6, a statement that the agency shall provide, upon request, a description of the proposed changes included in the proposed action, in the manner provided by Section 11346.6, to accommodate a person with a visual or other disability for which effective communication is required under state or federal law and that providing the description of proposed changes may require extending the period of public comment for the proposed action.

(b) The agency representative designated in paragraph ~~(14)~~ (15) of subdivision (a) shall make available to the public upon request the express terms of the proposed action. The representative shall also make available to the public upon request the location of public records, including reports, documentation, and other materials, related to the proposed action. If the representative receives an inquiry regarding the proposed action that the representative cannot answer, the representative shall refer the inquiry to another person in the agency for a prompt response.

(c) This section shall not be construed in any manner that results in the invalidation of a regulation because of the alleged inadequacy of the notice content or the summary or cost estimates, or the alleged inadequacy or inaccuracy of the housing cost estimates, if there has been substantial compliance with those requirements.

**SEC. 19.** *Section 11349 of the Government Code is amended to read:*

**11349.** The following definitions govern the interpretation of this chapter:

(a) "Necessity" means the record of the rulemaking proceeding demonstrates by substantial evidence the need for a regulation to effectuate the purpose of the statute, court decision, or other provision of law that the regulation implements, interprets, or makes specific, taking into account the totality of the record. For purposes of this standard, evidence includes, but is not limited to, facts, studies, and expert opinion.

(b) "Authority" means the provision of law which permits or obligates the agency to adopt, amend, or repeal a regulation.

(c) "Clarity" means written or displayed so that the meaning of regulations will be easily understood by those persons directly affected by them.

(d) "Consistency" means being in harmony with, and not in conflict with or contradictory to, existing statutes, court decisions, or other provisions of law.

(e) "Reference" means the statute, court decision, or other provision of law which the agency implements, interprets, or makes specific by adopting, amending, or repealing a regulation.

(f) "Nonduplication" means that a regulation does not serve the same purpose as a state or federal statute or another regulation. This standard requires that an agency proposing to amend or adopt a regulation must identify any state or federal statute or regulation which is overlapped or duplicated by the proposed regulation and justify any overlap or duplication. This standard is not intended to prohibit state agencies from printing relevant portions of enabling legislation in regulations when the duplication is necessary to satisfy the clarity standard in paragraph (3) of subdivision (a) of Section 11349.1. This standard is intended to prevent the indiscriminate incorporation of statutory language in a regulation.

*(g) "Competitive impact" means that the record of the rulemaking proceeding or other documentation demonstrates that the regulation is authorized by a clearly articulated and affirmatively expressed state law, that the regulation furthers the public protection mission of the state agency, and that the impact on competition is justified in light of the applicable regulatory rationale for the regulation.*

**SEC. 20.** *Section 11349.1 of the Government Code is amended to read:*

**11349.1.** (a) The office shall review all regulations adopted, amended, or repealed pursuant to the procedure specified in Article 5 (commencing with Section 11346) and submitted to it for publication in the California Code of Regulations Supplement and for transmittal to the Secretary of State and make determinations using all of the following standards:

(1) Necessity.

(2) Authority.

(3) Clarity.

(4) Consistency.

(5) Reference.

(6) Nonduplication.

*(7) For those regulations submitted by a state board on which a controlling number of decisionmakers are active market participants in the market the board regulates, the office shall review for competitive impact.*

In reviewing regulations pursuant to this section, the office shall restrict its review to the regulation and the record of the rulemaking ~~proceeding~~—*except as directed in subdivision (h)*. The office shall approve the regulation or order of repeal if it complies with the standards set forth in this section and with this chapter.

(b) In reviewing proposed regulations for the criteria in subdivision (a), the office may consider the clarity of the proposed regulation in the context of related regulations already in existence.

(c) The office shall adopt regulations governing the procedures it uses in reviewing regulations submitted to it. The regulations shall provide for an orderly review and shall specify the methods, standards, presumptions, and principles the office uses, and the limitations it observes, in reviewing regulations to establish compliance with the standards specified in subdivision (a). The regulations adopted by the office shall ensure that it does not substitute its judgment for that of the rulemaking agency as expressed in the substantive content of adopted regulations.

(d) The office shall return any regulation subject to this chapter to the adopting agency if any of the following occur:

(1) The adopting agency has not prepared the estimate required by paragraph (6) of subdivision (a) of Section 11346.5 and has not included the data used and calculations made and the summary report of the estimate in the file of the rulemaking.

(2) The agency has not complied with Section 11346.3. "Noncompliance" means that the agency failed to complete the economic impact assessment or standardized regulatory impact analysis required by Section 11346.3 or failed to include the assessment or analysis in the file of the rulemaking proceeding as required by Section 11347.3.

(3) The adopting agency has prepared the estimate required by paragraph (6) of subdivision (a) of Section 11346.5, the estimate indicates that the regulation will result in a cost to local agencies or school districts that is required to be reimbursed under Part 7 (commencing with Section 17500) of Division 4, and the adopting agency fails to do any of the following:

(A) Cite an item in the Budget Act for the fiscal year in which the regulation will go into effect as the source from which the Controller may pay the claims of local agencies or school districts.

(B) Cite an accompanying bill appropriating funds as the source from which the Controller may pay the claims of local agencies or school districts.

(C) Attach a letter or other documentation from the Department of Finance which states that the Department of Finance has approved a request by the agency that funds be included in the Budget Bill for the next following fiscal year to reimburse local agencies or school districts for the costs mandated by the regulation.

(D) Attach a letter or other documentation from the Department of Finance which states that the Department of Finance has authorized the augmentation of the amount available for expenditure under the agency's appropriation in the Budget Act which is for reimbursement pursuant to Part 7 (commencing with Section 17500) of Division 4 to local agencies or school districts from the unencumbered balances of other appropriations in the Budget Act and that this augmentation is sufficient to reimburse local agencies or school districts for their costs mandated by the regulation.

(4) The proposed regulation conflicts with an existing state regulation and the agency has not identified the manner in which the conflict may be resolved.

(5) The agency did not make the alternatives determination as required by paragraph (4) of subdivision (a) of Section 11346.9.

*(6) The office decides that the record of the rulemaking proceeding or other documentation for the proposed regulation does not demonstrate that the regulation is authorized by a clearly articulated and affirmatively expressed state law, that the regulation does not further the public protection mission of the state agency, or that the impact on competition is not justified in light of the applicable regulatory rationale for the regulation.*

(e) The office shall notify the Department of Finance of all regulations returned pursuant to subdivision (d).

(f) The office shall return a rulemaking file to the submitting agency if the file does not comply with subdivisions (a) and (b) of Section 11347.3. Within three state working days of the receipt of a rulemaking file, the office shall notify the submitting agency of any deficiency identified. If no notice of deficiency is mailed to the adopting agency within that time, a rulemaking file shall be deemed submitted as of the date of its original receipt by the office. A rulemaking file shall not be deemed submitted until each deficiency identified under this subdivision has been corrected.

(g) Notwithstanding any other law, return of the regulation to the adopting agency by the office pursuant to this section is the exclusive remedy for a failure to comply with subdivision (c) of Section 11346.3 or paragraph (10) of subdivision (a) of Section 11346.5.

*(h) The office may designate, employ, or contract for the services of independent antitrust or applicable economic experts when reviewing proposed regulations for competitive impact. When reviewing a regulation for competitive impact, the office shall do all of the following:*

*(1) If the Director of Consumer Affairs issued a written decision pursuant to subdivision (c) of Section 109 of the Business and Professions Code, the office shall review and consider the decision and all supporting documentation in the rulemaking file.*

*(2) Consider whether the anticompetitive effects of the proposed regulation are clearly outweighed by the public policy merits.*

*(3) Provide a written opinion setting forth the office's findings and substantive conclusions under paragraph (2), including, but not limited to, whether rejection or modification of the proposed regulation is necessary to ensure that restraints of trade are related to and advance the public policy underlying the applicable regulatory rationale.*

**SEC. 21.** *No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.*

# **Attachment 4**

**Self-Administered  
Hormonal  
Contraception**

**1746.1**

**BOARD OF PHARMACY**  
**Department of Consumer Affairs**

ORDER OF ADOPTION

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:

1. Dosage;
2. Effectiveness;
3. Potential side effects;
4. Safety;
5. The importance of receiving recommended preventative health screenings;
6. 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 Sheets:

(A) The pharmacist should provide the patient with a copy of a current, consumer-friendly, comprehensive birth control guide such as that created by the Food and Drug Administration (FDA). Examples of appropriate guides are available on the Board of Pharmacy's website.

(B) 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 Business and Professions Code Section 4052.3(c). The pharmacist shall answer any questions the patient may have regarding self-administered hormonal contraception.

(C) The pharmacist should provide the patient with a copy of an administration-specific factsheet. Examples of appropriate factsheets are available on the Board of Pharmacy's website.

(7) Follow-Up Care: Upon furnishing a self-administered hormonal contraceptive, or if it 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 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

**HORMONAL CONTRACEPTION SELF-SCREENING TOOL QUESTIONS**

|    |   |                              |                             |
|----|---|------------------------------|-----------------------------|
| 1  | What was the first date of your last menstrual period?  | / /                          |                             |
| 2a | Have you ever taken birth control pills, or used a birth control patch, ring, or shot/injection? (If no, go to question 3)  | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 2b | Did you ever experience a bad reaction to using hormonal birth control?   | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 2c | Are you currently using birth control pills, or a birth control patch, ring, or shot/injection?   | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 3  | Have you ever been told by a medical professional not to take hormones?   | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 4  | Do you smoke cigarettes?  | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 5  | Do you think you might be pregnant now?   | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 6  | Have you given birth within the past 6 weeks?   | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 7  | Are you currently breastfeeding an infant who is less than 1 month of age?  | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 8  | Do you have diabetes?   | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 9  | 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? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 10 | Do you have high blood pressure, hypertension, or high cholesterol?   | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 11 | Have you ever had a heart attack or stroke, or been told you had any heart disease?   | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 12 | Have you ever had a blood clot in your leg or in your lung?   | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 13 | 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?   | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 14 | Have you had bariatric surgery or stomach reduction surgery?  | Yes <input type="checkbox"/> | No <input type="checkbox"/> |

|     |  |                              |                             |
|-----|--|------------------------------|-----------------------------|
| 15  | Have you had recent major surgery or are you planning to have surgery in the next 4 weeks?   | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 16  | Do you have or have you ever had breast cancer?  | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 17  | 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)? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 18  | Do you have lupus, rheumatoid arthritis, or any blood disorders?   | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 19a | Do you take medication for seizures, tuberculosis (TB), fungal infections, or human immunodeficiency virus (HIV)?                                | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 19b | If yes, list them here:  |                              |                             |
| 20a | Do you have any other medical problems or take regular medication?   | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 20b | If yes, list them here:  |                              |                             |

Authority: Sections 4005 and 4052.3, Business and Professions Code.

Reference: Sections 733, 4052, 4052.3 and 4103, Business and Professions Code.

**Self-Administered  
Hormonal  
Contraception  
Press Release**

**Martinez, Lori@DCA**

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**From:** Damoth, Debbie@DCA  
**Sent:** Friday, April 08, 2016 4:24 PM  
**To:** DCA Pharmacy  
**Subject:** Press release being blocked for DCA emails

SACRAMENTO -- The California State Board of Pharmacy announces that California's protocol is now in effect, permitting pharmacists to furnish self-administered hormonal contraception to women without a prescription. While the protocol does not make hormonal contraception "over-the-counter," it does provide women with the ability to obtain self-administered birth control products upon completion of a self-screening questionnaire and consultation with a pharmacist. The protocol, enacted as a regulation, became effective April 8, 2016.

According to Board President Amy Gutierrez, "The ability to obtain hormonal contraception directly from a local pharmacist will lead to increased access to contraception therapy for women throughout California. Combining this access with the pharmacist's role in patient education and counseling increases the benefit to each woman who elects to take advantage of this new access."

Women who seek to obtain these products from a pharmacy will be asked to complete a self-screening questionnaire and review their information with the pharmacist. In order to provide this service, a pharmacist must have completed training as set forth in the protocol.

It is recommended that consumers check with their local pharmacists to confirm initiation of this new service.

The authority to adopt the new regulation and protocol were made possible through legislation authored by Senator Ed Hernandez, O.D. (Azusa).

Click here to view the regulation:

[http://www.pharmacy.ca.gov/publications/hormonal\\_contraception\\_protocol\\_rphs.pdf](http://www.pharmacy.ca.gov/publications/hormonal_contraception_protocol_rphs.pdf)

Click here to view the self-screening questionnaire for patient completion:

[http://www.pharmacy.ca.gov/publications/patient\\_screening\\_tool\\_consumers\\_english.pdf](http://www.pharmacy.ca.gov/publications/patient_screening_tool_consumers_english.pdf)

For more information on the Board of Pharmacy, go to <http://www.pharmacy.ca.gov>.

*The CA State Board of Pharmacy protects and promotes the health and safety of California consumers by pursuing the highest quality of pharmacist care and the appropriate use of pharmaceuticals through education, communication, licensing, legislation, regulation and enforcement.*

----- To unsubscribe from this email list please click on the link below and follow the instructions on the web page.

<https://www.dca.ca.gov/webapps/pharmacy/subscribe.php>

# **Attachment 5**

# **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)~~ [\(Rev. 10/14\)](#) entitled "Community Pharmacy Self-Assessment Hospital Outpatient Pharmacy Self- Assessment" and on Form 17M-14 ~~(Rev. 01/11)~~ [\(Rev. 10/14\)](#) entitled "Hospital Pharmacy Self-Assessment" which are hereby incorporated by reference to evaluate compliance with federal and state laws and regulations.

(d) Each self-assessment shall be kept on file in the pharmacy for three years after it is performed.

Authority: Business and Professions Code §4005 and §4127. Reference: Business and Professions Code §4021, §4022, §4029, §4030, §4037, §4038, §4040, §4050, §4052, §4070, §4081, §4101, §4105, §4113, §4115, §4119, §4127, §4305, §4330, §4332 and §4333.



## COMMUNITY PHARMACY SELF-ASSESSMENT HOSPITAL OUTPATIENT PHARMACY SELF-ASSESSMENT

Title 16 of the California Code of Regulations section 1715 requires the pharmacist-in-charge of each pharmacy licensed under section 4037 or 4029 of the Business and Professions Code to complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. **The assessment shall be performed before July 1 of every odd-numbered year. The pharmacist-in-charge must also complete a self-assessment within 30 days whenever: (1) a new pharmacy permit has been issued; (2) there is a change in the pharmacist-in-charge; or (3) there is a change in the licensed location of the pharmacy. The primary purpose of the self-assessment is to promote compliance through self-examination and education.**

The self-assessment must be completed in its entirety and may be completed online, printed 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. ~~4/11~~ 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: \_\_\_\_\_

~~or~~ Accredited by (optional): \_\_\_\_\_ From: \_\_\_\_\_ To: \_\_\_\_\_

DEA Registration #: \_\_\_\_\_ Exp. Date: \_\_\_\_\_ Date of DEA Inventory: \_\_\_\_\_

Hours: Weekdays ~~Daily~~ \_\_\_\_\_ Sat \_\_\_\_\_ Sun. \_\_\_\_\_ 24 Hours \_\_\_\_\_

PIC: \_\_\_\_\_ RPH # \_\_\_\_\_ Exp. Date: \_\_\_\_\_

Website address (optional): \_\_\_\_\_

**Pharmacy Staff (pharmacists, intern pharmacists, pharmacy technicians):**

{Please use an additional sheet if necessary} . APP=Advanced Practice Pharmacist, DEA =Drug Enforcement Administration.

|     |       |   |  |
|-----|-------|---|--|
| 1.  | _____ | RPH # _____<br>APP # _____<br>DEA # _____ | Exp. Date: _____<br>Exp. Date: _____<br>Exp. Date: _____ |
| 2.  | _____ | RPH # _____<br>APP # _____<br>DEA # _____ | Exp. Date: _____<br>Exp. Date: _____<br>Exp. Date: _____ |
| 3.  | _____ | RPH # _____<br>APP # _____<br>DEA # _____ | Exp. Date: _____<br>Exp. Date: _____<br>Exp. Date: _____ |
| 4.  | _____ | RPH # _____<br>APP # _____<br>DEA # _____ | Exp. Date: _____<br>Exp. Date: _____<br>Exp. Date: _____ |
| 5.  | _____ | RPH # _____<br>APP # _____<br>DEA # _____ | Exp. Date: _____<br>Exp. Date: _____<br>Exp. Date: _____ |
| 6.  | _____ | INT # _____                               | Exp. Date: _____   |
| 7.  | _____ | INT # _____                               | Exp. Date: _____   |
| 8.  | _____ | INT # _____                               | Exp. Date: _____   |
| 9.  | _____ | TCH # _____                               | Exp. Date: _____   |
| 10. | _____ | TCH # _____                               | Exp. Date: _____   |
| 11. | _____ | TCH # _____                               | Exp. Date: _____   |

12. \_\_\_\_\_ TCH # \_\_\_\_\_ Exp. Date: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

13. \_\_\_\_\_ TCH # \_\_\_\_\_ Exp. Date: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

14. \_\_\_\_\_ TCH # \_\_\_\_\_ Exp. Date: \_\_\_\_\_

15. \_\_\_\_\_ TCH # \_\_\_\_\_ Exp. Date: \_\_\_\_\_

# COMMUNITY PHARMACY SELF-ASSESSMENT

## HOSPITAL OUTPATIENT PHARMACY SELF-ASSESSMENT

All references to the California Code of Regulations (CCR) are to Title 16 unless otherwise noted.

Please mark the appropriate box for each item. If "NO", enter an explanation on "CORRECTIVE ACTION OR ACTION PLAN" lines at the end of the section. If more space is needed, you may add additional sheets.

### 1. Facility

Yes No N/A

- |  |   |
|--|---|
| <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | 1.1. The pharmacy has an area suitable for confidential patient consultation. (CCR 1764, 1714)  |
| <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | 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)  |
| <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | 1.3. The pharmacy is of sufficient size and has an unobstructed area to accommodate the safe practice of pharmacy. (CCR 1714)   |
| <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | 1.4. The pharmacy premises, fixtures, and equipment are maintained in a clean and orderly condition-, <u>properly lighted and free from rodents and insects.</u> (CCR 1714)   |
| <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | 1.5. The pharmacy sink has hot and cold running water. (CCR 1714)   |
| <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | 1.6. The pharmacy has a readily accessible restroom. (CCR 1714)   |
| <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | 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) |
| <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | 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])  |
| <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | 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)   |
| <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | 1.10. Does the pharmacy compound sterile <del>injectable</del> drugs?<br>(If yes, complete <del>section 24</del> <u>section 27</u> – "Compounding.")  |

Yes No N/A

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 ~~premise~~ 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)

5-1. 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))

5-2. 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)

5-3. 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)

\_\_\_\_\_  
PIC  
Initials

Yes No N/A

6.7. Only a pharmacist performs CLIA waived clinical laboratory tests, where the pharmacy is registered with CDPH to perform such services. (B&PC 1206.6)

CDPH (CLIA) Registration #: \_\_\_\_\_ Expiration: \_\_\_\_\_

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.~~ 8.1. The intern pharmacist may perform all the functions of a pharmacist only under the direct supervision of a pharmacist. A pharmacist may supervise **two interns** at any one time. (B&PC 4114, 4023.5, CCR 1726)

Yes No N/A

~~6.2.~~ 8.2. All prescriptions filled or refilled by an intern are, prior to dispensing, checked for accuracy by a licensed pharmacist and the prescription label initialed by the checking pharmacist. (CCR 1717[b][1], CCR 1712)

~~6.3.~~ 8.3. 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**

Yes No N/A

~~7.1.~~ 9.1. 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.~~ 9.2. Pharmacy technician ratio when only one pharmacist is present, is no more than one technician. For each additional pharmacist present, the ratio may not exceed 2 technicians for each additional pharmacist. (B&PC 4038, 4115, CCR 1793.7[f])

~~7.3.~~ 9.3. 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.~~ 9.4. The pharmacy has a job description for the pharmacy technician and written policies and procedures to ensure compliance with technician requirements. (CCR 1793.7[e])

9.5. A pharmacy technician trainee participating in an externship may perform packaging, manipulative, repetitive or other nondiscretionary tasks only under the direct supervision and control of a pharmacist; a pharmacist may only supervise one technician trainee and only for a period of no more than 120 hours. (B&PC 4115.5)

CORRECTIVE ACTION OR ACTION PLAN: \_\_\_\_\_  
\_\_\_\_\_

**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: \_\_\_\_\_  
\_\_\_\_\_

**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~~ direct supervision 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])

Yes No N/A

13.4. The label on a drug container dispensed to a patient in California conforms to the following format: (CCR 1707.5[a])

- 13.4.1 The name of the patient, name of the drug and strength of the drug, the directions for use of the drug, the condition or purpose for which the drug was prescribed, if indicated on the prescription, are clustered into one area of the label and comprise at least 50 percent of the label.
- 13.4.2 The label is highlighted in bold typeface or color or uses blank space to set off the items in 13.3.1; (CCR 1707.5[a][2])
- 13.4.3 When applicable, standardized directions for use are utilized. (CCR 1707.5[a][4])

~~11.4.~~ 13.5. The pharmacy is exempt from the prescription label requirements in CCR 1707.5.

Exemption approved by board from: \_\_\_\_\_ to \_\_\_\_\_

~~11.5.~~ 13.6. 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)

~~11.6.~~ 13.7. The trade name or generic name and manufacturer of the prescription drug is accurately identified on the label and prescription record. (B&PC 4076, CCR 1717[b][2])

~~11.7.~~ 13.8. Generic substitution is communicated to the patient. (B&PC 4073)

~~11.8.~~ 13.9. If the prescription is filled by a pharmacy technician, before dispensing the prescription is checked for accuracy by a licensed pharmacist and that pharmacist initials the prescription label. (B&PC 4115, CCR 1793.7, CCR 1712)

~~11.9.~~ 13.10. The federal warning label prohibiting transfer of controlled substances is on the prescription container. (21 CFR 290.5)

~~11.10.~~ 13.11. Prescriptions are dispensed in a new and child-resistant container, or senior-adult ease-of-opening tested container, or in a non-complying package only pursuant to the prescriber or when requested by the purchaser. (~~2515~~ USC 1473-section 4[b], 16 CFR 1700.15, CCR 1717)

~~11.11.~~ 13.12. Patient package inserts are dispensed with all estrogen medications. (21 CFR 310.515)

~~11.12.~~ 13.13. The pharmacy provides patients with Black Box Warning Information in conformance with 21 CFR 201.57[c].

~~11.13.~~ 13.14. ~~This~~ The pharmacy furnishes dangerous drugs in compliance with B&PC 4126.5 only to a patient pursuant to a prescription, a wholesaler from whom the dangerous drugs were purchased, a manufacturer from whom the drugs were purchased, a licensed wholesaler acting as a reverse distributor, another pharmacy to alleviate a temporary shortage with a quantity sufficient to alleviate the temporary shortage, a health care provider authorized to received drugs, or to another pharmacy of common ownership .

~~11.14.~~ 13.15. The label includes a physical description of the dispensed medication, including its color, shape, and any identification code that appears on the tablets or capsules. (B&PC 4076)

Yes No N/A

~~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: \_\_\_\_\_  
\_\_\_\_\_

**~~12-~~ 14. Refill Authorization**

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)

Yes No N/A

~~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&SC 11200)

CORRECTIVE ACTION OR ACTION PLAN: \_\_\_\_\_

**~~13.~~ 15. Quality Assurance and Medication Errors**

Yes No N/A

~~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: \_\_\_\_\_

**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])

Yes No N/A

~~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.~~ 19.2.5. Power of Attorney for completion of DEA 222 forms (21 CFR 1305.07)
- ~~17.2.6.~~ 19.2.6. Theft and Loss Reports (DEA Form 106) (21 CFR 1301.74[c])
- ~~17.2.7.~~ 19.2.7. Record documenting return of drugs to wholesaler or manufacturer (B&PC 4081)
- ~~17.2.8.~~ 19.2.8. Record documenting transfers or sales to other pharmacies, licensees and prescribers (B&PC 4081, 4105, CCR 1718)

Yes No N/A

~~17.3.~~ 19.3. 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.~~ 19.3.1. Persons known to the pharmacist and when the pharmacist has previously been provided with a prescription or other proof of legitimate medical need;
- ~~17.3.2.~~ 19.3.2. Use on animals, provided the person is known to the pharmacist or the person's identity can be properly established.
- ~~17.3.3.~~ 19.3.3. 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.~~ 19.3.4. For industrial use, as determined by the board. (B&PC 4144.5)
- ~~17.3.5.~~ 19.3.5. As a public health measure intended to prevent the transmission of HIV, viral hepatitis, and other bloodborne diseases, furnishing of 30 or fewer hypodermic needles and syringes for human use to a person 18 years of age or older for personal use. (B&PC 4145.5)

19.4. When hypodermic needles and syringes are furnished by a pharmacy or hypodermic needle and exchange program without a prescription, the pharmacy provides the consumer with written information or verbal counseling on how to access drug treatment, testing and treatment for HIV and hepatitis C and safe disposal of sharps waste; and provide one or more of the following disposal options: (B&PC 4145.5[e][f])

- 19.4.1. Onsite, safe, hypodermic needle and syringe collection and disposal program.
- 19.4.2. Furnish or make available mail-back sharps containers.
- 19.4.3. Furnish or make available sharps containers.

~~17.4.~~ 19.5. Records stored off-site (only for pharmacies who have obtained a waiver from the Board of Pharmacy to store records off-site) are secure and retrievable within two business days. Records for non-controlled substances are maintained on the licensed premises for at least one year from the date of dispensing. Controlled substances are maintained on the licensed premises for at least two years from the date of dispensing. (CCR 1707, B&PC 4105)

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                      |  |
|--------------------------|--------------------------|--------------------------|--|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <del>18.1.</del> <u>20.1.</u> Is completed biennially (every two years).<br>Date completed: _____ (21 CFR 1304.11[b])  |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <del>18.2.</del> <u>20.2.</u> Schedule II inventory is separate from Schedule III, IV and V. (21 CFR 1304.04[h][1], 1304.04[h][2])   |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <del>18.3.</del> <u>20.3.</u> Is available for inspection for three years. (CCR 1718)  |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <del>18.4.</del> <u>20.4.</u> 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])   |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <del>18.4.</del> <u>20.5.</u> Separate Schedule II records are maintained. This includes Schedule II prescriptions, invoices, US official order forms, and inventory records. (21 CFR 1304.04[h])  |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <del>18.5.</del> <u>20.6.</u> 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]) |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <del>18.6.</del> <u>20.7.</u> 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)  |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <del>18.7.</del> <u>20.8.</u> 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)   |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <del>18.8.</del> <u>20.9.</u> When a pharmacy distributes schedule II controlled substances to a DEA registrant (pharmacies, wholesales, manufacturers, prescribers) a DEA Form222 is prepared by the purchasing registrant and provided to the pharmacy selling the schedule II controlled substances. (21 CFR 1305.12)   |

Yes No N/A

~~18.9.~~ 20.10. When the pharmacy distributes Schedule II controlled substances to other DEA registrants, such as those listed above, Copy 2 of the DEA Form 222, 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.~~ 20.11. Sales of controlled substances to other pharmacies or prescribers do not exceed five percent of the total number of controlled substances dosage units dispensed per calendar year; otherwise a wholesaler registration is obtained from DEA and from the board. (21 CFR 1307.11[b], Prescription Drug Marketing Act of 1987 [Pub. L. 100-293, Apr. 22, 1988] 503. B&PC 4160)

~~18.11.~~ 20.12. When dispensed upon an "oral" order for a true emergency, a Schedule II prescription is provided by the prescriber by the 7<sup>th</sup> 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.~~ 20.13. The pharmacy generates a controlled substance printout for refills of Schedule III-V prescriptions at least every three days (72 hours) which contains the signature of the dispensing pharmacist, or the pharmacy maintains an alternate system to document the refilling of controlled substance prescriptions that complies with 21 CFR 1306.22.

~~18.13.~~ 20.14. Any controlled substances drug loss is reported upon discovery to the DEA and within 30 days of discovery to the Board of Pharmacy. (21 CFR 1301.74[c], CCR 1715.6)

~~18.14.~~ 20.15. Do pharmacy staff hand initial prescription records or prescription labels, or

~~18.15.~~ 20.16. Does the pharmacy comply with the requirement for a pharmacist to initial or sign a prescription record or prescription label by recording the identity of the reviewing pharmacist in a computer system by a secure means. This computer does not permit the record to be altered after made and the record of the pharmacist's identity made in the computer system is immediately retrievable in the pharmacy. (CCR 1712, 1717[b][1])

~~18.16.~~ 20.17. All Schedule II through IV controlled substance dispensing data is successfully transmitted to CURES weekly. (H&SC 11165[d])

20.18. When furnishing controlled substances for physician office use, a prescription is not issued in order for an individual practitioner to obtain controlled substances for supplying the practitioner's general dispensing to patients. (21 CFR 1306.04[b])

CORRECTIVE ACTION OR ACTION PLAN: \_\_\_\_\_

**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. 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. (21 CFR 1306.11[f], H&SC 11167.5)

~~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)

~~19.4. 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])

~~19.5. 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)

~~19.6. 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)

~~19.7. 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)

Yes No N/A

~~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])

Yes No N/A

~~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**

Yes No N/A

~~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.~~ 22.3.3. Stocking of the automated drug delivery system is done by a pharmacist. (H&SC 1261.6[f])

Yes No N/A

~~20.4.~~ 22.4. If the automated drug delivery system utilizes removable pockets, drawers, or similar technology, the stocking system is done outside the facility in a pharmacy and delivered to the facility:

- ~~20.4.1.~~ 22.4.1. Drugs are restocked by a pharmacist or by an intern or technician working under the supervision of a pharmacist. (H&SC 1261.6[f][1])
- ~~20.4.2.~~ 22.4.2. Removable pockets or drawers are transported between the pharmacy and the facility in a secure tamper-evident container. (H&SC 1261.1[f][2])

CORRECTIVE ACTION OR ACTION PLAN: \_\_\_\_\_

\_\_\_\_\_

### ~~21.~~ 23. Repackaging by the Pharmacy

Yes No N/A

~~21.1.~~ 23.1. Drugs are repackaged (precouned 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.~~ 23.2. A log is maintained for drugs pre-packed for future dispensing. (CCR 1751.1, 21 CFR Parts 210, 211)

~~21.3.~~ 23.3. Drugs previously dispensed are re-packaged at the patient's request in compliance with B&PC 4052.7.

CORRECTIVE ACTION OR ACTION PLAN: \_\_\_\_\_

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### ~~22.~~ 24. Refill Pharmacy

Yes No N/A

~~22.1.~~ 24.1. Pharmacy processes refills for another California licensed pharmacy (CCR 1707.4[a])

If the answer is "yes", name the pharmacy or pharmacies \_\_\_\_\_

~~22.2.~~ 24.2. Does the pharmacy employ the use of a common electronic file? If yes, are there policies and procedures in place to prevent unauthorized disclosures? (CCR 1717.1)

~~22.3.~~ 24.3. Some or all pharmacy refill orders are processed by another California licensed pharmacy. (CCR 1707.4[a])

If the answer is "yes," name of refilling pharmacy(s) \_\_\_\_\_

If the answer to both questions above is "no" or "not applicable" go to section 23.

**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~~ 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- 26. Policies and Procedures**

Yes No N/A

~~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 ~~effects~~ 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.~~ 26.1.3. Action to be taken to protect the public when a licensed individual employed by or with the pharmacy is known to have engaged in the theft or diversion or self-use of prescription drugs belonging to the pharmacy, including the reporting to the board within 14 days of receipt or development; (B&PC 4104[b],[c])
- ~~23.1.4.~~ 26.1.4. Oral consultation for discharge medications to an inpatient of a health care facility licensed pursuant to H&SC 1250, or to an inmate of an adult correctional facility or juvenile detention facility; (B&PC 4074, CCR 1707.2[b][3])
- ~~23.1.5.~~ 26.1.5. Operation of the pharmacy during the temporary absence of the pharmacist for breaks and meal periods including authorized duties of personnel, pharmacist's responsibilities for checking all work performed by ancillary staff, and pharmacist's responsibility for maintaining the security of the pharmacy; (CCR 1714.1[f])
- ~~23.1.6.~~ 26.1.6. Assuring confidentiality of medical information if your pharmacy maintains the required dispensing information for prescriptions, other than controlled substances, in a shared common electronic file; (CCR 1717.1[e])
- ~~23.1.7.~~ 26.1.7. The delivery of dangerous drugs and dangerous devices to a secure storage facility, if the pharmacy accepts deliveries when the pharmacy is closed and there is no pharmacist present;- (B&PC 4059.5[f][1])
- ~~23.1.8.~~ 26.1.8. Compliance with Title VII of Public Law 109-177 – Combat Methamphetamine Epidemic Act of 2005;
- ~~23.1.9.~~ 26.1.9. Reporting requirements to protect the public; (B&PC 4104)
- ~~23.1.10.~~ 26.1.10. Preventing the dispensing of a prescription drug that is contrary to the law;- (B&PC 733)
- ~~23.1.11.~~ 26.1.11. Preventing the dispensing of a prescription when the pharmacist determines that the prescribed drug or device would cause a harmful drug interaction or would otherwise adversely affect the patient's medical condition; and (B&PC 733)
- ~~23.1.12.~~ 26.1.12. Helping patients with limited or no English proficiency understand the information on the prescription container label in the patient's language, including the selected means to identify the patient's language and providing interpretive services in the patient's language. (CCR\_1707.5)

Yes No N/A

~~23.2.~~ 26.2. Does your pharmacy employ the use of a common electronic file?

- 23.2.1. 26.2.1. If yes, are there policies and procedures in place to prevent unauthorized disclosures? (CCR 1717.1)

26.3. Does your pharmacy furnish emergency contraceptives pursuant to B&PC 4052.3[a][1]? (B&PC 4052, CCR 1746) If yes, does the pharmacy

- 26.3.1. Follow the protocol for pharmacists furnishing Emergency Contraception (EC) approved by the California State Board of Pharmacy and the Medical Board of California? (CCR 1746)
- 26.3.2. Provide the patient with a copy of the current EC Fact Sheet approved by the Board of Pharmacy? (CCR 1746)

- 26.3.3. Maintain in the pharmacy EC medications and adjunctive medications (for nausea and vomiting when taken with EC containing estrogens) as listed in the protocol? (CCR 1746)
- 26.3.4. Prior to furnishing EC, the pharmacist has completed a minimum of one hour of continuing education specific to emergency contraception. (CCR 1746)
- 26.3.5. If no, EC services are not immediately available or any pharmacist declines to furnish pursuant to a conscience clause, does the pharmacist refer the patient to another emergency contraception provider? (CCR 1746)
- 26.3.6. Does the pharmacy have a protocol that ensures a patient has timely access to a prescribed drug or device despite a pharmacist's refusal to dispense a prescription or order? (B&PC 733[b])
- 26.3.7. If a pharmacist declines to dispense a prescription drug or device pursuant to an order or prescription, the pharmacist has previously notified his or her employer in writing? (B&PC 733[b], B&PC 4052.3)
- 26.3.8. If no, EC services are not immediately available or any pharmacist declines to furnish pursuant to a conscience clause, does the pharmacist refer the patient to another emergency contraception provider? (CCR 1746)

26.4. Furnishes naloxone hydrochloride in accordance with standardized procedures or protocols developed and approved by both the Board of Pharmacy and the Medical Board of California. (B&PC 4052.01[a])

- 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. ~~01/11~~ 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 150204[c][2])

29.4.2. Were received directly from a manufacturer or wholesaler. (H&SC 150202.5[a])

29.4.3. Were returned from a health facility to which the drugs were originally issued, in a manner consistent with state and federal law, and where the drugs were centrally stored; were under the control of a health facility staff member; and that were never in the possession of a patient or individual member of the public. (H&C 150202.5[b], 150204[c][3])

- 29.4.4. Are in unopened, tamper-evident packaging or modified unit dose containers with lot numbers and expiration dates affixed. (H&SC 105204[d])
- 29.4.5. For donated medications that require refrigeration, are medications that are stored, packaged and transported at appropriate temperatures and in accordance with USP standards and pharmacy law. (H&SC 150204[m])

**30. Pharmacies That Operate a Voluntary County-Approved Drug Repository and Distribution Program**

**Yes No N/A**

30.1. The pharmacy conducts a county-approved drug repository and distribution program. (H&SC 150201, 150204)

30.1.1. The pharmacy is licensed by and is not on probation with the California State Board of Pharmacy, and: (H&SC 150201[a][1])

30.1.1.1 Is county owned (H&SC 150201[b][1]) or

30.1.1.2 Contracts with the county to establish a voluntary drug repository and distribution program. (H&SC 150201[b][1], 150200)

30.1.2. The pharmacy is owned and operated by a primary care clinic licensed by the California Department of Public Health, and is not on probation with the California State Board of Pharmacy. (H&SC 150201[a][2])

**Yes No N/A**

30.2. The pharmacy has been prohibited by the county board of supervisors, the county public health officer, or the California State Board of Pharmacy from participating in the program because it does not comply with the provisions of the program. (H&SC 150204[a][5])

Issued By: \_\_\_\_\_ Date: \_\_\_\_\_

30.3. Date that the county health department confirmed receipt of the pharmacy's "notice of intent" to participate in the program: \_\_\_\_\_ (H&SC 150204[a][3])

30.4. The pharmacy provides the county health department on a quarterly basis the name and location of all sources of donated medication it receives. (H&SC 150204[a][4][A])

Date last quarterly report was submitted: \_\_\_\_\_

30.5. The pharmacy complies with the county's established written procedures. (H&SC 150204[b])

**Drugs and Maintenance of Drug Stock**

30.6. Donated medications are segregated from the participating entity's other drug stock by physical means, for purposes that include inventory, accounting and inspection. (H&SC 150204[j])

30.7. Records of acquisition and disposition of donated medications are kept separate from the participating entity's other drug acquisition and disposition records. (H&SC 150204[k])

30.8. The participating entity follows the same procedural drug pedigree requirements for donated drugs as it does for drugs purchased from a wholesaler or directly from a drug manufacturer. (H&SC 150204[n])

- 30.9. Donated medications received are unused, unexpired and meet the following requirements: (H&SC 150202, 150202.5, 150204[c])
- 30.9.1. Are received from authorized sources. (H&SC 150202, 150203)
  - 30.9.2. No controlled substances are received. (H&SC 150204[c][1])
  - 30.9.3. Are not adulterated, misbranded, or stored under conditions contrary to USP standards or the product manufacturer. (H&SC 150204[c][2])
  - 30.9.4. Medications received from a health care facility were centrally stored and under the control of a licensed health care professional or trained staff member of facility, and were never in the possession of a patient or member of the public. (H&SC 150204[c][3])
  - 30.9.5. Are received in unopened, tamper-evident packaging or modified unit dose containers with lot numbers and expiration dates affixed. (H&SC 150204[d])
  - 30.9.6. Are maintained in the donated packaging until dispensed to an eligible patient under the program, who presents a valid prescription. (H&SC 150204[i])
  - 30.9.7. For donated medications that require refrigeration, there are specific procedures to ensure that the medications are packaged, transported, stored, and dispensed at appropriate temperatures and in accordance with USP standards and pharmacy law. (H&SC 150204[m])

**Yes No N/A**

- 30.10. Donated medication received in open containers is not dispensed under the program or transferred to another participating entity; and once identified, is quarantined immediately and disposed of in accordance with the Medical Waste Management Act. (H&SC 150204[d], 150204[h])

**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:

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- 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](http://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](http://www.dea.gov))

**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](http://www.pharmacy.ca.gov)

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

Law-Tech Publishing Co.  
1060 Calle Cordillera, Suite 105  
San Clements, CA 92673  
Phone: (800) 498-0911 Ext. 5  
[www.lawtechpublishing.com](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**  
4949 Broadway  
Sacramento, CA 95820  
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:**

[http://www.deadiversion.usdoj.gov/drugreg/reg\\_apps/onlineforms\\_new.htm](http://www.deadiversion.usdoj.gov/drugreg/reg_apps/onlineforms_new.htm)

**Online Registration - Renewal:**

[www.deadiversion.usdoj.gov/drugreg/reg\\_apps/onlineforms.htm](http://www.deadiversion.usdoj.gov/drugreg/reg_apps/onlineforms.htm)

**Registration Changes (Forms):**

[http://www.deadiversion.usdoj.gov/drugreg/change\\_requests/index.html](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, 14<sup>th</sup> 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



**California State Board of Pharmacy**

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

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

## 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: \_\_\_\_\_

~~or~~ 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: \_\_\_\_\_

Pharmacy staff (pharmacists, interns, technicians):

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

|           |   |  |
|-----------|---|--|
| 1. _____  | RPH # _____<br>APP # _____<br>DEA # _____ | Exp. Date: _____<br>Exp. Date: _____<br>Exp. Date: _____ |
| 2. _____  | RPH # _____<br>APP # _____<br>DEA # _____ | Exp. Date: _____<br>Exp. Date: _____<br>Exp. Date: _____ |
| 3. _____  | RPH # _____<br>APP # _____<br>DEA # _____ | Exp. Date: _____<br>Exp. Date: _____<br>Exp. Date: _____ |
| 4. _____  | RPH # _____<br>APP # _____<br>DEA # _____ | Exp. Date: _____<br>Exp. Date: _____<br>Exp. Date: _____ |
| 5. _____  | RPH # _____<br>APP # _____<br>DEA # _____ | Exp. Date: _____<br>Exp. Date: _____<br>Exp. Date: _____ |
| 6. _____  | RPH # _____<br>APP # _____<br>DEA # _____ | Exp. Date: _____<br>Exp. Date: _____<br>Exp. Date: _____ |
| 7. _____  | RPH # _____<br>APP # _____<br>DEA # _____ | Exp. Date: _____<br>Exp. Date: _____<br>Exp. Date: _____ |
| 8. _____  | RPH # _____<br>APP # _____<br>DEA # _____ | Exp. Date: _____<br>Exp. Date: _____<br>Exp. Date: _____ |
| 9. _____  | INT # _____                               | Exp. Date: _____   |
| 10. _____ | INT # _____                               | Exp. Date: _____   |
| 11. _____ | INT # _____                               | Exp. Date: _____   |
| 12. _____ | INT # _____                               | Exp. Date: _____   |
| 13. _____ | TCH # _____                               | Exp. Date: _____   |
| 14. _____ | TCH # _____                               | Exp. Date: _____   |
| 15. _____ | TCH # _____                               | Exp. Date: _____   |
| 16. _____ | TCH # _____                               | Exp. Date: _____   |

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~~ 14 days of the receipt or development of the following information with regard to any licensed individual employed by or with the pharmacy: (1) any admission by a licensed individual of chemical, mental, or physical impairment affecting his or her ability to practice; (2) Any admission by a licensed individual of theft, diversion, or self-use of dangerous drugs; (3) Any video or documentary evidence demonstrating chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice; (4) Any video or documentary evidence demonstrating theft, diversion, or self-use of dangerous drugs by a licensed individual; (5) Any termination based on chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice; (6) Any termination of a licensed individual based on theft, diversion, or self-use of dangerous drugs. (B&PC 4104[c])
- 1.5. The pharmacy maintains “night stock” medications which are accessible without entering the pharmacy during hours when the pharmacy is closed, and the pharmacist is not available. Access is limited to designated registered nurses. (22 CCR 70263[n])
- 1.6. The pharmacy is of sufficient size and has an unobstructed area to accommodate the safe practice of pharmacy. (CCR 1714)
- 1.7. The pharmacy premises, fixtures, and equipment are maintained in a clean and orderly condition. (CCR 1714)
- 1.8. The pharmacy sink has hot and cold running water. (CCR 1714)
- 1.9. The pharmacy has a readily accessible restroom. (CCR 1714)

Yes No N/A

1.10. The original board-issued pharmacy license and the current renewal are posted where they may be clearly read by the purchasing public. (B&PC 4032, 4058)

1.11. Pharmacists, interns, pharmacy technicians, and pharmacy technician trainees wear nametags, in 18-point type, that contain their name and license status. (B&PC 680, B&PC 4115.5[e], CCR 1793.7[c])

1.12. Does the pharmacy compound sterile ~~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

Yes No N/A

2.1. Adequate space is available at ward or nursing station for the storage of drugs and preparation of medication doses. All such spaces and areas can be locked and are accessible to authorized personnel only. (22 CCR 70269)

2.2. The pharmacist, intern, or pharmacy technician completes the monthly inspections of all floor stock and drugs maintained in nursing stations. Any irregularities are reported to the director of nursing services, and as required by hospital policy. (B&PC 4119.7[c], 4115[i], 22 CCR 70263[q][10])

2.2.1. An intern shall report any irregularities to the pharmacist. (B&PC 4119.7[c]);

2.2.2. A pharmacy technician shall report any irregularities to the pharmacist-in-charge and to the director of the health care facility within 24 hours. (B&PC 4115[i][3]);

CORRECTIVE ACTION OR ACTION PLAN: \_\_\_\_\_

### 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: \_\_\_\_\_  
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### 4. Drug Stock

Yes No N/A

4.1. The drug stock is clean, orderly, properly stored, properly labeled and in-date. (B&PC 4342, H&SC 111255, CCR 1714 (b), 22 CCR 70263[q])

4.2. All ward/floor drug stock and drug supplies that are maintained for access when the pharmacist is not available are properly labeled and stored. (22 CCR 70263[n])

4.3. Preferentially priced drugs are furnished solely or predominately to inpatients in accordance with provisions of the Nonprofit Institutions Act (15 USC 13c). Such drugs also may be dispensed pursuant to prescriptions for inpatients at the time of discharge, for employees of the hospital, or on an emergency basis for a walk-in customer (provided that sales to walk-ins do not exceed one percent of the pharmacy's total prescription sales). (B&PC 4380, CCR 1710[a])

**Yes No N/A**

- 4.4. All unit-dose drugs received from a centralized hospital packaging pharmacy are correctly labeled, are barcoded, and the barcode is readable at the patient's bedside. (B&PC 4128.4, 4128.5)
- 4.5. All drugs are maintained in accordance with national standards regarding the storage area and refrigerator or freezer temperature and manufacturer's guidelines. (B&PC 4119.7[b])

CORRECTIVE ACTION OR ACTION PLAN: \_\_\_\_\_  
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**5. Pharmacies That Donate Drugs to a Voluntary County-Approved Drug Repository and Distribution Program**

**Yes No N/A**

- 5.1. The hospital pharmacy donates medications to a county-approved drug repository and distribution program, and meets the following requirements: (H&SC 150202, 150202.5, 150204)
  - 5.1.1. The hospital pharmacy is licensed by and is not on probation with the California State Board of Pharmacy, **and** (H&SC 150202.5)
  - 5.1.2. The hospital pharmacy's primary or sole type of pharmacy practice is limited to skilled nursing facility, home health care, board and care, or mail order. (H&SC 150202.5)
- 5.2. No controlled substances shall be donated. (H&SC 150204[c][1])
- 5.3. Drugs that are donated are unused, unexpired and meet the following requirements: (H&SC 150202.5, 150204[c])
  - 5.3.1. Have not been adulterated, misbranded, or stored under conditions contrary to standards set by the USP or the product manufacturer. (H&SC 150204[c][2])
  - 5.3.2. Were received directly from a manufacturer or wholesaler. (H&SC 150202.5[a])
  - 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)**

Yes No N/A

- ~~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: \_\_\_\_\_  
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**6. 7. Duties of a Pharmacist**

Yes No N/A

- ~~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)

CORRECTIVE ACTION OR ACTION PLAN: \_\_\_\_\_  
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**8. Duties of an Advanced Practice Pharmacist**

Yes No N/A

- 8.1. The pharmacist who is authorized to issue an order to initiate or adjust a controlled substance therapy is personally registered with the federal Drug Enforcement Administration. (B&PC 4052[b])
- 8.2. 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])

~~7.~~ **9. Duties of an Intern Pharmacist**

Yes No N/A

- ~~7.1.~~ 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])
- ~~7.2.~~ 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])

Yes No N/A

~~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: \_\_\_\_\_

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## **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-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 ~~received~~ receive drugs, to another pharmacy of common ownership, or to a patient or to another pharmacy pursuant to a prescription. (B&PC 4126.5)

CORRECTIVE ACTION OR ACTION PLAN: \_\_\_\_\_  
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**~~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: \_\_\_\_\_  
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**~~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)

Yes No N/A

~~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**

Yes No N/A

~~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])

Yes No N/A

~~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)

Yes No N/A

- ~~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 ~~1309.09~~ 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)

Yes No N/A

- ~~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: \_\_\_\_\_

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### **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: \_\_\_\_\_

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### **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])

CORRECTIVE ACTION OR ACTION PLAN: \_\_\_\_\_

**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)

Yes No N/A

~~21.11.~~ 23.11. Prescriptions are dispensed in a new and child-resistant container, or senior-adult ease-of-opening tested container, or in a non-complying package only pursuant to the prescriber or when requested by the purchaser. (25 USC 1473 section 4[b], 16 CFR 1700.15, CCR 1717)

~~21.12.~~ 23.12. 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.~~ 25.

~~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: \_\_\_\_\_

\_\_\_\_\_

### ~~23.~~ 26. Policies and Procedures

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](http://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](http://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: (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**

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.dea diversion.usdoj.gov>

**Online Registration – New Applicants:**

[http://www.dea diversion.usdoj.gov/drugreg/reg\\_apps/onlineforms\\_new.htm](http://www.dea diversion.usdoj.gov/drugreg/reg_apps/onlineforms_new.htm)

**Online Registration - Renewal:**

[www.dea diversion.usdoj.gov/drugreg/reg\\_apps/onlineforms.htm](http://www.dea diversion.usdoj.gov/drugreg/reg_apps/onlineforms.htm)

**Registration Changes (Forms):**

[http://www.dea diversion.usdoj.gov/drugreg/change\\_requests/index.html](http://www.dea diversion.usdoj.gov/drugreg/change_requests/index.html)

**DEA Registration Support (all of CA):**

(800) 882-9539

**Online DEA 106 Theft/Loss Reporting:**

<https://www.dea diversion.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

**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, 14<sup>th</sup> 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.

Authority: Business and Professions Code §4005. Reference: Business and Professions Code §4022.5, §4043, §4053, §4059, §4120, §4160, §4161, §4201, §4301 and §4305.5.



# WHOLESALE 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](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 \_\_\_\_\_

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 (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 22<sup>nd</sup> 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])

Yes No N/A

2.3. Are dangerous drugs and dangerous devices stored in a secured and locked area? (CCR 1780[a])

2.4. Is access to areas where dangerous drugs are stored limited to authorized personnel? (CCR 1780[c])

List personnel with keys to the area(s) where drugs are stored (list by name or job title):

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---

---

Yes No N/A

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

2.6. The wholesale premises is equipped with the following specific security features:

2.6.1. There is an alarm to detect after-hours entry. (CCR 1780[c][1]).

2.6.2. The outside perimeter of the building is well lit (CCR 1780[c][3]).

2.6.3. The security system provides protection against theft and diversion including tampering with computers and or electronic records. (~~CCR~~ CCR 1780[c][2]).

Explain how your security system complies with these requirements.

---

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Yes No N/A

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

CORRECTIVE ACTION OR ACTION PLAN \_\_\_\_\_

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Yes No N/A

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 \_\_\_\_\_

---

Yes No N/A

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 ~~H~~ 12 of this document.

### 3. Designated Representative-in-Charge / Owner Responsibilities

Yes No N/A

3.1. The owner and the designated representative-in-charge are both equally responsible for maintenance of the records and inventory. (B&PC 4081[b])

3.2. Is the designated representative-in-charge at least 18 years of age and is responsible for the wholesaler's compliance with all state and federal laws for the wholesale distribution of drugs? The designated representative-in-charge may be a pharmacist. (B&PC 4160[d], 4053.1(b))

3.3. The owner must notify the board within 30 days of termination of the designated representative-in-charge or pharmacist. (B&PC 4305.5[a])

3.4. The owner must identify and notify the board of the appointment of a new designated representative-in-charge within 30 days of the termination of the former designated representative-in-charge. (B&PC 4160[d], 4331[c]) The appropriate form for this notification is a "Change of Designated Representative-in-Charge," which is available on the board's website.

Yes No N/A

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

CORRECTIVE ACTION OR ACTION PLAN \_\_\_\_\_

**4. Designated Representative/Pharmacist**

Yes No N/A

- If a designated representative or pharmacist changes his/her name or personal address of record, he/she must notify the board in writing within 30 days. (B&PC 4100, CCR 1704)

CORRECTIVE ACTION OR ACTION PLAN \_\_\_\_\_

**5. Ordering Drugs by this Business for Future Sale/Transfer or Trade**

Yes No N/A

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

~~Yes No N/A~~

- 5.2. If drugs are returned to your premises by a business that originally purchased the drugs from you, do you document the return with an acquisition record for your business and a disposition record for the business returning the drugs? (B&PC 4081, 4332)

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

CORRECTIVE ACTION OR ACTION PLAN \_\_\_\_\_

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section ~~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 \_\_\_\_\_

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

## 7. Drug Stock

Yes No N/A

- 7.1. Is all drug stock open for inspection during regular business hours? (B&PC 4081[a])
- 7.2. Are all drugs you order maintained in a secure manner at your licensed wholesale premises? You cannot order, obtain or purchase drugs that you are not able to store on your licensed premises. (B&PC 4167)
- 7.3. Do all drugs you sell conform to the standards and tests for quality and strength provided in the latest edition of United States Pharmacopoeia or Sherman Food Drug and Cosmetic Act? (B&PC 4342[a])
- 7.4. Do all drug containers you store on your premises have a manufacturer's expiration date? Any drug without an expiration date is considered expired and may not be distributed. (CCR 1718.1)
- 7.5. Are outdated, damaged, deteriorated or misbranded drugs held in a quarantine area physically separated from other drugs until returned to the supplier or sent for destruction? (CCR 1780[e], CFR 1307.21)
- 7.6. Are drugs with the outer or secondary seal broken, or partially used or returned drugs held in a quarantine area and physically separated from other drugs until returned to the supplier or sent for destruction? (CCR 1780[e], CFR 1307.21)

Yes No N/A

- 7.7. When the conditions under which drugs were returned to your premises cast doubt on the drugs' safety, identity, strength, quality or purity, are the drugs quarantined and either returned to your supplier or destroyed? If testing or investigation proves the drugs meet USP standards, the drugs may be returned to normal stock. (CCR 1780[e], CFR 1307.21)

CORRECTIVE ACTION OR ACTION PLAN \_\_\_\_\_

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

**8. Sale or Transfer of Drugs by this Business**

Yes No N/A

- 8.1. Are drugs sold only to businesses or persons licensed by this board, licensed by a prescriber board, licensed as a manufacturer, or to a licensed health care entity authorized to receive drugs?

8.2. Describe how you verify a business or person is appropriately licensed. (B&PC 4059.5[a] [b][d], B&PC 4169)

\_\_\_\_\_  
\_\_\_\_\_

8.3. List any businesses or individuals that order drugs from you that are not licensed according to the list above:

\_\_\_\_\_  
\_\_\_\_\_

Yes No N/A

- 8.4. Are drugs only furnished by your business to an authorized person? (B&PC 4163[a]) Note: An authorized person can be a business or natural person.

8.5. Does your business only receive drugs from a pharmacy if:

- 8.5.1. the pharmacy originally purchased the drugs from you?
- 8.5.2. your business is a “reverse distributor”?
- 8.5.3. the drugs are needed to alleviate a shortage? (and only a quantity sufficient to alleviate a specific shortage). (B&PC 4126.5[a])

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.

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8.8. If your business sells, transfers, or delivers dangerous drugs or devices outside of California, either to another state within the United States or a foreign country, do you:

Yes No N/A

8.8.1. comply with all CA pharmacy laws related to the distribution of drugs?

8.8.2. comply with the pharmacy law of the receiving state within the United States?

8.8.3. comply with the statues and regulations of the Federal Food and Drug Administration and the Drug Enforcement Administration relating to the wholesale distribution of drugs?

8.8.4. comply with all laws of the receiving foreign country related to the wholesale distribution of drugs?

8.8.5. comply with all applicable federal regulations regarding the exportation of dangerous drugs?

8.9. Describe how you determine a business in a foreign country is authorized to receive dangerous drugs or dangerous devices. (B&PC 4059.5[e])

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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.~~

Yes No N/A

8.11. If preferentially priced drugs are sold by your business, that sale complies with the Prescription Drug Marketing Act of 1987 and CA Pharmacy Law. (B&PC 4380)

Yes No N/A

8.12. Does your business' advertisements for dangerous drugs or devices contain false, fraudulent, misleading or deceptive claims? (B&PC 4341, B&PC 651, CCR 1766)

8.13. Do you offer or receive any rebates, refunds, commissions or preferences, discounts or other considerations for referring patients or customers? If your business has any of these arrangements, please list with whom. (B&PC 650)

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Yes No N/A

8.14. Does your business sell dangerous drugs or devices to the master or first officer of an ocean vessel, after your business has received a written prescription? If so, describe how you comply with the ordering, delivery and record keeping requirements for drugs including controlled substances, and the requirement to notify the board of these sales. (B&PC 4066, CFR 1301.25)

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CORRECTIVE ACTION OR ACTION PLAN \_\_\_\_\_

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

**9. Donations of Medication to Voluntary Drug Repository and Distribution Programs (H&SC 150200, 150203, 150204)**

Yes No N/A

9.1. The wholesaler donates medications to a county-approved drug repository and distribution program, provided the following requirements are met: (H&SC 150203, 150204)

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

Yes No N/A

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

- 9.3.1. Have not been adulterated, misbranded, or stored under conditions contrary to standards set by the USP or the product manufacturer. (H&SC 150204[c][2])
- 9.3.2. Have never been in the possession of a patient or individual member of the public. (H&SC 150204[c][3])
- 9.3.3. Are in unopened, tamper-evident packaging or modified unit dose containers with lot numbers and expiration dates affixed. (H&SC 105204[d])
- 9.3.4. For donated medications that require refrigeration, are medications that are stored, packaged and transported at appropriate temperatures and in accordance with USP standards and pharmacy law. (H&SC 150204[m])

**9. 10. Outgoing Shipments of Drugs**

Yes No N/A

~~9.1.~~ 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])

~~9.2.~~ 10.2. Does your business use a common carrier (a shipping or delivery company —UPS, US Mail, FedEx, DHL) for delivery of drug orders to your customers? (B&PC 4166[a])

~~9.3.~~ 10.3. List the common carriers (shipping or delivery companies) you use.

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CORRECTIVE ACTION OR ACTION PLAN \_\_\_\_\_

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Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section ~~4~~ 12 of this document.

**10. 11. Delivery of Drugs**

Yes No N/A

~~10.1.~~ 11.1. Are all drugs ordered by a pharmacy or another wholesaler delivered to the address of the buyer’s licensed premises and signed for and received by a pharmacist or designated representative where allowed? (B&PC 4059.5[a])

Yes No N/A

~~10.2.~~ 11.2. Are all drugs ordered by a manufacturer or prescriber delivered to the manufacturer's or prescriber's licensed business address and signed for by a person duly authorized by the manufacturer or prescriber? (~~B&PC 4059[d]~~)  
(B&PC 4059.5[d])

~~10.3.~~ 11.3. All drugs delivered to a hospital are delivered either to the pharmacy premises or to a central receiving area within the hospital. (B&PC 4059.5[c])

~~10.4.~~ 11.4. If drugs are delivered to a pharmacy when the pharmacy is closed and a pharmacist is not on duty, documents are left with the delivery in the secure storage facility, indicating the name and amount of each dangerous drug delivered. (B&PC 4059.5[f])

CORRECTIVE ACTION OR ACTION PLAN \_\_\_\_\_

#### **~~11.~~ 12. Controlled Substances**

Yes No N/A

~~11.1.~~ 12.1. Are there effective controls to prevent theft or diversion of controlled substances? (CFR 1301.71)

~~11.2.~~ 12.2. Are DEA requirements for storage of Schedule II controlled substances being met? (specific requirements are listed in CFR 1301.72[a])

~~11.3.~~ 12.3. Are DEA requirements for storage of Schedule ~~III~~ III, IV and V controlled substances being met? (specific requirements are listed in CFR 1301.72[b])

Yes No N/A

~~11.4.~~ 12.4. Is a DEA inventory completed by your business every two years for all schedules (II - V) of controlled substances? (CFR 1304.11[a][c][e])

~~11.5.~~ 12.5. Is the biennial record of the DEA inventory required for Schedule II - V controlled substances conducted every 2 years, retained for 3 years? (CFR 1304.11, CCR 1718, 1780(f)[2])

12.6. Does the biennial inventory record document that the inventory was taken at the "close of business" or "opening of business." (CFR 1304.11)

~~11.6.~~ 12.7. Has the person within your business who signed the original DEA registration, or the last DEA registration renewal, created a power of attorney for each person allowed to order Schedule II controlled substances for this business? (CFR 1305.05)

~~11.7.~~ 12.7.1. List the individuals at this location authorized by power of attorney to order controlled substances.

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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

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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)

Yes No N/A

- ~~11.17.~~ 12.17. When your business fills orders for Schedule II controlled substances, is the date filled and the number of containers filled recorded on copies 1 and 2 of DEA 222 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.~~ 12.18. If a Schedule II controlled substance order cannot be filled, does your business return copy 1 and 2 of the DEA 222 order form to the buyer with a letter indicating why the order could not be filled? (CFR 1305.15)
- ~~11.19.~~ 12.19. When your business partially fills Schedule II controlled substances, is the balance provided within 60 days of the date of the order form? After the final partial filling, is copy 1 retained in your files and copy 2 of the completed DEA 222 order form sent to DEA by the close of that month? (~~CFR 1309.13[b]~~) (CFR 1305.13[b])
- ~~11.20.~~ 12.20. For all Schedule II controlled substances received by your business, is copy 3 of the DEA 222 order form completed by writing in for each item received, the date received and the number of containers received? (CFR 1305.13[e])
- ~~11.21.~~ 12.21. Does your business use the online CSOS secure transmission system offered by the Drug Enforcement Administration in place of a paper DEA 222 Form for Schedule II controlled substances? (CFR 1305.21, 1305.22)
- ~~11.22.~~ 12.22. Does your business follow the procedure outlined by DEA to obtain Schedule II controlled substances when the original DEA 222 order form is lost or stolen? (CFR 1305.16(a))
- ~~11.23.~~ 12.23. Are all records of purchase and sale for all schedules of controlled substances for your business kept on your licensed business premises for 3 years from the making? (B&PC 4081, CCR 1718, ~~CFR 1305.09[d]~~, CFR 1305.17[c], 1305.17[a] [b], and ~~H&S~~ H&SC 11252, 11253, 1304.03)
- ~~11.24.~~ 12.24. Are records of Schedule II controlled substances stored separate from all others? (CFR 1304.04 [f][1])
- ~~11.25.~~ 12.25. Are records for Schedule III-V controlled substances stored so that they are easily retrievable? (CFR 1304.04 [f][2])
- ~~11.26.~~ 12.26. Before your business distributes carfentanil etorphine HCL and or diprenorphine, do you contact the DEA to determine the person (individual or business) is authorized to receive these drugs? (CFR 1301.75[g], 1305.16[b])
- ~~11.27.~~ 12.27. Do you separate records for the sale of carfentanil etorphine hydrochloride and or diprenorphine from all other records? (~~CFR 1305.16~~) (CFR 1305.17[d])

Yes No N/A

~~11.28.~~ 12.28. Does the owner of your business notify the DEA, on a DEA 106 form, of any theft or significant loss of controlled substances upon discovery of the theft? (CFR 1301.74[c])

~~11.29.~~ 12.29. Does the owner of your business notify the board of any loss of controlled substances within 30 days of discovering the loss? (CCR 1715.6)

CORRECTIVE ACTION OR ACTION PLAN \_\_\_\_\_

**~~12.~~ 13. Policies and Procedures**

~~12.1.~~ 13.1. Does this business maintain and adhere to policies and procedures for the following: (CCR 1780[f])

Yes No N/A

~~12.1.1.~~ 13.1.1. Receipt of drugs?

~~12.1.2.~~ 13.1.2. Security of drugs?

~~12.1.3.~~ 13.1.3. Storage of drugs?(including maintaining records to document proper storage)

~~12.1.4.~~ 13.1.4. Inventory of drugs?(including correcting inaccuracies in inventories)

~~12.1.5.~~ 13.1.5. Distributing drugs?

~~12.1.6.~~ 13.1.6. Identifying, recording and reporting theft or losses?

~~12.1.7.~~ 13.1.7. Correcting ~~errors?~~ errors and inaccuracies in inventories?

Physically quarantining and separating:

~~12.1.8.~~ 13.1.8. returned, damaged, outdated, deteriorated, misbranded or adulterated drugs?

~~12.1.9.~~ 13.1.9. drugs that have been partially used?

~~12.1.10.~~ 13.1.10. drugs where the outer or secondary seals on the container have been broken?

~~12.1.11.~~ 13.1.11. drugs returned to your business, when there is doubt about the safety, identity, strength, quality, or purity of the drug?

~~12.1.12.~~ 13.1.12. drugs where the conditions of return cast doubt on safety, identity, strength, quality or purity?(CCR 1780[e][f])

CORRECTIVE ACTION OR ACTION PLAN \_\_\_\_\_

**13. 14. Training**

Yes No N/A

- ~~14.1~~ 15.1 Is 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.

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CORRECTIVE ACTION OR ACTION PLAN \_\_\_\_\_

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**14. 15. Dialysis Drugs**

Yes No N/A

- ~~14.1.~~ 15.1. Does your business provide dialysis drugs directly to patients, pursuant to a prescription? (B&PC 4054) (4059[c]) If so, please complete the next 4 questions, if not proceed to Section ~~15.~~ 16.
- ~~14.2.~~ 15.2. Do home dialysis patients complete a training program provided by a dialysis center licensed by Department of Health Services? Prescriber must provide proof of completion of this training to your business. (B&PC 4059[d])
- ~~14.3.~~ 15.3. Do you have written or oral orders for authorized dialysis drugs for each dialysis patient being serviced. Are such orders received by either a designated representative or a pharmacist? Note: refill orders cannot be authorized for more than 6 months from the date of the original order. (CCR 1787[a][b][c])
- ~~14.4.~~ 15.4. Does your business provide an “expanded invoice” for dialysis drugs dispensed directly to the patient including name of drug, manufacturer, quantities, lot number, date of shipment, and name of the designated representative or pharmacist responsible for distribution? A copy of the invoice must be sent to the prescriber, the patient and a copy retained by this business. Upon receipt of drugs, the patient or patient agent must sign for the receipt for the drugs with any irregularities noted on the receipt. (CCR 1790)
- ~~14.5.~~ 15.5. Is each case or full shelf package of the dialysis drugs dispensed labeled with the patient name and the shipment? Note that additional information as required is provided with each shipment. (CCR 1791)

CORRECTIVE ACTION OR ACTION PLAN \_\_\_\_\_

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**15. 16. Record Keeping Requirements**

Yes No N/A

- ~~15.1.~~ 16.1. Does your business' sales record for drugs include date of sale, your business name and address, the business name and address of the buyer, and the names and quantities of the drugs sold? (B&PC 4059[b])
- ~~15.2.~~ 16.2. 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.~~ 16.3. Are all purchase and sales records retained in a readily retrievable form? (B&PC 4105[a])
- ~~15.4.~~ 16.4. Is a current accurate inventory maintained for all dangerous drugs? (B&PC 4081, 4332, 1718)
- ~~15.5.~~ 16.5. 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.~~ 16.6. Are required records stored off-site only if a board issued written waiver has been granted?

~~15.7.~~ 16.7. 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.~~ 16.8. Is an off-site written waiver in place and is the storage area secure from unauthorized access? (CCR 1707[b][1])
- ~~15.9.~~ 16.9. 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.~~ 16.10. 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.~~ 16.11. Are records of training provided to employees to assure compliance with licensing requirements, retained for 3 years? (CCR 1780[f][4])

Yes No N/A

- ~~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]):
- 
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Yes No N/A

- ~~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 \_\_\_\_\_

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

### **16. 17. Reporting Requirements to the Board**

Yes No N/A

- ~~16.1.~~ 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]).
- ~~16.2.~~ 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])
- ~~16.3.~~ 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)
- ~~16.4.~~ 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])

Yes No N/A

- ~~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 \_\_\_\_\_

**17. 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.

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**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](http://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](http://www.pharmacy.ca.gov)

### Board of Registered Nursing

1625 N. Market Blvd., Suite N217  
Sacramento, CA 95834  
Phone: (916) 322-7697  
Fax: (916) 574-8637  
<http://www.rn.ca.gov/>

*Pharmacy Law* may be obtained by contacting:

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

### 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/>

### Pharmacist Recovery Program

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

### 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>

### Prescriber Boards:

#### Medical Board of California

2005 Evergreen St., Suite 1200  
Sacramento, CA 95815  
Phone: (800) 633-2322  
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<http://www.mbc.ca.gov>

#### Physician Assistant Committee

2005 Evergreen St., Suite 1100  
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<http://www.pac.ca.gov>

#### Dental Board of California

2005 Evergreen St., Suite 1550  
Sacramento, CA 95815  
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<http://www.dbc.ca.gov>

#### Board of Podiatric Medicine

2005 Evergreen St., Suite 1300  
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<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:**

[http://www.deadiversion.usdoj.gov/drugreg/reg\\_apps/onlineforms\\_new.htm](http://www.deadiversion.usdoj.gov/drugreg/reg_apps/onlineforms_new.htm)

**Online Registration - Renewal:**

[www.deadiversion.usdoj.gov/drugreg/reg\\_apps/onlineforms.htm](http://www.deadiversion.usdoj.gov/drugreg/reg_apps/onlineforms.htm)

**Registration Changes (Forms):**

[http://www.deadiversion.usdoj.gov/drugreg/change\\_requests/index.html](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.deacom.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, 14<sup>th</sup> 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

## BOARD OF PHARMACY

### Order of Adoption

**Add and Adopt** §1746.4, which is new regulation text as follows:

#### **§1746.4 Pharmacists Initiating and Administering Vaccines.**

- (a) A pharmacist initiating and/or administering vaccines pursuant to 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.**

## Board of Pharmacy

### Order of Adoption

To Amend § 1735 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

#### 1735. Compounding in Licensed Pharmacies.

(a) "Compounding" means any of the following activities occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a prescription:

- (1) Altering the dosage form or delivery system of a drug
- (2) Altering the strength of a drug
- (3) Combining components or active ingredients
- (4) Preparing a compounded drug product preparation from chemicals or bulk drug substances

(b) "Compounding" does not include reconstitution of a drug pursuant to a manufacturer's direction(s) ~~for oral, rectal, topical, or injectable administration~~, nor does it include the sole act of tablet splitting or crushing, capsule opening, or the addition of flavoring agent(s) to enhance palatability.

~~(c) "Compounding" does not include, except in small quantities under limited circumstances as justified by a specific, documented, medical need, preparation of a compounded drug product that is commercially available in the marketplace or that is essentially a copy of a drug product that is commercially available in the marketplace~~

~~(d)~~(c) The parameters and requirements stated by this Article 4.5 (Section 1735 et seq.) apply to all compounding practices. Additional parameters and requirements applicable solely to sterile ~~injectable~~ compounding are stated by Article 7 (Section 1751 et seq.).

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

**To Amend § 1735.1 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

**1735.1. Compounding Definitions.**

(a) “Ante-area” means an area with ISO Class 8 or better air quality where personnel hand hygiene and garbing procedures, staging of components, and other high-particulate-generating activities are performed, that is adjacent to the area designated for sterile compounding. It is a transition area that begins the systematic reduction of particles, prevents large fluctuations in air temperature and pressures in the cleanroom, and maintains air flows from clean to dirty areas. ISO Class 7 or better air quality is required for ante-areas providing air to a negative pressure room.

(b) “Beyond use date” means the date, or date and time, after which administration of a compounded drug preparation shall not begin, the preparation shall not be dispensed, and the preparation shall not be stored (other than for quarantine purposes).

(c) “Biological Safety Cabinet (BSC)” means a ventilated cabinet for compounding sterile drug preparations, having an open front with inward airflow for personnel protection, downward HEPA-filtered laminar airflow for product protection, and HEPA-filtered exhausted air for environmental protection. Where hazardous drugs are prepared, the exhaust air from the biological safety cabinet shall be appropriately removed by properly designed external building ventilation. This external venting should be dedicated to one BSC or CACI.

(d) “Bulk drug substance” means any substance that, when used in the preparation of a compounded drug preparation, processing, or packaging of a drug, is an active ingredient or a finished dosage form of the drug, but the term does not include any intermediate used in the synthesis of such substances.

(e) “Cleanroom or clean area or buffer area” means a room or area with HEPA-filtered air that provides ISO Class 7 or better air quality where the primary engineering control (PEC) is physically located.

(1) For nonhazardous compounding a positive pressure differential of 0.02- to 0.05-inch water column relative to all adjacent spaces is required.

(2) For hazardous compounding at least 30 air changes per hour of HEPA-filtered supply air and a negative pressure of between 0.01 to 0.03 inches of water column relative to all adjacent spaces is required.

(f) "Compounding Aseptic Containment Isolator (CACI)" means a unidirectional HEPA-filtered airflow compounding aseptic isolator (CAI) designed to provide worker protection from exposure to undesirable levels of airborne drug throughout the compounding and material transfer processes and to provide an aseptic environment for compounding sterile preparations. Air exchange with the surrounding environment should not occur unless the air is first passed through a microbial retentive filter (HEPA minimum) system capable of containing airborne concentrations of the physical size and state of the drug being compounded. Where hazardous drugs are prepared, the exhaust air from the isolator shall be appropriately removed by properly designed external building ventilation. This external venting should be dedicated to one BSC or CACI. Air within the CACI shall not be recirculated nor turbulent.

(g) "Compounding Aseptic Isolator (CAI)" means a form of isolator specifically designed for non-hazardous compounding of pharmaceutical ingredients or preparations while bathed with unidirectional HEPA-filtered air. It is designed to maintain an aseptic compounding environment within the isolator throughout the compounding and material transfer processes. Air exchange into the isolator from the surrounding environment should not occur unless the air has first passed through a microbial retentive filter (HEPA minimum) system capable of containing airborne concentrations of the physical size and state of the drug being compounded. Air within the CAI shall not be recirculated nor turbulent.

(h) "Controlled cold temperature" means 2 degrees to 8 degrees C (35 degrees to 46 degrees F).

(i) "Controlled freezer temperature" means -25 degrees to -10 degrees C (-13 degrees to 14 degrees F) or at a range otherwise specified by the pharmaceutical manufacturer(s) for that product.

(j) "Controlled room temperature" means 20 degrees to 25 degrees C (68 degrees to 77 degrees F).

(k) "Copy or essentially a copy" of a commercially available drug product includes all preparations that are comparable in active ingredients to commercially available drug

products, except that it does not include any preparations in which there has been a change, made for an identified individual patient, which produces for that patient a clinically significant difference, as determined by a prescribing practitioner, between that compounded preparation and the comparable commercially available drug product.

(l) "Daily" means occurring every day the pharmacy is operating, except when daily monitoring of refrigerator and freezer temperature are required, then daily means every 24 hours.

(m) "Displacement airflow method" means a concept which utilizes a low pressure differential, high airflow principle to maintain segregation from the adjacent ante-area by means of specific pressure differentials. This principle of displacement airflow shall require an air velocity of 40 ft per minute or more, from floor to ceiling and wall to wall, from the clean area across the line of demarcation into the ante-area. The displacement concept may not be used to maintain clean area requirements for sterile compounds which originate from any ingredient that was at any time non-sterile, regardless of intervening sterilization of the ingredient, or for hazardous compounds.

(n) "Dosage unit" means a quantity sufficient for one administration to one patient.

(o) "Equipment" means items that must be calibrated, maintained or periodically certified.

(p) "First air" means the air exiting the HEPA filter in a unidirectional air stream that is essentially particle free.

(q) "Gloved fingertip sampling" means a process whereby compounding personnel lightly press each fingertip and thumb of each hand onto appropriate growth media, which are then incubated at a temperature and for a time period conducive to multiplication of microorganisms, and then examined for growth of microorganisms.

(r) "Hazardous" means all anti-neoplastic agents identified by the National Institute for Occupational Safety and Health (NIOSH) as meeting the criteria for a hazardous drug and any other drugs, compounds, or materials identified as hazardous by the pharmacist-in-charge.

(s) "Integrity" means retention of potency until the ~~expiration~~ beyond use date ~~noted~~ provided on the label, so long as the preparation is stored and handled according to the label directions.

(t) "Lot" means one or more compounded drug preparation(s) prepared during one uninterrupted continuous cycle of compounding from one or more common active

ingredient(s).

(u) "Media-fill test" means a test used to measure the efficacy of compounding personnel in aseptic techniques whereby compounding procedures are mimicked using a growth-based media and then the resulting preparation is evaluated for sterility. The media-fill test must mimic the most complex compounding procedures performed by the pharmacy.

(v) "Non-sterile-to-sterile batch" means any compounded drug preparation containing two (2) or more dosage units with any ingredient that was at any time non-sterile, regardless of intervening sterilization of that ingredient.

(w) "Parenteral" means a preparation of drugs administered in a manner other than through the digestive tract. It does not include topical, sublingual, rectal or buccal routes of administration.

(x) "Personal protective equipment" means clothing or devices that protect the employee from exposure to compounding ingredients and/or potential toxins and minimize the contamination of compounded preparations. These include shoe covers, head and facial hair covers, face masks, gowns, and gloves.

(y) "Potency" means active ingredient strength within +/- 10% (or the range specified in USP37-NF32, 37th Revision, Through 2nd Supplement Effective December 1, 2014) of the labeled amount. Sterile injectable products compounded solely from commercially manufactured sterile pharmaceutical products in a health care facility licensed under section 1250 of the Health and Safety Code are exempt from this definition. For those exempt, the range shall be calculated and defined in the master formula.

(z) "Preparation" means a drug or nutrient compounded in a licensed pharmacy; the preparation may or may not be sterile.

(aa) "Prescriber's office" or "prescriber office" means an office or suite of offices in which a prescriber regularly sees patients for outpatient diagnosis and treatment. This definition does not include any hospital, pharmacy, or other facility, whether or not separately licensed, that may be affiliated with, adjacent to, or co-owned by, the prescriber's practice environment.

(ab) "Primary Engineering Control (PEC)" means a device that provides an ISO Class 5 or better environment through the use of non-turbulent, unidirectional HEPA-filtered first air for

compounding sterile preparations. Examples of PEC devices include, but are not limited to, laminar airflow workbenches, biological safety cabinets, sterile compounding automated robots, compounding aseptic isolators, and compounding aseptic containment isolators.

(ac) "Process validation" means demonstrating that when a process is repeated within specified limits, the process will consistently produce preparations complying with predetermined requirements. If any aspect of the process is changed, the process would need to be revalidated.

(ad) "Product" means a commercially manufactured drug or nutrient evaluated for safety and efficacy by the FDA.

(ae) "Quality" means the absence of harmful levels of contaminants, including filth, putrid, or decomposed substances, and the absence of active ingredients other than those listed on the label, and the absence of inactive ingredients other than those listed on the master formula document.

(af) "Segregated sterile compounding area" means a designated space for sterile-to-sterile compounding where a PEC is located within either a demarcated area (at least three foot perimeter) or in a separate room. Such area or room shall not contain and shall be void of activities and materials that are extraneous to sterile compounding. The segregated sterile compounding area shall not be in a location that has unsealed windows or doors that connect to the outdoors, in a location with high traffic flow, or in a location that is adjacent to construction sites, warehouses, or food preparation. The segregated sterile compounding area shall not have a sink, other than an emergency eye-washing station, located within three feet of a PEC. The segregated sterile compounding area shall be restricted to preparation of sterile-to-sterile compounded preparations.

(1) The BUD of a sterile drug preparation made in a segregated sterile compounding area is limited to 12 hours or less as defined by section 1751.8(d).

(2) When the PEC in the segregated sterile compounding area is a CAI or a CACI and the documentation provided by the manufacturer shows it meets the requirements listed in section 1751.4(f)(1)-(3), the assigned BUD shall comply with section 1751.8(a-b) or (d).

(ag) "Strength" means amount of active ingredient per unit of a compounded drug product

preparation.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

**To Amend § 1735.2 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

**1735.2. Compounding Limitations and Requirements; Self-Assessment.**

(a) Except as specified in (b) and (c), no drug ~~product~~ preparation shall be compounded prior to receipt by a pharmacy of a valid prescription for an individual patient where the prescriber has approved use of a compounded drug ~~product~~ preparation either orally or in writing. Where approval is given orally, that approval shall be noted on the prescription prior to compounding.

(b) A pharmacy may prepare and store a limited quantity of a compounded drug ~~product~~ preparation in advance of receipt of a patient-specific prescription where and solely in such quantity as is necessary to ensure continuity of care for an identified population of patients of the pharmacy based on a documented history of prescriptions for that patient population.

(c) A “reasonable quantity” ~~as used in~~ that may be furnished to a prescriber for office use by the prescriber as authorized by Business and Professions Code section 4052, subdivision (a)(1), means that amount of compounded drug ~~product~~ preparation that:

(1) ~~is~~ ordered by the prescriber or the prescriber’s agent using a purchase order or other documentation received by the pharmacy prior to furnishing that lists the number of patients seen or to be seen in the prescriber’s office for whom the drug is needed or anticipated, and the quantity for each patient that is sufficient for office administration or application to patients in the prescriber’s office, or for distribution of not more than a 72-hour supply to the prescriber’s patients, as estimated by the prescriber; and

(2) Is delivered to the prescriber’s office and signed for by the prescriber or the prescriber’s agent; and

(3) Is sufficient for administration or application to patients solely in the prescriber's office, or

for furnishing of not more than a 120-hour supply for veterinary medical practices, solely to the prescriber's own veterinary patients seen as part of regular treatment in the prescriber's office, as fairly estimated by the prescriber and documented on the purchase order or other documentation submitted to the pharmacy prior to furnishing; and

~~(2)~~(4) That the pharmacist has a credible basis for concluding it is a reasonable quantity for office use ~~is reasonable~~ considering the intended use of the compounded medication and the nature of the prescriber's practice; and

~~(3)~~ (5) for With regard to any individual prescriber to whom the pharmacy furnishes, and with regard to ~~for~~ all prescribers to whom the pharmacy furnishes, taken as a whole, is an amount which the pharmacy is capable of compounding in compliance with pharmaceutical standards for integrity, potency, quality and strength of the compounded drug product preparation; and

(6) Does not exceed an amount the pharmacy can reasonably and safely compound.

(d) No pharmacy or pharmacist shall compound a drug preparation that:

(1) Is classified by the FDA as demonstrably difficult to compound;

(2) Appears on an FDA list of drugs that have been withdrawn or removed from the market because such drugs or components of such drugs have been found to be unsafe or not effective; or

(3) Is a copy or essentially a copy of one or more commercially available drug products, unless that drug product appears on an ASHP (American Society of Health-System Pharmacists) or FDA list of drugs that are in short supply at the time of compounding and at the time of dispense, and the compounding of that drug preparation is justified by a specific, documented medical need made known to the pharmacist prior to compounding. The pharmacy shall retain a copy of the documentation of the shortage and the specific medical need in the pharmacy records for three years from the date of receipt of the documentation.

~~(d)~~(e) A drug product preparation shall not be compounded until the pharmacy has first prepared a written master formula record document that includes at least the following elements:

(1) Active ingredients to be used.

(2) Equipment to be used.

(3) ~~Expiration dating requirements.~~ The maximum allowable beyond use date for the preparation, and the rationale or reference source justifying its determination.

(4) Inactive ingredients to be used.

(5) ~~Process and/or procedure~~ Specific and essential compounding steps used to prepare the drug.

(6) Quality reviews required at each step in preparation of the drug.

(7) Post-compounding process or procedures required, if any.

(8) Instructions for storage and handling of the compounded drug preparation.

~~(e)(f)~~ Where a pharmacy does not routinely compound a particular drug ~~product~~ preparation, the master formula record for that ~~product~~ preparation may be recorded on the prescription document itself.

~~(f)(g)~~ The pharmacist performing or supervising compounding is responsible for the integrity, potency, quality, and labeled strength of a compounded drug ~~product~~ preparation until ~~it~~ the beyond use date indicated on the label, so long as label instructions for storage and handling are followed after the preparation is dispensed.

~~(g)(h)~~ All chemicals, bulk drug substances, drug products, and other components used for drug compounding shall be stored and used according to compendial and other applicable requirements to maintain their integrity, potency, quality, and labeled strength.

~~(h)(i)~~ Every compounded drug ~~product~~ preparation shall be given an ~~expiration-beyond use~~ date representing the date or date and time beyond which the compounded drug preparation should not be used, stored, transported or administered, and determined based on the professional judgment of the pharmacist performing or supervising the compounding. ~~in the professional judgment of the pharmacist performing or supervising the compounding, it should not be used.~~

(1) For non-sterile compounded drug preparation(s), the beyond use date ~~This “beyond use date” of the compounded drug product shall not exceed~~ any of the following: 180 days from preparation or

(A) the shortest expiration date or beyond use date of any component ingredient in the compounded drug product preparation,

- (B) the chemical stability of any one ingredient in the compounded drug preparation;
- (C) the chemical stability of the combination of all ingredients in the compounded drug preparation,
- (D) 180 days for non-aqueous formulations,
- (E) 14 days for water-containing oral formulations, and
- (F) 30 days for water-containing topical/dermal and mucosal liquid and semisolid formulations.

(2) For sterile compounded drug preparations, the beyond use date shall not exceed any of the following:

- (A) The shortest expiration date or beyond use date of any ingredient in the sterile compounded drug product preparation,
- (B) The chemical stability of any one ingredient in the sterile compounded drug preparation,
- (C) The chemical stability of the combination of all ingredients in the sterile compounded drug preparation, and
- (D) The beyond use date assigned for sterility in section 1751.8.

(3) Extension of a beyond use date is only allowable when supported by the following:

- (A) Method Suitability Test,
- (B) Container Closure Integrity Test, and
- (C) Stability Studies

~~unless a longer later date is supported by stability studies of~~

(4) In addition to the requirements of paragraph three (3), the ~~finished~~ drugs or compounded drug ~~products~~ preparations tested and studied shall be using the same identical components in ingredients, specific and essential compounding steps, quality reviews, and packaging as the finished drug or compounded drug preparation.

(5) Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.

~~(j)~~ (j) The pharmacist performing or supervising compounding is responsible for the proper preparation, labeling, storage, and delivery of the compounded drug ~~product~~ preparation.

~~(k)~~ (k) Prior to allowing any drug product preparation to be compounded in a pharmacy, the pharmacist-in-charge shall complete a self-assessment for compounding pharmacies developed

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

(l) Packages of ingredients, both active and inactive, that lack a supplier’s expiration date are subject to the following limitations:

(1) such ingredients cannot be used for any non-sterile compounded drug preparation more than three (3) years after the date of receipt by the pharmacy.

(2) such ingredients cannot be used for any sterile compounded drug preparation more than one (1) year after the date of receipt by the pharmacy.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code, Sections 1735, 1735.1, 1735.8, and 1751.1-1751.8 of Title 16, Division 17, of the California Code of Regulations.

**To Amend § 1735.3 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

**1735.3. ~~Records~~ Recordkeeping of for Compounded Drug Products Preparations.**

(a) For each compounded drug ~~product preparation~~, the pharmacy records shall include:

(1) The master formula ~~record~~ document.

(2) A compounding log consisting of a single document containing all of the following:

(A) Name and Strength of the compounded drug preparation.

(B) The date the drug ~~product preparation~~ was compounded.

~~(3)(C) The identity of the any pharmacy personnel who compounded the~~ engaged in compounding the drug ~~product preparation~~.

~~(4)(D) The identity of the pharmacist reviewing the final drug ~~product preparation~~.~~

~~(5)(E) The quantity of each component ingredient used in compounding the drug ~~product preparation~~.~~

~~(6)(F) The manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. If the manufacturer does not supply an expiration date for any component, the records shall include the date of receipt of the component in the pharmacy, and the limitations of section 1735.2, subdivision (l) shall apply.~~

(i) Exempt from the requirements in this paragraph (1735.3(a)(2)(F)) are sterile ~~products preparations~~ compounded ~~on a one-time basis in a single lot~~ for administration within seventy-two (72) hours to a patient in a health care facility licensed under section 1250 of the Health and Safety Code and stored in accordance with standards for “Redispensed CSPs” found in Chapter 797 of the United States Pharmacopeia – National Formulary (USP37-NF32) Through 2nd Supplement (35 37<sup>th</sup> Revision, Effective ~~May~~ December 1, 2012-2014), hereby incorporated by reference, ~~to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.~~

~~(7)(G) A pharmacy-assigned unique reference or lot number for the compounded drug ~~product preparation~~.~~

~~(8)(H)~~ The expiration beyond use date or beyond use date and time of the final compounded drug product preparation, expressed in the compounding record document in a standard date and time format.

~~(9)(I)~~ The final quantity or amount of drug product preparation compounded for dispensing.

(J) Documentation of quality reviews and required post-compounding process and procedures.

(b) Pharmacies shall maintain records of the proper acquisition, storage, and destruction of chemicals, bulk drug substances, drug products, and components used in compounding.

(c) Active ingredients shall be obtained from a supplier registered with the Food and Drug Administration (FDA). All other ~~C~~chemicals, bulk drug substances, and drug products, and components used to compound drug products preparations shall be obtained, whenever possible, from reliable FDA- registered suppliers. The pharmacy shall acquire and retain any available certificates of purity or analysis, either written in English or translated into English, for chemicals, bulk drug substances, and drug products, and components used in compounding. Certificates of purity or analysis are not required for drug products that are approved by the FDA. Any certificates of purity or analysis acquired by the pharmacy shall be matched to the corresponding chemical, bulk drug substance, or drug products received.

(d) Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was ~~created~~ last in effect. If only recorded and stored electronically, on magnetic media, or in any other computerized form, the records shall be maintained as specified by Business and Professions Code section 4070 subsection (c).

Authority cited: Sections 4005, 4127, and 4169, Business and Professions Code.

Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

To Amend § 1735.4 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

**1735.4. Labeling of Compounded Drug ~~Products~~ Preparations.**

(a) Each compounded drug preparation shall be affixed with a container label prior to dispensing that contains at least:

(1) Name of the compounding pharmacy and dispensing pharmacy (if different);

(2) Name (brand or generic) and strength, volume, or weight of each active ingredient. For admixed IV solutions, the intravenous solution utilized shall be included;

(3) Instructions for storage, handling, and administration. For admixed IV solutions, the rate of infusion shall be included;

(4) The beyond use date for the drug preparation;

(5) The date compounded; and

(6) The lot number or pharmacy reference number.

~~In addition to the labeling information required under Business and Professions Code section 4076 and under California Code of Regulations section 1707.5, the label of a compounded drug product preparation shall contain the generic or brand name(s) of the principal all active ingredient(s).~~

(b) Any compounded drug preparation dispensed to a patient or readied for dispensing to a patient shall also include on the label the information required under Business and Professions Code section 4076 and California Code of Regulations, title 16, section 1707.5.

~~A statement that the drug has been compounded by the pharmacy shall be included on the container or on the receipt provided to the patient.~~

(c) Any compounded drug preparation dispensed to a patient or readied for dispensing to a patient shall also include, on the container label or on a receipt provided to the patient, a statement that the drug has been compounded by the pharmacy. ~~Drug products preparations compounded into unit dose containers that are too small or otherwise impractical for full compliance with subdivisions (a) and (b) shall be labeled with at least the name(s) of the active ingredient(s), concentration or strength, volume or weight of the~~

~~preparation, pharmacy reference or lot number, and expiration date.~~

(d) Prior to dispensing drug preparations compounded into unit-dose containers that are too small or otherwise impractical for full compliance with subdivisions (a), (b), and (c) shall be labeled with at least the name of the compounding pharmacy and dispensing pharmacy, if different, the name(s) of the active ingredient(s), strength, volume or weight of the preparation, pharmacy reference or lot number, and beyond use date, and shall not be subject to minimum font size requirements. Once dispensed, outer packaging must comply with 1735.4(a) – (c).

(e) All hazardous agents shall bear a special label which states “Chemotherapy - Dispose of Properly” or “Hazardous – Dispose of Properly.”

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4076 and 4127, Business and Professions Code.

**To Amend § 1735.5 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

**1735.5. Compounding Policies and Procedures.**

(a) Any pharmacy engaged in compounding shall maintain ~~a~~ written policies and procedures manual for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding. Any material failure to follow the pharmacy’s written policies and procedures shall constitute a basis for disciplinary action.

(b) The policies and procedures manual shall be reviewed and such review shall be documented on an annual basis by the pharmacist-in-charge. ~~and~~ The policies and procedures manual shall be updated whenever changes in policies and procedures ~~processes~~ are implemented.

(c) The policies and procedures manual shall include at least the following:

- (1) Procedures for notifying staff assigned to compounding duties of any changes in ~~processes~~ or to the policies or procedures manual.
- (2) ~~Documentation of a~~ A written plan for recall of a dispensed compounded drug product preparation where subsequent verification information demonstrates the potential for adverse effects with continued use of a compounded drug product. The plan shall ensure that all affected doses can be accounted for during the recall and shall provide steps to identify which patients received the affected lot or compounded drug preparation(s).
- (3) ~~The p~~ Procedures for maintaining, storing, calibrating, cleaning, and disinfecting equipment used in compounding, and for training on these procedures as part of the staff training and competency evaluation process.
- (4) Procedures for evaluating, maintaining, certifying, cleaning, and disinfecting the facility (physical plant) used for compounding, and for training on these procedures as part of the staff training and competency evaluation process.
- (45) Documentation of the methodology used to ~~test~~ validate integrity, potency, quality, and labeled strength of compounded drug ~~products~~ preparations. The methodology must be appropriate to compounded drug preparations.
- (56) Documentation of the methodology and rationale or reference source used to determine appropriate ~~expiration~~ beyond use dates for compounded drug ~~products~~ preparations.
- (7) Dates and signatures reflecting all annual reviews of the policies and procedures by the pharmacist-in-charge.
- (8) Dates and signatures accompanying any revisions to the policies and procedures approved by the pharmacist-in-charge.
- (9) Policies and procedures for storage of compounded drug preparations in the pharmacy and daily documentation of all room, refrigerator, and freezer temperatures within the pharmacy.
- (10) Policies and procedures regarding ensuring appropriate functioning of refrigeration devices, monitoring refrigeration device temperatures, and actions to take regarding any out of range temperature variations within the pharmacy.
- (11) Policies and procedures for proper garbing when compounding with hazardous products. This shall include when to utilize double shoe covers.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, ~~and 4127~~, and 4301, Business and Professions Code.

**To Amend § 1735.6 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

**1735.6. Compounding Facilities and Equipment.**

(a) Any pharmacy engaged in compounding shall maintain written documentation regarding the facilities and equipment necessary for safe and accurate compounding of compounded drug ~~products~~ preparations. This shall include records of maintenance and cleaning of the facilities and equipment. Where applicable, this shall also include records of certification(s) of facilities or equipment.

(b) Any equipment used to compound drug ~~products~~ preparations shall be stored, used, ~~and~~ maintained, and cleaned in accordance with manufacturers' specifications.

(c) Any equipment that weighs, measures, or transfers ingredients used to compound drug ~~products~~ preparations for which calibration or adjustment is appropriate shall be calibrated prior to use, on a schedule and by a method determined by the manufacturer's specifications, to ensure accuracy. Documentation of each such calibration shall be recorded in writing in a form which is not alterable and these records of calibration shall be maintained and retained in the pharmacy.

(d) Any pharmacy engaged in any hazardous drug compounding shall maintain written documentation regarding appropriate cleaning of facilities and equipment to prevent cross-contamination with non-hazardous drugs.

(e) Hazardous drug compounding shall be completed in an externally vented physically separate room with the following requirements:

(1) Minimum of 30 air changes per hour except that 12 air changes per hour are acceptable for segregated compounding areas with a BSC or CACI when products are assigned a BUD of 12 hrs or less or when non sterile products are compounded; and

(2) Maintained at a negative pressure of 0.01 to 0.03 inches of water column relative to all adjacent spaces (rooms, above ceiling, and corridors); and

(3) Each PEC in the room shall also be externally vented; and

(4) All surfaces within the room shall be smooth, seamless, impervious, and non-shedding.

(f) Where compliance with the January 1, 2017 amendments to Article 4.5 or Article 7, requires physical construction or alteration to a facility or physical environment, the board or its designee may grant a waiver of such compliance for a period of time to permit such physical change(s). Application for any waiver shall be made by the licensee in writing, and the request shall identify the provision(s) requiring physical construction or alteration, and the timeline for any such change(s). The board or its designee may grant the waiver when, in its discretion, good cause is demonstrated for such waiver.

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code.

Reference: Sections 4005, 4036, 4037, 4051, 4052 and 4127, Business and Professions Code.

**To Amend § 1735.7 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

**1735.7. Training of Compounding Staff.**

(a) A pharmacy engaged in compounding shall maintain documentation demonstrating that personnel involved in compounding have the skills and training required to properly and accurately perform their assigned responsibilities and documentation demonstrating that all personnel involved in compounding are trained in all aspects of policies and procedures. This training shall include but is not limited to support personnel (e.g. institutional environmental services, housekeeping), maintenance staff, supervising pharmacist and all others whose jobs are related to the compounding process. ~~Any pharmacy engaged in compounding shall maintain written documentation sufficient to demonstrate that pharmacy personnel have the skills and training required to properly and accurately perform their assigned responsibilities relating to compounding.~~

(b) The pharmacy shall develop and maintain an ongoing competency evaluation process for pharmacy personnel involved in compounding, and shall maintain documentation of any and all training related to compounding undertaken by pharmacy personnel.

(c) Pharmacy personnel assigned to compounding duties shall demonstrate knowledge about processes and procedures used in compounding prior to compounding any drug ~~product~~ preparation.

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052 and 4127, Business and Professions Code.

**To Amend § 1735.8 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

**1735.8. Compounding Quality Assurance.**

(a) Any pharmacy engaged in compounding shall maintain, as part of its written policies and procedures, a written quality assurance plan designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug ~~products~~ preparations.

(b) The quality assurance plan shall include written procedures for verification, monitoring, and review of the adequacy of the compounding processes and shall also include written documentation of review of those processes by qualified pharmacy personnel.

(c) The quality assurance plan shall include written standards for qualitative and quantitative analysis of compounded drug preparations to ensure integrity, potency, quality, and labeled strength, including the frequency of testing ~~analysis of compounded drug products~~. All qualitative and quantitative analysis reports for compounded drug ~~products~~ preparations shall be retained by the pharmacy and ~~collected~~ maintained along with the compounding ~~log record~~ and master formula document. The quality assurance plan shall include a schedule for routine testing and analysis of specified compounded drug preparations to ensure integrity, potency, quality, and labeled strength, on at least an annual basis.

(d) The quality assurance plan shall include a written procedure for scheduled action in the

event any compounded drug ~~product~~ preparation is ever discovered to be ~~below~~ outside minimum standards for integrity, potency, quality, or labeled strength.

(e) The quality assurance plan shall include a written procedure for responding to out-of-range temperature variations within the pharmacy and within patient care areas of a hospital where furnished drug is returned for redispensing.

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052 and 4127, Business and Professions Code.

**To Amend § 1751 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

#### **Article 7. Sterile ~~Injectable~~ Compounding**

##### **1751. Sterile ~~Injectable~~ Compounding; Compounding Area; Self-Assessment.**

(a) Any pharmacy engaged in compounding sterile ~~injectable~~ drug ~~products~~ preparations shall conform to the parameters and requirements stated by Article 4.5 (Section 1735 et seq.), applicable to all compounding, and shall also conform to the parameters and requirements stated by this Article 7 (Section 1751 et seq.), applicable solely to sterile ~~injectable~~ compounding.

(b) Any pharmacy compounding sterile ~~injectable~~ drug ~~products~~ preparations shall have a ~~designated~~ compounding area designated for the preparation of sterile ~~injectable~~ drug products preparations that is in a restricted location where traffic has no impact on the performance of the PEC(s). The cleanroom, including the walls, ceilings, and floors, shall be constructed in accordance with Section 1250.4 of Title 24, Part 2, Chapter 12, of the California Code of Regulations. The pharmacy shall be ventilated in a manner in accordance with Section 505.5 of Title 24, Part 4, Chapter 5 of the California Code of Regulations. ~~which shall meet the following standards:~~ The environments within the pharmacy shall meet the following standards:

~~(1) Clean Room and Work Station Requirements, shall be in accordance with Section 1250 of Title 24, Part 2, Chapter 12, of the California Code of Regulations.~~

~~(2) Walls, ceilings and floors shall be constructed in accordance with Section 1250 of Title 24, Part 2, Chapter 12, of the California Code of Regulations.~~

~~(3) Be ventilated in a manner in accordance with Section 505.12 of Title 24, Chapter 5 of the California Code of Regulations.~~

~~(4) Be~~ Each ISO environment shall be certified annually at least every six months by a qualified technician ~~who is familiar with the methods and procedures for certifying laminar air flow hoods and clean room requirements, in accordance with standards adopted by the United States General Services Administration~~ in accordance with Section 1751.4. Certification records must be retained ~~for at least 3 years~~ in the pharmacy.

~~(5)-(2) The pharmacy shall be arranged in accordance with Section 1250 of Title 24, Part 2, Chapter 12, of the California Code of Regulations.~~ Items related to the compounding of sterile ~~injectable drug products~~ preparations within the compounding area shall be stored in such a way as to maintain the integrity of an aseptic environment.

~~(6)-(3) A sink shall be included in accordance with Section 1250.4 of Title 24, Part 2, Chapter 12, of the California Code of Regulations.~~ Sinks and drains shall not be present in any ISO Class 7 or better cleanroom, nor in a segregated sterile compounding area within three feet of an ISO Class 5 or better PEC, with the exception of emergency eye-rinsing stations. A sink may be located in an ante-area. When the PEC in the segregated sterile compounding area is a CAI or CACI and the documentation provided by the manufacturer shows it meets the requirements listed in 1751.4(f)(1)-(3) the sterile compounding area is exempt from the room requirement listed in 1751(b)(3).

~~(7)-(4) There shall be a refrigerator and, ~~for~~ where appropriate, a freezer, of sufficient capacity to meet the storage requirements for all material requiring refrigeration or freezing, and a backup plan to ensure continuity of available compounded drug preparations in the event of a power outage.~~

~~(c) Any pharmacy compounding a sterile injectable drug product preparation from one or more non-sterile ingredients shall comply with Business and Professions Code section 4127.7.~~

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127 and 4127.7, Business and Professions Code; Sections 1735, 1735.1-1735.8., and 1751.1-1751.8. of Title 16, Division 17, of the California Code of

Regulations; and Section 18944, Health and Safety Code.

**To Amend § 1751.1 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

**1751.1. Sterile ~~Injectable~~ Compounding Recordkeeping Requirements.**

(a) ~~Pharmacies compounding sterile injectable products for future use pursuant to section 1735.2 shall, in addition to those records required by section 1735.3, make and keep records indicating the name, lot number, amount, and date on which the products were provided to a prescriber.~~

~~(b) In addition to the records required by section 1735.3 and subdivision (a), any pharmacy engaged in any compounding of for sterile drug products preparations compounded from one or more non-sterile ingredients, shall maintain the following records, which must be made and kept by~~ readily retrievable, within the pharmacy:

(1) ~~The~~ Documents evidencing training and competency evaluations of employees in sterile product drug preparation policies and procedures.

(2) Results of hand hygiene and garbing assessments with integrated gloved fingertip testing.

(3) Results of assessments of personnel for aseptic techniques including results of media-fill tests and gloved fingertip testing performed in association with media-fill tests.

(4) Results of viable air and surface sampling.

(5) Video of smoke studies in all ISO certified spaces.

(6) Documents indicating daily documentation of room, R refrigerator, and freezer temperatures appropriate for sterile compounded drug preparations consistent with the temperatures listed in section 1735.1 for:

(A) Controlled room temperature.

(B) Controlled cold temperature.

(C) Controlled freezer temperature.

(7) Certification(s) of the sterile compounding environment(s).

(8) Documents indicating daily documentation of air pressure differentials or air velocity

measurements between all adjoining ISO rooms or areas, including those associated with compounding aseptic (containment) isolators, and air pressure differentials or air velocity measurements between all rooms or spaces with an immediate entry or opening to ISO rooms or areas.

(9) Other facility quality control logs records specific to the pharmacy's policies and procedures (e.g., cleaning logs for facilities and equipment).

(10) Logs or other documentation of inspections for expired or recalled ~~pharmaceutical products or raw ingredients~~ chemicals, bulk drug substances, drug products, or other ingredients.

(11) Preparation records including the master formula document work sheet, the preparation compounding log work sheet, and records of end-product evaluation testing and results.

(b) Pharmacies compounding sterile drug preparations for future use pursuant to section 1735.2 shall, in addition to those records required by section 1735.3, make and keep records indicating the name, lot number, and amount of any drug preparation compounded for future use, the date on which any preparation was provided to a prescriber, and the name, address, license type and number of the prescriber.

(c) Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was created. If only recorded and stored electronically, on magnetic media, or in any other computerized form, the records shall be maintained as specified by Business and Professions Code section 4070 subsection (c).

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

**To Amend § 1751.2 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

**1751.2. Sterile ~~Injectable~~ Compounding Labeling Requirements.**

In addition to the labeling information required under Business and Professions Code section 4076 and California Code of Regulations, title 16, sections 1707.5 and 1735.4, a pharmacy ~~which that~~ compounds sterile ~~injectable drug products~~ preparations shall include the following information on the labels for ~~each such those products~~ preparation:

- (a) ~~The~~ Telephone number of the pharmacy. ~~, except~~ The telephone number is not required on the label for sterile injectable drug products preparations dispensed administered for to inpatients of a within the hospital pharmacy.
- ~~(b) Name and concentration of ingredients contained in the sterile injectable drug product.~~
- ~~(c)~~ Instructions for storage, and handling, and administration.;
- ~~(d)~~ All cytotoxic hazardous agents shall bear a special label which states "Chemotherapy - Dispose of Properly" or "Cytotoxic Hazardous – Dispose of Properly."

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4076 and 4127, Business and Professions Code.

**To Amend § 1751.3 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

**1751.3. Sterile ~~Injectable~~ Compounding Policies and Procedures.**

(a) Any pharmacy engaged in compounding sterile drug preparations shall maintain written policies and procedures for compounding. Any material failure to follow the pharmacy's written policies and procedures shall constitute a basis for disciplinary action. In addition to the elements required by section 1735.5, there shall be written policies and procedures regarding the following:

- (1) Action levels for colony-forming units (CFUs) detected during viable surface sampling, glove

fingertip, and viable air sampling and actions to be taken when the levels are exceeded.

(2) Airflow considerations and pressure differential monitoring.

(3) An environmental sampling plan and procedures specific to viable air, surface and gloved fingertip sampling as well as nonviable particle sampling.

(4) Cleaning and maintenance of ISO environments and segregated compounding areas.

(5) Compounded sterile drug preparation stability and beyond use dating.

(6) Compounding, filling, and labeling of sterile drug preparations.

(7) Daily and monthly cleaning and disinfection schedule for the controlled areas and any equipment in the controlled area as specified in section 1751.4.

(8) Depyrogenation of glassware (if applicable)

(9) Facility management including certification and maintenance of controlled environments and related equipment.

(10) For compounding aseptic isolators and compounding aseptic containment isolators, documentation of the manufacturer's recommended purge time.

(11) Hand hygiene and garbing.

(12) Labeling of the sterile compounded drug preparations based on the intended route of administration and recommended rate of administration.

(13) Methods by which the supervising pharmacist will fulfill his or her responsibility to ensure the quality of compounded drug preparations.

(14) Orientation, training, and competency evaluation of staff in all aspects of the preparation of sterile drug preparations including didactic training and knowledge/competency assessments that include at minimum: hand hygiene and garbing; decontamination (where applicable); cleaning and disinfection of controlled compounding areas; and proper aseptic technique, demonstrated through the use of a media-fill test performed by applicable personnel; and aseptic area practices.

(15) Preparing sterile compounded drug preparations from non-sterile components (if applicable). This shall include sterilization method suitability testing for each master formula document.

(16) Procedures for handling, compounding and disposal of hazardous agents. The written

policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.

(17) Procedures for handling, compounding and disposal of infectious materials. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.

(18) Proper use of equipment and supplies.

(19) Quality assurance program compliant with sections 1711, 1735.8 and 1751.7.

(20) Record keeping requirements.

(21) Temperature monitoring in compounding and controlled storage areas.

(22) The determination and approval by a pharmacist of ingredients and the compounding process for each preparation before compounding begins.

(23) Use of automated compounding devices (if applicable).

(24) Visual inspection and other final quality checks of sterile drug preparations.

~~(a) Any pharmacy engaged in compounding sterile injectable drug products shall maintain a written policy and procedures manual for compounding that includes, in addition to the elements required by section 1735.5, written policies and procedures regarding the following:~~

~~(1) Compounding, filling, and labeling of sterile injectable compounds.~~

~~(2) Labeling of the sterile injectable product compounded drug preparations based on the intended route of administration and recommended rate of administration.~~

~~(3) Equipment and supplies.~~

~~(4) Training of staff in the preparation of sterile injectable products.~~

~~(5) Procedures for handling cytotoxic agents.~~

~~(6) Quality assurance program.~~

~~(7) Record keeping requirements.~~

~~(b) The ingredients and the compounding process for each preparation must be determined in writing before compounding begins and must be reviewed by a pharmacist.~~

~~(c) Pharmacies compounding sterile injectable drug products preparations shall have written policies and procedures for the disposal of infectious materials and/or materials containing cytotoxic hazardous residues. The written policies and procedures shall describe the pharmacy~~

~~protocols for cleanups and spills in conformity with local health jurisdiction standards.~~

(b) For lot compounding, the pharmacy shall maintain written policies and procedures that includes, in addition to the elements required by section 1735.5 and 1751.3(a), written policies and procedures regarding the following:

(1) Use of master formula documents and compounding logs.

(2) Appropriate documentation.

(3) Appropriate sterility and potency testing.

(c) For non-sterile-to-sterile batch compounding, the pharmacy shall maintain written policies and procedures for compounding that includes, in addition to the elements required by section 1735.5, 1751.3(a), and 1751.7(e), written policies and procedures regarding the following:

(1) Process validation for chosen sterilization methods.

(2) End-product evaluation, quantitative, and qualitative testing.

~~(d)(1) All written p~~olicies and procedures shall be immediately available to all personnel involved in these compounding activities and to board inspectors.

~~(d)(2)(e) All personnel involved must read the policies and procedures before compounding sterile injectable products—drug preparations, and any~~All personnel involved must read all additions, revisions, and deletions to the written policies and procedures—must be communicated to all personnel involved in sterile compounding. Each review must be documented by a signature and date.

~~(3) Policies and procedures must address at least the following:~~

~~(A) Competency evaluation.~~

~~(B) Storage and handling of products and supplies.~~

~~(C) Storage and delivery of final products.~~

~~(D) Process validation.~~

~~(E) Personnel access and movement of materials into and near the controlled area~~

~~(F) Use and maintenance of environmental control devices used to create the critical direct compounding area for manipulation of sterile products (e.g., laminar airflow workstations, biological safety cabinets, class 100 cleanrooms, and barrier isolator~~

workstations).

~~(G) Regular cleaning schedule for the controlled areas and any equipment in the controlled area and the alternation of disinfectants. Pharmacies subject to an institutional infection control policy may follow that policy as it relates to cleaning schedules and the alternation of disinfectants in lieu of complying with this subdivision.~~

~~(H) Disposal of packaging materials, used syringes, containers, and needles to enhance sanitation and avoid accumulation in the controlled area.~~

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

**To Amend § 1751.4 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

**1751.4. Facility and Equipment Standards for Sterile ~~Injectable~~ Compounding.**

(a) No sterile ~~injectable drug product~~ preparation shall be compounded if it is known, or reasonably should be known, that the compounding environment fails to meet criteria specified in the pharmacy's written policies and procedures for the safe compounding of sterile ~~injectable drug products~~ preparations.

(b) During the compounding of preparation of sterile ~~injectable drug products~~ preparations, access to the areas designated ~~area or cleanroom~~ for compounding must be limited to those individuals who are properly attired.

(c) All equipment used in the areas designated ~~area or cleanroom~~ for compounding must be made of a material that can be easily cleaned and disinfected.

(d) Cleaning shall be done using a germicidal detergent and sterile water. The use of a sporicidal agent is required to be used at least monthly.

(1) All ISO Class 5 surfaces, work table surfaces, carts, counters, and the cleanroom floor shall be cleaned at least daily. After each cleaning, disinfection using a suitable sterile agent shall occur on all ISO Class 5 surfaces, work table surfaces, carts, and counters.

(2) Walls, ceilings, storage shelving, tables, stools, and all other items in the ISO Class 7 or ISO Class 8 environment shall be cleaned at least monthly.

(3) Cleaning shall also occur after any unanticipated event that could increase the risk of contamination.

(4) All cleaning materials, such as wipers, sponges, and mops, shall be non-shedding and dedicated to use in the cleanroom, or ante-area, and segregated sterile compounding areas and shall not be removed from these areas except for disposal.

(e) Disinfection, using a suitable sterile agent, shall also occur on all surfaces in the ISO Class 5 PEC frequently, including:

(1) At the beginning of each shift;

(2) At least every 30 minutes when compounding involving human staff is occurring or before each lot;

(3) After each spill; and

(4) When surface contamination is known or suspected.

~~(d) Exterior workbench surfaces and other hard surfaces in the designated area, such as walls, floors, ceilings, shelves, tables, and stools, must be disinfected weekly and after any unanticipated event that could increase the risk of contamination.~~

(f) Pharmacies preparing sterile compounded preparations require the use of a PEC that provides ISO Class 5 air or better air quality. Certification and testing of primary and secondary engineering controls shall be performed no less than every six months and whenever the device or area designated for compounding is relocated, altered or a service to the facility is performed that would impact the device or area. Certification must be completed by a qualified technician who is familiar with certification methods and procedures in accordance with CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006-13, Revised May 20, 2015).

Certification records must be retained for at least 3 years. Unidirectional compounding aseptic isolators or compounding aseptic containment isolators may be used outside of an ISO Class 7 cleanroom if the isolator is certified to meet the following criteria:

(1) Particle counts sampled approximately 6-12 inches upstream of the critical exposure site shall maintain ISO Class 5 levels during compounding operations.

(2) Not more than 3520 particles (0.5 um and larger) per cubic meter shall be counted during material transfer, with the particle counter probe located as near to the transfer door as possible without obstructing transfer.

(3) Recovery time to achieve ISO Class 5 air quality shall be documented and internal procedures developed to ensure that adequate recovery time is allowed after material transfer before and during compounding operations.

Compounding aseptic isolators that do not meet the requirements as outlined in this subdivision or are not located within an ISO Class 7 cleanroom may only be used to compound preparations that meet the criteria specified in accordance with subdivision (d) of Section 1751.8 of Title 16, Division 17, of the California Code of Regulations.

(g) Pharmacies preparing parenteral cytotoxic sterile hazardous agents shall do so in accordance with Section 505.125.1 of Title 24, Chapter 5, of the California Code of Regulations, requiring a ~~laminar air flow hood~~ negative pressure PEC. Additionally, each PEC used to compound hazardous agents shall be externally vented. The ~~hood~~ negative pressure PEC must be certified ~~annually~~ every six months by a qualified technician who is familiar with CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006-13, Revised May 20, 2015). ~~the methods and procedures for certifying laminar air flow hoods and cleanroom requirements, in accordance with National Sanitation Foundation Standard 49 for Class II (Laminar Flow) Biohazard Cabinetry, as revised May, 1983 (available from the National Sanitation Foundation, 3475 Plymouth Road, P.O. Box 1468, Ann Arbor, Michigan 48106, phone number (313) 769-8010) or manufacturer's specifications. Certification records must be retained for at least 3 years.~~ Any drug preparation that is compounded in a PEC where hazardous drugs are prepared must be labeled as hazardous, regardless of whether the drug ingredients are considered hazardous.

(1) During the hazardous drug compounding that is performed in a compounding aseptic containment isolator, full hand hygiene and garbing must occur. Garbing shall include hair cover, facemask, beard cover (if applicable), polypropylene or low shedding gown that closes in the back, shoe covers, and two pairs of sterile ASTM D6978-05 standard gloves.

(h) If a compounding aseptic isolator is certified by the manufacturer to maintain ISO Class 5

air quality during dynamic operation conditions during compounding as well as during the transfer of ingredients into and out of the compounding aseptic isolator, then it may be placed into a non-ISO classified room. Individuals that use compounding aseptic isolators in this manner must ensure appropriate garbing, which consists of donning sterile gloves over the isolator gloves immediately before non-hazardous compounding. These sterile gloves must be changed by each individual whenever continuous compounding is ceased and before compounding starts again.

(i) Compounding aseptic isolator and compounding aseptic containment isolator used in the compounding of sterile drug preparations shall use non-turbulent unidirectional air flow patterns. A smoke patterned test shall be used to determine air flow patterns.

(j) Viable surface sampling shall be done at least every six months for all sterile-to-sterile compounding and quarterly for all non-sterile-to-sterile compounding. Viable air sampling shall be done by volumetric air sampling procedures which test a sufficient volume of air (400 to 1,000 liters) at each location and shall be done at least once every six months. Viable surface and viable air sampling shall be performed by a qualified individual who is familiar with the methods and procedures for surface testing and air sampling. Viable air sampling is to be performed under dynamic conditions that simulate actual production. Viable surface sampling is to be performed under dynamic conditions of actual compounding. When the environmental monitoring action levels are exceeded, the pharmacy shall identify the CFUs at least to the genus level in addition to conducting an investigation pursuant to its policies and procedures. Remediation shall include, at minimum, an immediate investigation of cleaning and compounding operations and facility management.

(k) The sterile compounding area in the pharmacy shall have a comfortable and well-lighted working environment, which includes a room temperature of 20-24 degrees Celsius (68-75 degrees Fahrenheit) or cooler to maintain comfortable conditions for compounding personnel when attired in the required compounding garb.

(l) A licensee may request a waiver of these provisions as provided in section 1735.6(f).

Note: Authority Cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052 and 4127, Business and Professions Code; and Section 18944, Health and Safety Code.

**To Amend § 1751.5 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

**1751.5. Sterile ~~Injectable~~ Compounding Attire.**

~~(a) When preparing cytotoxic agents, gowns and gloves shall be worn.~~

~~(b) (a) When compounding sterile drug products preparations from one or more non-sterile ingredients the following standards must be met:~~

~~(1) Cleanroom garb Personal protective equipment consisting of a ~~low~~ non-shedding coverall gown, head cover, face mask, facial hair covers (if applicable), and shoe covers must be worn inside the designated area at all times. For hazardous compounding double shoe covers are required.~~

~~(2) Cleanroom garb Personal protective equipment must be donned and removed ~~outside the designated area~~ in an ante-area or immediately outside the segregated compounding area.~~

~~(3) Personnel shall don personal protective equipment in an order that proceeds from those activities considered the dirtiest to those considered the cleanest. The following order is to be followed unless the pharmacy has a procedure in place that documents a method equivalent to or superior to the method described here: The donning of shoe covers or dedicated shoes, head and facial hair covers and face masks shall be followed by the washing of hands and forearms up to the elbows for 30 seconds with soap and water, drying hands, and then the donning of a non-shedding gown.~~

~~(3)-(4) Compounding personnel shall not wear any wrist, Hhand, finger, and or wrist other visible jewelry must be eliminated jewelry, piercing, headphones, earbuds, or personal electronic device. If jewelry cannot be removed then it must be thoroughly cleaned and covered with a sterile glove.~~

~~(4) Head and facial hair must be kept out of the critical area or be covered.~~

~~(5) Gloves made of low-shedding materials are required.~~ Sterile gloves that have been tested for compatibility with disinfection with isopropyl alcohol are required. Hand cleansing with a persistently active alcohol-based product followed by the donning of sterile gloves may occur within the ante or cleanroom. Gloves are to be routinely disinfected with sterile 70 percent isopropyl alcohol before entering or re-entering the PEC and after contact with non-sterile objects. Gloves shall also be routinely inspected for holes, punctures, or tears and replaced immediately if such are detected.

(6) Individuals experiencing exposed rashes, sunburn, weeping sores, conjunctivitis, active respiratory infections or other communicable disease, or those wearing cosmetics, nail polish, or artificial nails shall be excluded from the ISO Class 5 and ISO Class 7 compounding areas until their conditions are remedied.

~~(c) The requirements of subdivision (b) do not apply if a barrier isolator is used to compound sterile injectable products from one or more non-sterile ingredients.~~

(b) When preparing hazardous agents, appropriate gowns and personal protective equipment shall be worn regardless of the PECs used (e.g., biological safety cabinet and compounding aseptic containment isolator).

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

**To Amend § 1751.6 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

**~~1751.6 Training of Sterile Injectable Compounding Staff, Patient, and Caregiver.~~ Sterile Compounding Consultation; Training of Sterile Compounding Staff.**

(a) Consultation shall be available to the patient and/or primary caregiver concerning proper use, storage, handling, and disposal of sterile injectable ~~drug products~~ preparations and related supplies furnished by the pharmacy.

(b) The pharmacist-in-charge shall ~~be responsible to~~ ensure that all pharmacy personnel

engaging in compounding sterile ~~injectable drug products~~ preparations shall have training and demonstrated competence in the safe handling and compounding of sterile ~~injectable drug products~~ preparations, including ~~cytotoxic~~ hazardous agents if the pharmacy compounds products with ~~cytotoxic~~ hazardous agents.

(c) Records of training and demonstrated competence shall be available for each individual and shall be retained for three years beyond the period of employment.

(d) The pharmacist-in-charge shall be responsible to ensure the continuing competence of pharmacy personnel engaged in compounding sterile ~~injectable drug products~~ preparations.

(e) Pharmacies that compound sterile ~~drug products from one or more non-sterile ingredients~~ preparations must comply with the following training requirements:

(1) The pharmacy must establish and follow a written program of training and performance evaluation designed to ensure that each person working in the designated area has the knowledge and skills necessary to perform their assigned tasks properly. This program of training and performance evaluation must address at least the following:

(A) Aseptic technique.

(B) Pharmaceutical calculations and terminology.

(C) Sterile ~~product~~ preparation compounding documentation.

(D) Quality assurance procedures.

(E) Aseptic preparation procedures.

(F) Proper hand hygiene, gowning and gloving technique.

(G) General conduct in the controlled area (aseptic area practices).

(H) Cleaning, sanitizing, and maintaining of the equipment and ~~used in~~ the controlled area.

(I) Sterilization techniques for compounding sterile drug preparations from one or more non-sterile ingredients.

(J) Container, equipment, and closure system selection.

(2) Each person ~~assigned to the controlled area~~ engaged in sterile compounding must successfully complete practical skills training in aseptic technique and aseptic area practices using models that are comparable to the most complex manipulations to be performed by the individual. Each pharmacist responsible for, or directly supervising and controlling, aseptic

techniques or practices, must demonstrate the skills needed to ensure the sterility of compounded drug preparations. Evaluation must include written testing and a written protocol of periodic routine performance checks involving adherence to aseptic area policies and procedures. Each person's proficiency and continuing training needs must be reassessed at least every 12 months. Results of these assessments must be documented and retained in the pharmacy for three years.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

**To Amend § 1751.7 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

**1751.7. Sterile ~~Injectable~~ Compounding Quality Assurance and Process Validation.**

(a) Any pharmacy engaged in compounding sterile ~~injectable drug products~~ preparations shall maintain, as part of its written policies and procedures, a written quality assurance plan including, in addition to the elements required by section 1735.8, a documented, ongoing quality assurance program that monitors personnel performance, equipment, and facilities. The end product shall be examined on a periodic sampling basis as determined by the pharmacist-in-charge to assure that it meets required specifications. The ~~Quality Assurance Program~~ shall include at least the following:

(1) Procedures for Cleaning and sanitization of the parenteral medication sterile preparation area.

~~(2) The storage of compounded sterile injectable products in the pharmacy and periodic documentation of refrigerator temperature.~~

~~(3)~~(2) Actions to be taken in the event of a drug recall.

~~(4)~~(3) Written justification of Documentation justifying the chosen expiration beyond use dates for compounded sterile injectable drug products preparations.

(b)(1) The pharmacy and each individual involved in the compounding of sterile drug

preparations must successfully demonstrate competency on aseptic technique and aseptic area practices before being allowed to prepare sterile drug preparations. The validation process shall be carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation. The validation process shall be representative of the types of manipulations, products and batch sizes the individual is expected to prepare and include a media-fill test. The validation process shall be as complicated as the most complex manipulations performed by staff and contain the same amount or greater amount of volume transferred during the compounding process. The same personnel, procedures, equipment, and materials must be used in the testing. Media used must have demonstrated the ability to support and promote growth. Completed medium samples must be incubated in a manner consistent with the manufacturer's recommendations. If microbial growth is detected, then each individual's sterile preparation process must be evaluated, corrective action taken and documented, and the validation process repeated.

(2) Each individual's competency must be revalidated at least every twelve months for sterile to sterile compounding and at least every six months for individuals compounding sterile preparations from non-sterile ingredients.

(3) The pharmacy's validation process on aseptic technique and aseptic area practices must be revalidated whenever:

(A) the quality assurance program yields an unacceptable result,

(B) there is any change in the compounding process, the Primary Engineering Control (PEC), or the compounding environment. For purposes of this subsection, a change includes, but is not limited to, when the PEC is moved, repaired or replaced, when the facility is modified in a manner that affects airflow or traffic patterns, or when improper aseptic techniques are observed.

(4) The pharmacy must document the validation and revalidation process.

~~Each individual involved in the preparation of sterile injectable drug products preparations must first successfully demonstrate competency by successfully performing aseptic media fill tests complete a validation process on technique before being allowed to prepare sterile~~

~~injectable drug products preparations. The validation process shall be carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation. The validation process shall be representative of all types of manipulations, products and batch sizes the individual is expected to prepare. The media fill testing process shall be as complicated as the most complex manipulations performed by staff and contain the same amount or greater of volume transferred during the compounding process. The same personnel, procedures, equipment, and materials must be involved. Media used must have demonstrated the ability to support and promote growth. Completed medium media samples must be incubated in a manner consistent with the manufacturer's recommendations. If microbial growth is detected, then the employee's sterile preparation process must be evaluated, corrective action taken and documented, and the validation process media fill testing repeated. Personnel competency must be revalidated at least every twelve months for sterile to sterile compounding and at least every six months for individuals compounding sterile products from non-sterile ingredients. Aseptic work practice assessments via media fill tests must be revalidated, as appropriate to the circumstance or personnel found to be deficient, whenever the quality assurance program yields an unacceptable result, when the compounding process changes, equipment used in the compounding of sterile injectable drug products preparations is repaired or replaced, the facility is modified in a manner that affects airflow or traffic patterns, or whenever improper aseptic techniques are observed. Revalidation must be documented.~~

(c) All sterile compounding personnel must successfully complete an initial competency evaluation. In addition, immediately following the initial hand hygiene and garbing procedure, each individual who may be required to do so in practice must successfully complete a gloved fingertip (all fingers on both hands) sampling procedure (zero colony forming units for both hands) at least three times before initially being allowed to compound sterile drug preparations.

(d) Re-evaluation of garbing and gloving competency shall occur at least every 12 months for personnel compounding products made from sterile ingredients and at least every six months for personnel compounding products from non-sterile ingredients.

~~(e)~~(e)(1) Batch-produced sterile drug preparations compounded from one or more non-sterile ingredients, except as provided in paragraph (2), shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens. Sterility testing shall be USP chapter 71 compliant and pyrogens testing shall confirm acceptable levels of pyrogens per USP chapter 85 limits, before dispensing. This requirement of end product testing confirming sterility and acceptable levels of pyrogens prior to dispensing shall apply regardless of any sterility or pyrogen testing that may have been conducted on any ingredient or combination of ingredients that were previously non-sterile. Exempt from pyrogen testing are topical ophthalmic and inhalation preparations.

(2) The following non-sterile-to-sterile batch drug preparations do not require end product testing for sterility and pyrogens:

(A) Preparations for self-administered ophthalmic drops in a quantity sufficient for administration to a single patient for 30 days or less pursuant to a prescription.

(B) Preparations for self-administered inhalation in a quantity sufficient for administration to a single patient for 5 days or less pursuant to a prescription.

~~Batch-produced sterile injectable drug products compounded from one or more non-sterile ingredients shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens.~~

~~(d) Batch-produced sterile to sterile transfers shall be subject to periodic testing through process validation for sterility as determined by the pharmacist in charge and described in the written policies and procedures.~~

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

**To Amend § 1751.8 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

**1751.8. Beyond Use Dating for Sterile Compounded Drug Preparations.**

In conformity with and in addition to the requirements and limitations of section 1735.2, subdivision (h), every sterile compounded drug preparation shall be given and labeled with a beyond use date that does not exceed the shortest expiration date or beyond use date of any ingredient in sterile compounded drug preparation, nor the chemical stability of any one ingredient in the sterile compounded drug preparation, nor the chemical stability of the combination of all ingredients in the sterile compounded drug preparation, and that, in the absence of passing a sterility test in accordance with standards for sterility testing found in Chapter 797 of the United States Pharmacopeia – National Formulary (USP37-NF32) Through 2nd Supplement (37th Revision, Effective December 1, 2014), hereby incorporated by reference, that would justify an extended beyond use date, conforms to the following limitations:

(a) The beyond use date shall specify that storage and exposure periods cannot exceed 48 hours at controlled room temperature, 14 days at controlled cold temperature, and 45 days in solid frozen state, where the sterile compounded drug preparation is compounded solely with aseptic manipulations and all of the following apply:

(1) The preparation is compounded entirely within an ISO Class 5 PEC located in an ISO Class 7 cleanroom with an ante-area or compounded entirely within a CAI which meets the requirements in 1751.4(f)(1)-(3), using only sterile ingredients, products, components, and devices; and

(2) The compounding process involves transferring, measuring, and mixing manipulations using not more than three commercially manufactured packages of sterile preparations and not more than two entries into any one sterile container or package of sterile preparations or administration containers/devices to prepare the drug preparation; and

(3) Compounding manipulations are limited to aseptically opening ampules, penetrating disinfected stoppers on vials with sterile needles and syringes or spiked transfer devices, and transferring sterile liquids in sterile syringes to sterile administration devices, package

containers of other sterile preparations, and containers for storage dispensing.

(b) The beyond use date shall specify that storage and exposure periods cannot exceed 30 hours at controlled room temperature, 9 days at controlled cold temperature, and 45 days in solid frozen state, where the sterile compounded drug preparation is compounded solely with aseptic manipulations and all of the following apply:

(1) The preparation is compounded entirely within an ISO Class 5 PEC located in an ISO Class 7 cleanroom with an ante-area or compounded entirely within a CAI which meets the requirements in 1751.4(f)(1)-(3), using multiple individual or small doses of sterile preparations combined or pooled to prepare a compounded sterile preparation that will be administered either to multiple patients or to one patient on multiple occasions; and

(2) The compounding process involves complex aseptic manipulations other than the single-volume transfer; and

(3) The compounding process requires unusually long duration such as that required to complete dissolution or homogenous mixing.

(c) The beyond use date shall specify that storage and exposure periods cannot exceed 24 hours at controlled room temperature, 3 days at controlled cold temperature, and 45 days in solid frozen state, where the sterile compounded drug preparation is compounded solely with aseptic manipulations using non-sterile ingredients, regardless of intervening sterilization of that ingredient and the following applies:

(1) The preparation is compounded entirely within an ISO Class 5 PEC located in an ISO Class 7 cleanroom with an ante-area or compounded entirely within a CAI which meets the requirements in 1751.4(f)(1)-(3).

(d) The beyond use date shall specify that storage and exposure periods cannot exceed 12 hours where the sterile compounded drug preparation is compounded solely with aseptic manipulations and all of the following apply:

(1) The preparation was compounded entirely within an ISO Class 5 PEC that is located in a segregated sterile compounding area and restricted to sterile compounding activities, using only sterile ingredients, components, and devices, by personnel properly cleansed and garbed; and

(2) The compounding process involves simple transfer of not more than three commercially manufactured packages of sterile nonhazardous preparations or diagnostic radiopharmaceutical preparations from the manufacturer's original containers; and

(3) The compounding process involves not more than two entries into any one container or package (e.g., bag, vial) of sterile infusion solution or administration container/device.

(e) Where any sterile compounded drug preparation was compounded either outside of an ISO class 5 PEC or under conditions that do not meet all of the requirements for any of subdivisions

(a) through (d), the sterile compounded drug preparation shall be labeled "for immediate use only" and administration shall begin no later than one hour following the start of the compounding process. Unless the "immediate use" preparation is immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, the preparation shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the compounded sterile preparation, and the exact one-hour beyond use date and time. If administration has not begun within one hour following the start of the compounding process, the compounded sterile preparation shall be promptly, properly, entirely, and safely discarded. This provision does not preclude the use of a PEC to compound an "immediate use" preparation. A PEC used solely to compound 'immediate use' preparations need not be placed within an ISO Class 7 cleanroom, with an ante-area. Such "immediate use" preparations shall be compounded only in those limited situations where there is a need for immediate administration of a sterile preparation compounded outside of an ISO class 5 environment and where failure to administer could result in loss of life or intense suffering. Any such compounding shall be only in such quantity as is necessary to meet the immediate need and the circumstance causing the immediate need shall be documented in accordance with policies and procedures.

(f) The beyond use date for any compounded allergen extracts shall be the earliest manufacturer expiration date of the individual allergen extracts.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

**To Add § 1751.9 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

**1751.9 Single-Dose and Multi-Dose Containers; Limitations on Use**

(a) Single-dose ampules are for immediate use only, and once opened shall not be stored for any time period.

(b) Unless otherwise specified by the manufacturer, any single-dose container of a compounded sterile drug preparation other than an ampule, such as a bag, bottle, syringe or vial, shall be used in its entirety or its remaining contents shall be labeled with a beyond use date and discarded within the following time limit, depending on the environment:

(1) When needle-punctured in an environment with air quality worse than ISO Class 5, within one (1) hour;

(2) When needle-punctured in an environment with ISO Class 5 or better air quality, within six (6) hours. A container must remain within the ISO Class 5 or better air quality to be used for the full six hours, unless otherwise specified by the manufacturer.

(3) If the puncture time is not noted on the container, the container must immediately be discarded.

(c) Unless otherwise specified by the manufacturer, a multi-dose container stored according to the manufacturer's specifications shall be used in its entirety or its remaining contents shall be labeled with a beyond use date and discarded within twenty eight (28) days from initial opening or puncture. Any multi-dose container not stored according to the manufacturer's specifications shall be discarded immediately upon identification of such storage circumstance. If any open container is not labeled with a beyond use date or the beyond use date is not correct, the container must immediately be discarded.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

**To Amend § 1751.10 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

**~~1751.8.~~ 1751.10. Sterile ~~Injectable~~ Compounding Reference Materials.**

In any pharmacy engaged in compounding sterile ~~injectable drug products~~ preparations, there shall be current and appropriate reference materials regarding the compounding of sterile ~~injectable drug products~~ preparations located in or immediately available to the pharmacy.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

**To Add Article 7.5 of Division 17 of Title 16 of the California Code of Regulations to read as follow**

**Article 7.5 Furnishing for Home Administration**

**To Amend § 1751.10 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

**~~1751.10.~~ 1752. Furnishing to Parenteral Patient at Home.**

Subject to all provisions of this article, a pharmacist may carry and furnish to a patient at home dangerous drugs, other than controlled substances, and devices for parenteral therapy when the dangerous drug or device is one currently prescribed for the patient.

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

**To Amend § 1751.11 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

**~~1751.11.~~ 1753. Furnishing to Home Health Agencies and Licensed Hospices.**

Subject to the following conditions, a licensed pharmacy may furnish to a home health agency licensed under provisions of Chapter 8 (commencing with section 1725 of Division 2 of the Health and Safety Code) or to a hospice licensed under provisions of Chapter 8.5 (commencing with section 1745 of Division 2 of the Health and Safety Code) dangerous drugs for parenteral therapy other than controlled substances, in a portable container for furnishing to patients at home for emergency treatment or adjustment of parenteral drug therapy by the home health agency or licensed hospice.

(a) The pharmacy, having ownership and responsibility for the portable containers, shall ensure that each portable container is:

- (1) furnished by a registered pharmacist;
- (2) sealed in such a manner that a tamper-proof seal must be broken to gain access to the drugs;
- (3) under the effective control of a registered nurse, pharmacist or delivery person at all times when not in the pharmacy;
- (4) labeled on the outside of the container with a list of the contents;
- (5) maintained at an appropriate temperature according to United States Pharmacopeia Standards (1995, 23rd Revision), and protected at all times from extreme temperatures that could damage the contents.

(b) The portable container may contain up to:

- (1) 1000mL of 0.9% sodium chloride intravenous infusion in containers of a size determined by the pharmacy;
- (2) 1000mL of 5% dextrose in water injection in containers of a size determined by the

pharmacy;

(3) two vials of urokinase 5000 units;

(4) Each of the following items shall be in sealed, unused containers; the furnishing pharmacy may select any or all of these dangerous drugs in up to five dosage units for inclusion in the sealed, portable container:

(A) heparin sodium lock flush 100 units/mL;

(B) heparin sodium lock flush 10 units/mL;

(C) epinephrine HCl solution 1:1,000;

(D) epinephrine HCl solution 1:10,000;

(E) diphenhydramine HCl 50mg/mL;

(F) methylprednisolone 125mg/2mL;

(G) normal saline, preserved, up to 30 mL vials;

(H) naloxone 1mg/mL 2 mL;

(I) droperidol 5mg/2mL;

(J) prochlorperazine 10mg/2mL;

(K) promethazine 25mg/mL;

(L) dextrose 25gms/50mL;

(M) glucagon 1mg/mL;

(N) insulin (human) 100 units/mL;

(O) bumetamide 0.5mg/2mL;

(P) furosemide 10mg/mL;

(Q) EMLA Cream 5 gm tube;

(R) Lidocaine 1 percent 30mL vials.

(5) The pharmacy shall ensure that the specific dangerous drugs and quantities to be included in the portable container are listed in the home health agency's or licensed hospice's policies and procedures.

(c) The pharmacy shall not supply a portable container to a home health agency or licensed hospice which does not:

(1) implement and maintain policies and procedures for:

- (A) the storage, temperature stability and transportation of the portable container;
  - (B) the furnishing of dangerous drugs from the portable container upon the written or oral authorization of a prescriber; and
  - (C) a specific treatment protocol for the administration of each medication contained in the portable container.
- (2) have the policies, procedures and protocols reviewed and revised (as needed) annually by a group of professional personnel including a physician and surgeon, a pharmacist and a registered nurse.
- (d) A copy of these policies, procedures and protocols shall be maintained by the furnishing pharmacy from each home health agency or licensed hospice for which the pharmacy furnishes portable containers.
  - (e) In cases where a drug has been administered to a patient pursuant to the oral order of a licensed prescriber, the pharmacy shall ensure that the oral order is immediately written down by the registered nurse or pharmacist and communicated by copy or fax within 24 hours to the furnishing pharmacy, with a copy of the prescriber-signed document forwarded to the dispensing pharmacy within 20 days.
  - (f) The pharmacy shall ensure that within seven days (168 hours) after the seal has been broken on the portable container, the home health agency's director of nursing service or a registered nurse employed by the home health agency or licensed hospice returns the container to the furnishing pharmacy. The furnishing pharmacy shall then perform an inventory of the drugs used from the container, and if the container will be reused, must restock and reseal the container before it is again furnished to the home health agency or licensed hospice.
  - (g) The furnishing pharmacy shall have written policies and procedures for the contents, packaging, inventory monitoring, labeling and storage instructions of the portable container.
  - (h) The furnishing pharmacy shall ensure that the home health agency or licensed hospice returns the portable containers to the furnishing pharmacy at least every 60 days for verification of product quality, quantity, integrity and expiration dates, or within seven days (168 hours) after the seal has been broken.

(i) The furnishing pharmacy shall maintain a current inventory and record of all items placed into and furnished from the portable container.

Note: Authority cited: Sections 4005 and ~~and~~ 4057, Business and Professions Code. Reference: Sections 4040, 4057, 4081 and 4332, Business and Professions Code.

**To Amend § 1751.12 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

**~~1751.12~~ 1754. Obligations of a Pharmacy Furnishing Portable Containers.**

(a) A licensed pharmacy shall not issue portable containers to any home health agency or licensed hospice unless the home health agency or licensed hospice complies with provisions of section ~~1751.11~~ 1753.

(b) A licensed pharmacy shall cease to furnish portable containers to a home health agency or licensed hospice if the home health agency or licensed hospice does not comply with provisions of section ~~1751.11~~ 1753.

Note: Authority cited: Sections 4005 and 4057, Business and Professions Code. Reference: Sections 4040, 4057, 4081 and 4332, Business and Professions Code.

**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).**

Note: Authority cited: Section 4005, 4210 and 4400, Business and Professions Code. Reference: Section 4052.1, 4052.2, 4052.6, 4210 and 4400, Business and Professions Code.

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

(2) The fee for application of an advanced practice pharmacist license is three hundred dollars (\$300). If granted, there is no fee for the initial license issued, which will expire at the same time the pharmacist's license expires.

(g)(1) The fee for the biennial renewal of a pharmacist's license is ~~two hundred seven dollars (\$207)~~ **one hundred ninety-five dollars (\$195)**. The penalty fee for failure to renew is ninety-seven dollars fifty cents (\$97.50).

(2) The fee for the biennial renewal of an advanced practice pharmacist license is three hundred dollars (\$300). The penalty fee for failure to renew is one hundred fifty dollars (\$150). The fees in this paragraph are in addition to the fees required to renew the pharmacist's license as specified in paragraph 1.

(h) The fee for the issuance or renewal of a wholesaler's license is seven hundred eighty dollars (\$780). The penalty for failure to renew is one hundred fifty dollars (\$150).

(i) The fee for the issuance or renewal of a hypodermic license is one hundred sixty five dollars (\$165). The penalty for failure to renew is eighty two dollars fifty cents (\$82.50).

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

(k) The fee for the issuance or renewal of a license as a nonresident wholesaler is seven hundred eighty dollars (\$780). The penalty for failure to renew is one hundred fifty dollars (\$150).

- (l) The fee for an intern pharmacist license is one hundred fifteen dollars (\$115). The fee for transfer of intern hours or verification of licensure to another state is thirty dollars (\$30).
- (m) The fee for the reissuance of any permit, license, or certificate, or renewal thereof, which must be reissued because of change in the information, other than name change, is one hundred dollars (\$100).
- (n) The fee for evaluation of continuing education courses for accreditation is forty dollars (\$40) for each hour of accreditation requested.
- (o) The fee for the issuance of a clinic license is five hundred twenty dollars (\$520). The fee for the annual renewal of a clinic license is three hundred twenty-five dollars (\$325) . The penalty for failure to renew is one hundred fifty dollars (\$150).
- (p) The fee for the issuance of a nongovernmental license, or renewal of a license, to compound sterile drug products is seven hundred eighty dollars (\$780). The penalty for failure to renew is one hundred fifty dollars (\$150).
- (q) The fee for the issuance of a license as a designated representative for a veterinary food-animal drug retailer shall be three hundred thirty dollars (\$330). The fee for the annual renewal of a license as a designated representative shall be one hundred and ninety-five dollars (\$195). The penalty for failure to renew is ninety-seven dollars and fifty cents (\$97.50).
- (r) The fee for a veterinary food-animal drug retailer license is four hundred twenty-five dollars (\$425). The annual renewal fee for a veterinary food-animal drug retailer is three hundred twenty-five dollars (\$325). The fee for the issuance of a temporary license is two hundred and fifty dollars (\$250). The penalty for failure to renew is one hundred twenty-five dollars (\$125).
- (s) The fee for the issuance of a retired pharmacist license shall be forty-five dollars (\$45).
- (t) The fee for the issuance of a centralized hospital packaging pharmacy license shall be \$800. The annual renewal fee for a centralized hospital packaging pharmacy license shall be \$800. The penalty for failure to renew is one hundred fifty dollars.

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

**Advanced Practice  
Pharmacist –  
Certification Programs  
1730.2**

**Title 16. Board of Pharmacy  
Order of Adoption**

Add Section 1730.2 of Article 3.5 of Division 17 of Title 16 of the California Code of Regulations as follows:

§ 1730.2 Certification Programs

- (a) For purposes of Business and Professions Code section 4210, subdivision (a)(2)(A), general clinical pharmacy practice is among the relevant areas of practice for which certification may be earned.
- (b) For a pharmacist seeking to demonstrate certification in general clinical pharmacy as a criterion for advanced practice pharmacist licensure by the board, the certification may be earned from an organization recognized as a continuing education provider by the Accreditation Council for Pharmacy Education or accredited by the National Commission for Certifying Agencies as a certification provider, so long as:
  - (1) The certification program includes specified learning objectives in at least five sequentially-ordered education modules, covering the following topics: performing patient assessments; ordering and interpreting drug therapy-related tests; referring patients to other health care providers; participating in the evaluation and management of diseases and health conditions in collaboration with other health care providers; and initiating, adjusting, modifying or discontinuing drug therapy;
  - (2) The certification program requires assessment after completion of each of the education modules in an examination format or by other assessment methodology that confirms the participant's understanding, knowledge, and application of the specified learning objectives for the module, where any failure to successfully complete the assessment in any module prevents advancement to the next module;
  - (3) The certification program requires that instruction and assessments in each of the modules are developed and provided by either:
    - (A) An advanced practice pharmacist licensed by the board or
    - (B) An expert with experience in the respective area(s) of focus specified in subparagraph (1), where "expert" means a person who qualifies to teach at a school of pharmacy recognized by the board.
  - (4) The certification program requires that, upon successful completion of all modules and their respective assessments, each participant shall earn a passing score on a final overall assessment before being awarded certification. The assessment shall be either a final written examination or an objective structured clinical examination developed and administered in collaboration with an accredited school of pharmacy recognized by the board; and
  - (5) The certification program require(s) a minimum of ten hours of continuing education on the topics identified in (b)(1) every two years to maintain certification.

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

Reference: Sections 4052.6, 4210, and 4233, Business and Professions Code.

# **Attachment 6**

**Board Accredited  
Continuing Education  
1732.02, 1732.2, and  
1732.5**

## BOARD OF PHARMACY

**Proposal to amend** § 1732.05 in Article 4 of Division 17 of Title 16 of the California Code of Regulations to read:

### **§1732.05. Accreditation Agencies for Continuing Education**

(a) The following organizations are approved accreditation agencies:

- (1) The Accreditation Council for Pharmacy Education.
- (2) The ~~Pharmacy Foundation of California~~ California Pharmacists Association.

(b) Accreditation agencies shall:

- (1) Evaluate each continuing education provider seeking accreditation in accordance with the provider's ability to comply with the requirements of section 1732.1 of this Division.
- (2) Maintain a list of the name and address of the person responsible for the provider's continuing education program. The accreditation agency shall require that any change in the responsible person's identity shall be reported to the accreditation agency within 15 days of the effective date of the change.
- (3) Provide the board with the names, addresses and responsible party of each provider, upon request.
- (4) Respond to complaints from the board, providers or from pharmacists concerning activities of any of its accredited providers or their coursework.
- (5) Review at least one course per year offered by each provider accredited by the agency for compliance with the agency's requirements and requirements of the board and, on request, report the findings of such reviews to the board.
- (6) Take such action as is necessary to assure that the continuing education coursework offered by its providers meets the continuing education requirements of the board.
- (7) Verify the completion of a specific continuing education course by an individual pharmacist upon request of the board.

(c) Substantial failure of an approved accreditation agency to evaluate continuing education providers as set forth in subdivision (b) shall constitute cause for revocation of its approval as an accreditation agency by the board.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4232, Business and Professions Code.

**Proposal to amend** § 1732.2 in Article 4 of Division 17 of Title 16 of the California Code of Regulations to read:

**§ 1732.2. Board Accredited Continuing Education**

(a) Individuals may petition the board to allow continuing education credit for specific coursework which is not offered by a provider but meets the standards of Section 1732.3.

(b) Notwithstanding subdivision (a) of this section, coursework which meets the standard of relevance to pharmacy practice and has been approved for continuing education by the Medical Board of California, the California Board of Podiatric Medicine, the California Board of Registered Nursing or the Dental Board of California shall, upon satisfactory completion, be considered approved continuing education for pharmacists.

(c) A pharmacist serving on a designated subcommittee of the board for the purpose of developing the California Practice Standards and Jurisprudence Examination for pharmacists pursuant to section 4200.2 of the Business and Professions Code may annually be awarded up to six (6) hours of continuing education for conducting a review of exam test questions. A subcommittee member shall not receive continuing education hours pursuant to this subdivision if that subcommittee member requests reimbursement from the board for time spent conducting a review of exam test questions.

(d) A pharmacist or pharmacy technician who attends a full day board meeting may be awarded six (6) hours of continuing education per renewal period. The board shall designate on its public agenda which day shall be eligible for continuing education credit. A pharmacist or pharmacy technician requesting continuing education pursuant to this subdivision must sign in and out on an attendance sheet at the board meeting that requires the individual to provide his or her first and last name, license number, time of arrival and time of departure from the meeting.

(e) A pharmacist or pharmacy technician who attends a full committee meeting of the board may be awarded two (2) hours of continuing education per renewal period. A pharmacist or pharmacy technician requesting continuing education hours pursuant to this subdivision must sign in and out on an attendance sheet at the committee meeting that requires the individual to provide his or her first and last name, license number, time of arrival and time of departure from the meeting.

(f) An individual may be awarded three (3) hours of continuing education for successfully passing the examination administered by the Commission for Certification in Geriatric Pharmacy.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4232, Business and Professions Code.

**Proposal to amend** § 1732.5 of Article 4 of Division 17 of Title 16 of the California Code of Regulations to read:

**§1732.5 Renewal Requirements for Pharmacists**

(a) Except as provided in Section 4234 of the Business and Professions Code and Section 1732.6 of this Division, each applicant for renewal of a pharmacist license shall submit proof satisfactory to the board, that the applicant has completed 30 hours of continuing education in the prior 24 months.

(b) At least six (6) of the thirty (30) hours required for pharmacist license renewal shall be completed in one or more of the following subject areas:

- (1) Emergency/Disaster Response
- (2) Patient Consultation
- (3) Maintaining Control of a Pharmacy's Drug Inventory
- (4) Ethics
- (5) Substance Abuse, Including Indications of Red Flags and a Pharmacist's Corresponding Responsibility
- (6) Compounding

Pharmacists renewing their licenses which expire on or after July 1, 2018, shall be subject to the requirements of this subdivision.

~~(b)~~ (c) All pharmacists shall retain their certificates of completion for four (4) years following completion of a continuing education course.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4231 and 4232, Business and Professions Code.

# **Attachment 7**

# **Section 100 Requirements**

## Board of Pharmacy

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

**§ 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; and make changes to its regulations without regulatory effect pursuant to Title, California Code of Regulations section 100 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 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 . omitting ~~T~~raffic infractions under ~~\$300~~ \$500 not involving alcohol, dangerous drugs, or controlled substances do not need to be disclosed.

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

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

Authority: Sections 4001.1 and 4005, Business and Professions Code.

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

## Board of Pharmacy

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

### **1702. 1 Pharmacy Technician Renewal Requirements**

(a) A pharmacy technician applicant for renewal who has not previously submitted fingerprints as a condition of licensure or for whom an electronic record of the licensee's fingerprints does not exist in the Department of Justice's criminal offender record identification database shall successfully complete a state and federal level criminal offender record information search conducted through the Department of Justice by the licensee's or registrant's renewal date that occurs on or after July 1, 2014.

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

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

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

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

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

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

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

Authority: Sections 4001.1 and 4005, Business and Professions Code.

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

## Board of Pharmacy

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

### **1702. 2 Designated Representative Renewal Requirements**

(a) A designated representative applicant for renewal who has not previously submitted fingerprints as a condition of licensure or for whom an electronic record of the licensee's fingerprints does not exist in the Department of Justice's criminal offender record identification database shall successfully complete a state and federal level criminal offender record information search conducted through the Department of Justice by the licensee's or registrant's renewal date that occurs on or after July 1, 2014.

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

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

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

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

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

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

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

Authority : Sections 4001.1 and 4005, Business and Professions Code.

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

## Board of Pharmacy

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

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

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

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

### **1780.1. Minimum Standards for Veterinary Food-Animal Drug Retailers.**

*Not relevant to third-party logistics providers*

### **1781. Exemption Certificate.**

A registered pharmacist, ~~or an~~ designated representative or designated representative –3PL certified in accordance with Section 4053, 4053.1 or 4054 of the Business and Professions Code shall be present and in control of a manufacturer's ~~or~~ wholesaler's or a third-party logistics provider's licensed premises during the conduct of business.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4053, 4053.1 or 4054, Business and Professions Code.

### **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.