



Legislation and Regulation Committee

Greg Lippe, CPA, Chairperson, Public Member
Lavanza Butler, Vice Chairperson, Licensee Member
Ryan Brooks, Public Member
Amjad Khan, Public Member
Maria Serpa, Licensee Member

Part 1: Legislation for Discussion and Consideration

a. Board Proposed Legislation

Attachment 1

Consistent with the board's strategic plan goals 3.2 and 3.3, the board has approved several legislative proposals for sponsorship. Below is summary of each of the proposals. The approved proposed text for each measure is provided in **Attachment 1**.

1. Amend Health and Safety Code (HSC) Section 11165

Summary

The measure is intended to expand CURES reporting to include Schedule V controlled substances and reduce the time frame for reporting to the CURES system to one working day. Similar changes were sought last year in AB 1752 (Low). That measure failed passage.

This measure was approved for sponsorship at the November 2017 Board Meeting.

2. Amend Business and Professions Code (BPC) 4200

Summary

This measure relates to the time period that a test score will remain valid for consideration for licensure. Enactment of this legislation would establish that a passing score on the NAPLEX or CPJE Pharmacist examinations would be valid for licensure only while the occupational analysis that was used to develop that examination is valid or was replaced no more than one year prior.

This measure was approved for sponsorship at the May 2018 Board Meeting.

3. Add BPC Sections 4038.5, 4115.6, 4211

Summary

This measure would create a new licensing category—Advanced Pharmacy Technician (APT). This proposal would establish the licensing requirements, detail the proposed

duties and requirements, and define the conditions a pharmacy must satisfy if using APT personnel.

This measure was approved for sponsorship at the November 2017 Board Meeting.

4. Add BPC Sections 4038.6, 4115.7, 4211.1 and 4234.5 and Amend BPC Section 4400

Summary

This measure would create a new licensing category—Advanced Hospital Pharmacy Technician (AHT). This proposal would establish the licensing requirements, detail the proposed duties and requirements, and define the conditions a hospital must satisfy if using AHT personnel.

This proposal was approved for sponsorship during the February 2018 Board Meeting.

5. Amend BPC Section 4163

Summary

This measure would allow a reverse distributor to accept medications for destruction under limited circumstances.

This proposal was approved for sponsorship during the July 2018 Board Meeting.

6. Amend BPC Section 4400

Summary

This measure would allow the board to assess an application fee from government-owned facilities. Further, this measure would clarify the fees for updating a licensing record and the fee to reissue a printed license certificate.

The proposal related to government-owned facilities was approved during the November 2017 Board Meeting. The proposal related to updating a license record was approved for sponsorship during the October 2018 Board Meeting.

7. Add BPC Section 4112.5

Summary

This measure would align establish USP compounding chapters as the foundation for the board's regulation of sterile and non-sterile compounded drug preparations.

This measure was approved for sponsorship during the May 2018 Board Meeting.

8. Amend BPC Section 4115.5

Summary

This measure would increase the maximum number of hours a pharmacy technician trainee can gain and remove a conflict for completing an ASHP-accredited pharmacy technician training program. This type of training program is currently one pathway to licensure.

This proposal was approved for sponsorship during the October 2018 Board Meeting.

9. Add BPC Section 4233.5

Summary

This measure would align the advanced practice pharmacist renewal requirements with the renewal requirements for pharmacists.

This proposal was approved for sponsorship during the October 2018 Board Meeting.

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

The legislature reconvened on January 7, 2019. Since that time board staff have been monitoring new legislative proposals to be brought to both the committee and board for consideration. Such proposals generally impact either the board's jurisdiction or board operations. The deadline to introduce bills this year is February 22, 2019.

As it is still early in the session, board staff have only identified one measure. A summary of the measure is provided below, and the full text is included in **Attachment 2**. Board staff recommend that the committee monitor the measure but not take a position at this time.

1. Assembly Bill 193 (Patterson) Professions and Vocations

Attachment 2

Summary

This measure would require DCA to conduct a comprehensive review of all occupational licensing requirements and identify unnecessary licensing requirements that cannot be adequately justified. DCA would also be required to report to the legislature on its findings. The bill contains additional provisions that either do not apply or impact the board, (e.g. remove tree trimmers from regulation by the Contractors State Licensing Board; remove shampooing another person's hair from regulation by the Board of Barbering and Cosmetology; remove custom upholsters from regulation by the Bureau of Household Goods and Services.)

Part 2: Regulations for Discussion and Consideration

c. Board Adopted – Submitted for Administrative Review to the Office of Administrative Law (OAL)

Attachment 3

1. Proposed Regulations to Amend Title 16, California Code of Regulations (CCR), Sections 1735.1, 1735.2, 1735.6, 1751.1, & 1751.4 Related to Compounded Drug Preparations

Summary of Regulation:

This regulation formally amends the board's regulations regarding the establishment of compounding beyond-use dates as it relates to sterile and non-sterile compounded drug

preparations.

Status:

Submitted to OAL for Final Review: December 14, 2018

OAL must complete its review by January 30, 2019. An update will be provided during the meeting if available.

Attachment 3 contains the complete timeline for this rulemaking and the board adopted text.

d. Board Approved to Initiate Rulemaking - Undergoing Pre-Notice Review by the Department of Consumer Affairs or the Business, Consumer Services and Housing Agency

Attachment 4

Provided below is a summary of each of the regulations currently undergoing pre-notice review. As there are many steps included in the pre-review process, the current status is detailed below. Members have previously requested that regulations without action for over 30 days be highlighted. As such, regulations with inactivity for over 30 days are indicated below in **red**. The full timelines for each of the regulations are included in **Attachment 4**.

1. Proposed Regulations to Amend Title 16 CCR Section 1793.5 Related to the Pharmacy Technician Application, Section 1793.6 Related to the Pharmacy Technician Training Requirements and Section 1793.65 Related to the Pharmacy Technician Certification Programs

Summary of Regulation:

This proposal establishes the training requirements and certification programs and updates the application for licensure for pharmacy technicians.

Status:

Resubmitted to DCA for Pre-Notice Review: October 26, 2018. This regulation is currently undergoing review by DCA counsel.

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

Summary of Regulation

This proposal amends the board's regulations regarding ownership to include provisions relating to trust ownership of pharmacies.

Status

Resubmitted to DCA for Pre-Notice Review: December 20, 2018. This regulation is

currently undergoing review by DCA counsel.

3. Proposed Regulations to Amend Title 16 CCR Sections 1780-1783 et seq., Related to Dangerous Drug Distributors and Third-Party Logistics Providers

Summary of Regulation

This proposal establishes the regulatory framework for third-party logistics providers.

Status

Resubmitted to DCA for Pre-Notice Review: December 20, 2018. This regulation is currently undergoing review by DCA counsel.

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

Summary of Regulation:

This proposal amends the board's regulations regarding the waiver requirements for off-site storage of records to allow those cited for a records violation to receive a waiver to store records off-site.

Status:

Formal DCA Pre-Notice Review began: August 20, 2018. This regulation is currently undergoing review by the DCA Legal office.

5. Proposed Regulations to Add Title 16 CCR Sections 1717.5 Related to Automatic Refill Programs

Summary of Regulation:

This proposal establishes regulatory requirements for automatic refill programs.

Status:

Resubmitted to DCA for Pre-Notice Review: September 20, 2018. This regulation is currently undergoing review by the DCA Legal office.

6. Proposed Regulations to Amend Title 16 CCR Section 1746.3 Related to the Naloxone Fact Sheet

Summary of Regulation:

This proposal amends the board's regulations regarding the naloxone fact sheet that must be provided to consumers upon furnishing naloxone hydrochloride.

Status:

Formal DCA Pre-Notice Review began: July 2, 2018. This regulation is currently undergoing review by the DCA Legal office.

7. Proposed Regulations to Amend Title 16 CCR Section 1715 to Update Self-Assessment Forms 17M-13 and 17M-14

Summary of Regulation:

This proposal updates the Self-Assessment forms 17M-13 (rev. 10/16) and 17M-14 (rev. 10/16) as incorporated by reference in Title 16 CCR section 1715. Additionally, this regulation updates section 1715 with clarifying language as to the completion and certification requirements of the self-assessment forms.

Status:

Resubmitted to DCA for Pre-Notice Review: December 24, 2018. This regulation is currently undergoing review by DCA counsel.

8. Proposed Regulations to Amend Title 16 CCR Section 1784 to Update the Wholesaler/3PL Self-Assessment Form 17M-26

Summary of Regulation:

This proposal updates the Self-Assessment form 17M-26 (rev. 10/16) as incorporated by reference in Title 16 CCR section 1784. Additionally, this regulation updates section 1784 with clarifying language as to the completion and certification requirements of the self-assessment form.

Status:

Submitted to DCA for Pre-Notice Review: December 26, 2018. This regulation is currently undergoing review by DCA counsel.

9. Proposed Regulations to Add Title 16 CCR Section 1793.9 Related to Remote Dispensing Technicians

Summary of Regulation:

This proposal establishes regulatory requirements for pharmacy technicians working in a remote dispensing site pharmacy.

Status:

Formal DCA Pre-Notice Review began: August 29, 2018. This regulation is currently undergoing review by the Business, Consumer Services and Housing Agency.

10. Proposed Regulations to Amend Title 16 CCR Section 1706.2 Related to Abandonment of Applications

Summary of Regulation:

This proposal updates the application abandonment language to include all licensing programs to ensure that all applicants have appropriate notice about the requirements for abandoning an application. It will also reduce the administrative workload

associated with the need for frequent amendments when new licensing programs are established.

Status:

Formal DCA Pre-Notice Review began: August 3, 2018. This regulation is currently undergoing review by the DCA Legal office.

11. Proposed Regulations to Amend Title 16 CCR Sections 1702, 1702.1, 1702.2, and 1702.5 Related to Renewal Requirements

Summary of Regulation:

This proposal updates the renewal requirement language to include all licensing programs. It will also reduce the administrative workload associated with the need for frequent amendments when new licensing programs are established.

Status:

Formal DCA Pre-Notice Review began: October 16, 2018. This regulation is currently undergoing review by the DCA Budget office.

12. Proposed Regulations to Amend Title 16 CCR Section 1707.2 Related to Mail-Order Pharmacy Consultation

Summary of Regulation:

This proposal amends the board's regulations regarding the duty to provide consultation for mail-order pharmacies.

Status:

Formal DCA Pre-Notice Review began: October 1, 2018. This regulation is currently undergoing review by the DCA Budget office.

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

Summary of Regulation:

This proposal updates the board's fee schedule by increasing the board's fees to address the structural imbalance within the board's budget.

Status:

Formal DCA Pre-Notice Review began: January 16, 2019. This regulation is currently undergoing review by the DCA Legal office.

e. Future Meeting Dates

- May 7, 2019

- July 24, 2019
- November 5, 2019

Attachment 1

Proposal to Amend HSC 11165

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

11165.

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

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

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

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

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

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

(d) For each prescription for a Schedule II, Schedule III, ~~or Schedule IV~~ IV, or Schedule V controlled substance, as defined in the controlled substances schedules in federal law and regulations, specifically Sections 1308.12, 1308.13, ~~and 1308.14,~~ and 1308.15, respectively, of Title 21 of the Code of Federal Regulations, the dispensing pharmacy, clinic, or other dispenser shall report the following information to the Department of Justice as soon as reasonably possible, but not more than ~~seven days~~ one working day after the date a controlled substance is dispensed, in a format specified by the Department of Justice:

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

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

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

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

(5) Quantity of the controlled substance dispensed.

...

Proposal to Amend BPC 4200 Exam Requirements

4200. Pharmacist License Requirements: Age; Education; Experience; Examination; Proof of Qualifications; Fees

(a) The board may license as a pharmacist an applicant who meets all the following requirements:

(1) Is at least 18 years of age.

(2) (A) Has graduated from a college of pharmacy or department of pharmacy of a university recognized by the board; or

(B) If the applicant graduated from a foreign pharmacy school, the foreign-educated applicant has been certified by the Foreign Pharmacy Graduate Examination Committee.

(3) Has completed at least 150 semester units of collegiate study in the United States, or the equivalent thereof in a foreign country. No less than 90 of those semester units shall have been completed while in resident attendance at a school or college of pharmacy.

(4) Has earned at least a baccalaureate degree in a course of study devoted to the practice of pharmacy.

(5) Has completed 1,500 hours of pharmacy practice experience or the equivalent in accordance with Section 4209.

(6) Has passed the North American Pharmacist Licensure Examination ~~and the California Practice Standards and Jurisprudence Examination for Pharmacists on or after January 1, 2004~~ and satisfies one of the following:

(A) (i) Has passed the North American Pharmacist Licensure Examination on or after January 1, 2004, and (ii) holds an active pharmacist license in another state or territory of the United States;

(B) Has passed a version of the North American Pharmacist Licensure Examination that, at the time of application for licensure, was based on an occupational analysis that either remains current or was replaced no more than [one year] prior.

(7) Has passed a version of the California Practice Standards and Jurisprudence Examination for Pharmacists that, at the time of application for licensure, was based on an occupational analysis that either remains current or was replaced no more than [one year] prior.

(b) Proof of the qualifications of an applicant for licensure as a pharmacist shall be made to the satisfaction of the board and shall be substantiated by affidavits or other evidence as may be required by the board.

(c) Each person, upon application for licensure as a pharmacist under this chapter, shall pay to the executive officer of the board the fees provided by this chapter. The fees shall be compensation to the board for investigation or examination of the applicant.

Proposal to Add BPC 4038.5 (Definition)

“Advanced Pharmacy Technician” means an individual licensed by the board who is authorized to perform technical pharmacy tasks as authorized in Section 4115.6. Such an individual may also perform nondiscretionary tasks as specified in Section 4115.

Proposal to Add BCP 4211 (Licensing Requirement)

(a) The board may issue an advanced pharmacy technician license to an individual who meets all the following requirements:

- (1) Holds an active pharmacy technician license issued pursuant to this chapter that is in good standing,
 - (2) Possesses a certification issued by a pharmacy technician certifying program as defined in Section 4202(a)(4).
 - (3) Has obtained a minimum of an associate degree in pharmacy technology, obtained a bachelor’s degree, or higher or completed a board approved training program.
 - (4) Has obtained 3,000 hours of experience performing the duties of a licensed pharmacy technician in a pharmacy.
 - (5) Has passed an advanced pharmacy technician examination.
- (b) As an alternative to the requirements in subdivision (a), has graduated from a school of pharmacy recognized by the board.
- (c) A license issued pursuant to this section shall be valid for two years.

Proposal to Add BPC 4115.6 (Duties)

(a) In a pharmacy as defined in Business and Professions Code Section 4037, a licensed advanced pharmacy technician may perform these technical tasks:

- (1) Verify the accuracy of the typed prescription label and verify the filling of a prescription container by confirming that the medication and quantity reflected on the label accurately reflects the container’s contents for drug orders that previously have been reviewed and approved by a pharmacist. A pharmacist is responsible for performing all reviews and verification requiring professional judgement including drug utilization review.
 - (2) Except for controlled substances, accept new or seek clarification about a prescription from a prescriber’s office unless the prescription requires the professional judgment of a pharmacist.
 - (3) Inquire about the intended purpose or indication for prescribed medication on verbal orders received from a prescriber’s office.
 - (4) Except for controlled substances, transfer a prescription to another pharmacy.
 - (5) Receive the transfer of a prescription from another pharmacy.
 - (6) Provide the technical task of administration of an immunization under the supervision of a pharmacist trained in immunizations.
 - (7) Compile a medication list by interviewing patient.
 - (8) Perform other technical tasks including taking patient’s blood pressure or temperature.
- (b) A pharmacy as used in subdivision (a) may use the services of an advanced pharmacy technician if all the following conditions are met:

- (1) The duties authorized in subdivision (a) are performed under the supervision of a pharmacist and are specified in the pharmacy's policies and procedures.
- (2) The pharmacist-in-charge is responsible for ongoing evaluation of the performance of personnel as authorized in subdivision (a).
- (3) A pharmacist shall personally provide all new prescription medications directly to the patient or patient's agent, and must provide patient information consistent with the provisions of Section 4052 (a) (8) or other clinical services.
- (4) A pharmacist shall provide other clinical services beyond required consultation.
- (5) A record is created identifying the personnel responsible for the preparing and dispensing of the prescription medication.

Advanced Hospital Pharmacy Technician Statutory Proposal

Proposal to Add BPC 4038.6

“Advanced Hospital Pharmacy Technician” means an individual licensed by the board who is authorized to perform technical pharmacy tasks as authorized in Section 4115.7.

Proposal to Add 4115.7

(a) In a hospital pharmacy, licensed advanced hospital pharmacy technician may perform the nondiscretionary tasks authorized in Section 4115 in addition to the following technical tasks under the general direction of a pharmacist:

- (1) Package emergency supplies for use in the health care facility.
- (2) Seal emergency containers for use in health care facility.
- (3) Prepare and seal drug kits for use in the health care facility.
- (4) Perform unit inspections of the drug supplies stored throughout the health care facility. Irregularities shall be reported within 24 hours to the pharmacist in-charge and the director or chief executive officer of the health facility in accordance with the health care facility’s policies and procedures;
- (5) Verify the accuracy of a pharmacy technician’s filling of floor and ward stock and unit dose distribution systems for hospital patient orders that have been previously reviewed and approved by a licensed pharmacist.
- (6) Other technical tasks deemed appropriate by the board.

(b) A hospital pharmacy may use the services of an advanced hospital pharmacy technician if all of the following conditions are met:

- (1) The duties authorized in (a) are performed under general direction of a pharmacist and are specified in the hospital pharmacy’s policies and procedures
- (2) The pharmacist-in-charge is responsible for ongoing evaluation of the performance of personnel as authorized in subdivision (a).
- (3) Pharmacists are deployed to the inpatient care setting to provide clinical services.

Proposal to Add BCP 4211.1

(a) The board may issue an advanced hospital pharmacy technician license to an individual who meets all the following requirements:

- (1) Holds an active pharmacy technician license issued pursuant to this chapter that is in good standing,
- (2) Possesses a certification issued by a pharmacy technician certifying program as defined in Section 4202(a)(4).
- (3) Has obtained a minimum of an associate degree in pharmacy technology, obtained a bachelor’s degree, or higher or completed a board-approved training program.
- (4) Has obtained 3,000 hours of experience performing the duties of a licensed pharmacy technician in a hospital pharmacy.
- (5) Has passed an advanced pharmacy technician examination.

(b) As an alternative to the requirements in subdivision (a), the applicant has graduated from a school of pharmacy recognized by the board.

(a) A license issued pursuant to this section shall be valid for two years.

(b) Each person, upon application for licensure, shall pay to the executive officer of the board the fees provided by this chapter. The fees shall be compensation to the board for investigation or examination of the applicant.

Proposal to Add BPC 4234.5

An advanced hospital pharmacy technician shall complete 20 hours of continuing education each renewal cycle. A licensee must also maintain certification as specified in Section 4211.1

(a)(2).

Proposal to Amend BPC 4400

(z) ~~This section shall become operative on July 1, 2017.~~ The fee for the advanced hospital pharmacy technician application and examination shall be \$260 dollars and may be increased to \$285. The fee for initial licensure and biennial renewal of as an advanced hospital pharmacy technician shall be \$140 and may be increased to \$195.

Proposal to Amend BCP 4163. Unauthorized Furnishing by Manufacturer or Wholesaler

(a) A manufacturer, wholesaler, repackager, or pharmacy may not furnish a dangerous drug or dangerous device to an unauthorized person.

(b) Except as provided in subdivision (c), dangerous drugs or dangerous devices shall be acquired from a person authorized by law to possess or furnish dangerous drugs or dangerous devices. If the person acquiring the dangerous drugs or dangerous devices is a wholesaler, the obligation of the wholesaler shall be limited to obtaining confirmation of licensure of those sources from whom it has not previously acquired dangerous drugs or dangerous devices.

(c) Upon approval of the board, a reverse distributor licensed as a wholesaler, may acquire dangerous drugs or dangerous devices from an unlicensed source for the sole purpose of destruction of the dangerous drugs or dangerous devices, if the unlicensed source was previously licensed with the board.

Proposal to Amend BPC 4400.

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

(a) The fee for a ~~nongovernmental~~ pharmacy license shall be five hundred twenty dollars (\$520) and may be increased to five hundred seventy dollars (\$570). The fee for the issuance of a temporary ~~nongovernmental~~ pharmacy permit shall be two hundred fifty dollars (\$250) and may be increased to three hundred twenty-five dollars (\$325).

(b) The fee for a ~~nongovernmental~~ pharmacy license annual renewal shall be six hundred sixty-five dollars (\$665) and may be increased to nine hundred thirty dollars (\$930).

(c) The fee for the pharmacist application and examination shall be two hundred sixty dollars (\$260) and may be increased to two hundred eighty-five dollars (\$285).

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

(e) The fee for a pharmacist license shall be one hundred ninety-five dollars (\$195) and may be increased to two hundred fifteen dollars (\$215). The fee for a pharmacist biennial renewal shall be three hundred sixty dollars (\$360) and may be increased to five hundred five dollars (\$505).

(f) The fee for a ~~nongovernmental~~ wholesaler or third-party logistics provider license and annual renewal shall be seven hundred eighty dollars (\$780) and may be increased to eight hundred twenty dollars (\$820). The application fee for any additional location after licensure of the first 20 locations shall be three hundred dollars (\$300) and may be decreased to no less than two hundred twenty-five dollars (\$225). A temporary license fee shall be seven hundred fifteen dollars (\$715) and may be decreased to no less than five hundred fifty dollars (\$550).

(g) The fee for a hypodermic license shall be one hundred seventy dollars (\$170) and may be increased to two hundred forty dollars (\$240). The fee for a hypodermic license renewal shall be two hundred dollars (\$200) and may be increased to two hundred eighty dollars (\$280).

(h) (1) The fee for application, investigation, and issuance of a license as a designated representative pursuant to Section 4053, as a designated representative-3PL pursuant to Section 4053.1, or as a designated representative-reverse distributor pursuant to Section 4053.2 shall be one hundred fifty dollars (\$150) and may be increased to two hundred ten dollars (\$210).

(2) The fee for the annual renewal of a license as a designated representative, designated representative-3PL, or designated representative-reverse distributor shall be two hundred fifteen dollars (\$215) and may be increased to three hundred dollars (\$300).

(i) (1) The fee for the application, investigation, and issuance of a license as a designated representative for a veterinary food-animal drug retailer pursuant to Section 4053 shall be one hundred fifty dollars (\$150) and may be increased to two hundred ten dollars (\$210).

(2) The fee for the annual renewal of a license as a designated representative for a veterinary food-animal drug retailer shall be two hundred fifteen dollars (\$215) and may be increased to three hundred dollars (\$300).

(j) (1) The application fee for a nonresident wholesaler or third-party logistics provider license issued pursuant to Section 4161 shall be seven hundred eighty dollars (\$780) and may be increased to eight hundred twenty dollars (\$820).

(2) For nonresident wholesalers or third-party logistics providers that have 21 or more facilities operating nationwide the application fees for the first 20 locations shall be seven hundred eighty dollars (\$780) and may be increased to eight hundred twenty dollars (\$820). The application fee for any additional location after licensure of the first 20 locations shall be three hundred dollars (\$300) and may be decreased to no less than two hundred twenty-five dollars (\$225). A temporary license fee shall be seven hundred fifteen dollars (\$715) and may be decreased to no less than five hundred fifty dollars (\$550).

(3) The annual renewal fee for a nonresident wholesaler license or third-party logistics provider license issued pursuant to Section 4161 shall be seven hundred eighty dollars (\$780) and may be increased to eight hundred twenty dollars (\$820).

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

(l) The fee for an intern pharmacist license shall be one hundred sixty-five dollars (\$165) and may be increased to two hundred thirty dollars (\$230). The fee for transfer of intern hours or verification of licensure to another state shall be twenty-five dollars (\$25) and may be increased to thirty dollars (\$30).

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

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

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

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

(q) The fee for any applicant for a ~~nongovernmental~~ clinic license shall be five hundred twenty dollars (\$520) for each license and may be increased to five hundred seventy dollars (\$570). The annual fee for renewal of the license shall be three hundred twenty-five dollars (\$325) for each license and may be increased to three hundred sixty dollars (\$360).

(r) The fee for the issuance of a pharmacy technician license shall be one hundred forty dollars (\$140) and may be increased to one hundred ninety-five dollars (\$195). The fee for renewal of a pharmacy technician license shall be one hundred forty dollars (\$140) and may be increased to one hundred ninety-five dollars (\$195).

(s) The fee for a veterinary food-animal drug retailer license shall be four hundred thirty-five dollars (\$435) and may be increased to six hundred ten dollars (\$610). The annual renewal fee for a veterinary food-animal drug retailer license shall be three hundred thirty dollars (\$330) and may be increased to four hundred sixty dollars (\$460).

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

(u) The fee for issuance of a ~~nongovernmental~~ sterile compounding pharmacy license or a hospital satellite compounding pharmacy shall be one thousand six hundred forty-five dollars (\$1,645) and may be increased to two thousand three hundred five dollars (\$2,305). The fee for a temporary license shall be five hundred fifty dollars (\$550) and may be increased to seven hundred fifteen dollars (\$715). The annual renewal fee of the license shall be one thousand three hundred twenty-five dollars (\$1,325) and may be increased to one thousand eight hundred fifty-five dollars (\$1,855).

(v) The fee for the issuance of a nonresident sterile compounding pharmacy license shall be two thousand three hundred eighty dollars (\$2,380) and may be increased to three thousand three hundred thirty-five dollars (\$3,335). The annual renewal of the license shall be two thousand two hundred seventy dollars (\$2,270) and may be increased to three thousand one hundred eighty dollars (\$3,180). In addition to paying that application fee, the nonresident sterile compounding pharmacy shall deposit, when submitting the application, a reasonable amount, as determined by the board, necessary to cover the board's estimated cost of performing the inspection required by Section 4127.2. If the required deposit is not submitted with the application, the application shall be deemed to be incomplete. If the actual cost of the inspection exceeds the amount deposited, the board shall provide to the applicant a written invoice for the remaining amount and shall not take action on the application until the full amount has been paid to the board. If the amount deposited exceeds the amount of actual and necessary costs incurred, the board shall remit the difference to the applicant.

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

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

addition to paying that application fee, the nonresident outsourcing facility shall deposit, when submitting the application, a reasonable amount, as determined by the board, necessary to cover the board's estimated cost of performing the inspection required by Section 4129.2. If the required deposit is not submitted with the application, the application shall be deemed to be incomplete. If the actual cost of the inspection exceeds the amount deposited, the board shall provide to the applicant a written invoice for the remaining amount and shall not take action on the application until the full amount has been paid to the board. If the amount deposited exceeds the amount of actual and necessary costs incurred, the board shall remit the difference to the applicant.

(y) The fee for the issuance of a centralized hospital packaging license shall be eight hundred twenty dollars (\$820) and may be increased to one thousand one hundred fifty dollars (\$1,150). The annual renewal of the license shall be eight hundred five dollars (\$805) and may be increased to one thousand one hundred twenty-five dollars (\$1,125).

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

Add Section BPC 4122.5 as follows:

The compounding of drug preparations for furnishing, distribution, or use in California must be done consistent with standards established in the latest edition of the United States Pharmacopeia-National Formulary chapters on pharmacy compounding, including all relevant testing, and quality assurance. This does not, however, prevent the board from adopting regulations requiring additional standards for compounding drug preparations.

Proposal to Amend Section 4115.5 subdivision (c)(1) and (2) of the Business and Professions Code as follows:

4115.5. Pharmacy Technician Trainee; Placement; Supervision; Requirements

(a) Notwithstanding any other provision of law, a pharmacy technician trainee may be placed in a pharmacy to complete an externship for the purpose of obtaining practical training required to become licensed as a pharmacy technician.

(b) (1) A pharmacy technician trainee participating in an externship as described in subdivision (a) may perform the duties described in subdivision (a) of Section 4115 only under the direct supervision and control of a pharmacist.

(2) A pharmacist supervising a pharmacy technician trainee participating in an externship as described in subdivision (a) shall be directly responsible for the conduct of the trainee.

(3) A pharmacist supervising a pharmacy technician trainee participating in an externship as described in subdivision (a) shall verify any prescription prepared by the trainee under supervision of the pharmacist by initialing the prescription label before the medication is disbursed to a patient or by engaging in other verification procedures that are specifically approved by board regulations.

(4) A pharmacist may only supervise one pharmacy technician trainee at any given time.

(5) A pharmacist supervising a pharmacy technician trainee participating in an externship as described in subdivision (a) shall certify attendance for the pharmacy technician trainee and certify that the pharmacy technician trainee has met the educational objectives established by a California public postsecondary education institution or the private postsecondary vocational institution in which the trainee is enrolled, as established by the institution.

(c) (1) Except as described in paragraph (2), an externship in which a pharmacy technician trainee is participating as described in subdivision (a) shall be for a period of no ~~more~~-less than 120 and no more than 140 hours.

(2) When an externship in which a pharmacy technician trainee is participating as described in subdivision (a) involves rotation between a community and hospital pharmacy for the purpose of training the student in distinct practice settings, the externship may be for a period of up to ~~320~~ 340 hours. ~~No more than 120 of the 320 hours may be completed in a community pharmacy setting or in a single department in a hospital pharmacy~~

(d) An externship in which a pharmacy technician trainee may participate as described in subdivision (a) shall be for a period of no more than six consecutive months in a community pharmacy and for a total of no more than 12 months if the externship involves rotation between a community and hospital pharmacy. The externship shall be completed while the trainee is enrolled in a course of instruction at the institution.

(e) A pharmacy technician trainee participating in an externship as described in subdivision (a) shall wear identification that indicates his or her trainee status.

Proposal to Add section 4233.5 an Advanced Practice Pharmacist Renewal Requirements as follows:

§ 4233.5 Renewal Requirements for an Advanced Practice Pharmacist

(a) An applicant for renewal of an advanced practice pharmacist license shall maintain a current and active pharmacist license and shall submit all of the follow as part of the renewal:

(1) Application and payment of the renewal fee.

(2) Submit proof satisfactory to the board that the licensee has completed 10 hours of continuing education. This is in addition to continuing education requirements necessary for pharmacist license renewal.

(b) Notwithstanding subdivision (a), the board shall not require completion of continuing education for the first renewal cycle of an advanced practice pharmacist license.

(c) The board may issue an inactive advanced practice pharmacist license under any of the following conditions:

(1) The pharmacist license becomes inactive.

(2) The licensee fails to provide documentation of the completion of the required continuing education.

(3) As part of an investigation or audit conducted by the board, an advanced practice pharmacist fails to provide documentation substantiating the completion of continuing education as required.

(d) An inactive advanced practice pharmacist license may only be reactivated by paying the renewal fees due, submitting satisfactory proof to the board that the licensee has completed 10 hours of continuing education, and is confirmed have met all licensure renewal requirements.

(f) An advanced practice pharmacist shall retain documentation of completion of continuing education for four (4) years following completion.

Attachment 2

ASSEMBLY BILL

No. 193

Introduced by Assembly Member Patterson

January 10, 2019

An act to amend Sections 7026.1, 7316, 7332, 7334, 7337.5, 7396, 7423, 19011, 19017, 19051, 19059.5, 19060.6, and 19170 of, to add and repeal Section 101.5 of, and to repeal Sections 7326, 7365, 19010.1, and 19052 of, the Business and Professions Code, and to amend Section 110371 of the Health and Safety Code, relating to professions and vocations.

LEGISLATIVE COUNSEL'S DIGEST

AB 193, as introduced, Patterson. Professions and vocations.

(1) Existing law establishes the Department of Consumer Affairs in the Business, Consumer Services, and Housing Agency to, among other things, ensure that certain businesses and professions that have potential impact upon the public health, safety, and welfare are adequately regulated.

This bill would require the department, beginning on January 1, 2021, to conduct a comprehensive review of all occupational licensing requirements and identify unnecessary licensing requirements that cannot be adequately justified. The bill would require the department to report to the Legislature on January 1, 2023, and every 2 years thereafter, on the department's progress, and would require the department to issue a final report to the Legislature no later than January 1, 2033. The bill would require the department to apply for federal funds that have been made available specifically for the purpose of reviewing, updating, and eliminating overly burdensome licensing requirements, as provided.

(2) Existing law provides for the licensure and regulation of contractors by the Contractors’ State License Board in the department and includes within the term “contractor” a person who performs tree removal, tree pruning, stump removal, or engages in tree or limb cabling or guying.

This bill would delete tree pruning from those provisions.

(3) Existing law, the Barbering and Cosmetology Act, provides for the licensure and regulation of the practice of cosmetology by the State Board of Barbering and Cosmetology in the department and defines the practice of both barbering and cosmetology to include shampooing the hair of any person. The act also specifies that, within the practice of cosmetology, there is the specialty branch of skin care, which includes applying makeup, and the specialty branch of nail care, which includes cutting, trimming, polishing, coloring, tinting, cleansing, manicuring, or pedicuring the nails of any person.

This bill would delete shampooing another person from the practice of barbering and cosmetology, would delete the act of applying makeup on another person from the specialty practice of skin care, and would delete nail care from the practice of cosmetology.

(4) Existing law provides for the regulation of custom upholsterers by the Bureau of Household Goods and Services in the department, and requires every custom upholsterer to hold a custom upholsterer’s license.

This bill would delete those provisions requiring licensure of custom upholsterers.

(5) The bill would make conforming and other nonsubstantive changes.

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

3 (a) Many entities, including the Federal Trade Commission, the
4 United States Department of Labor, and the Milton Marks “Little
5 Hoover” Commission on California State Government Organization
6 and Economy, have acknowledged the unnecessary burdens that
7 occupational licensing places on otherwise qualified workers.

8 (b) Unnecessary licensing increases costs for consumers and
9 restricts opportunities for workers.

1 (c) Researchers show that occupational licensing restrictions
2 can result in almost three million fewer jobs and a cost of over
3 \$200,000,000,000 to consumers.

4 (d) The Institute for Justice estimates that burdensome licensing
5 in California results in a loss of 195,917 jobs and \$22,000,000,000
6 in misallocated resources.

7 (e) California is the most broadly and onerously licensed state
8 in the nation and has been identified as the nation’s worst licensing
9 environment for workers in lower-income occupations.

10 (f) Licensing is also believed to disproportionately affect
11 minorities and exacerbate income inequality.

12 SEC. 2. Section 101.5 is added to the Business and Professions
13 Code, to read:

14 101.5. (a) The department shall apply for federal funds that
15 have been made available specifically for the purposes of
16 reviewing, updating, and eliminating overly burdensome licensing
17 requirements.

18 (b) Beginning on January 1, 2021, the department shall conduct
19 a comprehensive review of all occupational licensing requirements
20 and shall identify unnecessary licensing requirements that cannot
21 be adequately justified. The department shall conduct the review
22 whether or not the state receives federal funds pursuant to
23 subdivision (a).

24 (c) The department shall report to the Legislature on January
25 1, 2023, and every two years thereafter until the department has
26 completed its review, on the department’s progress in conducting
27 the review. The department shall issue a final report to the
28 Legislature no later than January 1, 2033.

29 (d) A report to be submitted pursuant to subdivision (c) shall
30 be submitted in compliance with Section 9795 of the Government
31 Code.

32 (e) Notwithstanding Section 10231.5 of the Government Code,
33 this section is repealed on January 1, 2034.

34 SEC. 3. Section 7026.1 of the Business and Professions Code
35 is amended to read:

36 7026.1. (a) The term “contractor” includes all of the following:

37 (1) Any person not exempt under Section 7053 who maintains
38 or services air-conditioning, heating, or refrigeration equipment
39 that is a fixed part of the structure to which it is attached.

1 (2) (A) Any person, consultant to an owner-builder, firm,
 2 association, organization, partnership, business trust, corporation,
 3 or company, who or which undertakes, offers to undertake, purports
 4 to have the capacity to undertake, or submits a bid to construct
 5 any building or home improvement project, or part thereof.

6 (B) For purposes of this paragraph, a consultant is a person,
 7 other than a public agency or an owner of privately owned real
 8 property to be improved, who meets either of the following criteria
 9 as it relates to work performed pursuant to a home improvement
 10 contract as defined in Section 7151.2:

11 (i) Provides or oversees a bid for a construction project.

12 (ii) Arranges for and sets up work schedules for contractors and
 13 subcontractors and maintains oversight of a construction project.

14 (3) A temporary labor service agency that, as the employer,
 15 provides employees for the performance of work covered by this
 16 chapter. The provisions of this paragraph shall not apply if there
 17 is a properly licensed contractor who exercises supervision in
 18 accordance with Section 7068.1 and who is directly responsible
 19 for the final results of the work. Nothing in this paragraph shall
 20 require a qualifying individual, as provided in Section 7068, to be
 21 present during the supervision of work covered by this chapter. A
 22 contractor requesting the services of a temporary labor service
 23 agency shall provide ~~his or her~~ *the contractor's* license number to
 24 that temporary labor service agency.

25 (4) Any person not otherwise exempt by this ~~chapter~~, *chapter*
 26 who performs tree removal, ~~tree pruning~~, stump removal, or
 27 engages in tree or limb cabling or guying. The term contractor
 28 does not include a person performing the activities of a
 29 nurseryperson who in the normal course of routine work performs
 30 incidental pruning of trees, or guying of planted trees and their
 31 limbs. The term contractor does not include a gardener who in the
 32 normal course of routine work performs incidental pruning of trees
 33 measuring less than 15 feet in height after planting.

34 (5) Any person engaged in the business of drilling, digging,
 35 boring, or otherwise constructing, deepening, repairing,
 36 re-perforating, or abandoning any water well, cathodic protection
 37 well, or monitoring well.

38 (b) The term “contractor” or “consultant” does not include a
 39 common interest development manager, as defined in Section
 40 11501, and a common interest development manager is not required

1 to have a contractor's license when performing management
2 services, as defined in subdivision (d) of Section 11500.

3 SEC. 4. Section 7316 of the Business and Professions Code is
4 amended to read:

5 7316. (a) The practice of barbering is all or any combination
6 of the following practices:

7 (1) Shaving or trimming the beard or cutting the hair.

8 (2) Giving facial and scalp massages or treatments with oils,
9 creams, lotions, or other preparations either by hand or mechanical
10 appliances.

11 (3) Singeing, ~~shampooing~~, arranging, dressing, curling, waving,
12 chemical waving, hair relaxing, or dyeing the hair or applying hair
13 tonics.

14 (4) Applying cosmetic preparations, antiseptics, powders, oils,
15 clays, or lotions to scalp, face, or neck.

16 (5) Hairstyling of all textures of hair by standard methods that
17 are current at the time of the hairstyling.

18 (b) The practice of cosmetology is all or any combination of
19 the following practices:

20 (1) Arranging, dressing, curling, waving, machineless permanent
21 waving, permanent waving, cleansing, cutting, ~~shampooing~~,
22 relaxing, singeing, bleaching, tinting, coloring, straightening,
23 dyeing, applying hair tonics to, beautifying, or otherwise treating
24 by any means, the hair of any person.

25 (2) Massaging, cleaning, or stimulating the scalp, face, neck,
26 arms, or upper part of the human body, by means of the hands,
27 devices, apparatus or appliances, with or without the use of
28 cosmetic preparations, antiseptics, tonics, lotions, or creams.

29 (3) Beautifying the face, neck, arms, or upper part of the human
30 body, by use of cosmetic preparations, antiseptics, tonics, lotions,
31 or creams.

32 (4) Removing superfluous hair from the body of any person by
33 the use of depilatories or by the use of tweezers, chemicals, or
34 preparations or by the use of devices or appliances of any kind or
35 description, except by the use of light waves, commonly known
36 as rays.

37 (5) ~~Cutting, trimming, polishing, tinting, coloring, cleansing,~~
38 ~~or manieuring the nails of any person.~~

39 (6)

1 (5) Massaging, cleansing, treating, or beautifying the hands or
2 feet of any person.

3 (c) Within the practice of cosmetology there ~~exist~~ *exists* the
4 specialty branches of skin care and nail care.

5 ~~(1) Skin care branch of skin care, which is any one or more of~~
6 the following practices:

7 ~~(A)~~

8 ~~(1) Giving facials, applying makeup, giving skin care, removing~~
9 ~~superfluous hair from the body of any person by the use of~~
10 ~~depilatories, tweezers or waxing, or applying eyelashes to any~~
11 ~~person.~~

12 ~~(B)~~

13 ~~(2) Beautifying the face, neck, arms, or upper part of the human~~
14 ~~body, by use of cosmetic preparations, antiseptics, tonics, lotions,~~
15 ~~or creams.~~

16 ~~(C)~~

17 ~~(3) Massaging, cleaning, or stimulating the face, neck, arms, or~~
18 ~~upper part of the human body, by means of the hands, devices,~~
19 ~~apparatus, or appliances, with the use of cosmetic preparations,~~
20 ~~antiseptics, tonics, lotions, or creams.~~

21 ~~(2) Nail care is the practice of cutting, trimming, polishing,~~
22 ~~coloring, tinting, cleansing, manicuring, or pedicuring the nails of~~
23 ~~any person or massaging, cleansing, or beautifying from the elbow~~
24 ~~to the fingertips or the knee to the toes of any person.~~

25 (d) The practice of barbering and the practice of cosmetology
26 do not include any of the following:

27 (1) The mere sale, fitting, or styling of wigs or hairpieces.

28 (2) Natural hair braiding. Natural hair braiding is a service that
29 results in tension on hair strands or roots by twisting, wrapping,
30 weaving, extending, locking, or braiding by hand or mechanical
31 device, provided that the service does not include haircutting or
32 the application of dyes, reactive chemicals, or other preparations
33 to alter the color of the hair or to straighten, curl, or alter the
34 structure of the hair.

35 (3) Threading. Threading is a technique that results in removing
36 hair by twisting thread around unwanted hair and pulling it from
37 the skin and the incidental trimming of eyebrow hair.

38 (e) Notwithstanding paragraph (2) of subdivision (d), a person
39 who engages in natural hairstyling, which is defined as the
40 provision of natural hair braiding services together with any of the

1 services or procedures defined within the regulated practices of
2 barbering or cosmetology, is subject to regulation pursuant to this
3 chapter and shall obtain and maintain a barbering or cosmetology
4 license as applicable to the services respectively offered or
5 performed.

6 (f) Electrolysis is the practice of removing hair from, or
7 destroying hair on, the human body by the use of an electric needle
8 only.

9 “Electrolysis” as used in this chapter includes electrolysis or
10 thermolysis.

11 SEC. 5. Section 7326 of the Business and Professions Code is
12 repealed.

13 ~~7326. The board shall admit to examination for a license as a~~
14 ~~manicurist to practice nail care, any person who has made~~
15 ~~application to the board in proper form, paid the fee required by~~
16 ~~this chapter, and is qualified as follows:~~

17 ~~(a) Is not less than 17 years of age.~~

18 ~~(b) Has completed the 10th grade in the public schools of this~~
19 ~~state or its equivalent.~~

20 ~~(c) Is not subject to denial pursuant to Section 480.~~

21 ~~(d) Has done any of the following:~~

22 ~~(1) Completed a course in nail care from a school approved by~~
23 ~~the board.~~

24 ~~(2) Practiced nail care, as defined in this chapter, outside of this~~
25 ~~state for a period of time equivalent to the study and training of a~~
26 ~~qualified person who has completed a course in nail care from a~~
27 ~~school the curriculum of which complied with requirements~~
28 ~~adopted by the board. Each three months of practice shall be~~
29 ~~deemed the equivalent of 100 hours of training for qualification~~
30 ~~under paragraph (1).~~

31 ~~(3) Completed the apprenticeship program in nail care specified~~
32 ~~in Article 4 (commencing with Section 7332).—~~

33 SEC. 6. Section 7332 of the Business and Professions Code is
34 amended to read:

35 7332. (a) An apprentice is any person who is licensed by the
36 board to engage in learning or acquiring a knowledge of barbering,
37 cosmetology, skin care, ~~nail care~~, or electrology, in a licensed
38 establishment under the supervision of a licensee approved by the
39 board.

1 (b) For purposes of this section, “under the supervision of a
2 licensee” means that the apprentice shall be supervised at all times
3 by a licensee approved by the board while performing services in
4 a licensed establishment. At no time shall an apprentice be the
5 only individual working in the establishment. An apprentice that
6 is not being supervised by a ~~licensee~~, *licensee* that has been
7 approved by the board to supervise an ~~apprentice~~, *apprentice* shall
8 be deemed to be practicing unlicensed under this chapter.

9 SEC. 7. Section 7334 of the Business and Professions Code is
10 amended to read:

11 7334. (a) The board may license as an apprentice in barbering,
12 cosmetology, ~~or skin care, or nail care~~ any person who has made
13 application to the board upon the proper form, has paid the fee
14 required by this chapter, and who is qualified as follows:

15 (1) Is over 16 years of age.

16 (2) Has completed the 10th grade in the public schools of this
17 state or its equivalent.

18 (3) Is not subject to denial pursuant to Section 480.

19 (4) Has submitted evidence acceptable to the board that any
20 training the apprentice is required by law to obtain shall be
21 conducted in a licensed establishment and under the supervision
22 of a licensee approved by the board.

23 (b) The board may license as an apprentice in electrolysis any
24 person who has made application to the board upon the proper
25 form, has paid the fee required by this chapter, and who is qualified
26 as follows:

27 (1) Is not less than 17 years of age.

28 (2) Has completed the 12th grade or an accredited senior high
29 school course of study in schools of this state or its equivalent.

30 (3) Is not subject to denial pursuant to Section 480.

31 (4) Has submitted evidence acceptable to the board that any
32 training the apprentice is required by law to obtain shall be
33 conducted in a licensed establishment and under the supervision
34 of a licensee approved by the board.

35 (c) All persons making application as an apprentice in barbering
36 shall also complete a minimum of 39 hours of preapprentice
37 training in a facility approved by the board prior to serving the
38 general public.

39 (d) All persons making application as an apprentice in
40 cosmetology, skin care, ~~nail care~~, or electrology shall also complete

1 minimum preapprentice training for the length of time established
2 by the board in a facility approved by the board prior to serving
3 the general public.

4 (e) Apprentices may only perform services on the general public
5 for which they have received technical training.

6 (f) Apprentices shall be required to obtain at least the minimum
7 hours of technical instruction and minimum number of practical
8 operations for each subject as specified in board regulations for
9 courses taught in schools approved by the board, in accordance
10 with Sections 3074 and 3078 of the Labor Code.

11 SEC. 8. Section 7337.5 of the Business and Professions Code
12 is amended to read:

13 7337.5. (a) The board shall adopt regulations providing for
14 the submittal of applications for admission to examination of
15 students of approved cosmetology, electrology, or barbering
16 schools who have completed at least 75 percent of the required
17 course clock hours and curriculum requirements (60 percent for
18 students of the manicurist course), or any person licensed as an
19 apprentice in barbering, cosmetology, *or* skin-care, ~~or nail care~~
20 who has completed at least 75 percent of the required
21 apprenticeship training hours. The regulations shall include
22 provisions that ensure that all proof of qualifications of the
23 applicant is received by the board before the applicant is examined.

24 (b) An application for examination submitted by a student of
25 an approved cosmetology, electrology, or barbering school under
26 this section shall be known as a “school preapplication” and an
27 additional preapplication fee may be required.

28 (c) An application for examination submitted by a person
29 licensed as an apprentice in barbering, cosmetology, *or* skin-care,
30 ~~or nail care~~ shall be known as an “apprenticeship preapplication”
31 and an additional fee may be required.

32 (d) The board shall administer the licensing examination not
33 later than 10 working days after graduation from an approved
34 cosmetology, electrology, or barbering school to students who
35 have submitted an application for admission for examination under
36 the preapplication procedure, or not later than 10 working days
37 after completion of an approved barbering, cosmetology, *or* skin
38 care, ~~or nail care~~ apprenticeship program for a person licensed as
39 an apprentice.

1 SEC. 9. Section 7365 of the Business and Professions Code is
2 repealed.

3 ~~7365. A nail care course established by a school shall consist~~
4 ~~of not less than 350 hours of practical training and technical~~
5 ~~instruction in accordance with a curriculum established by board~~
6 ~~regulation.~~

7 SEC. 10. Section 7396 of the Business and Professions Code
8 is amended to read:

9 7396. The form and content of a license issued by the board
10 shall be determined in accordance with Section 164.

11 The license shall prominently state that the holder is licensed as
12 a barber, cosmetologist, esthetician, ~~manicurist~~, electrologist, or
13 apprentice, and shall contain a photograph of the licensee.

14 SEC. 11. Section 7423 of the Business and Professions Code
15 is amended to read:

16 7423. The amounts of the fees required by this chapter relating
17 to licenses for individual practitioners are as follows:

18 (a) (1) ~~Cosmetologist~~—*A cosmetologist* application and
19 examination fee shall be the actual cost to the board for developing,
20 purchasing, grading, and administering the examination.

21 (2) A cosmetologist initial license fee shall not be more than
22 fifty dollars (\$50).

23 (b) (1) An esthetician application and examination fee shall be
24 the actual cost to the board for developing, purchasing, grading,
25 and administering the examination.

26 (2) An esthetician initial license fee shall not be more than forty
27 dollars (\$40).

28 (c) (1) ~~A manicurist application and examination fee shall be~~
29 ~~the actual cost to the board for developing, purchasing, grading,~~
30 ~~and administering the examination.~~

31 (2) ~~A manicurist initial license fee shall not be more than~~
32 ~~thirty-five dollars (\$35).~~

33 (d)

34 (c) (1) A barber application and examination fee shall be the
35 actual cost to the board for developing, purchasing, grading, and
36 administering the examination.

37 (2) A barber initial license fee shall be not more than fifty dollars
38 (\$50).

39 (e)

1 (d) (1) An electrologist application and examination fee shall
2 be the actual cost to the board for developing, purchasing, grading,
3 and administering the examination.

4 (2) An electrologist initial license fee shall be not more than
5 fifty dollars (\$50).

6 ~~(f)~~

7 (e) An apprentice application and license fee shall be not more
8 than twenty-five dollars (\$25).

9 ~~(g)~~

10 (f) The license renewal fee for individual practitioner licenses
11 that are subject to renewal shall be not more than fifty dollars
12 (\$50).

13 ~~(h)~~

14 (g) Notwithstanding Section 163.5 the license renewal
15 delinquency fee shall be 50 percent of the renewal fee in effect on
16 the date of renewal.

17 ~~(i)~~

18 (h) Any preapplication fee shall be established by the board in
19 an amount sufficient to cover the costs of processing and
20 administration of the preapplication.

21 SEC. 12. Section 19010.1 of the Business and Professions
22 Code is repealed.

23 ~~19010.1. "Custom upholsterer" means a person who, either by
24 himself or herself or through employees or agents, repairs,
25 reupholsters, re-covers, restores, or renews upholstered furniture,
26 or who makes to order and specification of the user any article of
27 upholstered furniture, using either new materials or owner's
28 materials.~~

29 SEC. 13. Section 19011 of the Business and Professions Code
30 is amended to read:

31 19011. "Manufacturer" means a person who, either by himself
32 or herself *themselves* or through employees or agents, makes any
33 article of upholstered furniture or bedding in whole or in part, or
34 who does the upholstery or covering of any unit thereof, using
35 either new or secondhand material. "Manufacturer" does not,
36 however, include a "custom upholsterer," as defined in Section
37 ~~19010.1.~~

38 SEC. 14. Section 19017 of the Business and Professions Code
39 is amended to read:

1 19017. “Owner’s material” means any article or material
2 belonging to a person for ~~his or her~~ *their* own, or *their* tenant’s
3 use, that is sent to any ~~manufacturer, manufacturer or bedding~~
4 ~~renovator, or custom upholsterer to be repaired or renovated,~~
5 *renovator* or used in repairing or renovating.

6 SEC. 15. Section 19051 of the Business and Professions Code
7 is amended to read:

8 19051. Every upholstered-furniture retailer, unless ~~he or she~~
9 *the person* holds an importer’s license, a furniture and bedding
10 manufacturer’s license, a wholesale furniture and bedding dealer’s
11 license, ~~a custom upholsterer’s license,~~ or a retail furniture and
12 bedding dealer’s *license*, shall hold a retail furniture dealer’s
13 license.

14 (a) This section does not apply to a person whose sole business
15 is designing and specifying for interior spaces, and who purchases
16 specific amenable upholstered furniture items on behalf of a client,
17 provided that the furniture is purchased from an appropriately
18 licensed importer, wholesaler, or retailer. This section does not
19 apply to a person who sells “used” and “antique” furniture as
20 defined in Sections 19008.1 and 19008.2.

21 (b) This section does not apply to a person who is licensed as
22 a home medical device retail facility by the State Department of
23 Health Services, provided that the furniture is purchased from an
24 appropriately licensed importer, wholesaler, or retailer.

25 SEC. 16. Section 19052 of the Business and Professions Code
26 is repealed.

27 ~~19052. Every custom upholsterer, unless he or she holds a~~
28 ~~furniture and bedding manufacturer’s license, shall hold a custom~~
29 ~~upholsterer’s license.~~

30 SEC. 17. Section 19059.5 of the Business and Professions
31 Code is amended to read:

32 19059.5. Every sanitizer shall hold a sanitizer’s license unless
33 ~~he or she~~ *the person* is licensed as a home medical device retail
34 facility by the State Department of Health Services or as an
35 upholstered furniture and bedding manufacturer, retail furniture
36 and bedding dealer, *or* retail bedding dealer, ~~or custom upholsterer.~~
37 *dealer.*

38 SEC. 18. Section 19060.6 of the Business and Professions
39 Code is amended to read:

1 19060.6. ~~(a) Except as provided in subdivision (b), every~~ Every
 2 person who, on ~~his or her~~ *their* own account, advertises, ~~solicits~~
 3 ~~solicits~~, or contracts to ~~manufacture, repair or renovate~~ *manufacture*
 4 upholstered furniture or bedding, and who either does the work
 5 ~~himself or herself~~ *themselves* or has others do it for him or her, *it*,
 6 shall obtain the particular license required by this chapter for the
 7 particular type of work that ~~he or she~~ *the person* solicits or
 8 advertises that ~~he or she~~ *the person* will do, regardless of whether
 9 ~~he or she~~ *the person* has a shop or factory.

10 ~~(b) Every person who, on his or her own account, advertises,~~
 11 ~~solicits or contracts to repair or renovate upholstered furniture and~~
 12 ~~who does not do the work himself or herself nor have employees~~
 13 ~~do it for him or her but does have the work done by a licensed~~
 14 ~~custom upholsterer need not obtain a license as a custom~~
 15 ~~upholsterer but shall obtain a license as a retail furniture dealer.~~
 16 However, nothing in this section shall exempt a retail furniture
 17 dealer from complying with Sections 19162 and 19163.

18 SEC. 19. Section 19170 of the Business and Professions Code
 19 is amended to read:

20 19170. (a) The fee imposed for the issuance and for the
 21 biennial renewal of each license granted under this chapter shall
 22 be set by the chief, with the approval of the director, at a sum not
 23 more nor less than that shown in the following table:
 24

	Maximum	Minimum
	fee	fee
26 Importer's license	\$940	\$120
28 Furniture and bedding manufacturer's		
29 license	940	120
30 Wholesale furniture and bedding		
31 dealer's license	675	120
32 Supply dealer's license	675	120
33 Custom upholsterer's license	450	80
34 Sanitizer's license	450	80
35 Retail furniture and bedding dealer's license	300	40
36 Retail furniture dealer's license	150	20
37 Retail bedding dealer's license	150	20

38
 39 (b) Individuals who, in their own homes and without the
 40 employment of any other person, make, sell, advertise, or contract

1 to make pillows, quilts, quilted pads, or comforters are exempt
 2 from the fee requirements imposed by subdivision (a). However,
 3 these individuals shall comply with all other provisions of this
 4 chapter.

5 (c) Retailers who only sell “used” and “antique” furniture as
 6 defined in Sections 19008.1 and 19008.2 are exempt from the fee
 7 requirements imposed by subdivision (a). Those retailers are also
 8 exempt from the other provisions of this chapter.

9 (d) A person who makes, sells, or advertises upholstered
 10 furniture and bedding as defined in Sections 19006 and 19007,
 11 and who also makes, sells, or advertises furniture used exclusively
 12 for the purpose of physical fitness and exercise, shall comply with
 13 the fee requirements imposed by subdivision (a).

14 (e) A person who has paid the required fee and who is licensed
 15 either as an upholstered furniture and bedding manufacturer or a
 16 custom upholsterer under this chapter shall not be required to
 17 additionally pay the fee for a sanitizer’s license.

18 SEC. 20. Section 110371 of the Health and Safety Code is
 19 amended to read:

20 110371. (a) A professional cosmetic manufactured on or after
 21 July 1, 2020, for sale in this state shall have a label affixed on the
 22 container that satisfies all of the labeling requirements for any
 23 other cosmetic pursuant to the Federal Food, Drug, and Cosmetic
 24 Act (21 U.S.C. Sec. 301, et seq.), and the federal Fair Packaging
 25 and Labeling Act (15 U.S.C. Sec. 1451, et seq.).

26 (b) The following definitions shall apply to this section:

27 (1) “Ingredient” has the same meaning as in Section 111791.5.

28 (2) “Professional” means a person that has been granted a license
 29 by the State Board of Barbering and Cosmetology to practice in
 30 the field of cosmetology, ~~nail care~~, barbering, or esthetics.

31 (3) “Professional cosmetic” means a cosmetic product as it is
 32 defined in Section 109900 that is intended or marketed to be used
 33 only by a professional on account of a specific ingredient, increased
 34 concentration of an ingredient, or other quality that requires safe
 35 handling, or is otherwise used by a professional.

Attachment 3

Regulation Timeline

1. Proposed Regulations to Amend Title 16, California Code of Regulations (CCR), Sections 1735.1, 1735.2, 1735.6, 1751.1, & 1751.4 Related to Compounded Drug Preparations

Timeline:

Approved by Board: July 25, 2017

Submitted to DCA for Pre-Notice Review: November 20, 2017

Approved by DCA and Agency: July 18, 2018

Noticed for 45-day Public Comment: August 3, 2018

Noticed for 15-day Public Comment: September 26, 2018

Adopted by Board: October 23, 2018

Submitted to DCA for Final Review: November 2, 2018

Submitted to OAL for Final Review: December 14, 2018

The Final Review Date is January 30, 2019 – An update will be provided at the board meeting.

**Compounded Drug
Preparations
16 CCR §§ 1735.1,
1735.2, 1735.6, 1751.1,
and 1751.4**

**Title 16. Board of Pharmacy
Modified Text**

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

Proposed changes to the current regulation language are shown by ~~strikethrough~~ for deleted language and underline for added language. Additionally, text in [brackets] indicates language that is not being amended.

Note: The board adopted an emergency regulation affecting regulation section 1735.2 effective December 19, 2017. The strikethrough and underline to the text of that section reflects changes from the board's non-emergency regulation.

Amend section 1735.1, subdivisions (c) and (f), in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1735.1. Compounding Definitions.

[...]

(c) "Biological Safety Cabinet (BSC)" means a ventilated cabinet for compounding sterile drug preparations, having an open front with inward airflow for personnel protection, downward HEPA-filtered laminar airflow for product protection, and HEPA-filtered exhausted air for environmental protection. Where hazardous drugs are prepared, the exhaust air from the biological safety cabinet shall be appropriately removed by properly designed external building ~~ventilation~~ exhausting. This external ~~venting exhaust~~ exhaust should be dedicated to one BSC or CACI.

[...]

(f) "Compounding Aseptic Containment Isolator (CACI)" means a unidirectional HEPA-filtered airflow compounding aseptic isolator (CAI) designed to provide worker protection from exposure to undesirable levels of airborne drug throughout the compounding and material transfer processes and to provide an aseptic environment for compounding sterile preparations. Air exchange with the surrounding environment should not occur unless the air is first passed through a microbial retentive filter (HEPA minimum) system capable of containing airborne concentrations of the physical size and state of the drug being compounded. Where hazardous drugs are prepared, the exhaust air from the isolator shall be appropriately removed by properly designed external building ~~ventilation-exhaust~~ exhaust. This external ~~venting-exhaust~~ exhaust should be dedicated to one BSC or CACI. Air within the CACI shall not be recirculated nor turbulent.

[...]

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code.
Reference: Sections 4005, 4029, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

Amend section 1735.2, subdivision (i), in Article 4.5 of Division 17 of Title 16 California Code of Regulations to read as follows:

1735.2. Compounding Limitations and Requirements; Self-Assessment.

[...]

- (i) Every compounded drug preparation shall be given a beyond use date representing the date or date and time beyond which the compounded drug preparation should not be used, stored, transported or administered, and determined based on the professional judgment of the pharmacist performing or supervising the compounding.
- (1) For non-sterile compounded drug preparation(s), the beyond use date shall not exceed any of the following:
- (A) the shortest expiration date or beyond use date of any ingredient in the compounded drug preparation,
 - (B) the chemical stability of any one ingredient in the compounded drug preparation;
 - (C) the chemical stability of the combination of all ingredients in the compounded drug preparation,
 - (D) ~~180 days~~ for non-aqueous formulations, 180 days or an extended date established by the pharmacist's research, analysis, and documentation,
 - (E) ~~14 days~~ for water-containing oral formulations, 14 days or an extended date established by the pharmacist's research, analysis, and documentation, and
 - (F) ~~30 days~~ for water-containing topical/dermal and mucosal liquid and semisolid formulations, 30 days or an extended date established by the pharmacist's research, analysis, and documentation.
 - (G) A pharmacist, using his or her professional judgment may establish an extended date as provided in (D), (E), and (F), if the pharmacist researches by consulting and applying drug-specific and general stability documentation and literature; analyzes such documentation and literature as well as the other factors set forth in this subdivision, and maintains documentation of the research, analysis and conclusion. The factors the pharmacist must analyze include:
 - (i) the nature of the drug and its degradation mechanism,
 - (ii) the dosage form and its components,
 - (iii) the potential for microbial proliferation in the preparation,

- (iv) the container in which it is packaged,
- (v) the expected storage conditions, and
- (vi) the intended duration of therapy.

Documentation of the pharmacist's research and analysis supporting an extension must be maintained in a readily retrievable format as part of the master formula.

- (2) For sterile compounded drug preparations, the beyond use date shall not exceed any of the following:
 - (A) The shortest expiration date or beyond use date of any ingredient in the sterile compounded drug product preparation,
 - (B) The chemical stability of any one ingredient in the sterile compounded drug preparation,
 - (C) The chemical stability of the combination of all ingredients in the sterile compounded drug preparation, and
 - (D) The beyond use date assigned for sterility in section 1751.8.
- (3) For sterile compounded drug preparations, ~~E~~-extension of a beyond use date is only allowable when supported by the following:
 - (A) Method Suitability Test,
 - (B) Container Closure Integrity Test, and
 - (C) Stability Studies
- (4) In addition to the requirements of paragraph three (3), the drugs or compounded drug preparations tested and studied shall be identical in ingredients, specific and essential compounding steps, quality reviews, and packaging as the finished drug or compounded drug preparation.
- (5) Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.

[...]

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code.

Reference: Sections 4005, 4029, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

Amend section 1735.6, subdivision (e), in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1735.6. Compounding Facilities and Equipment.

[...]

- (e) Hazardous drug compounding shall be completed in an externally ~~vented~~-exhausted 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 hours 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) ~~(A) For sterile compounding, each Each PEG BSC or CACI in the room shall also be externally vented/exhausted, except that a BSC used only~~
(B) For nonsterile compounding, a BSC, a CACI, or other containment ventilated enclosure shall be used and shall either ~~may~~ use a redundant-HEPA filter in series or be externally exhausted.; and For purposes of this paragraph, a containment ventilated enclosure means a full or partial enclosure that uses ventilation principles to capture, contain, and remove airborne contaminants through high-efficiency particulate air (HEPA) filtration and to prevent their release into the work environment.
- (4) All surfaces within the room shall be smooth, seamless, impervious, and non-shedding.

[...]

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code.
 Reference: Sections 4005, 4029, 4036, 4037, 4051, 4052 and 4127, Business and Professions Code.

Amend section 1751.1, subdivision (a)(5), in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1751.1. Sterile Compounding Recordkeeping Requirements.

- (a) In addition to the records required by section 1735.3, any pharmacy engaged in any compounding of sterile drug preparations shall maintain the following records, which must be readily retrievable, within the pharmacy:

[...]

- (5) Biannual ~~video~~ of smoke studies in all ISO Class 5 certified spaces.

[...]

[...]

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code.
 Reference: Sections 4005, 4029, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

Amend section 1751.4, subdivision (k), in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1751.4. Facility and Equipment Standards for Sterile Compounding.

[...]

(k) The sterile compounding area in the pharmacy shall have a comfortable and well-lighted working environment, which typically 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.

[...]

Note: Authority Cited: Sections 4005 and 4127, Business and Professions Code.
Reference: Sections 4005, 4029, 4036, 4037, 4051, 4052 and 4127, Business and Professions Code; and Section 18944, Health and Safety Code.

Attachment 4

Regulation Timelines

1. Proposed Regulations to Amend Title 16 CCR Section 1793.5 Related to the Pharmacy Technician Application, Section 1793.6 Related to the Pharmacy Technician Training Requirements and Section 1793.65 Related to the Pharmacy Technician Certification Programs

Timeline:

Approved by board: October 26, 2016

Submitted to DCA for Pre-Notice Review: January 23, 2017

Returned to the board: March 28, 2017

Re-submitted to DCA for Pre-Notice Review: August 21, 2017

Returned to the board: February 24, 2018

Modified language approved by board: March 27, 2018

Re-submitted to DCA for Pre-Notice Review: July 11, 2018

Returned to the board: August 20, 2018

Re-submitted to DCA for Pre-Notice Review: October 26, 2018

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

Timeline:

Approved by Board: October 26, 2016

Submitted to DCA for Pre-Notice Review: January 26, 2017

Returned to the Board on: March 28, 2017

Re-submitted to DCA for Pre-Notice Review: May 24, 2018

Returned to the board: August 6, 2018

Re-submitted to DCA for Pre-Notice Review: August 16, 2018

Returned to the board: November 2, 2018

Re-submitted to DCA for Pre-Notice Review: December 20, 2018

3. Proposed Regulations to Amend Title 16 CCR Sections 1780-1783 et seq., Related to Dangerous Drug Distributors and Third-Party Logistics Providers

Timeline:

Approved by board: October 26, 2016

Submitted to DCA for Pre-Notice Review: February 9, 2017

Returned to the board on: February 28, 2017

Re-submitted to DCA for Pre-Notice Review: October 25, 2017

Returned to the board on: March 26, 2018

Re-submitted to DCA for Pre-Notice Review: June 28, 2018

Returned to the board on: August 28, 2018

Re-submitted to DCA for Pre-Notice Review: September 6, 2018

Returned to the board on: October 30, 2018

Re-submitted to DCA for Pre-Notice Review: December 20, 2018

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

Timeline:

Approved by Board: January 24, 2017

Submitted to DCA for Pre-Notice Review: April 27, 2017

Returned to the board: January 18, 2018

Re-submitted to DCA for Pre-Notice Review: June 25, 2018

Returned to the board: July 3, 2018

Re-submitted to DCA for Pre-Notice Review: July 13, 2018

Formal DCA Pre-Notice Review began: August 20, 2018

5. Proposed Regulations to Add Title 16 CCR Sections 1717.5 Related to Automatic Refill Programs

Timeline:

Approved by Board: May 3, 2017

Submitted to DCA for Pre-Notice Review: November 7, 2017

Returned to the Board on: March 26, 2018

Re-submitted to DCA for Pre-Notice Review: June 29, 2018

Returned to the Board on: August 20, 2018

Re-submitted to DCA for Pre-Notice Review: September 20, 2018

6. Proposed Regulations to Amend Title 16 CCR Section 1746.3 Related to the Naloxone Fact Sheet

Timeline:

Approved by Board: May 4, 2017

Submitted to DCA for Pre-Notice Review: May 31, 2017

Returned to the board: January 18, 2018

Modified language approved by board: March 27, 2018

Re-submitted to DCA for Pre-Notice Review: June 13, 2018

Returned to the board on: July 2, 2018

Re-submitted to DCA for Pre-Notice Review: July 2, 2018

Formal DCA Pre-Notice Review began: July 2, 2018

7. Proposed Regulations to Amend Title 16 CCR Section 1715 to Update Self-Assessment Forms 17M-13 and 17M-14

Timeline:

Approved by Board: November 8, 2017

Submitted to DCA for Pre-Notice Review: February 2, 2018

Returned to the Board on: April 17, 2018

Re-submitted to DCA for Pre-Notice Review: July 23, 2018

Returned to the Board on: November 13, 2018

Re-submitted to DCA for Pre-Notice Review: December 24, 2018

8. Proposed Regulations to Amend Title 16 CCR Section 1784 to Update the Wholesaler/3PL Self-Assessment Form 17M-26

Timeline:

Approved by Board: November 8, 2017

Submitted to DCA for Pre-Notice Review: December 26, 2018

9. Proposed Regulations to Add Title 16 CCR Section 1793.9 Related to Remote Dispensing Technicians

Timeline:

Approved by Board: February 6, 2018

Submitted to DCA for Pre-Notice Review: June 11, 2018

Formal DCA Pre-Notice Review began: August 29, 2018

10. Proposed Regulations to Amend Title 16 CCR Section 1706.2 Related to Abandonment of Applications

Timeline:

Approved by Board: February 6, 2018

Submitted to DCA for Pre-Notice Review: July 2, 2018

Formal DCA Pre-Notice Review began: August 3, 2018

11. Proposed Regulations to Amend Title 16 CCR Sections 1702, 1702.1, 1702.2, and 1702.5 Related to Renewal Requirements

Timeline:

Approved by Board: May 2, 2018

Submitted to DCA for Pre-Notice Review: July 12, 2018

Returned to the board: September 6, 2018

Re-submitted to DCA for Pre-Notice Review: September 18, 2018

Returned to the board: September 28, 2018

Re-submitted to DCA for Pre-Notice Review: October 4, 2018

Formal DCA Pre-Notice Review began: October 16, 2018

12. Proposed Regulations to Amend Title 16 CCR Section 1707.2 Related to Mail-Order Pharmacy Consultation

Timeline:

Approved by Board: May 2, 2018

Submitted to DCA for Pre-Notice Review: July 23, 2018

Returned to the board on: August 23, 2018

Re-submitted to DCA for Pre-Notice Review: September 14, 2018

Formal DCA Pre-Notice Review began: October 1, 2018

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

Timeline:

Approved by Board: December 14, 2018

Submitted to DCA for Pre-Notice Review: December 17, 2018

Formal DCA Pre-Notice Review began: January 16, 2019

Pharmacy Technician

**16 CCR § 1793.5,
1793.6, and 1793.65**

**Title 16. Board of Pharmacy
Proposed Regulation Text**

Proposal to amend §1793.5 of Article 11 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1793.5. Pharmacy Technician Application.

The "Pharmacy Technician Application" (Form 17A-5 (Rev. ~~10/15~~ 7/2018)), incorporated by reference herein, required by this section is available from the Board of Pharmacy upon request.

(a) Each application for a pharmacy technician license shall include:

(1) Information sufficient to identify the applicant.

(2) A description of the applicant's qualifications and supporting documentation for those qualifications.

(3) A criminal background check that will require submission of fingerprints in a manner specified by the board and the fee authorized in Penal Code section 11105(e).

(4) A sealed, original Self-Query from the National Practitioner Data Bank (NPDB) dated no earlier than 60 days of the date an application is submitted to the board.

(b) The applicant shall sign the application under penalty of perjury and shall submit it to the Board of Pharmacy.

(c) The board shall notify the applicant within 30 days if an application is deficient; and what is needed to correct the deficiency. Once the application is complete, and upon completion of any investigation conducted pursuant to section 4207 of the Business and Professions Code, the board will notify the applicant within 60 days of a license decision.

(d) Before expiration of a pharmacy technician license, a pharmacy technician must renew that license by payment of the fee specified in subdivision (r) of section 4400 of the Business and Professions Code.

Note: Authority cited: Sections ~~163.5, 4005, 4007, 4038,~~ 4115, and 4202, ~~4207 and 4400,~~ Business and Professions Code. Reference: Sections 144, 144.5, 163.5, 4005, 4007, 4038, 4115, 4202, 4207, 4400 and ~~4402 and 4400,~~ Business and Professions Code; and Section 11105, Penal Code.

Proposal to amend §1793.6 of Article 11 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1793.6. Training Courses Specified by the Board.

A course of training that meets the requirements of Business and Professions Code section 4202

(a)(2) is:

(a) Any pharmacy technician training program accredited by the American Society of Health--System Pharmacists,

(b) Any pharmacy technician training program provided by a branch of the federal armed services for which the applicant possesses a certificate of completion, or

(c) (1) Any other course that provides a training period of at least 240 hours of instruction covering at least the following:

(± A) Knowledge and understanding of different pharmacy practice settings.

(2 B) Knowledge and understanding of the duties and responsibilities of a pharmacy technician in relationship to other pharmacy personnel and knowledge of standards and ethics, laws and regulations governing the practice of pharmacy.

(3 C) Knowledge and ability to identify and employ pharmaceutical and medical terms, abbreviations and symbols commonly used in prescribing, dispensing and record keeping of medications.

(4 D) Knowledge of and the ability to carry out calculations required for common dosage determination, employing both the metric and apothecary systems.

(5 E) Knowledge and understanding of the identification of drugs, drug dosages, routes of administration, dosage forms and storage requirements.

(6 F) Knowledge of and ability to perform the manipulative and record-keeping functions involved in and related to dispensing prescriptions.

(7 G) Knowledge of and ability to perform procedures and techniques relating to manufacturing, packaging, and labeling of drug products.

(2) In addition to the content of coursework specified in subdivision (c)(1), the course of training must also satisfy all of the following:

(A) Prior to admission to the course of training, an administrator or instructor must conduct a criminal background check and counsel applicants to the program about the negative impact to securing licensure if the background check reveals criminal history.

(B) Administer at least one drug screening to each student to evaluate use of illicit drugs or use of drugs without a prescription. The results of any screen shall be considered as part of the evaluation criteria to determine (1) acceptance into the course of training, or (2) appropriateness for continuation in the course of training. An administrator or instructor shall counsel students about the negative impact of a positive drug screen on eligibility for licensure.

(C) Require students to be at least 18 years of age prior to the beginning of instruction.

(D) Require a final examination that demonstrates students' understanding and ability to perform or apply each subject area identified in subsection (1) above.

Authority cited: Sections 4005, ~~4007, 4038, 4115~~, and 4202, Business and Professions Code. Reference: Sections 4005, 4007, 4038, 4115, 4115.5, and 4202, Business and Professions Code.

Proposal to add §1793.65 of Article 11 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1793.65 Pharmacy Technician Certification Programs Approved by the Board.

(a) Pursuant to Business and Professions Code section 4202(a)(4), the board approves the pharmacy technician certification program offered by:

(1) The Pharmacy Technician Certification Board, and

(2) The National Healthcareer Association.

(b) Approval of these programs is valid through December 31, 2021.

Note: Authority cited: Business and Professions Code Sections 4005 and 4202. Reference: Business and Professions Code Sections 4038 and 4202.



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

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

PHARMACY TECHNICIAN APPLICATION

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

- Military Expedite** **MILITARY** (Are you serving in the United States military?)
 VETERAN (Have you ever served in the United States military?)
 ACTIVE DUTY MILITARY-Spouse or Partner (Check here)

Applicant Information - Please Type or Print if you meet the requirements for expediting your application.)

Full Legal Name: Last Name:	First Name:	Middle Name:
Previous Names (AKA, Maiden Name, Alias, etc):		
*Official Mailing/Public Address of Record (Street Address, PO Box #, etc):		
City:	State:	Zip Code:
Residence Address (if different from above):		
City:	State:	Zip Code:
Home#: ()	Cell#: ()	Work#: ()
Email Address:		
Date of Birth (Month/Day/Year):	**US Social Security # or Individual Tax ID	ITIN #:
Driver's License No:		State:

Mandatory Education (check one box)

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

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

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

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

Pharmacy Technician Qualifying Method (check one box)

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

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

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

Attached is a ~~certified~~ copy of your military training DD214

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

State	Registration Number	Active or Inactive	Issued Date	Expiration Date

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

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

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

You must provide a written explanation for all affirmative answers indicated below. Failure to do so may result in this application being deemed incomplete and being withdrawn.

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

<p>7. Are you currently or have you previously been listed as a corporate officer, partner, owner, manager, member, administrator or medical director on a permit to conduct a pharmacy, wholesaler, medical device retailer or any other entity licensed in this state or any other state? If "yes," provide company name, type of permit, permit number and state where licensed.</p>	Yes <input type="checkbox"/> No <input type="checkbox"/>																				
<p>8. Have you ever been convicted of, or pleaded guilty or nolo contendere/no contest to, any crime, in any state, the United States or its territories, a military court, or any foreign country? Include any felony or misdemeanor offense, and any infraction involving drugs or alcohol with a fine of \$500 or more. You must disclose a conviction even if it was: (1) later dismissed or expunged pursuant to Penal Code section 1203.4 et seq., or an equivalent release from penalties and disabilities provision from a non-California jurisdiction, or (2) later dismissed or expunged pursuant to Penal Code section 1210 et seq., or an equivalent post-conviction drug treatment diversion dismissal provision from a non-California jurisdiction. Failure to answer truthfully and completely may result in the denial of your application.</p> <p>— NOTE: You may answer "NO" regarding, and need not disclose, any of the following: (1) criminal matters adjudicated in juvenile court; (2) criminal charges dismissed or expunged pursuant to Penal Code section 1000.4 or an equivalent deferred entry of judgment provision from a non-California jurisdiction; (3) convictions more than two years old on the date you submit your application for violations of California Health and Safety Code section 11357, subdivisions (b), (c), (d), or (e), or California Health and Safety Code section 11360, subdivision (b); and (4) infractions or traffic violations with a fine of less than \$500 that do not involve drugs or alcohol.</p> <p>— You may wish to provide the following information in order to assist in the processing of your application: descriptive explanation of the circumstances surrounding the conviction (i.e. dates and location of incident and all circumstances surrounding the incident). If documents were purged by the arresting agency and/or court, a letter of explanation from these agencies is required.</p> <p><u>You may wish to provide the following information in order to assist in the processing of your application: 1) certified copies of the arresting agency report; 2) certified copies of the court documents; 3) and a descriptive explanation of the circumstances surrounding the conviction (i.e. dates and location of incident and all circumstances surrounding the incident.) If documents were purged by the arresting agency and/or court, a letter of explanation from these agencies is required.</u></p> <p>— Failure to disclose a disciplinary action or conviction may result in the license being denied or revoked for falsifying the application. Attach additional sheets if necessary.</p> <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 10px;"> <thead> <tr style="background-color: #cccccc;"> <th style="width: 15%;">Arrest Date</th> <th style="width: 15%;">Conviction Date</th> <th style="width: 20%;">Violation(s)</th> <th style="width: 10%;">Case #</th> <th style="width: 40%;">Court of Jurisdiction (Full Name and Address)</th> </tr> </thead> <tbody> <tr> <td> </td> <td> </td> <td> </td> <td> </td> <td> </td> </tr> <tr> <td> </td> <td> </td> <td> </td> <td> </td> <td> </td> </tr> <tr> <td> </td> <td> </td> <td> </td> <td> </td> <td> </td> </tr> </tbody> </table>	Arrest Date	Conviction Date	Violation(s)	Case #	Court of Jurisdiction (Full Name and Address)																Yes <input type="checkbox"/> No <input type="checkbox"/>
Arrest Date	Conviction Date	Violation(s)	Case #	Court of Jurisdiction (Full Name and Address)																	

APPLICANTS MUST ANSWER THE FOLLOWING QUESTIONS.

<p>Ownership Information - For any affirmative answer, attach a statement of explanation including company name, type of license, license number, and identify the state, territory, foreign country, or other jurisdiction where licensed.</p> <p>1. <u>Are you currently or have you previously been listed as a corporate officer, partner, owner, manager, member, administrator, or medical director on a license to conduct a pharmacy, wholesaler, third-party logistics provider, or any other entity licensed in any state, territory, foreign country, or other jurisdiction?</u></p>	<p>1. Yes <input type="checkbox"/> No <input type="checkbox"/></p>
<p>Disciplinary History - The following questions pertain to a license sought or held in any state, territory, foreign country, or other jurisdiction. For any affirmative answer, attach a statement of explanation including type of license, license number, type of action, date of action, and identify the state, territory, foreign country, or other jurisdiction.</p> <p>2. <u>Have you ever had an application for pharmacy technician, intern pharmacist, pharmacist, any type of designated representative, and/or any other professional or vocational license or registration denied?</u></p> <p>3. <u>Have you ever had a pharmacy technician, intern pharmacist, pharmacist, any type of designated representative, and/or any other professional or vocational license or registration suspended, revoked, placed on probation, or had other disciplinary action taken against it?</u></p> <p>4. <u>Have you ever had a pharmacy, wholesaler, third-party logistics provider, and/or any other entity license denied, suspended, revoked, placed on probation, or had other disciplinary action taken?</u></p>	<p>2. Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>3. Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>4. Yes <input type="checkbox"/> No <input type="checkbox"/></p>
<p>Practice Impairment or Limitation <u>The board will make an individualized assessment of the nature, the severity, and the duration of the risks associated with any identified condition to determine whether an unrestricted license should be issued, whether conditions should be imposed, or whether the applicant is not qualified for licensure. If the board is unable to make a determination based on the information provided, the board may require an applicant to be examined by one or more physicians or psychologists, at the board's cost, to obtain an independent evaluation of whether the applicant is able to safely practice despite the mental illness or physical illness affecting competency. A copy of any independent evaluation would be provided to the applicant. For any affirmative answer, attach a statement of explanation.</u></p> <p>5. <u>Have you ever been diagnosed with an emotional, mental, or behavioral disorder that may impair your ability to practice safely?</u></p> <p>6. <u>Have you ever been diagnosed with a physical condition that may impair your ability to practice safely?</u></p> <p>7. <u>Do you have any other condition that may in any way impair or limit your ability to practice safely?</u></p> <p>8. <u>Have you ever participated in, been enrolled in, or required to enter into any drug, alcohol, or substance abuse recovery program?</u></p> <p>9. <u>If you answered "Yes" to questions 5 through 8 above, have you ever received treatment or participated in any program that improves your ability to practice safely?</u></p>	<p>5. Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>6. Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>7. Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>8. Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>9. Yes <input type="checkbox"/> No <input type="checkbox"/> ___ N/A <input type="checkbox"/></p>

Criminal Record History

Applicants who answer "No" to the questions below, but have a previous conviction or plea, may have their application denied for knowingly falsifying the application. If in doubt as to whether a conviction should be disclosed, it is best to disclose the conviction on the application.

For each conviction, you must submit with the application: 1) certified copies of the arresting agency records, 2) certified copies of the court documents (court docket), 3) a signed and dated descriptive explanation of the circumstances surrounding the conviction (i.e., dates and location of the incident and all circumstances surrounding the incident), and 4) proof of compliance with probation or parole. If the documents were purged by the arresting agency and/or court, a letter of explanation from these agencies is recommended. In addition, you may submit evidence of rehabilitation or any information you deem appropriate.

10. Have you EVER been convicted of, or pleaded guilty or nolo contendere/no contest to, ANY crime, in any state, the United States or its territories, a military court, or any foreign country?

10. Yes No

This includes any felony or misdemeanor offense and any infraction. You must disclose a conviction even if it was: (1) later dismissed or expunged pursuant to Penal Code section 1203.4 or an equivalent release from penalties and disabilities provision from a non-California jurisdiction, or (2) later dismissed or expunged pursuant to Penal Code section 1210.1 or an equivalent post-conviction drug treatment diversion dismissal provision from a non-California jurisdiction.

NOTE: You may answer "No" regarding, and need not disclose, any of the following: (1) criminal matters adjudicated in juvenile court; (2) criminal charges dismissed or expunged pursuant to Penal Code section 1000.4 or an equivalent deferred entry of judgment provision from a non-California jurisdiction; (3) convictions for violations of Health and Safety Code section 11357, subdivisions (b), (c), (d), or (e), or Health and Safety Code section 11360, subdivision (b), that are more than two years old on the date you sign your application; and (4) traffic violations that do not involve drugs or alcohol.

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

11. Is any criminal action pending against you, or are you currently awaiting judgement and sentencing following entry of a plea or jury verdict?

11. Yes No

<u>Arrest Date</u>	<u>Violation(s)</u>	<u>Case #</u>	<u>Court of Jurisdiction (Full Name and Address)</u>

APPLICANT AFFIDAVIT

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

All items of information requested in this application are mandatory. Failure to provide any of the requested information may result in the application being deemed rejected as incomplete, including failing to provide a statement of explanation for any affirmative answers. The board must receive your application within 60 days of your signature below.

Collection and Use of Personal Information. The California State Board of Pharmacy of the Department of Consumer Affairs collects the personal information requested on this form pursuant to Business and Professions Code sections 30 and 4000 and following and California Code of Regulations title 16, division 17. The California State Board of Pharmacy of the Department of Consumer Affairs collects the personal information requested on this form as authorized by Business and Professions Code sections 4200 and 4202 and Title 16 California Code of Regulations section 1793.5 and 1793.6. The California State Board of Pharmacy uses this information principally to identify and evaluate applicants for licensure, issue and renew licenses, and enforce licensing standards set by law and regulation.

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

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

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

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

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

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

NOTICE: The State Board of Equalization and the Franchise Tax Board may share taxpayer information with the board. You are obligated to pay your state tax obligation. This application may be denied or your license may be suspended if your state tax obligation is not paid.

MANDATORY REPORTER

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

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

APPLICANT AFFIDAVIT

~~(must be signed and dated by the applicant)~~ Must be signed and dated by the applicant. Must be received by the board within 60 days.

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

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

Original Signature of Applicant

Date



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

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

**AFFIDAVIT OF COMPLETED COURSEWORK OR GRADUATION
 FOR PHARMACY TECHNICIAN**

Instructions: ~~This form must be completed by the university, college, school, or pharmacist. The Director, Registrar, or Pharmacist must complete and sign this form certifying the identified individual has met the specified requirements in section 4202 of the Business and Professions Code and, if applicable, board regulations. (The person who must complete this form will depend on how the applicant is qualifying).~~ All dates must include the month, day, and year ~~in order~~ for the form to be accepted.

This is to certify that _____ has
Print Name of Applicant

- Completed a pharmacy technician training program accredited by the American Society of Health-System Pharmacists (ASHP) as specified in Title 16, California Code of Regulations section 1793.6(a) on ____/____/____
(completion date must be included)
- Completed a training course that provided at least 240 hours of instruction as specified in Title 16, California Code of Regulations section 1793.6(c) on ____/____/____
(completion date must be included)
- Completed an Associate Degree in Pharmacy Technology and was conferred on her/him on ____/____/____
(graduation date must be included)
- Graduated from a school of pharmacy accredited or granted candidate status by the ~~American Council on Pharmaceutical Education Accreditation Council for Pharmacy Education (ACPE)~~. The degree of Bachelor of Science in Pharmacy or the degree of PharmD was conferred on her/him on ____/____/____
(graduation date must be included)

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

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

<p style="text-align: center;">Affix school seal here.</p> <p style="text-align: center; margin-top: 20px;">OR</p> <p style="text-align: center; margin-top: 20px;">Attach a business card of the pharmacist who provided the training pursuant to section 1793.6(c) of Title 16, of the California Code of Regulations here. The pharmacist's license number shall be listed.</p>	<p>Name of Pharmacy Technician Training Program <u>University, College,</u> or School of Pharmacy Name: _____</p> <p>Address: _____ _____</p> <p>Print Name of Director, Registrar, or Pharmacist: _____</p> <p>Phone Number: _____</p> <p>Email: _____</p>
---	---

**Pharmacy Ownership,
Management, and
Control, Including
Through Trusts
16 CCR § 1709**

**Title 16. Board of Pharmacy
Proposed Text**

To Amend Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1709. Names of Owners and Pharmacist In Charge Disclosure and Notification Requirements

- (a) Each ~~permit~~ license issued by the board to operate a pharmacy shall reflect ~~show~~ the name and address of the pharmacy, the form of ownership (~~individual, partnership or corporation~~) and the pharmacist-in-charge. Each pharmacy shall, in its initial application and on the annual renewal form, report the name of the pharmacist-in-charge, the names of all owners and the names of the corporate officers (if a corporation). Any changes in the pharmacist-in-charge, or the owners, or corporate officers shall be reported to the ~~B~~board within 30 days.
- (b) Any transfer, in a single transaction or in a series of transactions, of 10 percent or more of the beneficial interest in a business entity licensed by the board to a person or entity who did not hold a beneficial interest at the time the original ~~permit~~ license was issued, shall require written notification to the board within 30 days.
- (c) A license issued by the board shall not be transferred from one owner to another. The following shall constitute a change of ownership transfer of permit and shall require a new application for a change of ownership licensure:
- (1) any transfer of a beneficial interest in a business entity licensed by the board, in a single transaction or in a series of transactions, to any person or entity, which transfer results in the transferee's holding 50% or more of the beneficial interest in that license. A change of ownership application shall be filed with the board in advance of the proposed transaction taking place.
- (d) If any beneficial interest of the pharmacy is held in trust, the applicant, licensee, or any person with management or control of the pharmacy, shall do the following:
- (1) In addition to the requirements in subdivision (a), as part of their application and annual renewal, report the name of any other person in any position with management or control of the pharmacy.
- (2) As part of the application, disclose the full name of the trust, and provide to the board a complete copy of, and any amendments to the trust document. A trust document and any related amendments shall be considered confidential financial documents by the board.

(3) As part of the renewal, provide to the board a complete copy of any amendments to the trust document made after submission of the original application.

(4) Include in the application and the annual renewal, the name, address and contact information for each grantor, settlor, trustee, and trust protector, as applicable.

(5) The application and annual renewal shall also include the name, address, and contact information for each named beneficiary of the trust, who is age 18 or older.

(6) Notify the board in writing within 30 days of all the following:

(A) A change in trustee, protector or any other person with management or control of the pharmacy.

(B) Any change in the beneficiaries of the trust, where the beneficiary is age 18 or older.

(C) The revocation of the trust.

(D) The dissolution of the trust.

(E) Any amendment to the trust since the original application.

(F) Any change in the character of the trust, including, but not limited to, the trust changing from revocable to irrevocable.

(e) An application may be denied, or a license may be suspended or revoked based on the failure of any individual required to be disclosed to the board to qualify pursuant to the provisions of sections 4302, 4307 and 4308 of the Business and Professions Code.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4035, 4058, 4110, 4111, 4112, 4113, 4120, 4124, 4130, 4133, 4141, 4149, 4160, 4161, 4196, 4201, 4302, 4304, 4305, 4307, 4308, and 4330, Business and Professions Code.

**Third-Party Logistics
Providers and
Dangerous Drug
Distributors
16 CCR §§ 1780-1783**

Title 16. Board of Pharmacy

Proposed Language

To Amend Article 10 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

Article 10. ~~Wholesalers~~ Dangerous Drug Distributors

To Amend Section 1780 of Article 10 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1780. Minimum Standards for Wholesalers and Third-Party Logistics Providers.

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

- (a) A wholesaler and a third-party logistics provider shall store dangerous drugs in a secured and lockable area.
- (b) All wholesaler and third-party logistics provider premises, fixtures and equipment therein shall be maintained in a clean and orderly condition. Wholesale and third-party logistics provider premises shall be well ventilated, free from rodents and insects, and adequately lighted. Plumbing shall be in good repair. Temperature and humidity monitoring shall be conducted to assure compliance with the standards set forth in the latest edition of the United States Pharmacopeia-Standards (1990, 22nd Revision).
- (c) Entry into areas where prescription drugs are held shall be limited to authorized personnel.
 - (1) All facilities shall be equipped with an alarm system to detect entry after hours.
 - (2) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.
 - (3) The outside perimeter of the ~~wholesaler~~ premises shall be well-lighted.
- (d) All materials must be examined upon receipt and ~~or~~ before shipment.
 - (1) Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated prescription drugs or prescription drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.
 - (2) Each outgoing shipment shall be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have been damaged in storage or held under improper conditions.
- (e) The following procedures must be followed for handling returned, damaged and outdated prescription drugs.
 - (1) Prescription drugs that are outdated, damaged, deteriorated, misbranded or adulterated shall be placed in a quarantine area and physically separated from other drugs until they are destroyed or returned to their supplier.
 - (2) Any prescription drugs whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be placed in a quarantine area and physically separated from other prescription drugs until they are either destroyed or returned to the supplier.

- (3) If the conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality or purity, the drug shall be destroyed or returned to the supplier unless testing or other investigation proves that the drug meets the standards set forth in the latest edition of the appropriate United States Pharmacopeia-Standards (1990, 22nd Revision).
- (f) Policies and procedures must be written and made available upon request by the board.
- (1) ~~Each W wholesaler and third-party logistics provider drug distributors~~ shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory and distribution of prescription drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, for correcting all errors and inaccuracies in inventories, and for maintaining records to document proper storage.
 - (2) The records required by paragraph (1) shall be in accordance with Title 21, Code of Federal Regulations, Section 205.50(g). These records shall be maintained for three years after disposition of the drugs.
 - (3) ~~Each W wholesaler and third-party logistics provider drug distributors~~ shall establish and maintain lists of officers, directors, managers and other persons in charge of ~~wholesale~~ drug distribution, storage and handling, including a description of their duties and a summary of their qualifications.
 - (4) Each wholesaler ~~and third-party logistics provider~~ shall provide adequate training and experience to assure compliance with licensing requirements by all personnel.
- (g) The board shall require an applicant for a licensed premise or for renewal of that license to certify that it meets the requirements of this section at the time of licensure or renewal.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4025, 4043, 4045, 4051, 4053, 4053.1, 4054, 4059, 4120, 4160, 4161, 4161.5 and 4304, and 4342 of the Business and Professions Code; Sections 109985 and 111280 of the Health and Safety Code; Section 321 of Title 21, U.S. Code; and Section 205.50 of Title 21, Code of Federal Regulations.

To Amend Section 1781 of Article 10 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1781. Exemption Certificate Pharmacist or Designated Representative on Premises and In Control.

- (a) A registered pharmacist, or a designated representative certified in accordance with Section 4053 ~~or 4054~~ of the Business and Professions Code, shall be present and in control of a manufacturer's, or wholesaler's licensed premises during the conduct of business.
- (b) A designated representative – 3PL certified in accordance with Section 4053.1 of the Business and Professions Code, shall be present and in control of a third-party logistics provider's licensed premises during the conduct of business.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4022.5, 4022.7, 4053, 4053.1, 4160, and 4161 ~~4054~~, Business and Professions Code.

To Amend Section 1782 of Article 10 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1782. Reporting Sales of Drugs Subject to Abuse.

~~All~~ Each manufacturer, and wholesaler, and third-party logistics provider shall report to the Board or its designee, up to twelve (12) times a year, all sales of dangerous drugs subject to abuse as designated by the Board for reporting, in excess of amounts to be determined by the Board from time to time. Reports shall be made within thirty (30) days of the request in the form specified by the Board.

Note: Authority cited: Section 4005, Business and Professions Code; ~~and Section 26692, Health and Safety Code.~~ Reference: Sections 4053.1, 4081, 4164, 4165, and 4332, Business and Professions Code; ~~and Section 26692, Health and Safety Code.~~

To Amend Section 1786 of Article 10 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1783. Manufacturer, ~~or Wholesaler,~~ or Third-Party Logistics Provider Furnishing Drugs and Devices.

- (a) A manufacturer, ~~or wholesaler,~~ or third-party logistics provider shall furnish dangerous drugs or devices only to an authorized person; prior to furnishing dangerous drugs and devices to a person not known to the furnisher, the manufacturer, ~~or wholesaler,~~ or third-party logistics provider shall contact the board or, if the person is licensed or registered by another government entity, that entity, to confirm the recipient is an authorized person.
- (b) “Authorized person” means a person to whom the board has issued a permit which enables the permit holder to purchase dangerous drugs or devices for use within the scope of its permit. “Authorized person” also means any person in this state or in another jurisdiction within the United States to the extent such furnishing is authorized by the law of this state, any applicable federal law, and the law of the jurisdiction in which that person is located. The manufacturer, ~~or wholesaler,~~ or third-party logistics provider furnishing to such person shall, prior to furnishing the dangerous drugs and devices, establish the intended recipient is legally authorized to receive the dangerous drugs or devices.
- (c) Dangerous drugs or devices furnished by a manufacturer, ~~or wholesaler,~~ or third-party logistics provider shall be delivered only to the premises listed on the permit; provided that a manufacturer, ~~or wholesaler,~~ or third-party logistics provider may furnish drugs to an authorized person or an agent of that person at the premises of the manufacturer, ~~or wholesaler,~~ or third-party logistics provider if (1) the identity and authorization of the recipient is properly established and (2) this method of receipt is employed only to meet the immediate needs of a particular patient of the authorized person. Dangerous drugs or devices may be furnished to a hospital pharmacy receiving area provided that a pharmacist or authorized receiving personnel signs, at the time of delivery, a receipt showing the type and quantity of the dangerous drugs or devices so received. Any discrepancy between the receipt and the type and quantity of dangerous drugs and devices actually received shall be reported to the delivering manufacturer, ~~or wholesaler,~~ or third-party logistics provider by the next business day after the delivery to the pharmacy receiving area.
- (d) A manufacturer, ~~or wholesaler,~~ or third-party logistics provider shall not accept payment for or allow the use of an entity’s credit to establish an account for the purchase of dangerous

drugs or devices from any person other than: (1) the owner(s) of record, chief executive officer, or chief financial officer listed on the ~~p~~ermit 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.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4025, 4043, 4053.1, 4059, 4059.5, 4080, 4081, 4105, 4120, 4160, 4161, 4163, 4165 and 4304, Business and Professions Code; and Section 11209, Health and Safety Code.

Offsite Storage

16 CCR § 1707

**Title 16. Board of Pharmacy
Proposed Text**

Proposal to Amend § 1707 in Article 2 of Division 17 of Title 16 of the California Code of Regulations to read:

§ 1707. Waiver Requirements for Off-Site Storage of Records

(a) Pursuant to subdivision (e) of Section 4105 of the Business and Professions Code and subdivision (c) of Section 4333 of the Business and Professions Code, a waiver ~~shall~~ may, on a case-by-case basis, be granted to any entity licensed by the board for ~~off-site~~ storage of the records outside the licensed area of the pharmacy described in subdivisions (a), (b) and (c) of Section 4105 of the Business and Professions Code ~~unless the applicant has, within the preceding five years, failed to produce records pursuant to Section 4081 of the Business and Professions Code or has falsified records covered by Section 4081 of the Business and Professions Code.~~

(b) An entity that is granted a waiver pursuant to subdivision (a) shall:

(1) maintain the storage area so that the records are secure, including from unauthorized access; and
(2) be able to produce the records within two business days upon the request of the board or an authorized officer of the law.

(c) In the event that a licensee fails to comply with the conditions set forth in subdivision (b), the board may cancel the waiver without a hearing. Upon notification by the board of cancellation of the waiver, the licensee shall maintain all records at the licensed premises.

(d) A licensee whose waiver has been cancelled pursuant to the provisions set forth in subsection (c) may reapply to the board when compliance with the conditions set forth in subsection (b) can be confirmed by the board.

(e) Notwithstanding any waiver granted pursuant to subdivision (a), all prescription records for non controlled substances shall be maintained on the licensed premises for a period of one year from the date of dispensing.

(f) Notwithstanding any waiver granted pursuant to subdivision (a), all prescription records for controlled substances shall be maintained on the licensed premises for a period of two years from the date of dispensing.

(g) Notwithstanding the requirements of this section, any entity licensed by the board may store the records described in subdivisions (a), (b) and (c) of Section 4105 of the Business and Professions Code in a storage area at the same address or adjoining the licensed premises without obtaining a waiver from the board if the following conditions are met:

(1) The records are readily accessible to the pharmacist-in-charge (or other pharmacist on duty, or designated representative) and upon request to the board or any authorized officer of the law.

(2) The storage area is maintained so that the records are secure and so that the confidentiality of any patient-related information is maintained.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4081, 4105 and 4333, Business and Professions Code.

Automatic Refill Programs

16 CCR § 1717.5

Title 16. BOARD OF PHARMACY
Proposed Text

Proposal to add § 1717.5 in Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1717.5. Automatic Refill Programs.

- (a) A pharmacy may offer a program to automatically refill prescription medications provided the pharmacy complies with this section.
- (1) Written notice regarding the program shall be given to the patient or patient's agent. Such notice shall include instructions about how to withdraw a prescription medication from the program.
 - (2) The patient or patient's agent shall enroll by written, online or electronic consent to participate in the program.
 - (3) The pharmacy shall keep a copy of the written consent to enroll on file for one year from date of dispensing.
 - (4) The pharmacy shall have written policies and procedures in place that outline specifics of the program. The policies and procedures shall specify the medications that may be refilled through the program.
 - (5) The patient or patient's agent shall have the option to withdraw from the program at any time.
 - (6) The pharmacy shall complete a drug regimen review for each prescription refilled through the program.
 - (7) Each time a prescription is refilled through the program, the pharmacy shall provide a written notification to the patient or patient's agent confirming that the prescription medication is enrolled in the program.
 - (8) The pharmacy shall provide a full refund to the patient, patient's agent, or payer for any prescription medication in the program reported as unneeded or unnecessary, if the pharmacy had been notified of withdrawal or disenrollment from the program.
 - (9) A pharmacy shall make available any written notification required by this section in alternate languages as required by state or federal law.
- (b) A health care facility licensed pursuant to Health and Safety Code section 1250 that automatically refills prescription medications for its patients need not comply with the provisions of this section.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4001.1, 4005, 4063 and 4076.6, Business and Professions Code and Section 1250, Health and Safety Code.

Naloxone Fact Sheet

16 CCR § 1746.3

BOARD OF PHARMACY

Proposal to amend § 1746.3 in Article 5 of Division 17 of Title 16 of the California Code of Regulations to read:

§ 1746.3. Protocol for Pharmacists Furnishing Naloxone Hydrochloride.

A pharmacist furnishing naloxone hydrochloride pursuant to section 4052.01 of the Business and Professions Code shall satisfy the requirements of this section.

(a) As used in this section:

(1) "Opioid" means naturally derived opiates as well as synthetic and semi-synthetic opioids.

(2) "Recipient" means the person to whom naloxone hydrochloride is furnished.

(b) Training. Prior to furnishing naloxone hydrochloride, pharmacists who use this protocol must have successfully completed a minimum of one hour of an approved continuing education program specific to the use of naloxone hydrochloride in all routes of administration recognized in subsection (c)(4) of this protocol, or an equivalent curriculum-based training program completed in a board recognized school of pharmacy.

(c) Protocol for Pharmacists Furnishing Naloxone Hydrochloride.
Before providing naloxone hydrochloride, the pharmacist shall:

(1) Screen the potential recipient by asking the following questions:

(A) Whether the potential recipient currently uses or has a history of using illicit or prescription opioids. (If the recipient answers yes, the pharmacist may skip screening question B.);

(B) Whether the potential recipient is in contact with anyone who uses or has a history of using illicit or prescription opioids. (If the recipient answers yes, the pharmacist may continue.);

(C) Whether the person to whom the naloxone hydrochloride would be administered has a known hypersensitivity to naloxone. (If the recipient answers yes, the pharmacist may not provide naloxone. If the recipient responds no, the pharmacist may continue.)

The screening questions shall be made available on the Board of Pharmacy's website in alternate languages for patients whose primary language is not English.

(2) Provide the recipient training in opioid overdose prevention, recognition, response, and administration of the antidote naloxone.

(3) When naloxone hydrochloride is furnished:

(A) The pharmacist shall provide the recipient with appropriate counseling and information on the product furnished, including dosing, effectiveness, adverse effects, storage conditions, shelf-life, and safety. The recipient is not permitted to waive the required consultation.

(B) The pharmacist shall provide the recipient with any informational resources on hand and/or referrals to appropriate resources if the recipient indicates interest in addiction treatment, recovery services, or medication disposal resources at this time.

(C) The pharmacist shall answer any questions the recipient may have regarding naloxone hydrochloride.

(4) Product Selection: A pharmacist shall advise the recipient on how to choose the route of administration based on the formulation available, how well it can likely be administered, the setting, and local context. A pharmacist may supply naloxone hydrochloride as an intramuscular injection, intranasal spray, auto-injector or in another FDA-approved product form. A pharmacist may also recommend optional items when appropriate, including alcohol pads, rescue breathing masks, and rubber gloves.

(5) Labeling: A pharmacist shall label the naloxone hydrochloride consistent with law and regulations. Labels shall include an expiration date for the naloxone hydrochloride furnished. An example of appropriate labeling is available on the Board of Pharmacy's website.

(6) Fact Sheet: The pharmacist shall provide the recipient a copy of the current naloxone fact sheet approved by the Board of Pharmacy or a fact sheet approved by the executive officer. The executive officer may only approve a fact sheet that has all the elements and information that are contained in the current board-approved fact sheet. ~~This~~ The board-approved fact sheet shall be made available on the Board of Pharmacy's website in alternate languages for patients whose primary language is not English. Fact sheets in alternate languages must be the current naloxone fact sheet approved by the Board of Pharmacy.

(7) Notifications: If the recipient of the naloxone hydrochloride is also the person to whom the naloxone hydrochloride would be administered, then the naloxone recipient is considered a patient for purposes of this protocol and notification may be required under this section.

If the patient gives verbal or written consent, then the pharmacist shall notify the patient's primary care provider of any drug(s) and/or device(s) furnished, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by the patient and that primary care provider.

If the patient does not have a primary care provider, or chooses not to give notification consent, then the pharmacist shall provide a written record of the drug(s) and/or device(s) furnished and advise the patient to consult an appropriate health care provider of the patient's choice.

(8) Documentation: Each naloxone hydrochloride product furnished by a pharmacist pursuant to this protocol shall be documented in a medication record for the naloxone recipient, and securely stored within the originating pharmacy or health care facility for a period of at least three years from the date of dispense. The medication record shall be maintained in an automated data or manual record mode such that the required information under title 16, sections 1707.1 and 1717 of the California Code of Regulations is readily retrievable during the pharmacy or facility's normal operating hours.

(9) Privacy: All pharmacists furnishing naloxone hydrochloride in a pharmacy or health care facility shall operate under the pharmacy or facility's policies and procedures to ensure that recipient confidentiality and privacy are maintained.

Note: Authority cited: Section 4052.01, Business and Professions Code. Reference: Section 4052.01, Business and Professions Code.

Self-Assessment Forms

16 CCR § 1715

17M – 13

17M – 14

**Title 16. Board of Pharmacy
Proposed Regulation**

Proposal to amend §1715 of Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 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) A pharmacist-in-charge of a community pharmacy shall use the the components of this assessment shall be on Form 17M-13 (Rev. 10/14 16) entitled "Community Pharmacy Self-Assessment/Hospital Outpatient Pharmacy Self-Assessment." Form 17M-13 shall be used for all pharmacies serving retail or outpatient consumers. A pharmacist-in-charge of a hospital pharmacy serving inpatient consumers, shall use the components of this assessment and on Form 17M-14 (Rev. 10/14 16) entitled "Hospital Pharmacy Self-Assessment." ~~which are Both forms are~~ hereby incorporated by reference ~~to evaluate compliance with federal and state laws and regulations.~~

(1) The pharmacist-in-charge shall provide identifying information about the pharmacy including

(A) Name and license number of the pharmacy

- (B) Address, phone number, and website address, if applicable, of the pharmacy
- (C) DEA registration number, expiration date and date of most recent DEA inventory
- (D) Hours of operation of the pharmacy

(2) The pharmacist-in-charge shall list the name of each licensed staff person working in the pharmacy, the person's license type and number, and the expiration date for each license.

(3) The pharmacist-in-charge shall respond "yes", "no" or "not applicable" (N/A) about whether the pharmacy is, at the time of the self-assessment, in compliance with each of the requirements that apply to that pharmacy setting.

(4) For each "no" response, the pharmacist-in-charge shall provide a written corrective action or action plan to come into compliance with the law.

(5) The pharmacist-in-charge shall initial each page of the self-assessment form.

(6) The pharmacist-in-charge shall provide a certification on the final page of the self-assessment that affirms he or she has completed the self-assessment of the pharmacy of which he or she is the pharmacist-in-charge. The certification shall also provide a timeframe within which any deficiency identified within the self-assessment will be corrected and that all responses are subject to verification by the Board of Pharmacy. The certification shall be made under penalty of perjury of the laws of the State of California that the information provided in the self-assessment form is true and correct.

(7) The pharmacy owner or hospital administrator shall provide a certification on the final page of the self-assessment that affirms that he or she has read and reviewed the completed self-assessment and that failure to correct any deficiency identified in the self-assessment could result in the revocation of the pharmacy's license issued by the board. This certification shall be made under penalty of perjury of the laws of the State of California.

(d) Each self-assessment shall be completed in its entirety and kept on file in the pharmacy for three years after it is performed.

(e) Any identified areas of noncompliance shall be corrected as specified in the certification.

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference:
Sections 4019, 4021, 4022, 4029, 4030, 4036, 4037, 4038, 4040, 4050, 4051, 4052, 4059, 4070,
4081, 4101, 4105, 4110, 4113, 4115, 4119, 4120, 4127, 4201, 4301, 4305, 4330, 4332 and 4333,
Business and Professions Code.



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

Notes: If a hospital pharmacy dispenses prescriptions for outpatient use, this Hospital Outpatient Pharmacy Self-Assessment must be completed in addition to the Hospital Pharmacy Self-Assessment (17M-14 Rev. ~~10/14~~ 10/16). Any pharmacy that compounds drug products must also complete the Compounding Self-Assessment (17M-39 Rev. 02/12).

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

Pharmacy Name: _____

Address: _____ Phone: _____

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

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

Licensed Sterile Compounding Permit License# _____ Expiration: _____

Accredited by (optional): _____ From: _____ To: _____

DEA Registration #: _____ Exp. Date: _____ Date of DEA Inventory: _____

Hours: Weekdays _____ Sat. _____ Sun. _____ 24 Hours _____

PIC: _____ RPH # _____ Exp. Date: _____

Website address (optional): _____

Pharmacy Staff (pharmacists, intern pharmacists, pharmacy technicians):

Please use an additional sheet if necessary. APP APH=Advanced Practice Pharmacist, DEA =Drug Enforcement Administration.

- 1. _____ RPH # _____ Exp. Date: _____
APP APH# _____ Exp. Date: _____
DEA # _____ Exp. Date: _____
- 2. _____ RPH # _____ Exp. Date: _____
APP APH # _____ Exp. Date: _____
DEA # _____ Exp. Date: _____
- 3. _____ RPH # _____ Exp. Date: _____
APP APH # _____ Exp. Date: _____
DEA # _____ Exp. Date: _____
- 4. _____ RPH # _____ Exp. Date: _____
APP APH # _____ Exp. Date: _____
DEA # _____ Exp. Date: _____
- 5. _____ RPH # _____ Exp. Date: _____
APP APH # _____ Exp. Date: _____
DEA # _____ Exp. Date: _____
- 6. _____ INT # _____ Exp. Date: _____
- 7. _____ INT # _____ Exp. Date: _____
- 8. _____ INT # _____ Exp. Date: _____
- 9. _____ TCH # _____ Exp. Date: _____
- 10. _____ TCH # _____ Exp. Date: _____
- 11. _____ TCH # _____ Exp. Date: _____

**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, properly lighted and free from rodents and insects. (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. <u>A pharmacy may also or instead display the notice on a video screen in lieu of the poster.</u> Additional “Notice to Consumers” in languages other than English may also be posted. (B&PC 4122, CCR 1707.2 <u>1707.6</u>) |
| <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | <u>1.8. “Point to Your Language” poster is posted or provided in a place conspicuous to and readable by a prescription drug consumer or adjacent to each counter in a pharmacy where drugs are dispensed. (CCR 1707.6[c])</u> |
| <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | 1.8 <u>1.9.</u> 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 <u>1.10.</u> The original board-issued pharmacy license and the current renewal are posted where they may be clearly read by the purchasing public. (B&PC 4032, 4058) |

~~1.10~~ 1.11. Does the pharmacy compound sterile drugs? (If yes, complete section 27 – “Compounding.”)

Yes No N/A

~~1.11~~ 1.12. The pharmacy has procedures in place to take action to protect the public when a licensed individual employed by or with the pharmacy is discovered or known to be chemically, mentally, or physically impaired to the extent it affects his or her ability to practice the profession or occupation authorized by his or her license, or is discovered or known to have engaged in the theft, diversion, or self-use of dangerous drugs. (B&PC 4104[a])

~~1.12~~ 1.13. The pharmacy has written policies and procedures for addressing chemical, mental, or physical impairment, as well as theft, diversion, or self-use of dangerous drugs, among licensed individual employed by or with the pharmacy. (B&PC 4104[b])

~~1.13~~ 1.14. The pharmacy reports to the board within 14 days of the receipt or development of the following information with regard to any licensed individual employed by or with the pharmacy: (1) any admission by a licensed individual of chemical, mental, or physical impairment affecting his or her ability to practice; (2) Any admission by a licensed individual of theft, diversion, or self-use of dangerous drugs; (3) Any video or documentary evidence demonstrating chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice; (4) Any video or documentary evidence demonstrating theft, diversion, or self-use of dangerous drugs by a licensed individual; (5) Any termination based on chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice; (6) Any termination of a licensed individual based on theft, diversion, or self-use of dangerous drugs. (B&PC 4104[c])

~~1.14~~ 1.15. The pharmacy is subscribed to the board’s e-mail notifications. (B&PC 4013)

Date Last Notification Received: _____

E-mail address registered with the board: _____

~~1.15~~ 1.16. For a pharmacy whose owner owns two or more pharmacies, the pharmacy receives the board’s e-mail notifications through the owner’s electronic notice system. (B&PC 4013[c])

Date Last Notification Received: _____

E-mail address registered with the board: _____

CORRECTIVE ACTION OR ACTION PLAN: _____

2. Delivery of Drugs

Yes No N/A

2.1. Dangerous drugs and dangerous devices are only delivered to the licensed premises, and signed for and received by a pharmacist. (B&PC 4059.5[a], H&SC 1120{[a]})

2.2. A pharmacy may take delivery of dangerous drugs and dangerous devices when the pharmacy is closed and no pharmacist is on duty if all of the following requirements are met: (B&PC 4059.5[f]):

- 2.2.1. The drugs are placed in a secure storage facility in the same building as the pharmacy (B&PC 4059.5[f][1]);
- 2.2.2. Only the pharmacist-in-charge or a pharmacist designated by the pharmacist-in-charge has access to the secure storage facility after dangerous drugs or dangerous devices have been delivered (B&PC 4059.5[f][2]);
- 2.2.3. The secure storage facility has a means of indicating whether it has been entered after dangerous drugs or dangerous devices have been delivered (B&PC 4059.5[f][3]);
- 2.2.4. The pharmacy maintains written policies and procedures for the delivery of dangerous drugs and dangerous devices to a secure storage facility (B&PC 4059.5[f][4]); and
- 2.2.5. The agent delivering dangerous drugs and dangerous devices pursuant to this subdivision leaves documents indicating the name and amount of each dangerous drug or dangerous device delivered in the secure storage facility. The pharmacy shall be responsible for the dangerous drugs and dangerous devices delivered to the secure storage facility. The pharmacy shall also be responsible for obtaining and maintaining records relating to the delivery of dangerous drugs and dangerous devices to a secure storage facility. B&PC 4059.5[f][5]

2.3 Prior to, or at the time of, accepting ownership of a product included in the Drug Supply Chain Security Act from an authorized trading partner, the pharmacy is provided transaction history, transaction information, and a transaction statement. (21 USC 360eee-1[d][A][i])

2.4 Prior to, or at the time of, each transaction in which the pharmacy transfers ownership of a product included in the Drug Supply Chain Security Act to an authorized trading partner, the subsequent owner is provided transaction history, transaction information, and a transaction statement for the product. This requirement does not apply to sales by a pharmacy to another pharmacy to fulfill a specific patient need. (21 USC 360eee-1[d][A][ii])

2.5 The pharmacy captures transaction information (including lot level information, if provided), transaction history, and transaction statements, as necessary to investigate a suspect product, and maintains such information, history, and statements for not less than 6 years after the transaction. (21 USC 360eee-1[d][A][iii])

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 [donate drugs] or Section 30 [operate program] of this Self-Assessment.)

5. Pharmacist-in-Charge (PIC)

Yes No N/A

5.1. The pharmacy has a PIC that is responsible for the daily operation of the pharmacy. (B&PC 4101, 4113, 4305, 4330, CCR 1709, 1709.1)

5.2. The PIC has adequate authority to assure the pharmacy's compliance with laws governing the operation of a pharmacy. (BPC 4113[c], CCR 1709.1[b])

5.3. The PIC has completed a biennial pharmacy self-assessment before July 1 of each odd numbered year. An additional self-assessment will be completed within 30 days if a new permit is issued or a new PIC employed. Each self-assessment will be maintained in the pharmacy for three years. (CCR 1715)

5.4. Is the PIC in charge of another pharmacy?

5.5. If yes, are the pharmacies within 50 driving miles of each other? (CCR 1709.1[c])

Name of the other pharmacy _____

5.6. Any change of PIC is reported by the pharmacy and the departing PIC to the board in writing within 30 days. (B&PC 4101, 4113)

~~5.7. Is the PIC serving concurrently as the designated representative in charge for a wholesaler or veterinary food animal retailer? (CCR 1709.1[d])~~

~~If yes, name the wholesaler or veterinary food animal retailer. _____~~

~~5.8-5.7.~~ The PIC is responsible for directing and overseeing the performance of waived clinical laboratory tests, if the pharmacy holds a registration from CDPH to conduct such tests. (H&SC 1206, 1265)

CORRECTIVE ACTION OR ACTION PLAN: _____

6. Duties of a Pharmacist

Yes No N/A

6.1. The pharmacist furnishes a reasonable quantity of compounded drug products to a prescriber office for office use by the prescriber; transmits a valid prescription to another pharmacist; administers drugs and biological products ordered by the prescriber; manufactures, measures, fits to the patient or sells and repairs dangerous devices or furnishes instructions to the patient or patient representative concerning the use of the dangerous devices; provides consultation, training and education to patients about drug therapy disease management and disease prevention; provides professional information and participates in multidiscipline review of patient progress; furnishes medication including emergency contraception drug therapy and self-administered hormonal contraceptives, nicotine replacement products, prescription medication not requiring a diagnosis recommended by the Centers for Disease Control when traveling outside of the US; administers immunizations pursuant to a protocol; orders and interprets tests for monitoring and managing efficacy and toxicity of drug therapies. (B&PC 4052)

Only a pharmacist:

- . transmits a valid prescription to another pharmacist; (B&PC 4052[a][2])
- administers drugs and biological products ordered by the prescriber; (B&PC 4052[a][3])
- 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; (B&PC 4052[a][7])
- provides consultation, training and education to patients about drug therapy disease management and disease prevention; (B&PC 4052[a][8])
- provides professional information and participates in multidiscipline review of patient progress; (B&PC 4052[a][9])
- furnishes medication including emergency contraception drug therapy, self-administered hormonal contraceptives, nicotine replacement products, naloxone, or prescription medication not requiring a diagnosis recommended by the Centers for Disease Control when traveling outside of the US; administers immunizations pursuant to a protocol; (B&PC 4052 [a][10], B&PC 4052[a][11], B&PC 4052.01, B&PC 4052.3, B&PC 4052.8, B&PC 4052.9)
- dispenses aid-in-dying drugs; (H&SC 443.5 [b][2]) or
- orders and interprets tests for monitoring and managing efficacy and toxicity of drug therapies (B&PC 4052 [a][12]).

6.2. ~~The pharmacist receives a new prescription order from the prescriber, consults with the patient, identifies, evaluates and interprets a prescription, interprets the clinical data in a patient medication record, consults with any prescriber, nurse, health professional or agent thereof, supervises the packaging of drugs, checks the packaging procedure and product upon completion, is responsible for all activities of pharmacy technicians to ensure that all such activities are performed completely, safely and without risk of harm to patients, performs any other duty which federal or state law or regulation authorizes only a registered pharmacist to perform and performs all functions which require professional judgment. (CCR 1707.2, 1793.1, B&PC 4052, 4052.1, 4052.2, 4052.3, 4052.4, 4070(a))~~

Only a pharmacist:

- receives a new prescription order from the prescriber; (BP&C 4070 [a]), CCR 1793.1 [a])
- consults with the patient; (BP&C 4052 [a][8], CCR 1707.2, CCR 1793.1[b])
- identifies, evaluates and interprets a prescription; (CCR 1793.1 [c])
- interprets the clinical data in a patient medication record; (CCR 1793.1 [d])
- consults with any prescriber, nurse, health professional or agent thereof; (CCR 1793.1 [e])
- supervises the packaging of drugs; (CCR 1793.1 [f])
- checks the packaging procedure and product upon completion; (CCR 1793.1 [f])
- 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; (CCR 1793.7 [e]) or
- 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, 4052.1, 4052.2, 4052.3, 4052.4, CCR 1793.1 [g])

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 have obtained approval to access information on the Internet that is maintained by the California Department of Justice regarding controlled substance history of a patient who is under the care of the pharmacy based on data obtained through the CURES Prescription Drug Monitoring Program (PDMP). (H&SC 11165.1)~~

6.5. The pharmacist dispenses emergency contraceptive pursuant to the statewide protocol found in 16 CCR 1746.

6.6. Only a pharmacist performs blood glucose, hemoglobin A1c, or cholesterol tests that are waived under CLIA. (No CDPH registration required.) (B&PC 1206.6)

Yes No N/A

6.7. Only a pharmacist performs CLIA waived clinical laboratory tests, where the pharmacy is registered with CDPH to perform such services. (B&PC 1206.6)

CDPH (CLIA) Registration #: _____ Expiration: _____

6.8. The pharmacist who is authorized to issue an order to initiate or adjust a controlled substance therapy is personally registered with the federal Drug Enforcement Administration. (B&PC 4052[b])

CORRECTIVE ACTION OR ACTION PLAN: _____

7. Duties of an Advance Practice Pharmacist

Yes No N/A

~~7.1. The pharmacist who is authorized to issue an order to initiate or adjust a controlled substance therapy is personally registered with the federal Drug Enforcement Administration. (B&PC 4052[b])~~

7.2 7.1. The advance practice pharmacist has received an advance practice pharmacist recognition license by from the board and may do the following: (B&PC 4016.5, 4210)

- ~~7.2.1~~ 7.1.1 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~~ 7.1.2 Participate in the evaluation and management of diseases and health conditions in collaboration with other health care providers; (B&PC 4052.6[a])
- ~~7.2.2~~ 7.1.3 Initiate drug therapy and promptly transmit written notification to, or enter the appropriate information in to a patient record system shared with the patient's primary care provider or diagnosing provider; (B&PC 4052.6[b])
- ~~7.2.2~~ 7.1.4 Adjust or discontinue drug therapy and promptly transmit written notification to the patient's diagnosing prescriber or enters the appropriate information in a patient's record system shared with the prescriber; (B&PC 4052.6[b])
- ~~7.2.2~~ 7.1.5 Prior to initiating or adjusting a controlled substance therapy, the advance practice pharmacist is personally registered with the federal Drug Enforcement Administration; (B&PC 4052.6[d])
- ~~7.2.2~~ 7.1.6 Ordering of tests is done in coordination with the patient's primary care provider or diagnosing prescriber, including promptly transmitting written notification to the prescriber or entering information in a patient record system shared with the prescriber. (B&PC 4052.6[e])

8. Duties of an Intern Pharmacist

Yes No N/A

8.1. The intern pharmacist may perform all the functions of a pharmacist only under the direct supervision of a pharmacist. A pharmacist may supervise **two interns** at any one time. (B&PC 4114, 4023.5, CCR 1726)

Yes No N/A

8.2. All prescriptions filled or refilled by an intern are, prior to dispensing, checked for accuracy by a licensed pharmacist and the prescription label initialed by the checking pharmacist. (CCR 1717[b][1], CCR 1712)

8.3. The intern hours affidavits are signed by the pharmacist under whom the experience was earned, when applicable. (B&PC 4209[b], [c], [d], 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: _____

9. Duties of a Pharmacy Technician

Yes No N/A

9.1. ~~Registered p~~Pharmacy technicians ~~are performing only perform~~ packaging, manipulative, repetitive, or other nondiscretionary tasks, while assisting and under the direct supervision and control of a pharmacist. (B&PC 4023.5, 4038, 4115, CCR 1793, 1793.2, 1793.7)

9.2. Pharmacy technician ratio when only one pharmacist is present, is no more than one technician. For each additional pharmacist present, the ratio may not exceed 2 technicians for each additional pharmacist. (B&PC 4038, 4115, CCR 1793.7[f])

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

9.4. The pharmacy has a job description for the pharmacy technician and written policies and procedures to ensure compliance with technician requirements. (CCR 1793.7[e])

9.5. A pharmacy technician trainee participating in an externship may perform packaging, manipulative, repetitive or other nondiscretionary tasks only under the direct supervision and control of a pharmacist; a pharmacist may only supervise one technician trainee and only for a period of no more than 120 hours. (B&PC 4115.5)

CORRECTIVE ACTION OR ACTION PLAN: _____

10. Duties of Non-Licensed Personnel

Yes No N/A

10.1. A non-licensed person (clerk/typist) is permitted to type a prescription label or otherwise enter prescription information into a computer record system, and—at the direction of a pharmacist—may request and receive refill authorization. (CCR 1793.3)

10.2. The number of non-licensed personnel supervised by each pharmacist does not interfere with the effective performance of the pharmacist’s responsibilities under the Pharmacy Law. (CCR 1793.3[b])

CORRECTIVE ACTION OR ACTION PLAN: _____

PHARMACY PRACTICE

11. Consultation/Patient Profile/Review of Drug Therapy

Yes No N/A

11.1. Pharmacists provide oral consultation: (~~B&PC 4052[a][7]~~, BPC 4052[a][8], CCR 1707.2):

- 11.1.1. whenever the prescription drug has not been previously dispensed to the patient;
- 11.1.2. whenever a refill prescription drug is dispensed in a different dosage form, strength, or with new written directions;
- 11.1.3. upon request; and
- 11.1.4. whenever the pharmacist deems it is warranted in the exercise of his or her professional judgment.
- 11.1.5. unless a patient or patient’s agent declines the consultation directly to the pharmacist.

11.2. The pharmacy maintains patient profile information including allergies, date of birth or age, gender and other prescription and nonprescription drugs that the patient takes. (CCR 1707.1)

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

11.4. Consultation is performed in a manner that protects the patient’s protected health care information and in an area suitable for confidential patient consultation. (Civil Code 56.10, CCR 1714[a])

- 11.5. Appropriate drug warnings are provided orally or in writing. (B&PC 4074, CCR 1744)
- 11.6. If prescription medication is mailed or delivered, written notice about the availability of consultation is provided. (CCR 1707.2[b][2])

CORRECTIVE ACTION OR ACTION PLAN: _____

12. Prescription Requirements

Yes No N/A

- 12.1. Prescriptions are complete with all the required information. (B&PC 4040, 4070)
- 12.2. Orally transmitted prescriptions are received and reduced to writing only by a pharmacist or intern pharmacist working under the direct supervision of a pharmacist. (B&PC 4070, CCR 1717)
- 12.3. If a prescription is orally or electronically transmitted by the prescriber’s agent, the pharmacist makes a reasonable attempt to verify that the prescriber’s agent is authorized to do so, and the agent’s name is recorded. (B&PC 4071)
- 12.4. If orally transmitted, the pharmacist who received the prescription is identified by initialing the prescription, and if dispensed by another pharmacist, the dispensing pharmacist also initials the prescription. (CCR 1717, 1712)
- 12.5. The security and confidentiality of electronically transmitted prescriptions are maintained. (B&PC 4070[c], CCR 1717.4[h])
- 12.6. Facsimile prescriptions are received only from a prescriber’s office. (B&PC 4040[c])
- 12.7. Internet prescriptions patients (human or animal) in this state are only dispensed or furnished pursuant to a prior good faith examination. (B&PC 4067[a])
- 12.8. With the exception of those prescriptions written under H&SC 11159.2 and H&SC 11167.5, all written controlled substances prescriptions (Schedules II – V) are on California Security Prescription forms. (H&SC 11164[a], H&SC 11167.5)
- 12.9. All controlled substance prescriptions are valid for six months and are signed and dated by the prescriber. (H&SC 11164[a][1], 11166)
- 12.10. All controlled substance prescriptions that are e-prescribed conform to provisions of federal law. (21 CFR 1306.08, 1306.11, 1311.100)

CORRECTIVE ACTION OR ACTION PLAN: _____

13. Prescription Labeling, Furnishing and Dispensing

Yes No N/A

- 13.1. The prescription label contains all the required information. (B&PC 4076)
- 13.2. The prescription label is formatted in accordance with CCR 1707.5.
- ~~13.3. If requested by the consumer, the pharmacy provides the consumer with a prescription label that is printed in 12 point typeface. (CCR 1707.5[a])~~

Yes No N/A

- ~~13.4. The label on a drug container dispensed to a patient in California conforms to the following format: (CCR 1707.5[a])~~
- ~~13.4.1 The name of the patient, name of the drug and strength of the drug, the directions for use of the drug, the condition or purpose for which the drug was prescribed, if indicated on the prescription, are clustered into one area of the label and comprise at least 50 percent of the label.~~
 - ~~13.4.2 The label is highlighted in bold typeface or color or uses blank space to set off the items in 13.4.1; (CCR 1707.5[a][2])~~
 - ~~13.4.3 When applicable, standardized directions for use are utilized. (CCR 1707.5[a][4])~~
- ~~13.5. The pharmacy is exempt from the prescription label requirements in CCR 1707.5.~~
- ~~Exemption approved by board from: _____ to _____~~
- 13.63. The expiration dates of a drug's effectiveness is accurately identified on the label are consistent with those of the manufacturer if the information is required on the original manufacturer's label. (B&PC 4076)
- 13.74. The trade name or generic name and manufacturer of the prescription drug is accurately identified on the label and prescription record. (B&PC 4076, CCR 1717[b][2])
- 13.85. Generic substitution is communicated to the patient. (B&PC 4073)
- 13.96. If the prescription is filled by a pharmacy technician, before dispensing the prescription is checked for accuracy by a licensed pharmacist and that pharmacist initials the prescription label or as otherwise allowed for those filled by a pharmacy technician trainee. (B&PC 4115, 4115.5, CCR 1793.7, CCR 1712)
- 13.107. The federal warning label prohibiting transfer of controlled substances is on the prescription container. (21 CFR 290.5)

- 13.118. Prescriptions are dispensed in a new and child-resistant container, or senior-adult ease-of-opening tested container, or in a non-complying package only pursuant to the prescriber or when requested by the purchaser. (15 USC 1473[b], 16 CFR 1700.15, CCR 1717)
- 13.129. Patient package inserts are dispensed with all estrogen medications. (21 CFR 310.515)
- 13.1310. The pharmacy provides patients with Black Box Warning Information in conformance with 21 CFR 201.57[c].
- 13.11. Medication guides are provided on required medications. (21 CFR, Part 208, Section 208.24[e])
- 13.1412. 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 receive drugs, or to another pharmacy of common ownership.
- 13.1513. The label includes a physical description of the dispensed medication, including its color, shape, and any identification code that appears on the tablets or capsules. (B&PC 4076)
- Yes No N/A
 13.1614. Controlled substance prescriptions are not filled or refilled more than six months from the date written. (H&SC 11200[a])
- 13.15. Refills for Schedule III and IV controlled substance prescriptions are limited to a maximum of 5 times and an amount, for all refills of that prescription taken together, exceeding a 120 day supply. (H&SC 11200[b])
- 13.17 16. The pharmacy dispenses not more than a 90-day supply of a dangerous drug with the following exceptions (other than controlled substances, or psychotropic medication or drugs): (B&PC 4064.5)
- Controlled substances
 - Psychotropic medications
 - Self-administered hormonal contraception

- 13. ~~1716~~.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. ~~1716~~.1.1 The prescriber has not indicated “no change to quantity” or words of similar meaning; (B&PC 4064.5[d])
 - 13. ~~1716~~.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. ~~1716~~.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. ~~1716~~.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. ~~1716~~.1.5. The pharmacist is exercising his or her professional judgment. (B&PC 4064.5[a][4])
- 13. ~~1716~~.2. The pharmacist notifies the prescriber of the increase in quantity dispensed. (B&PC 4064.5[c])

13. ~~1817~~. The pharmacist includes a written label on the drug container indicating that the drug may impair a person’s ability to operate a vehicle or vessel. The label may be printed on an auxiliary label affixed to the prescription container. (B&PC 4074[b], CCR 1744)

CORRECTIVE ACTION OR ACTION PLAN: _____

14. Refill Authorization

Yes No N/A

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

14.2. Refills are documented. (CCR 1717)

14.3. Prescriptions for dangerous drugs or devices are filled without the prescriber's authorization if the prescriber is unavailable to authorize the refill and if, in the pharmacist's professional judgment, failure to refill the prescription might interrupt the patient’s ongoing care and have a significant adverse effect on the patient’s well-being. (B&PC 4064)

14.4. Refills for Schedule II controlled substances are prohibited. (H&SC 11200)

Yes No N/A

~~14.5. Refills for Schedule III and IV controlled substance prescriptions are limited to a maximum of 5 times within 6 months, and all refills taken together do not exceed a 120 day supply. (H&SC 11200)~~

CORRECTIVE ACTION OR ACTION PLAN: _____

15. Quality Assurance and Medication Errors

Yes No N/A

- 15.1. Pharmacy has established quality assurance program that documents medication errors attributable, in whole or in part, to the pharmacy or its personnel. (B&PC 4125, CCR 1711)
- 15.2. Pharmacy quality assurance policies and procedures are maintained in the pharmacy and are immediately retrievable. (CCR 1711[c])
- 15.3. The pharmacist communicates with the patient or patient’s agent that a medication error has occurred and the steps required to avoid injury or mitigate the error. (CCR 1711[c][2][A], 1711[c][3])
- 15.4. When a medication error has occurred (drug was administered to or by the patient, or resulted in a clinically significant delay in therapy) the pharmacist communicates to the prescriber that a medication error has occurred. (CCR 1711[c][2][B], 1711[c][3])
- 15.5. Investigation of pharmacy medication errors is initiated within two business days from the date the medication error is discovered. (CCR 1711[d])
- 15.6. The record for quality assurance review for a medication error contains: (CCR 1711[e])
 - 15.6.1. Date, location, and participants in the quality assurance review;
 - 15.6.2. Pertinent data and other information related to the medication error(s) reviewed;
 - 15.6.3. Findings and determinations; and
 - 15.6.4. Recommended changes to pharmacy policy, procedure, systems or processes, if any.
- 15.7. The record of the quality assurance review is immediately retrievable in the pharmacy and is maintained in the pharmacy for at least one year from the date it was created. (CCR 1711[f])
- 15.8. Pharmacists are not deviating from the requirements of a prescription except upon the prior consent of the prescriber, and selection of the drug product is in accordance with B&PC 4073 (generic substitution). (CCR 1716)

CORRECTIVE ACTION OR ACTION PLAN: _____

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

Yes No N/A

16.1. Before dispensing a prescription that contains any significant error, omission, irregularity, uncertainty, ambiguity or alteration, the pharmacist contacts the prescriber to obtain information needed to validate the prescription. (CCR 1761[a])

16.2. Pharmacists are aware of their corresponding responsibility to determine that a prescription written for a controlled substance was issued for legitimate medical purposes only. (H&SC 11153)

16.3. Even after conferring with the prescriber, the pharmacist does not dispense a controlled substance prescription if he or she knows or has objective reason to know that the prescription was not issued for a legitimate medical purpose. (CCR 1761[b], HSC 11153)

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

16.5 4. Internet prescriptions for controlled substances are only dispensed if in compliance with the Ryan Haight Online Pharmacy Consumer Protection Act of 2008. (21 USC 829, 21 USC 802.)

~~16.6. All pharmacists have obtained approval to access information online regarding the controlled substance history of a patient that is stored on the Internet and maintained by the California Department of Justice (HSC 11165.1[a][1][A][i])~~

CORRECTIVE ACTION OR ACTION PLAN: _____

17. Prescription Transfer

Yes No N/A

17.1. Only pharmacists may transfer prescriptions from pharmacy to pharmacy, and records of prescription transfers are kept as required. (CCR 1717 [e][1-6])

17.2. Complete and accurate transfer records are kept on each prescription and refill when dispensed by pharmacies sharing a common electronic file. (CCR 1717.1)

a. Schedule III, IV and V Controlled Substance Prescription Transfers

17.3. For the **transferring pharmacy**: the prescription hard copy is pulled and “void” is written on its face. The name of the pharmacy to which the prescription is transferred is written on the back of the voided prescription and all other information is recorded as required. The prescription can be transferred only once unless the pharmacies electronically share a real-time, on-line database, in which case the prescription is transferred up to the maximum refills permitted by law and the prescriber’s authorization. (CFR 1306.25, CCR 1717[f])

Yes No N/A

17.4. For the **receiving pharmacy**: the prescription is reduced to writing by the pharmacist and “transfer” is written on the face of the transferred prescription and all other information is recorded as required. (CCR 1717[e], CFR 1306.25)

CORRECTIVE ACTION OR ACTION PLAN: _____

18. Confidentiality of Prescriptions

Yes No N/A

18.1. Patient information is maintained to safeguard confidentiality. (Civil Code 56.10 et seq.)

18.2. All prescriptions are kept confidential and only disclosed as authorized by law. (CCR 1764)

18.3. The pharmacy ensures electronically transmitted prescriptions are received, maintained and transmitted in a secure and confidential manner. (CCR 1717.4[h])

18.4. If electronically transmitted prescriptions are received by an interim storage device (to allow for retrieval at a later time), the pharmacy maintains the interim storage device in a manner to prevent unauthorized access. (CCR 1717.4[d])

18.5. If pharmacy has established and utilizes common electronic prescription files to maintain required dispensing information, the system shall not permit disclosure of confidential medical information except as authorized by law. (CCR 1717.1)

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

CORRECTIVE ACTION OR ACTION PLAN: _____

19. Record Keeping Requirements

Yes No N/A

19.1. A All completed ~~biennial~~ pharmacy self -assessments is are on file in the pharmacy and maintained for three years. (CCR 1715)

19.2. All drug acquisition and disposition records (complete accountability) are maintained for at least three years. These records include (B&PC 4081, 4105, 4333):

19.2.1. Prescription records (B&PC 4081[a])

19.2.2. Purchase Invoices for all prescription drugs (B&PC 4081[b])

- 19.2.3. Biennial controlled substances inventory (21 CFR 1304.11, CCR 1718)
- 19.2.4. U.S. Official Order Forms (DEA Form 222) (21 CFR 1305.13)
- 19.2.5. Power of Attorney for completion of DEA 222 forms (21 CFR 1305.07)
- 19.2.6. Theft and Loss Reports (DEA Form 106) (21 CFR 1301.74[c])
- 19.2.7. Record documenting return of drugs to wholesaler or manufacturer (B&PC 4081)
- 19.2.8. Record documenting transfers or sales to other pharmacies, licensees and prescribers (B&PC 4081, 4105, CCR 1718)

Yes No N/A

19.3. Hypodermic needle and syringe sales by a pharmacist to a person without a prescription are limited to: (B&PC 4145.5)

- 19.3.1. Persons known to the pharmacist and when the pharmacist has previously been provided with a prescription or other proof of legitimate medical need;
- 19.3.2. Use on animals, provided the person is known to the pharmacist or the person's identity can be properly established.
- 19.3.3. The sale of hypodermic needles or syringes at any one time to a person 18 or older **only** if the pharmacy is registered in their local county or city with the Disease Prevention Demonstration Project, and complies with the requirements of that project. (H&S 11364, B&PC 4145.5)
- 19.3.4. For industrial use, as determined by the board. (B&PC 4144.5)
- 19.3.5. As a public health measure intended to prevent the transmission of HIV, viral hepatitis, and other bloodborne diseases, furnishing of ~~30 or fewer~~ hypodermic needles and syringes for human use to a person 18 years of age or older for personal use. (B&PC 4145.5)

19.4. When hypodermic needles and syringes are furnished by a pharmacy ~~or hypodermic needle and exchange program~~ without a prescription, the pharmacy provides the consumer with written information or verbal counseling on how to access drug treatment, testing and treatment for HIV and hepatitis C and safe disposal of sharps waste; and provide one or more of the following disposal options: (B&PC 4145.5[e],[f])

- 19.4.1. Onsite, safe, hypodermic needle and syringe collection and disposal program.
- 19.4.2. Furnish or make available mail-back sharps containers.
- 19.4.3. Furnish or make available sharps containers.

19.5. Records stored off-site (only for pharmacies who have obtained a waiver from the Board of Pharmacy to store records off-site) are secure and retrievable within two business days. Records for non-controlled substances are maintained on the licensed premises for at least one year from the date of dispensing. Controlled substances are maintained on the licensed premises for at least two years from the date of dispensing. (CCR 1707, B&PC 4105)

Date Waiver Approved _____ Waiver Number _____

Address of offsite storage location: _____

19.6. The pharmacy ~~dispenses~~ furnishes an epinephrine auto-injector to an authorized entity a prehospital emergency medical care person or lay rescuer for the purpose of rendering emergency care in accordance with H&SC 1797.197a. (B&PC 4119.3, 4119.4)

- 19.6.1. An ~~physician/surgeon~~ authorized healthcare provider provides a written order that specifies the quantity of epinephrine auto-injectors to be dispensed. (B&PC 4119.3[a][1], 4119.4[a][2])
- 19.6.2. The pharmacy labels each epinephrine auto-injector with the name of the person to whom the prescription was issued, the designation "Section 1797.197a responder" and "First Aid Purposes Only", the dosage, use and expiration date. (B&PC 4119.3[a][1], 4119.4[b])
- 19.6.3. Each dispensed prescription includes the manufacturer's product information sheet for epinephrine auto-injectors. (B&PC 4119.3[a][2], 4119.4[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

20. DEA Controlled Substances Inventory

- Inventory:
- Yes No N/A
- 20.1. Is completed biennially (every two years).
Date completed: _____ (21 CFR 1304.11[b])
 - 20.2. Schedule II inventory is separate from Schedule III, IV and V. (21 CFR 1304.04[h][1], 1304.04[h][2])
 - 20.3. All completed inventories are ~~is~~ available for inspection for three years. (CCR 1718)
 - 20.4. Indicates on the inventory record whether the inventory was taken at the "open of business" or at the "close of business." (21 CFR 1304.11[a])
 - 20.5. Separate Schedule II records are maintained. This includes Schedule II prescriptions, invoices, US official order forms, and inventory records. (21 CFR 1304.04[h])
 - 20.6. Schedule III-V prescriptions are filed separately from all prescription records or are designated with a red "C." However, the red C requirement is waived if the pharmacy uses an automated data processing or other record keeping system for identification of controlled substances by prescription number and the original prescription documents can be retrieved promptly. (21 CFR 1304.04[h][2])
 - 20.7. Inventories and records for Schedule III-V controlled substances are filed separately or are designated in some manner that makes the required information readily retrievable from ordinary business records. (21 CFR 1304.04)

- 20.8. U.S. Official Order Form (DEA Form222) or electronic equivalent (CSOS) is utilized when ordering all schedule II controlled substances. When schedule II controlled substance orders are received by the pharmacy, for each item received, the date and quantity received is indicated on the DEA Form222. (21 CFR 1305.03, 1305.12)
- 20.9. When a pharmacy distributes schedule II controlled substances to a DEA registrant (pharmacies, wholesales, manufacturers, prescribers) a DEA Form222 is prepared by the purchasing registrant and provided to the pharmacy selling the schedule II controlled substances. (21 CFR 1305.12)
- ~~Yes No N/A~~
- 20.10. When the pharmacy distributes Schedule II controlled substances to other DEA registrants, such as those listed above, Copy 2 of the DEA Form222, is properly completed by the pharmacy selling the controlled substances and that copy is submitted at the end of each month to the DEA regional office. (21 CFR 1305.13)
- 20.11. Sales of controlled substances to other pharmacies or prescribers do not exceed five percent of the total number of controlled substances dosage units dispensed per calendar year; otherwise a wholesaler registration is obtained from DEA and from the board. (21 CFR 1307.11[b], ~~Prescription Drug Marketing Act of 1987 [Pub. L. 100-293, Apr. 22, 1988] 503. Drug Supply Chain Security Act. B&PC 4160~~)
- 20.12. When dispensed upon an “oral” order for a true emergency, a Schedule II prescription is provided by the prescriber by the 7th day following the transmission of the oral order. If not received, the pharmacy reports failure to provide prescription document to the California Bureau of Narcotic Enforcement within 144 hours of the failure to provide prescription. (H&SC 11167[d])
- 20.13. The pharmacy generates a controlled substance printout for refills of Schedule III-V prescriptions at least every three days (72 hours) which contains the signature of the dispensing pharmacist, or the pharmacy maintains an alternate system to document the refilling of controlled substance prescriptions that complies with 21 CFR 1306.22.
- 20.14. Any controlled substances drug loss is reported upon discovery to the DEA and within 30 days of discovery to the Board of Pharmacy. (21 CFR 1301.74[c], CCR 1715.6)
- 20.15. Do pharmacy staff hand initial prescription records or prescription labels, or
- 20.16. Does the pharmacy comply with the requirement for a pharmacist to initial or sign a prescription record or prescription label by recording the identity of the reviewing pharmacist in a computer system by a secure means. This computer does not permit the record to be altered after made and the record of the pharmacist’s identity made in the computer system is immediately retrievable in the pharmacy. (CCR 1712, 1717[b][1])
- 20.17. All Schedule II through IV controlled substance dispensing data is successfully transmitted to CURES weekly. (H&SC 11165[d])

20.18. When furnishing controlled substances for physician office use, a prescription is not issued in order for an individual practitioner to obtain controlled substances for supplying the practitioner's general dispensing to patients. (21 CFR 1306.04[b])

CORRECTIVE ACTION OR ACTION PLAN: _____

21. Inventory Reconciliation Report of Controlled Substances

Yes No N/A

21.1. The pharmacy performs periodic inventory and inventory reconciliation functions to detect and prevent the loss of controlled substances. (CCR 1715.65 [a])

21.2. The pharmacist-in-charge of the pharmacy reviews all inventory and inventory reconciliation reports taken, and establishes and maintains secure methods to prevent losses of controlled drugs. Written policies and procedures are developed for performing the inventory reconciliation reports required by pharmacy law. (CCR 1715.65 [b])

21.3. A pharmacy compiles an inventory reconciliation report of all federal Schedule II controlled substances at least every three months. This compilation shall require: (CCR 1715.65 [c])

21.3.1. A physical count, not an estimate, of all quantities of federal Schedule II controlled substances. The biennial inventory of controlled substances required by federal law may serve as one of the mandated inventories under this section in the year where the federal biennial inventory is performed, provided the biennial inventory was taken no more than three months from the last inventory required by this section; (CCR 1715.65[c][1])

21.3.2. A review of all acquisitions and dispositions of federal Schedule II controlled substances since the last inventory reconciliation report; (CCR 1715.65[c][2])

21.3.3. A comparison of the two above-mentioned items to determine if there are any variances; (CCR 1715.65[c][3])

21.3.4. All records used to compile each inventory reconciliation report shall be maintained in the pharmacy or clinic for at least three years in a readily retrievable form; and (CCR 1715.65[c][4])

21.3.5. Possible causes of overages shall be identified in writing and incorporated into the inventory reconciliation report. (CCR 1715.65[c][5])

21.4. The pharmacy reports in writing identified losses and known causes to the board within 30 days of discovery unless the cause of the loss is theft, diversion, or self-use in which case the report shall be made within 14 days of discovery. If the pharmacy is unable to identify the cause of the loss, further investigation is undertaken to identify the cause and actions necessary to prevent additional losses of controlled substances. (CCR 1715.65 [d])

21.5. The inventory reconciliation report is dated and signed by the individual(s) performing the inventory, and countersigned by the pharmacist-in-charge and be readily retrievable in the pharmacy

for three years. A countersignature is not required if the pharmacist-in-charge personally completed the inventory reconciliation report. (CCR 1715.65 [e])

21.6. A new pharmacist-in-charge of the pharmacy completes an inventory reconciliation report as identified in CCR 1715.65 (c) within 30 days of becoming pharmacist-in-charge. When possible, the outgoing pharmacist-in-charge also completes an inventory reconciliation report as required in CCR 1715.65 (c). (CCR 1715.65 [f])

CORRECTIVE ACTION OR ACTION PLAN: _____

2122. Oral/Electronic Transmission and Fractionation of Schedule II Controlled Substance Prescriptions

Yes No N/A

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

212.2. An oral or electronically transmitted prescription for a Schedule II controlled substance for a patient in a licensed skilled nursing facility, licensed intermediate care facility, licensed home health agency or a licensed hospice care is dispensed only after the pharmacist has reduced the prescription to writing on a pharmacy-generated prescription form, and: (21 CFR 1306.11, 21 CFR 1306.11[f], H&SC 11167.5)

- 212.2.1. The licensed facility provides the pharmacy with a copy of the prescriber's signed order, when available.
- 212.2.2. The prescription is endorsed by the pharmacist with the pharmacy's name, license, and address.
- 212.2.3. The physician has signed the original prescription or provides a facsimile signature on the prescription.
- 212.2.4. 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)

212.3. 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])

- 212.4. 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)
- 22.5 The pharmacist maintains records of each partial filling (filled within 30 days from the date of prescription issuance) of an original prescription for a Schedule II controlled substance written when requested by the patient or practitioner. (21 USC 829[f])
- 212.56. 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)
- 212.67. 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)
- 212.78. 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])
- 212.89. 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
- 212.910. 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])
- 212.1011. 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)
- 212.1112. 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)
- 212.1213. 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: _____

223. Automated Dispensing/Delivery Devices

Yes No N/A

- 223.1. Does the pharmacy use an automated dispensing/delivery device and/or prescription drop box? (CCR 1713)
- 223.2. The pharmacy that owns or provides dangerous drugs dispensed through an automated drug delivery system has registered with the board all automated drug delivery systems that it operates in any location within 30 days of installation, removal, and at the time of renewal. (B&PC 4105.5[b])
- 223.3. The pharmacy has policies and procedures for security measures and monitoring of the inventory to prevent theft and diversion. (B&PC 4105.5[c][2])
- 223.4. The pharmacy reports drugs losses as required by law. (B&PC 4105.5[c][3])

- 223.25. The drugs in an automated dispensing unit are properly labeled and identified with at least the following information: name of drug, strength and dosage form, manufacturer and manufacturer’s lot number, and expiration date. (21 CFR Part 210, 211, B&PC 4342, 21 CFR Part 201.17, HSC 111355)
- 223.36. 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:
 - 223.36.1. 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])
 - 223.36.2. A pharmacist reviews the order and patient’s profile prior to the drug being removed. (H&SC 1261.6[e][2])
 - 223.36.3. Stocking of the automated drug delivery system is done by a pharmacist. (H&SC 1261.6[f])
- 223.47. 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:
 - 223.47.1. 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])
 - 223.47.2. 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: _____

234. Repackaging by the Pharmacy

Yes No N/A

- 234.1. Drugs are repackaged (precounted or poured) in quantities suitable for dispensing to patients of the pharmacy. Such repackaging is performed according to the Current Good Manufacturing Practice (CGMP), and the drugs are properly labeled with at least the following information: name of drug, strength, dosage form, manufacturer’s name and lot number, expiration date, and quantity per repackaged unit. (21 CFR Part 210, 211 [CGMP], B&PC 4342, H&SC 110105, 111430, CCR 1707.5)

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

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

CORRECTIVE ACTION OR ACTION PLAN: _____

245. Refill Pharmacy

Yes No N/A

- 245.1. Pharmacy processes refills for another California licensed pharmacy (CCR 1707.4[a])
If the answer is "yes", name the pharmacy or pharmacies _____

- 245.2. 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)

- 245.3. 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 2326.

- 245.4. Originating pharmacy and refill pharmacy have a contract outlining the refill arrangement, or the pharmacies have the same owner. (CCR 1707.4[a][1])

- 245.5. 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])

- 245.6. Patient is provided with written information, either on the prescription label or prescription container that describes which pharmacy to contact for questions. (CCR 1707.4[a][3])

Yes No N/A

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

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

245.9. 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: _____

26. Standards of Service for Providers of Blood Clotting Products for Home Use (HSC 125286.10)

Yes No N/A

256.1. The pharmacy is a provider of blood clotting products for home use. (HSC 125286.20)

256.1.1. Health system pharmacy. (HSC 125286.20[j][1][B])

256.1.2. Pharmacy affiliated with hemophilia treatment centers. (HSC 125286.20[j][1][C])

256.1.3. Specialty home care pharmacy. (HSC 125286.20[j][1][D])

256.1.4. Retail pharmacy. (HSC 125286.20[j][1][E])

256.2. The pharmacy meets the following requirements:

256.2.1. 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])

256.2.2. 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])

256.2.3. 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])

256.2.4. 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])

256.2.5. Supplies all necessary ancillary infusion equipment and supplies with each prescription, as needed. (HSC 125286.25[e])

256.2.6. 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])

- 256.2.7. 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])
- 256.2.8. 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])
- 256.2.9. 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])
- 256.2.10. 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])
- 256.2.11. Provides language interpretive services over the telephone or in person, as needed by the patient. (HSC 125286.25[k])
- 256.2.12. 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])

267. Policies and Procedures

Yes No N/A

267.1. There are written policies and procedures in place for:

- ~~26.1.1. The pharmacist's administration of immunizations by injection pursuant to a prescriber's order or state protocol for immunizations; (B&PC 4052.1[a][3])~~
- 267.1.21. Action to be taken to protect the public when a licensed individual employed by or with the pharmacy is known to be chemically, mentally, or physically impaired to the extent that it affects his or her ability to practice the profession or occupation authorized by his or her license, including the reporting to the board within 14 days of receipt or development; (B&PC 4104[a],[c])
- 267.1.32. 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])
- 267.1.43. 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])

- 267.1.54. 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])
- 267.1.65. 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])
- 267.1.76. 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])
- 267.1.87. Compliance with Title VII of Public Law 109-177 – Combat Methamphetamine Epidemic Act of 2005;
- 267.1.98. Reporting requirements to protect the public; (B&PC 4104)
- 267.1.109. Preventing the dispensing of a prescription drug that is contrary to the law; A policy to establish how a patient will receive a medication when a pharmacist has a conscientious objection. (B&PC 733)
- 267.1.1110. 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)
- 267.1.1211. 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

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

- 26.2.1. If yes, are there policies and procedures in place to prevent unauthorized disclosures? (CCR 1717.1)

267.3. Does your pharmacy furnish emergency contraceptives pursuant to B&PC 4052.3[a][1]? (B&PC 4052, CCR 1746) If yes, does the pharmacy

- 267.3.1. 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)
- 267.3.2. Provide the patient with a copy of the current EC Fact Sheet approved by the Board of Pharmacy? (CCR 1746)
- 267.3.3. 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)
- 267.3.4. Prior to furnishing EC, the pharmacist has completed a minimum of one hour of continuing education specific to emergency contraception. (CCR 1746)

- 267.3.5. 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)
- 267.3.6. 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])
- 267.3.7. 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)
- 267.3.8. 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)

267.4. Furnishes naloxone hydrochloride in accordance with standardized procedures or protocols developed and approved by both the Board of Pharmacy and the Medical Board of California. (B&PC 4052.01[a], CCR 1746.3)

- 267.4.1. 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.
- 267.4.2. 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.

27.5. Furnishes nicotine replacement products in accordance with standardized procedures or protocols developed and approved by both the Board of Pharmacy and the Medical Board of California. (B&PC 4052.9, CCR 1746.2)

27.6. Furnishes hormonal contraception products in accordance with standardized procedures or protocols developed and approved by both the Board of Pharmacy and the Medical Board of California. (B&PC 4052.3, CCR 1746.1)

CORRECTIVE ACTION OR ACTION PLAN: _____

278. Compounding

Yes No N/A

278.1. Prior to allowing any drug product to be compounded in a pharmacy, the pharmacist-in-charge must complete the "Compounding Self-Assessment" Form 17M-39 (Rev. 02/12) (CCR 1735.2[~~h~~][k])

289. Nuclear Pharmacy

Yes No N/A

289.1. All pharmacists handling radioactive drugs are competent in the preparation, handling, storage, receiving, dispensing, disposition and pharmacology of radioactive drugs. (CCR 1708.4)

289.2. 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)

289.3. The pharmacy possesses a current Sterile Compounding Permit (B&PC 4127) and is compliant with CCR 1751. (Must also complete Compounding Self-Assessment, 17M-39 Rev. 02/12.) (CCR 1735.2 et al.)

CORRECTIVE ACTION OR ACTION PLAN: _____

2930. Pharmacies That Donate Drugs to a Voluntary County-Approved Drug Repository and Distribution Program

Yes No N/A

2930.1. 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)

2930.1.1. The pharmacy is licensed by and is not on probation with the California State Board of Pharmacy, **and** (H&SC 150202.5)

2930.1.2. 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)

2930.2. 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)

2930.3. No controlled substances shall be donated. (H&SC 150204[c][1])

2930.4. Drugs that are donated are unused, unexpired and meet the following requirements: (H&SC 150202.5, 150204[c])

- 2930.4.1. 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])
- 2930.4.2. Were received directly from a manufacturer or wholesaler. (H&SC 150202.5[a])
- 2930.4.3. 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])
- 2930.4.4. Are in unopened, tamper-evident packaging or modified unit dose containers with lot numbers and expiration dates affixed. (H&SC 105204[d])
- 2930.4.5. 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])

301. Pharmacies That Operate a Voluntary County-Approved Drug Repository and Distribution Program

Yes No N/A

301.1. The pharmacy conducts a county-approved drug repository and distribution program. (H&SC 150201, 150204)

- 301.1.1. The pharmacy is licensed by and is not on probation with the California State Board of Pharmacy, **and:** (H&SC 150201[a][1])
 - 301.1.1.1 Is county owned (H&SC 150201[b][1]) or
 - 301.1.1.2 Contracts with the county to establish a voluntary drug repository and distribution program. (H&SC 150201[b][1], 150200)
- 301.1.2. 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

301.2. 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: _____

301.3. 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])

301.4. 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: _____

301.5. The pharmacy complies with the county's established written procedures. (H&SC 150204[b])

Drugs and Maintenance of Drug Stock

301.6. 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])

301.7. 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])

301.8. 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])

301.9. Donated medications received are unused, unexpired and meet the following requirements: (H&SC 150202, 150202.5, 150204[c])

- 301.9.1. Are received from authorized sources. (H&SC 150202, 150203)
- 301.9.2. No controlled substances are received. (H&SC 150204[c][1])
- 301.9.3. Are not adulterated, misbranded, or stored under conditions contrary to USP standards or the product manufacturer. (H&SC 150204[c][2])
- 301.9.4. 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])
- 301.9.5. Are received in unopened, tamper-evident packaging or modified unit dose containers with lot numbers and expiration dates affixed. (H&SC 150204[d])
- 301.9.6. Are maintained in the donated packaging until dispensed to an eligible patient under the program, who presents a valid prescription. (H&SC 150204[i])
- 301.9.7. 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

301.10. 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

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

301.12. 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:

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

301.14. 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])

301.15. 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

301.16. 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])

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

PHARMACIST-IN-CHARGE CERTIFICATION:

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

Signature _____ Date _____
(Pharmacist-in-Charge)

ACKNOWLEDGEMENT BY PHARMACY OWNER OR HOSPITAL ADMINISTRATOR:

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

Signature _____ Date _____

The following **Legal References** are used in the self-assessment form. Many of these references can be viewed on the Board of Pharmacy Web site at www.pharmacy.ca.gov (see *Laws and Regulations*), at the California State Law Library, or at other libraries or Internet web sites:

California Code of Regulations (CCR), Title 16 and Title 24

Business and Professions Code (B&PC), Chapter 9, Division 2

Health and Safety Code (H&SC), Division 10, Uniform Controlled Substances Act

California Code of Regulations (CCR), Chapter 1, Division 5, Title 22

Code of Federal Regulations (CFR), Title 21, Chapter II, Drug Enforcement Administration (www.dea.gov)

California Board of Pharmacy

1625 N. Market Blvd., Suite N219

Sacramento, CA 95834

Phone: (916) 574-7900

Fax: (916) 574-8618

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

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.dea.gov>

Online Registration — New Applicants:

http://www.dea.gov/onlineforms_new.htm

Online Registration — Renewal:

www.dea.gov/onlineforms.htm

Registration Changes (Forms):

http://www.dea.gov/change_requests/index.html

DEA Registration Support (all of CA):

(800) 882-9539

Online DEA 106 Theft/Loss Reporting:

<https://www.dea.gov/webforms/app106Login.jsp>

Online DEA 222 Controlled Substance Ordering

System (CSOS): <http://www.deaecom.gov/>

DEA — Fresno

2444 Main Street, Suite 240
 Fresno, CA 93721
 Registration: (888) 304-3251 or (415) 436-7900
 Diversion or Investigation: (559) 487-5406

DEA — Los Angeles

255 East Temple Street, 20th Floor
 Los Angeles, CA 90012
 Registration: (888) 415-9822 or (213) 621-6960
 Diversion or Investigation: (213) 621-6942

DEA — Oakland

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

DEA — Redding

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

DEA — Riverside

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

DEA — Sacramento

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

DEA — San Diego and Imperial Counties

4560 Viewridge Avenue
 San Diego, CA 92123-1637
 Registration: (800) 284-1152
 Diversion or Investigation: (858) 616-4100

DEA — San Francisco

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

DEA — San Jose

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

The following **Legal References** are used in the self-assessment form. Many of these references can be viewed on the Board of Pharmacy Web site at www.pharmacy.ca.gov (see *Laws and Regulations*), at the California State Law Library, or at other libraries or Internet web sites.

Business and Professions Code (BPC), Division 1, Chapter 1 – General Provisions

BPC, Division 2, Chapter 1 – General Provisions

BPC, Division 2, Chapter 3 – Clinical Laboratory Technology

BPC, Division 2, Chapter 9 – Pharmacy

California Code of Regulation (CCR), Title 16, Division 17 – California State Board of Pharmacy

Civil Code, Division 1, Part 2.6, Chapter 2 – Disclosure of Medical Information by Providers

Code of Federal Regulations (CFR), Title 16, Chapter II, Subchapter E, Part 1700 – Poison Prevention Packaging

CFR, Title 21, Chapter I, Subchapter C, Part 201, Subpart B – Labeling Requirements for Prescription Drugs and/or

Insulin

CFR, Title 21, Chapter I, Subchapter C, Part 208 – Medication Guides for Prescription Drug Products

CFR, Title 21, Chapter I, Subchapter C, Part 210 – Current Good Manufacturing Practice in Manufacturing,

Processing, Packaging, or Holding of Drugs; General

CFR, Title 21, Chapter I, Subchapter C, Part 211 – Current Good Manufacturing Practice for Finished

Pharmaceuticals

CFR, Title 21, Chapter I, Subchapter D, Part 310, Subpart E – Requirements for Specific New Drugs and Devices

CFR, Title 21, Chapter II - Drug Enforcement Administration, Department of Justice Combat Methamphetamine

Epidemic Act of 2005. Pub. L. 109-177. 120 Stat. 256.9 Mar. 2006

Health and Safety Code (HSC), Division 2, Chapter 1 – Licensing Provisions

HSC, Division 10 – Uniform Controlled Substances Act

HSC, Division 104, Part 5 (Sherman Food, Drug, and Cosmetics Law), Chapter 2 – Administration

HSC, Division 106, Part 5, Chapter 2 – Genetic Disease Services

HSC, Division 116 – Surplus Medication Collection and Distribution

United States Code (USC), Title 15, Chapter 39A – Special Packaging of Household Substances for Protection of

Children

USC, Title 21, Chapter 9, Subchapter V, Part H – Pharmaceutical Distribution Supply Chain (Drug Supply Chain

Security Act)

USC, Title 21, Chapter 13 – Drug Abuse Prevention and Control



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

Notes: If dispensing prescriptions for outpatient use, a Community Pharmacy Self-Assessment/Hospital Outpatient Pharmacy Self-Assessment (17M-13, Rev. 40/44 10/16) must be completed also. A hospital that compounds drug products must also complete the Compounding Self-Assessment (17M-39 Rev. 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 License #: _____ Exp. Date: _____ Other Permit License #: _____ Exp. Date: _____

Licensed Sterile Compounding Permit License # _____ Expiration: _____

Accredited by (optional): _____ From: _____ To: _____

Centralized Hospital Packaging#: _____ Exp. Date: _____

DEA Registration #: _____ Exp. Date: _____ Date of DEA Inventory: _____

Hours: Weekdays _____ Sat. _____ Sun. _____ 24 Hours _____

PIC: _____ RPH # _____ Exp. Date: _____

Pharmacy staff (pharmacists, interns, technicians):

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

- 1. _____ RPH # _____ Exp. Date: _____
APP APH# _____ Exp. Date: _____
DEA # _____ Exp. Date: _____
- 2. _____ RPH # _____ Exp. Date: _____
APP APH # _____ Exp. Date: _____
DEA # _____ Exp. Date: _____
- 3. _____ RPH # _____ Exp. Date: _____
APP APH # _____ Exp. Date: _____
DEA # _____ Exp. Date: _____
- 4. _____ RPH # _____ Exp. Date: _____
APP APH # _____ Exp. Date: _____
DEA # _____ Exp. Date: _____
- 5. _____ RPH # _____ Exp. Date: _____
APP APH # _____ Exp. Date: _____
DEA # _____ Exp. Date: _____
- 6. _____ RPH # _____ Exp. Date: _____
APP APH # _____ Exp. Date: _____
DEA # _____ Exp. Date: _____
- 7. _____ RPH # _____ Exp. Date: _____
APP APH # _____ Exp. Date: _____
DEA # _____ Exp. Date: _____
- 8. _____ RPH # _____ Exp. Date: _____
APP APH # _____ Exp. Date: _____
DEA # _____ Exp. Date: _____
- 9. _____ INT # _____ Exp. Date: _____
- 10. _____ INT # _____ Exp. Date: _____
- 11. _____ INT # _____ Exp. Date: _____
- 12. _____ INT # _____ Exp. Date: _____
- 13. _____ TCH # _____ Exp. Date: _____
- 14. _____ TCH # _____ Exp. Date: _____
- 15. _____ TCH # _____ Exp. Date: _____
- 16. _____ TCH # _____ Exp. Date: _____

HOSPITAL PHARMACY SELF-ASSESSMENT

All references to the California Code of Regulations (CCR) are Title 16 unless otherwise noted.

Please mark the appropriate box for each question. If “NO,” enter an explanation on “CORRECTIVE ACTION or ACTION PLAN” lines below. If more space is needed, you may add additional sheets.

1. Pharmacy

Yes No N/A

- 1.1. The pharmacy is secure and has provisions for effective control against the theft of dangerous drugs and devices. (B&PC 4116, 4117, CCR 1714)
- 1.2. The pharmacy has procedures in place to take action to protect the public when a licensed individual employed by or with the pharmacy is discovered or known to be chemically, mentally, or physically impaired to the extent it affects his or her ability to practice the profession or occupation authorized by his or her license, or is discovered or known to have engaged in the theft, diversion, or self-use of dangerous drugs. (B&PC 4104[a])
- 1.3. The pharmacy has written policies and procedures for addressing chemical, mental, or physical impairment, as well as theft, diversion, or self-use of dangerous drugs, among licensed individual employed by or with the pharmacy. (B&PC 4104[b])
- 1.4. The pharmacy reports to the board within 14 days of the receipt or development of the following information with regard to any licensed individual employed by or with the pharmacy: (1) any admission by a licensed individual of chemical, mental, or physical impairment affecting his or her ability to practice; (2) Any admission by a licensed individual of theft, diversion, or self-use of dangerous drugs; (3) Any video or documentary evidence demonstrating chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice; (4) Any video or documentary evidence demonstrating theft, diversion, or self-use of dangerous drugs by a licensed individual; (5) Any termination based on chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice; (6) Any termination of a licensed individual based on theft, diversion, or self-use of dangerous drugs. (B&PC 4104[c])
- 1.5. The pharmacy maintains “night stock” medications which are accessible without entering the pharmacy during hours when the pharmacy is closed, and the pharmacist is not available. Access is limited to designated registered nurses. (22 CCR 70263[n])
- 1.6. The pharmacy is of sufficient size and has an unobstructed area to accommodate the safe practice of pharmacy. (CCR 1714)
- 1.7. The pharmacy premises, fixtures, and equipment are maintained in a clean and orderly condition. (CCR 1714)
- 1.8. The pharmacy sink has hot and cold running water. (CCR 1714)
- 1.9. The pharmacy has a readily accessible restroom. (CCR 1714)

Yes No N/A

1.10. The original board-issued pharmacy license and the current renewal are posted where they may be clearly read by the purchasing public. (B&PC 4032, 4058)

1.11. Pharmacists, interns, pharmacy technicians, and pharmacy technician trainees wear nametags, in 18-point type, that contain their name and license status. (B&PC 680, B&PC 4115.5[e], CCR 1793.7[c])

1.12. Does the pharmacy compound sterile drugs?
(If yes, complete section 27—"Compounding") (If yes, complete Compounding Self-Assessment Form 17M-39, Rev. 10/12)

1.13. The pharmacy is subscribed to the board's e-mail notifications. (B&PC 4013)

Date Last Notification Received: _____

E-mail address registered with the board: _____

1.14. For a pharmacy whose owner owns two or more pharmacies, the pharmacy receives the board's e-mail notifications through the owner's electronic notice system. (B&PC 4013[c])

Date Last Notification Received: _____

E-mail address registered with the board: _____

CORRECTIVE ACTION OR ACTION PLAN: _____

2. Nursing Stations

Yes No N/A

2.1. Adequate space is available at ward or nursing station for the storage of drugs and preparation of medication doses. All such spaces and areas can be locked and are accessible to authorized personnel only. (22 CCR 70269)

2.2. The pharmacist, intern, or pharmacy technician completes the monthly inspections of all floor stock and drugs maintained in nursing stations. Any irregularities are reported to the director of nursing services, and as required by hospital policy. (B&PC 4119.7[c], 4115[j], 22 CCR 70263[q][10])

2.2.1. An intern shall report any irregularities to the pharmacist. (B&PC 4119.7[c]);

2.2.2. A pharmacy technician shall report any irregularities to the pharmacist-in-charge and to the director of the health care facility within 24 hours. (B&PC 4115[i][3]);

CORRECTIVE ACTION OR ACTION PLAN: _____

3. Delivery of Drugs

Yes No N/A

- 3.1. Delivery to the pharmacy of dangerous drugs and dangerous devices are only delivered to the licensed premise and signed for and received by a pharmacist. (B&PC 4059.5[a])
- 3.2. Deliveries to a hospital pharmacy may be made to a central receiving location within the hospital. However, the dangerous drugs or dangerous devices shall be delivered to the licensed pharmacy premise within one working day following receipt by the hospital, and the pharmacist on duty at that time shall immediately inventory the drugs or devices. (B&PC 4059.5[c])
- 3.3. A pharmacy may take delivery of dangerous drugs and dangerous devices when the pharmacy is closed and no pharmacist is on duty if all of the following requirements are met (B&PC 4059.5[f]):
- 3.3.1. The drugs are placed in a secure storage facility in the same building as the pharmacy (B&PC 4059.5[f][1]);
 - 3.3.2. Only the pharmacist-in-charge or a pharmacist designated by the pharmacist-in-charge has access to the secure storage facility after dangerous drugs or dangerous devices have been delivered (B&PC 4059.5[f][2]);
 - 3.3.3. The secure storage facility has a means of indicating whether it has been entered after dangerous drugs or dangerous devices have been delivered (B&PC 4059.5[f][3]);
 - 3.3.4. The pharmacy maintains written policies and procedures for the delivery of dangerous drugs and dangerous devices to a secure storage facility (B&PC 4059.5[f][4]); and
 - 3.3.5. The agent delivering dangerous drugs and dangerous devices pursuant to this subdivision leaves documents indicating the name and amount of each dangerous drug or dangerous device delivered in the secure storage facility. The pharmacy shall be responsible for the dangerous drugs and dangerous devices delivered to the secure storage facility. The pharmacy shall also be responsible for obtaining and maintaining records relating to the delivery of dangerous drugs and dangerous devices to a secure storage facility. (B&PC 4059.5[f][5])
- 3.4. Prior to, or at the time of, accepting ownership of a product included in the Drug Supply Chain Security Act from an authorized trading partner, the pharmacy is provided transaction history, transaction information, and a transaction statement. (21 USC 360eee-1[d][A][i])
- 3.5. Prior to, or at the time of, each transaction in which the pharmacy transfers ownership of a product included in the Drug Supply Chain Security Act to an authorized trading partner, the subsequent owner is provided transaction history, transaction information, and a transaction statement for the product. Note: This requirement does not apply to sales by a pharmacy to another pharmacy to fulfill a specific patient need. (21 USC 360eee-1[d][A][ii])
- 3.6. The pharmacy captures transaction information (including lot level information, if provided), transaction history, and transaction statements, as necessary to investigate a suspect product, and maintains such information, history, and statements for not less than 6 years after the transaction. (21 USC 360eee-1[d][A][iii])

CORRECTIVE ACTION OR ACTION PLAN: _____

4. Drug Stock

Yes No N/A

- 4.1. The drug stock is clean, orderly, properly stored, properly labeled and in-date. (B&PC 4342, H&SC 111255, CCR 1714 (b), 22 CCR 70263[q])
- 4.2. All ward/floor drug stock and drug supplies that are maintained for access when the pharmacist is not available are properly labeled and stored. (22 CCR 70263[n])
- 4.3. Preferentially priced drugs are furnished solely or predominately to inpatients in accordance with provisions of the Nonprofit Institutions Act (15 USC 13c). Such drugs also may be dispensed pursuant to prescriptions for inpatients at the time of discharge, for employees of the hospital, or on an emergency basis for a walk-in customer (provided that sales to walk-ins do not exceed one percent of the pharmacy's total prescription sales). (B&PC 4380, CCR 1710[a])

Yes No N/A

- 4.4. All unit-dose drugs received from a centralized hospital packaging pharmacy are correctly labeled, are barcoded, and the barcode is readable at the patient's bedside. (B&PC 4128.4, 4128.5)
- 4.5. All drugs are maintained in accordance with national standards regarding the storage area and refrigerator or freezer temperature and manufacturer's guidelines. (B&PC 4119.7[b])

CORRECTIVE ACTION OR ACTION PLAN: _____

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

Yes No N/A

- 5.1. The hospital pharmacy donates medications to a county-approved drug repository and distribution program, and meets the following requirements: (H&SC 150202, 150202.5, 150204)
- 5.1.1. The hospital pharmacy is licensed by and is not on probation with the California State Board of Pharmacy, **and** (H&SC 150202.5)
 - 5.1.2. The hospital pharmacy's primary or sole type of pharmacy practice is limited to skilled nursing facility, home health care, board and care, or mail order. (H&SC 150202.5)
- 5.2. No controlled substances shall be donated. (H&SC 150204[c][1])
- 5.3. Drugs that are donated are unused, unexpired and meet the following requirements: (H&SC 150202.5, 150204[c])
- 5.3.1. Have not been adulterated, misbranded, or stored under conditions contrary to standards set by the USP or the product manufacturer. (H&SC 150204[c][2])
 - 5.3.2. Were received directly from a manufacturer or wholesaler. (H&SC 150202.5[a])

- 5.3.3. Were centrally stored and under the control of a health facility staff member, and were never in the possession of a patient or individual member of the public. (H&SC 150202.5[b], 150204[c][3])
- 5.3.4. Are in unopened, tamper-evident packaging or modified unit dose containers with lot numbers and expiration dates affixed. (H&SC 105204[d])
- 5.3.5. For donated medications that require refrigeration, are medications that are stored, packaged and transported at appropriate temperatures and in accordance with USP standards and pharmacy law. (H&SC 150204[m])

5.4. The hospital pharmacy follows the same procedural drug pedigree requirements for donated drugs as it does for drugs purchased from a wholesaler or directly from a drug manufacturer. (H&SC 150204[n])

6. Pharmacist-in-Charge (PIC)

Yes No N/A

6.1. The pharmacy has a PIC who is responsible for the daily operation of the pharmacy. (B&PC 4101, 4113, 4305, 4330, CCR 1709, 1709.1)

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

6.3. Is the PIC in charge of another pharmacy?

If yes, the pharmacies are within 50 driving distance miles of each other. (CCR 1709.1[c])

If yes, name of other pharmacy _____

6.4. Any change of PIC is reported by the pharmacy and the departing PIC to the board in writing within 30 days. (B&PC 4101, 4330)

~~6.5. Is the PIC serving concurrently as the designated representative in charge for a wholesaler or veterinary food animal retailer? (CCR 1709.1 [d])~~

~~_____ If yes, name the wholesaler or veterinary food animal retailer. _____~~

CORRECTIVE ACTION OR ACTION PLAN: _____

7. Duties of a Pharmacist

Yes No N/A

7.1. ~~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) Only a pharmacist: (BPC 4019, BPC 4052, BPC 4051, BPC 4052.2, CCR 1717[c], CCR 1793.1, CCR 1793.7)~~

- The pharmacist receives a chart order for an inpatient; (BPC 4019, BPC 4051 [b], BPC 4052, BPC 4052.2, CCR 1717, CCR 1793.1[a])
- Identifies, evaluates and interprets the chart order; (CCR 1717[c], CCR 1793.1[c])
- Reviews patient's drug regimen and interprets the clinical data in the patient's medication record; (BPC 4052.1[a][4], BPC 4052.2[a][4], CCR 1793.1[d])
- Consults with any prescriber, nurse or health care professional; (CCR 1793.1[e])
- Calculates drug doses; (BPC 4052 [a][3], BPC 4052.2 [a][3], BPC 4052.2 [a][4])
- Supervises the packaging of drugs and checks the packaging procedures and products upon completion; (CCR 1793.1[f])
- 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; (CCR 1793.7[e])
- 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. (BPC 4052, BPC 4052.2, CCR 1793.1[g])

~~7.2 Pharmacists in a licensed health care facility who are performing the following functions are doing so in accordance with the hospital's policies, procedures and protocols which have been developed by health professionals including physicians, pharmacists, and registered nurses, with the concurrence of the facility administrator; ordering or performing routine drug therapy-related patient assessment procedures; ordering drug therapy-related laboratory tests; administering drugs or biologicals by injection; initiating or adjusting the drug regimen of a patient, and/or performing moderate or waived laboratory tests. Prior to performing any of these functions, the pharmacist must have either (1) successfully completed clinical residency training, or (2) demonstrated clinical experience in direct patient care delivery as specified in B&PC section 4052.2.~~

Pharmacists in a licensed health care facility who are performing the following functions are doing so in accordance with the hospital's policies, procedures and protocols which have been developed by health professionals including physicians, pharmacists, and registered nurses, with the concurrence of the facility administrator: (B&PC 4027, 4051, 4052, 4052.2)

- Ordering or performing routine drug therapy-related patient assessment procedures; (BPC 4052.1[a][1]; 4052.2[a][1])
- Ordering drug therapy-related laboratory tests; administering drugs or biologicals by injection; (BPC 4052.1[a][2], [3]; 4052.2[a][2], [3])
- Initiating or adjusting the drug regimen of a patient; (BPC 4052.1[a][4], BPC 4052.2[a][4])

- 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 BPC section 4052.2[d]. (BPC 4052.4)

7.3. The pharmacist who is authorized to issue an order to initiate or adjust a controlled substance therapy is personally registered with the federal Drug Enforcement Administration. (B&PC 4052[b])

CORRECTIVE ACTION OR ACTION PLAN: _____

8. Duties of an Advanced Practice Pharmacist

Yes No N/A

~~8.1. The pharmacist who is authorized to issue an order to initiate or adjust a controlled substance therapy is personally registered with the federal Drug Enforcement Administration. (B&PC 4052[b])~~

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

- ~~8.2.1~~ 8.1.1 Perform patient assessments, order and interpret drug therapy-related tests, and refer patients to other health care providers; (B&PC 4052.6[a])
- ~~8.2.1~~ 8.1.2 Participate in the evaluation and management of diseases and health conditions in collaboration with other health care providers; (B&PC 4052.6[a])
- ~~8.2.1~~ 8.1.3 Initiate drug therapy and promptly transmit written notification to, or enter the appropriate information into a patient record system shared with the patient's primary care provider or diagnosing provider; (B&PC 4052.6[b])
- ~~8.2.1~~ 8.1.4 Adjust or discontinue drug therapy and promptly transmit written notification to the patient's diagnosing prescriber or enters the appropriate information in a patient's record system shared with the prescriber; (B&PC 4052.6[b])
- ~~8.2.1~~ 8.1.5 Prior to initiating or adjusting a controlled substance therapy, the advance practice pharmacist is personally registered with the federal Drug Enforcement Administration; (B&PC 4052.6[d])
- ~~8.2.1~~ 8.1.6 Ordering of tests is done in coordination with the patient's primary care provider or diagnosing prescriber, including promptly transmitting written notification to the prescriber or entering information in a patient record system shared with the prescriber. (B&PC 4052.6[e])

9. Duties of an Intern Pharmacist

Yes No N/A

- 9.1. Intern pharmacists are performing all the functions of a pharmacist only under the direct supervision of a pharmacist, and the pharmacist is supervising no more than **two interns** at any one time. (B&PC 4023.5, 4030, 4114, 4119.6, 4119.7, CCR 1726)
- 9.1.1 Stock, replenish and inspect the emergency pharmaceutical supply container and the emergency medical system supplies. (B&PC 4119.6)
- 9.1.2. Inspect the drugs maintained in the health care facility at least once per month. (B&PC 4119.7[c])

Yes No N/A

- 9.2. All prescriptions filled or refilled by an intern are initialed or documented by secure computer entry by a pharmacist prior to dispensing. (CCR 1712[a], 1717[b][1])
- 9.3. During a temporary absence of a pharmacist for a meal period or duty free break, an intern pharmacist does not perform any discretionary duties or act as a pharmacist. (CCR 1714.1[d])
- 9.4. The intern hours affidavits are signed by the pharmacist under whom the experience was earned, when applicable. (B&PC 4209[b], [c], [d], CCR 1726)

CORRECTIVE ACTION OR ACTION PLAN: _____

10. Duties of a Pharmacy Technician

Yes No N/A

- 10.1. Registered pharmacy technicians are performing packaging, manipulative, repetitive, or other nondiscretionary tasks related to the furnishing of drugs, while assisting and under the direct supervision and control of a pharmacist. (B&PC 4023.5, 4038, 4115, CCR 1793.2, CCR 1793.7)
- 10.2. The ratio is no less than one pharmacist to two technicians. (B&PC 4115[f], CCR 1793.7[f])
- ~~10.2~~ 10.3. ~~The ratio for technicians performing the tasks above, related to the furnishing of drugs to inpatients, does not exceed one pharmacist on duty for two technicians on duty. However,~~ 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[f], CCR 1793.7[f])
- ~~10.2~~ 10.4. Any function performed by a technician in connection with the dispensing of a prescription or chart order, including repackaging from bulk and storage of pharmaceuticals is verified and documented in writing by a pharmacist or documented by a pharmacist using secure computer entry. (CCR 1712, 1793.7)
- ~~10.2~~ 10.5. A pharmacy technician or pharmacy technician trainee wears identification, in 18-point type that identifies him or her ~~self~~ herself as a pharmacy technician or pharmacy technician trainee. (B&PC 680, B&PC 4115.5[e], CCR 1793.7[d])

~~10.2~~ 10.6. The pharmacy has a job description for the pharmacy technician and written policies and procedures to ensure compliance with the technician requirements. (CCR 1793.7)

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

10.7. During a temporary absence of a pharmacist for a meal period or duty free break, a pharmacy technician may, at the discretion of the pharmacist, remain in the pharmacy but may only perform nondiscretionary tasks. Any task performed by the pharmacy technician during the pharmacist's temporary absence is reviewed by the pharmacist. (B&PC 4115[g], CCR 1714.1[c])

Yes No N/A

10.8. The general acute-care hospital has an ongoing clinical pharmacy program and allows specially trained pharmacy technicians to check the work of other pharmacy technicians when the following conditions are met: (CCR 1793.8)

- 10.8.1. Pharmacists are deployed to the inpatient care setting to provide clinical services.
- 10.8.2. Compounded or repackaged products are previously checked by a pharmacist, then used by the technician to fill unit dose distribution and floor and ward stock.
- 10.8.3. The overall operations are the responsibility of the pharmacist-in-charge.
- 10.8.4. The pharmacy technician checking technician program is under the direct supervision of the Pharmacist as specified in the policies and procedures.
- 10.8.5. There is an ongoing evaluation of the program that uses specialized and advanced trained pharmacy technicians to check the work of other pharmacy technicians.

10.9. Pharmacy technician duties include the following:

- 10.9.1. Package emergency supplies for use in the health care facility and the hospital's emergency medical system. (B&PC 4119, 4115[i])
- 10.9.2. Seal emergency containers for use in the health care facility. (B&PC 4115[i])
- 10.9.3. Perform monthly checks of the drug supplies stored throughout the health care facility and report any irregularities within 24 hours to the pharmacist-in-charge and to the director or chief executive officer. (B&PC 4115[i])

CORRECTIVE ACTION OR ACTION PLAN: _____

11. Duties of Non-Licensed Personnel

Yes No N/A

11.1. A non-licensed person (clerk/typist) is permitted to type a prescription label or otherwise enter prescription information into a computer record system, and at the direction of a pharmacist, may request and receive refill authorization. (B&PC 4007, CCR 1793.3)

11.2. The number of non-licensed personnel supervised by each pharmacist does not interfere with the effective performance of the pharmacist's responsibilities under the Pharmacy Law. (CCR 1793.3[b])

CORRECTIVE ACTION OR ACTION PLAN: _____

PHARMACY PRACTICE

12. Pharmaceutical Service Requirements

Yes No N/A

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

- 12.1.1. Basic information concerning investigational drugs and adverse drug reactions;
- 12.1.2. Repackaging and compounding records;
- 12.1.3. Physician orders;
- 12.1.4. Wards, nursing stations and night stock medications;
- 12.1.5. Drugs brought into the facility by patients for storage or use;
- 12.1.6. Bedside medications;
- 12.1.7. Emergency drug supply;
- 12.1.8. Pass medications;
- 12.1.9. Inspection of ward stock, nursing stations and night lockers no less frequently than every 30-days\\Outdated drugs;
- 12.1.10. Routine distribution of inpatient medications;
- 12.1.11. Preparation, labeling and distribution of IV admixtures and cytotoxic agents;
- 12.1.12. Handling of medication when pharmacist not on duty; and
- 12.1.13. Use of electronic image and data order transmissions.

Yes No N/A

12.2. The pharmacy complies with the requirements of 22 CCR 70263, addressing the following areas:

- 12.2.1. Destruction of controlled substances; and
- 12.2.2. Development and maintenance of the hospital's formulary. (22 CCR 70263, CCR 1751, CCR 1751.8)

CORRECTIVE ACTION OR ACTION PLAN: _____

13. Medication/Chart Order

Yes No N/A

- 13.1. The pharmacy receives the original, the electronic transmission, or a copy of the medication order. Faxed copies, tele-autograph copies, or transmissions between computers are permissible. (B&PC 4019, 4040, CCR 1717.4)

- 13.2. The chart or medical record of the patient contains all of the information required by B&PC 4040 and the chart order is signed by the practitioner authorized by law to prescribe drugs if present or, if not present, within a specified time frame not exceeding 48 hours. (B&PC 4019, 4040, 22 CCR 70263[g])

Yes No N/A

- 13.3. A copy of the chart order is maintained on the premises for three years. (B&PC 4081, 4105, 4333)

- 13.4. The pharmacy furnishes dangerous drugs or dangerous devices pursuant to preprinted or electronic standing orders, order sets and protocols established under policies and procedures. (B&PC 4119.7)

CORRECTIVE ACTION OR ACTION PLAN: _____

14. Labeling and Distribution

Yes No N/A

- 14.1. Unit dose medication and ~~parenteral admixtures~~ 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[b], ~~CCR 1751.2~~)

- 14.2. The pharmacist is responsible for the proper labeling, storage and distribution of investigational drugs pursuant to the written order of the investigator. (22 CCR 70263[o]).

- 14.3. This pharmacy furnishes dangerous drugs in compliance with B&PC 4126.5 only to a patient pursuant to a prescription, a wholesaler from whom the dangerous drugs were purchased, a manufacturer from whom the drugs were purchased, a licensed wholesaler acting as a reverse distributor, another pharmacy to alleviate a temporary shortage with a quantity sufficient to alleviate the temporary shortage, a health care provider authorized to receive drugs, to another pharmacy of common ownership, or to a patient or to another pharmacy pursuant to a prescription. (B&PC 4126.5)

CORRECTIVE ACTION OR ACTION PLAN: _____

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[jj])

CORRECTIVE ACTION OR ACTION PLAN: _____

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

Yes No N/A

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

16.2. Patient medical information, all prescriptions (chart orders, patient discharge and employee prescriptions) are confidential and are not disclosed unless authorized by law. (B&PC 4040, CCR 1764, Civil Code 56 et seq.)

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

16.4. The pharmacy ensures electronically transmitted prescriptions (chart orders, discharge patient or employee prescriptions) are received, maintained and transmitted in a secure and confidential manner. (CCR 1717.4)

16.5. Records regarding dangerous drugs and dangerous devices 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 three business days. Records for non-controlled substances are maintained on the licensed premises for at least one year from the date of dispensing. Records for controlled substances are maintained on the licensed premises for at least two years from the date of dispensing. (BPC 4105, CCR 1707)

Date Waiver Approved _____

Waiver Number _____

Address of offsite storage location: _____

CORRECTIVE ACTION OR ACTION PLAN: _____

17. Quality Assurance and Medication Errors

Yes No N/A

- 17.1. Pharmacy has established quality assurance program that documents medication errors attributable, in whole or in part, to the pharmacy or its personnel. (B&PC 4125, CCR 1711)
- 17.2. Pharmacy quality assurance policies and procedures are maintained in the pharmacy and are immediately retrievable. (CCR 1711[c])
- 17.3. When a medication error has occurred (drug was administered to or by the patient, or resulted in a clinically significant delay in therapy) the pharmacist communicates with the patient or patient's agent that a medication error has occurred and the steps required to avoid injury or mitigate the error. (CCR 1711[c][2][A], 1711 [c][3])

Yes No N/A

- 17.4. When a medication error has occurred (drug was administered to or by the patient, or resulted in a clinically significant delay in therapy) the pharmacist communicates to the prescriber that a medication error has occurred. (CCR 1711[c][2][B], 1711 [c][3])
- 17.5. Investigation of pharmacy medication errors is initiated within two business days from the date the medication error is discovered. (CCR 1711[d])
- 17.6. The record for quality assurance review for a medication error contains: (CCR 1711[e]);
- 17.6.1. Date, location, and participants in the quality assurance review;
 - 17.6.2. Pertinent data and other information related to the medication error(s) reviewed;
 - 17.6.3. Findings and determinations;
 - 17.6.4. Recommended changes to pharmacy policy, procedure, systems or processes, if any.
- 17.7. The record of the quality assurance review is immediately retrievable in the pharmacy and is maintained in the pharmacy for at least one year from the date it was created. (CCR 1711[f])
- 17.8. Pharmacists are not deviating from the requirements of a prescription except upon the prior consent of the prescriber, and selection of the drug product is in accordance with B&PC 4073 (generic substitution). (CCR 1716)

CORRECTIVE ACTION OR ACTION PLAN: _____

18. Record Keeping Requirements

Yes No N/A

- 18.1. A All completed ~~biennial~~ pharmacy self -assessments is are on file in the pharmacy and is are maintained for three years. (CCR 1715)
- 18.2. All drug acquisition and disposition records (complete accountability) are maintained for at least three years. These records include:
- 18.2.1. Prescription records (B&PC 4081[a])
 - 18.2.2. Purchase Invoices for all prescription drugs (B&PC 4081[b])

- 18.2.3. Biennial controlled substances inventory (21 CFR 1304.11)
- 18.2.4. U.S. Official Order Forms (DEA Form- 222) (21 CFR 1305.13)
- 18.2.5. Power of Attorney for completion of DEA 222 forms (21 CFR 1305.07)
- 18.2.6. Theft and Loss Reports (DEA Form 106) (21 CFR 1301.74[c])
- 18.2.7. Record documenting return of drugs to wholesaler or manufacturer (B&PC 4081)
- 18.2.8. Record documenting transfers or sales to other pharmacies and prescribers (B&PC 4059, 4081, 4105, 4332, CCR 1718)
- 18.2.9. Centrally stored unused medications donated to a drug repository and distribution program. (H&SC 150200, 150202[a][1]), 150204{k}, B&PC 4105{c}.

Yes No N/A

- 18.3. Transfers or sales to other pharmacies and prescribers do not exceed five percent of the pharmacy's total annual purchases of dangerous drugs or devices. If more than five percent, registration with the board as a wholesaler has been obtained. (21 CFR 1307.11, ~~Prescription Drug Marketing Act [PDMA] [Pub. L. 100-293, Apr. 11, 1988]~~ 503 Drug Supply Chain Security Act (DSCSA), B&PC 4160)
- 18.4. If sales or distributions of controlled substances to other hospitals, pharmacies, or prescribers exceed five percent of the total number of controlled substances dosage units (that are furnished to the inpatients or dispensed on prescriptions to discharge patients or employees) per calendar year, the following have been obtained: a separate DEA distributor registration and a wholesaler's permit from the board. (21 CFR 1307.11, ~~PDMA 503~~ DSCSA, B&PC 4160)
- 18.5. A controlled substances inventory is completed biennially (every two years).
Date completed: _____ (21 CFR 1304.11)
- 18.6. All completed controlled substances inventories are available for inspection for three years. (CCR 1718)
- ~~18.6~~ 18.7. Separate Schedule II records are maintained. This includes triplicate prescriptions, invoices, US official order forms and inventory records. (21 CFR 1304.04)
- ~~18.7~~ 18.8. Inventories and records for Schedule III-V controlled substances are filed separately or maintained in a readily retrievable manner that distinguishes them from other ordinary business records. (21 CFR 1304.04)
- ~~18.8~~ 18.9. DEA Forms 222 are properly executed. (21 CFR 1305.12)
- ~~18.9~~ 18.10. When the pharmacy distributes Schedule II controlled substances to other DEA registrants, Copy 2 of the DEA Form 222, properly completed, are submitted at the end of each month to the DEA Regional Office. (21 CFR 1305.13)
- ~~18.10~~ 18.11. Any controlled substances drug loss is reported upon discovery to the DEA and to the Board of Pharmacy within 30 days. (21 CFR 1301.74[c], CCR 1715.6)
- ~~18.11~~ 18.12. Records stored off-site (only for pharmacies who have obtained a waiver from the Board of Pharmacy to store records off-site) are secure and retrievable within two business days.

Records for non-controlled substances are maintained on the licensed premises for at least one year from the date of dispensing. Controlled substances are maintained on the licensed premises for at least two years from the date of dispensing. (CCR 1707)

- ~~18.12~~ 18.13. Do pharmacy staff hand initial prescription records and prescription labels, OR
- ~~18.13~~ 18.14. Does the pharmacy comply with the requirement for a pharmacist to initial or sign a prescription record or prescription label by recording the identity of the reviewing pharmacist in a computer system by a secure means. This computer does not permit the record to be altered after made and the record of the pharmacist's identity made in the computer system is immediately retrievable in the pharmacy. (CCR 1712)

CORRECTIVE ACTION OR ACTION PLAN: _____

19. Inventory Reconciliation Report of Controlled Substances

Yes No N/A

- 19.1. The pharmacy performs periodic inventory and inventory reconciliation functions to detect and prevent the loss of controlled substances. (CCR 1715.65 [a])
- 19.2 The pharmacist-in-charge of the pharmacy reviews all inventory and inventory reconciliation reports taken, and establishes and maintains secure methods to prevent losses of controlled drugs. Written policies and procedures are developed for performing the inventory reconciliation reports required by pharmacy law. (CCR 1715.65 [b])
- 19.3 A pharmacy compiles an inventory reconciliation report of all federal Schedule II controlled substances at least every three months. This compilation shall require: (CCR 1715.65 [c])
- 19.3.1 A physical count, not an estimate, of all quantities of federal Schedule II controlled substances. The biennial inventory of controlled substances required by federal law may serve as one of the mandated inventories under this section in the year where the federal biennial inventory is performed, provided the biennial inventory was taken no more than three months from the last inventory required by this section; (CCR 1715.65[c][1])
 - 19.3.2 A review of all acquisitions and dispositions of federal Schedule II controlled substances since the last inventory reconciliation report; (CCR 1715.65[c][2])
 - 19.3.3 A comparison of the two above-mentioned items to determine if there are any variances; (CCR 1715.65[c][3])
 - 19.3.4 All records used to compile each inventory reconciliation report shall be maintained in the pharmacy or clinic for at least three years in a readily retrievable form; and (CCR 1715.65[c][4])
 - 19.3.5 Possible causes of overages shall be identified in writing and incorporated into the inventory reconciliation report. (CCR 1715.65[c][5])
- 19.4 The pharmacy reports in writing identified losses and known causes to the board within 30 days of discovery unless the cause of the loss is theft, diversion, or self-use in which case the report shall be made within 14 days of discovery. If the pharmacy is unable to identify the cause of the loss, further investigation is undertaken to identify the cause and actions necessary to prevent additional losses of controlled substances. (CCR 1715.65 [d])

- 19.5 The inventory reconciliation report is dated and signed by the individual(s) performing the inventory, and countersigned by the pharmacist-in-charge and be readily retrievable in the pharmacy for three years. A countersignature is not required if the pharmacist-in-charge personally completed the inventory reconciliation report. (CCR 1715.65 [e])
- 19.6 A new pharmacist-in-charge of the pharmacy completes an inventory reconciliation report as identified in CCR 1715.65 (c) within 30 days of becoming pharmacist-in-charge. When possible, the outgoing pharmacist-in-charge also completes an inventory reconciliation report as required in CCR 1715.65 (c). (CCR 1715.65 [f])
- 19.7 A separate quarterly inventory reconciliation report shall be required for federal Schedule II controlled substances stored within the pharmacy and for each pharmacy satellite location. (CCR 1715.65 [g])
- 19.8 The pharmacist-in-charge of an inpatient hospital pharmacy or of a pharmacy servicing onsite or offsite automated drug delivery systems shall ensure that:
- 19.8.1 All controlled substances added to an automated drug delivery system are accounted for;
 - 19.8.2 Access to automated drug delivery systems is limited to authorized facility personnel;
 - 19.8.3 An ongoing evaluation of discrepancies or unusual access associated with controlled substances is performed; and
 - 19.8.4 Confirmed losses of controlled substances are reported to the board.

CORRECTIVE ACTION OR ACTION PLAN: _____

1920. After-Hours Supply of Medication

Yes No N/A

- 1920.1. 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: _____

2021. Drug Supplies for Use in Medical Emergencies

Yes No N/A

- 2021.1. 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])
- 2021.2. 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])

2021.3. 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])

2021.4. The pharmacist is responsible for inspection of the drug supply at periodic intervals (no less frequently than every 30 days) specified in the writ-ten policies. Records of the inspection are kept for at least three years. (22 CCR 70263[f][3])

CORRECTIVE ACTION OR ACTION PLAN: _____

2122. Schedule II-V Controlled Substances Floor Stock Distribution Records

Yes No N/A

2122.1. 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: _____

2223. Emergency Room Dispensing

Yes No N/A

- 2223.1. 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])
- 2223.1.1. The hospital pharmacy is closed and there is no pharmacist available in the hospital;
 - 2223.1.2. The dangerous drug is acquired by the hospital pharmacy;
 - 2223.1.3. The dispensing information is recorded and provided to the pharmacy when the pharmacy reopens;
 - 2223.1.4. 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;
 - 2223.1.5. 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
 - 2223.1.6. 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;

- ~~2223~~.2. The prescriber shall ensure that the label on the drug contains all the information required by Section 4076. (B&PC 4068[a][7])
- ~~2223~~.3. The prescriber shall be responsible for any error or omission related to the drugs dispensed. (B&PC 4068[b])
- ~~2223~~.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)
- ~~2223~~.5. Controlled substances are dispensed in prescription containers bearing a federal warning label prohibiting transfer of the drugs. (21 CFR 290.5)
- ~~2223~~.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)
- ~~2223~~.7. Patient package inserts are dispensed with all estrogen medications (21 CFR 310.515)
- 23.8. The pharmacy provides patients with required Black Box Warning Information.
(21 CFR 201.57[c])
- 23.9. Medication guides are provided on required medications. (21 CFR Part 208)

CORRECTIVE ACTION OR ACTION PLAN: _____

2324. Discharge Medication/Consultation Services

Yes No N/A

- ~~2324~~.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)
- ~~2324~~.2. Prescriptions are transmitted to another pharmacy as required by law. (B&PC 4072, CCR 1717[f], 1717.4)

- ~~2324.3.~~ The prescription label contains all the required information and is formatted in accordance with CCR 1707.5. (B&PC 4076, CCR 1707.5)
- ~~23.4.~~ If requested by the patient, the prescription label is printed in 12 point typeface. (CCR 1707.5[a])
- ~~23.5.~~ The pharmacy is exempt from the prescription label requirements in CCR 1707.5.
 _____ Exemption approved by board from: _____ to _____
- ~~2324.64.~~ Appropriate drug warnings are provided orally or in writing. (B&PC 4074, CCR 1744)
- ~~2324.75.~~ 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)
- ~~2324.86.~~ 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)
- ~~2324.97.~~ 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)
- ~~2324.108.~~ Controlled substances are dispensed in prescription containers bearing a federal warning label prohibiting transfer of the drugs. (21 CFR 290.5)
- ~~2324.119.~~ 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~~ 15 USC 1473 section ~~4~~4[b], 16 CFR 1700.15, CCR 1717)
- ~~2324.1210.~~ Patient package inserts are dispensed with all estrogen medications. (21 CFR 310.515)
- 24.11. The pharmacy provides patients with required Black Box Warning. (21 CFR 201.57[c])
- 24.12. Medication guides are provided on required medications. (21 CFR Part 208)

CORRECTIVE ACTION OR ACTION PLAN: _____

2425. Central Filling of Patient Cassettes For Other Hospital Pharmacies

Yes No N/A

- 2425.1. 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: _____

- 2425.2. 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~~.
26.
- 2425.3. Prescription information is electronically transferred between the two pharmacies. (CCR 1710[b][6])
- 2425.4. Pharmacy has a contract with the ordering hospital pharmacy or has the same owner. (CCR 1710[b][1])
- 2425.5. Filled cassettes are delivered directly to the ordering hospital pharmacy. (CCR 1710[b][2])
- 2425.6. Each cassette or container meets the requirements of Business and Professions Code section 4076. (CCR 1710[b][3])
- 2425.7. 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])

2526. Centralized Hospital Packaging Pharmacy

Yes No N/A

- 2526.1. The pharmacy prepares medications, by performing the following specialize functions, for administration only to inpatients within its own general acute care hospital and one or more general acute care hospitals under common ownership and located packages-unit dose medication for inpatients of one or more hospitals under common ownership within a 75-mile radius: (B&PC 4128)

Hospitals to which central packaged unit dose medications are provided:

- 2526.1.1. _____ Distance (miles):

- 2526.1.2. _____ Distance (miles):

- 2526.1.3. _____ Distance (miles):

- 2526.1.4. _____ Distance (miles):

- 26.1.5 Prepares unit dose packages for single administration to inpatients from bulk containers, if each unit dose package is barcoded pursuant to BPC 4128.4.
- 26.1.6 Prepares sterile compounded unit dose drugs for administration to inpatients, if each unit dose drug is barcoded pursuant to BPC 4128.4.
- 26.1.7 Prepares compounded unit dose drugs for administration to inpatients, if each unit dose package is barcoded pursuant to BPC 4128.4.

- 2526.2. 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)
- 2526.3. All Any unit dose medications produced by a centralized hospital packaging pharmacy are barcoded and readable to be machine readable at the inpatient's bedside using barcode medication administrative software. ~~The barcode information contains:~~ (B&PC 4128.4)
- ~~25.3.1. The date the medication was prepared. The barcode medication administration software permits health care practitioners to ensure that before a medication is administered to an inpatient, it is the right medication, for the right inpatient, in the right dose, and via the right route of administration.~~
 - ~~25.3.2. The components used in the drug product. The software verifies that the medication satisfies the above criteria by reading the barcode on the medication and comparing the information retrieved to the electronic medical record of the inpatient.~~
 - ~~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.~~

Yes No N/A

- 2526.4. ~~The Any label for each unit dose medication produced by a centralized hospital packaging pharmacy contains the expiration date, the established name of the drug, the quantity of the active ingredient, and special storage or handling requirements displays a human-readable label that contains the following:~~ (B&PC 4128.5[a])
- 26.4.1 The date the medication was prepared.
 - 26.4.2 The beyond-use date
 - 26.4.3 The established name of the drug.
 - 26.4.4 The quantity of each active ingredient.
 - 26.4.5 The lot number or control number assigned by the centralized hospital packaging pharmacy.
 - 26.4.6 Special storage or handling requirements.
 - 26.4.7 The name of the centralized hospital packaging pharmacy.

- 26.5 The pharmacist is able to retrieve all of the following information using the lot number or control number: (BPC 4128.5[b])
- 26.5.1 The components used in the drug product.
 - 26.5.2 The expiration date of each of the drug's components.
 - 26.5.3 The National Drug Code Directory number.

~~2526.56~~. 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: _____

2627. Policies and Procedures

Yes No N/A

- ~~2627.1~~. There are written policies and procedures in place for:
- ~~2627.1.1~~. The assurance that each patient received information regarding each medication given at the time of discharge.
 - ~~2627.1.2~~. 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])
 - ~~2627.1.3~~. 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])
 - ~~2627.1.4~~. 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])
 - ~~2627.1.5~~. Reporting to the board within 14 days of the receipt or development of information as specified in B&PC 4104[c][1-6].
 - ~~2627.1.6~~. 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])
 - ~~2627.1.7~~. 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])
 - ~~2627.1.8~~. 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])
 - ~~2627.1.9~~. 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: _____

2728. Compounding

Prior to allowing any drug product to be compounded in a pharmacy, the pharmacist-in-charge must complete the "Compounding Self-Assessment" Form 17M-39 (Rev. 02/12). (CCR 1735.244)

PHARMACIST-IN-CHARGE CERTIFICATION:

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

Signature _____ Date _____
(Pharmacist-in-Charge)

ACKNOWLEDGEMENT BY HOSPITAL ADMINISTRATOR:

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

Signature _____ Date _____

The following **Legal References** are used in the self-assessment form. Many of these references can be viewed on the Board of Pharmacy Web site at www.pharmacy.ca.gov (see *Laws and Regulations*), at the California State Law Library, or at other libraries or Internet web sites.

California Code of Regulations (CCR), Title 16 and Title 24

Business and Professions Code (B&PC), Chapter 9, Division 2

Health and Safety Code (H&SC), Division 10, Uniform Controlled Substances Act

California Code of Regulations (CCR), Chapter 1, Division 5, Title 22

Code of Federal Regulations (CFR), Title 21, Chapter II, Drug Enforcement Administration (www.dea.gov)

California Board of Pharmacy

1625 N. Market Blvd., Suite N219

Sacramento, CA 95834

Phone: (916) 574-7900

Fax: (916) 574-8618

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

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

Online Registration — Renewal:

www.deadiversion.usdoj.gov/drugreg/reg_apps/onlineforms.htm

Registration Changes (Forms):

http://www.deadiversion.usdoj.gov/drugreg/change_requests/index.html

DEA Registration Support (all of CA):

(800) 882-9539

Online DEA 106 Theft/Loss Reporting:

<https://www.deadiversion.usdoj.gov/webforms/app106Login.jsp>

Online DEA 222 Controlled Substance Ordering System (CSOS): <http://www.deaecom.gov/>**DEA—Fresno**

2444 Main Street, Suite 240

Fresno, CA 93721

Registration: (888) 304-3251 or (415) 436-7900

Diversion or Investigation: (559) 487-5406

DEA—Los Angeles

255 East Temple Street, 20th Floor

Los Angeles, CA 90012

Registration: (888) 415-9822 or (213) 621-6960

Diversion or Investigation: (213) 621-6942

DEA—Oakland

1301 Clay Street, Suite 460N

Oakland, CA 94612

Registration: (888) 304-3251

Diversion or Investigation: (510) 637-5600

DEA—Redding

310 Hensted Drive, Suite 310

Redding, CA 96002

Registration: (888) 304-3251 or (415) 436-7900

Diversion or Investigation: (530) 246-5043

DEA—Riverside

4470 Olivewood Avenue

Riverside, CA 92501-6210

Registration: (888) 415-9822 or (213) 621-6960

Diversion or Investigation: (951) 328-6200

DEA—Sacramento

4328 Watt Avenue

Sacramento, CA 95821

Registration: (888) 304-3251 or (415) 436-7900

Diversion or Investigation: (916) 480-7250

DEA—San Diego and Imperial Counties

4560 Viewridge Avenue

San Diego, CA 92123-1637

Registration: (800) 284-1152

Diversion or Investigation: (619) 444-4100

DEA—San Francisco

450 Golden Gate Avenue, 14th Floor

San Francisco, CA 94102

Registration: (888) 304-3251

Theft Reports or Diversion: (415) 436-7900

DEA—San Jose

One North First Street, Suite 405

San Jose, CA 95113

Registration: (888) 304-3251

Diversion or Investigation: (408) 291-2631

The following **Legal References** are used in the self-assessment form. Many of these references can be viewed on the Board of Pharmacy Web site at www.pharmacy.ca.gov (see *Laws and Regulations*), at the California State Law Library, or at other libraries or Internet web sites.

Business and Professions Code (BPC), Division 2, Chapter 1 – General Provisions

BPC, Division 2, Chapter 9 – Pharmacy

California Code of Regulation (CCR), Title 16, Division 17 – California State Board of Pharmacy

CCR, Title 22, Division 5, Chapter 1 – General Acute Care Hospitals

Civil Code, Division 1, Part 2.6, Chapter 2 – Disclosure of Medical Information by Providers

Code of Federal Regulations (CFR), Title 16, Chapter II, Subchapter E, Part 1700 – Poison Prevention Packaging

CFR, Title 21, Chapter I, Subchapter C, Part 201, Subpart B – Labeling Requirements for Prescription Drugs and/or

Insulin

CFR, Title 21, Chapter I, Subchapter C, Part 208 – Medication Guides for Prescription Drug Products

CFR, Title 21, Chapter I, Subchapter C, Part 290 – Controlled Drugs

CFR, Title 21, Chapter I, Subchapter D, Part 310, Subpart E – Requirements for Specific New Drugs and Devices

CFR, Title 21, Chapter II - Drug Enforcement Administration, Department of Justice

Health and Safety Code (HSC), Division 10 – Uniform Controlled Substances Act

HSC, Division 104, Part 5 (Sherman Food, Drug, and Cosmetics Law), Chapter 2 – Administration

HSC, Division 116 – Surplus Medication Collection and Distribution

United States Code (USC), Title 15, Chapter 39A – Special Packaging of Household Substances for Protection of

Children

USC, Title 21, Chapter 9, Subchapter V, Part H – Pharmaceutical Distribution Supply Chain (Drug Supply Chain Security Act)

Self-Assessment Form

**16 CCR § 1784
17M – 26**

Proposal to Amend 16 CCR Amend § 1784

§ 1784. Self-Assessment of a Wholesaler/Third Party Logistics Provider by the Designated Representative-In- Charge or Responsible Manager.

(a) ~~The designated representative-in-charge of~~ Each wholesaler and third-party logistics provider, as defined under section 4160 of the Business and Professions Code, shall complete a self-assessment of ~~the wholesaler's~~ its compliance with federal and state pharmacy law. The assessment shall be performed by the designated representative-in-charge of the wholesaler, or by the responsible manager of the third-party logistics provider, 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 or responsible manager shall complete a self-assessment within 30 days whenever:

(1) A new ~~wholesaler permit~~ license is issued, ~~or~~

(2) There is a change in the designated representative-in-charge or responsible manager.

The new designated representative-in-charge of a wholesaler or responsible manager of a third-party logistics provider is responsible for compliance with this subdivision.

(3) There is a change in the licensed location of a wholesaler or third-party logistics provider to a new address.

(c) ~~The components of this assessment shall be on Form 17M-26 (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.~~ Each wholesaler and third-party logistics provider conducting business in California, through its designated representative-in-charge or responsible manager, shall complete "Wholesaler/Third Party Logistics Provider Self-Assessment," Form 17M-26 (Rev. 10/17) which is hereby incorporated by reference. The form shall include the information required by this section.

(1) The designated representative-in-charge or responsible manager shall provide identifying information about the wholesaler or third-party logistics provider including:

(A) Name and license number of the premises;

(B) Address, phone number, website address, if applicable, and type of ownership;

(C) DEA registration number and expiration date and date of most recent DEA;
inventory;

(D) Verified-Accredited Wholesale Distributor accreditation number and expiration date,
if applicable; and

(E) Hours of operation of the licensee.

(2) The designated representative-in-charge or responsible manager shall list the name of
each Board-licensed staff person currently employed by the licensee in the facility at the
time the self-assessment is completed, the person's license type and number, and the
expiration date for each license.

(3) The designated representative-in-charge or responsible manager shall respond "yes",
"no" or "not applicable" (N/A) about whether the licensed premises is, at the time of the
self-assessment, in compliance with each of the requirements.

(4) For each "no" response, the designated representative-in-charge or responsible
manager shall provide a corrective action or action plan to come into compliance with the
law.

(5) The designated representative-in-charge or responsible manager shall initial each page
of the self-assessment form.

(6) The designated representative-in-charge or responsible manager shall certify, under
penalty of perjury, on the final page of the self-assessment that:

(A) He or she has completed the self-assessment of the licensed premises for which he
or she is responsible;

(B) Any deficiency identified within the self-assessment will be corrected and the
timeframe for correction;

(C) He or she understands that all responses are subject to verification by the Board of
Pharmacy; and

(D) The information provided in the self-assessment form is true and correct.

(7) The licensed premises owner, partner or corporate officer shall certify on the final page
of the self-assessment that he or she has read and reviewed the completed self-assessment
and understands that failure to correct any deficiency identified in the self-assessment

could result in the revocation of the license issued by the board. This certification shall be made under penalty of perjury of the laws of the State of California.

(d) Each self-assessment shall be kept on file in the licensed ~~wholesale~~ premises for three years after it is completed.

(e) The wholesaler or third-party logistics provider is jointly responsible with the designated representative-in-charge or responsible manager, respectively, for compliance with this section.

(f) Any identified areas of noncompliance shall be corrected as specified in the certification.

Authority: Business and Professions Code §4005. Reference: Business and Professions Code §4022.5, §4043, §4053, §4044.5, §4045, §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 21.

All references to “drugs” throughout this self-assessment refer to dangerous drugs and dangerous devices as defined in Business & Professions Code (B&PC) section 4022.
(http://www.pharmacy.ca.gov/laws_regs/lawbook.pdf).

Wholesaler Name _____

Address _____

Phone _____

Wholesaler E-mail address _____

Ownership: Please mark one

- sole owner partnership corporation LLC
- non- licensed owner Other (please specify) _____

CA Wholesaler Permit # _____ Expiration Date _____

Other Permit # _____ Expiration Date _____
(Use additional sheets if needed.)

DEA Registration # _____ Expiration Date _____

VAWD Accreditation # _____ Expiration Date _____

Date of most recent DEA Inventory _____

Hours: Weekdays _____ Sat _____ Sun _____ 24 Hours

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

DRIC License # / RPH License # _____ Expiration Date _____

Website Address (optional): _____

Licensed Wholesaler Staff (designated representative (DR), pharmacist):

- 1. _____ ~~DREXE#~~/RPH# _____ Exp. Date
- 2. _____ ~~DREXE#~~/RPH# _____ Exp. Date
- 3. _____ ~~DREXE#~~/RPH# _____ Exp. Date
- 4. _____ ~~DREXE#~~/RPH# _____ Exp. Date
- 5. _____ ~~DR#EXE~~/RPH# _____ Exp. Date
- 6. _____ ~~DREXE#~~/RPH# _____ Exp. Date
- 7. _____ ~~DREXE#~~/RPH# _____ Exp. Date
- 8. _____ ~~DREXE#~~/RPH# _____ Exp. Date
- 9. _____ ~~DREXE#~~/RPH# _____ Exp. Date
- 10. _____ ~~DREXE#~~/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 1780[f][3]) **Please attach a copy of the list to this document.** (This list should be dated.)

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

CORRECTIVE ACTION OR ACTION PLAN _____

2. Facility

2.1. Premises, fixtures and equipment:

Yes No N/A

- 2.1.1. Are clean and orderly
- 2.1.2. Are well ventilated
- 2.1.3. Are free from rodents and insects
- 2.1.4. Are adequately lit
- 2.1.5. Have plumbing in good repair
- 2.1.6. Have temperature & humidity monitoring to assure compliance with USP Standards. (The standards for various drugs may differ, see USP 1990 22nd Edition) (CCR 1780[b])
- 2.2. Is there a quarantine area for outdated, damaged, deteriorated, or misbranded drugs, drugs with the outer or secondary seal broken, partially used containers, or any drug returned under conditions that cast doubt on the drugs safety, identity, strength, quality or purity? (CCR 1780[e])

Yes No N/A

2.3. Are dangerous drugs and dangerous devices stored in a secured and locked area?
(CCR 1780[a])

2.4. Is access to areas where dangerous drugs are stored limited to authorized personnel? (CCR 1780[c])

List personnel with keys to the area(s) where drugs are stored (list by name or job title):

Yes No N/A

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

2.6. The wholesale premises is equipped with the following specific security features:
 2.6.1. There is an alarm to detect after-hours entry. (CCR 1780[c][1]).
 2.6.2. The outside perimeter of the building is well lit (CCR 1780[c][3]).
 2.6.3. The security system provides protection against theft and diversion including tampering with computers and or electronic records. (CCR 1780[c][2]).

Explain how your security system complies with these requirements.

Yes No N/A

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

CORRECTIVE ACTION OR ACTION PLAN _____

Yes No N/A

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

Date Last Notification Received: _____

Email ~~E-mail~~ address registered with the board: _____

CORRECTIVE ACTION OR ACTION PLAN _____

Yes No N/A

2.9. The facility receives the board’s email ~~e-mail~~ notifications through the owner’s electronic notice system. (B&PC 4013[c])

Date Last Notification Received: _____

Email ~~E-mail~~ address registered with the board: _____

CORRECTIVE ACTION OR ACTION PLAN _____

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

3. Designated Representative-in-Charge / Owner Responsibilities

Yes No N/A

3.1. The owner and the designated representative-in-charge are both equally responsible for maintenance of the records and inventory. (B&PC 4081[b])

3.2. Is the designated representative-in-charge at least 18 years of age and is responsible for the wholesaler’s compliance with all state and federal laws for the wholesale distribution of drugs? The designated representative-in-charge may be a pharmacist. (B&PC 4160[d], 4053.1(b))

3.3. The owner must notify the board within 30 days of termination of the designated representative-in-charge or pharmacist. (B&PC 4305.5[a])

3.4. The owner must identify and notify the board of the appointment of a new designated representative-in-charge within 30 days of the termination of the former designated representative-in-charge. (B&PC 4160[d], 4331[c]) The appropriate form for this notification is a “Change of Designated Representative-in-Charge,” which is available on the board’s website.

Yes No N/A

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

CORRECTIVE ACTION OR ACTION PLAN _____

4. Designated Representative/Pharmacist

Yes No N/A

- If a designated representative or pharmacist changes his/her name or personal address of record, he/she must notify the board in writing within 30 days. (B&PC 4100, CCR 1704)

CORRECTIVE ACTION OR ACTION PLAN _____

5. Ordering Drugs by this Business for Future Sale/Transfer or Trade

Yes No N/A

- 5.1. Are drugs ordered only from a business licensed by this board or from a licensed manufacturer? (B&PC 4163[b], 4169)
- 5.2. If drugs are returned to your premises by a business that originally purchased the drugs from you, do you document the return with an acquisition record for your business and a disposition record for the business returning the drugs? (B&PC 4081, 4332)
- 5.3. For license verification, the wholesaler may use the licensing information displayed on the board’s Internet web site. (B&PC 4106)

CORRECTIVE ACTION OR ACTION PLAN _____

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

6. Receipt of Drugs by this Business

Yes No N/A

6.1. When drugs are received by your business, are they delivered to the licensed wholesale premises, and received by and signed for only by a designated representative or a pharmacist? (B & P 4059.5[a])

6.2. When drugs are received by your business, are the outside containers visibly inspected to identify the drugs and prevent acceptance of contaminated drugs by detecting container damage? (CCR 1780[d][1])

CORRECTIVE ACTION OR ACTION PLAN _____

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

7. Drug Stock

Yes No N/A

7.1. Is all drug stock open for inspection during regular business hours? (B&PC 4081[a])

7.2. Are all drugs you order maintained in a secure manner at your licensed wholesale premises? You cannot order, obtain or purchase drugs that you are not able to store on your licensed premises. (B&PC 4167)

7.3. Do all drugs you sell conform to the standards and tests for quality and strength provided in the latest edition of United States Pharmacopoeia or Sherman Food Drug and Cosmetic Act? (B&PC 4342[a])

7.4. Do all drug containers you store on your premises have a manufacturer’s expiration date? Any drug without an expiration date is considered expired and may not be distributed. (CCR 1718.1)

7.5. Are outdated, damaged, deteriorated or misbranded drugs held in a quarantine area physically separated from other drugs until returned to the supplier or sent for destruction? (CCR 1780[e], CFR 1307.21)

7.6. Are drugs with the outer or secondary seal broken, or partially used or returned drugs held in a quarantine area and physically separated from other drugs until returned to the supplier or sent for destruction? (CCR 1780[e], CFR1307.21)

Yes No N/A

- 7.7. When the conditions under which drugs were returned to your premises cast doubt on the drugs' safety, identity, strength, quality or purity, are the drugs quarantined and either returned to your supplier or destroyed? If testing or investigation proves the drugs meet USP standards, the drugs may be returned to normal stock. (CCR 1780[e], CFR 1307.21)

CORRECTIVE ACTION OR ACTION PLAN _____

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

8. Sale or Transfer of Drugs by this Business

Yes No N/A

- 8.1. Are drugs sold only to businesses or persons licensed by this board, licensed by a prescriber board, licensed as a manufacturer, or to a licensed health care entity authorized to receive drugs?

8.2. Describe how you verify a business or person is appropriately licensed. (B&PC 4059.5[a] [b][d], B&PC 4169)

8.3. List any businesses or individuals that order drugs from you that are not licensed according to the list above:

Yes No N/A

- 8.4. Are drugs only furnished by your business to an authorized person? (B&PC 4163[a]) Note: An authorized person can be a business or natural person.

8.5. Does your business only receive drugs from a pharmacy if:

- 8.5.1. the pharmacy originally purchased the drugs from you?
- 8.5.2. your business is a “reverse distributor”?
- 8.5.3. the drugs are needed to alleviate a shortage? (and only a quantity sufficient to alleviate a specific shortage). (B&PC 4126.5[a])

Yes No N/A

8.6 Are all drugs that are purchased from another business or that are sold, traded or transferred by your business:

8.6.1. transacted with a business licensed with this board as a wholesaler or pharmacy?

8.6.2. free of adulteration as defined by the CA Health & Safety Code section 111250?

8.6.3. free of misbranding as defined by CA Health & Safety Code section 111335?

8.6.4. **confirmed** to not be beyond their use date (expired drugs)? (B&PC 4169)

8.7. List any incidents where adulterated, misbranded or expired drugs were purchased, sold, traded or transferred by this business in the past 2 years.

8.8. If your business sells, transfers, or delivers dangerous drugs or devices outside of California, either to another state within the United States or a foreign country, do you:

Yes No N/A

8.8.1. comply with all CA pharmacy laws related to the distribution of drugs?

8.8.2. comply with the pharmacy law of the receiving state within the United States?

8.8.3. comply with the statues and regulations of the Federal Food and Drug Administration and the Drug Enforcement Administration relating to the wholesale distribution of drugs?

8.8.4. comply with all laws of the receiving foreign country related to the wholesale distribution of drugs?

8.8.5. comply with all applicable federal regulations regarding the exportation of dangerous drugs?

8.9. Describe how you determine a business in a foreign country is authorized to receive dangerous drugs or dangerous devices. (B&PC 4059.5[e])

Yes No N/A

~~8.10. When you are not an authorized distributor for a drug, a pedigree must accompany the product when sold, traded, or transferred (Prescription Drug Marketing Act of 1987).~~

Yes No N/A

8.10. For products included in the Drug Supply Chain Security Act, transaction histories, transaction information, and transaction statements are provided to authorized trading partners when the products are sold, traded, or transferred. (Title II of the DQSA Section 582[c])

8.11. If preferentially priced drugs are sold by your business, that sale complies with the Prescription Drug Marketing Act of 1987 and CA Pharmacy Law. (B&PC 4380)

Yes No N/A

8.12. Does your business' advertisements for dangerous drugs or devices contain false, fraudulent, misleading or deceptive claims? (B&PC 4341, B&PC 651, CCR 1766)

8.13. Do you offer or receive any rebates, refunds, commissions or preferences, discounts or other considerations for referring patients or customers? If your business has any of these arrangements, please list with whom. (B&PC 650)

8.14. Does your business sell dangerous drugs or devices to the master or first officer of an ocean vessel, after your business has received a written prescription? If so, describe how you comply with the ordering, delivery and record keeping requirements for drugs including controlled substances, and the requirement to notify the board of these sales. (B&PC 4066, CFR 1301.25)

CORRECTIVE ACTION OR ACTION PLAN _____

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

9. Donations of Medication to Voluntary Drug Repository and Distribution Programs (H&SC 150200, 150203, 150204)

Yes No N/A

9.1. The wholesaler donates medications to a county-approved drug repository and distribution program, provided the following requirements are met: (H&SC 150203, 150204)

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

Yes No N/A

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

- 9.3.1. Have not been adulterated, misbranded, or stored under conditions contrary to standards set by the USP or the product manufacturer. (H&SC 150204[c][2])
- 9.3.2. Have never been in the possession of a patient or individual member of the public. (H&SC 150204[c][3])
- 9.3.3. Are in unopened, tamper-evident packaging or modified unit dose containers with lot numbers and expiration dates affixed. (H&SC 105204[d])
- 9.3.4. For donated medications that require refrigeration, are medications that are stored, packaged and transported at appropriate temperatures and in accordance with USP standards and pharmacy law. (H&SC 150204[m])

10. Outgoing Shipments of Drugs

Yes No N/A

10.1. Before you ship drugs to a purchaser, do you inspect the shipment to assure the drugs were not damaged while stored by your business? (CCR 1780[d][2])

10.2. Does your business use a common carrier (a shipping or delivery company — UPS, US Mail, FedEx, DHL) for delivery of drug orders to your customers? (B&PC 4166[a])

10.3. List the common carriers (shipping or delivery companies) you use.

CORRECTIVE ACTION OR ACTION PLAN _____

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

11. Delivery of Drugs

Yes No N/A

11.1. Are all drugs ordered by a pharmacy or another wholesaler delivered to the address of the buyer’s licensed premises and signed for and received by a pharmacist or designated representative where allowed? (B&PC 4059.5[a])

Yes No N/A

11.2. Are all drugs ordered by a manufacturer or prescriber delivered to the manufacturer's or prescriber's licensed business address and signed for by a person duly authorized by the manufacturer or prescriber? (B&PC 4059.5[d])

11.3. All drugs delivered to a hospital are delivered either to the pharmacy premises or to a central receiving area within the hospital. (B&PC 4059.5[c])

11.4. If drugs are delivered to a pharmacy when the pharmacy is closed and a pharmacist is not on duty, documents are left with the delivery in the secure storage facility, indicating the name and amount of each dangerous drug delivered. (B&PC 4059.5[f])

CORRECTIVE ACTION OR ACTION PLAN _____

12. Controlled Substances

Yes No N/A

12.1. Are there effective controls to prevent theft or diversion of controlled substances? (CFR 1301.71)

12.2. Are DEA requirements for storage of Schedule II controlled substances being met? (specific requirements are listed in CFR 1301.72[a])

12.3. Are DEA requirements for storage of Schedule III, IV and V controlled substances being met? (specific requirements are listed in CFR 1301.72[b])

12.4. Is a DEA inventory completed by your business every two years for all schedules (II - V) of controlled substances? (CFR 1304.11[a][c][e])

12.5. Is the biennial record of the DEA inventory required for Schedule II – V controlled substances conducted every 2 years, retained for 3 years? (CFR 1304.11, CCR 1718, 1780(f)[2])

12.6. Does the biennial inventory record document that the inventory was taken at the "close of business" or "opening of business." (CFR 1304.11)

12.7. Has the person within your business who signed the original DEA registration, or the last DEA registration renewal, created a power of attorney for each person allowed to order Schedule II controlled substances for this business? (CFR 1305.05)

12.7.1. List the individuals at this location authorized by power of attorney to order controlled substances.

Yes No N/A

12.8. Does your business follow employee-screening procedures required by DEA to assure the security of controlled substances? (CFR 1301.90)

12.9. If any employee of this business possesses, sells, uses or diverts controlled substances, in addition to the criminal liability you must evaluate the circumstances of the illegal activity and determine what action you should take against the employee. (CFR 1301.92)

12.10. Are all controlled substances purchased, sold or transferred by your business, done so for legitimate medical purposes? (H & S 11153.5[a][b][c])

12.11. If your business distributes controlled substances through an agent (i.e. detail person), do you have adequate security measures in place to prevent theft or diversion of those controlled substances (CFR 1301.74[f])

12.12. If a person attempts to purchase controlled substances from your business and the person is unknown to you, you make a good faith effort to determine the person (individual or business) is appropriately licensed to purchase controlled substances. (CFR 1301.74 [a])

12.13. Explain how your business determines an unknown business or individual is appropriately licensed to purchase controlled substances

12.14. If your business uses a common carrier to deliver controlled substances, your business determines the common carrier has adequate security to prevent the theft or diversion of controlled substances. (CFR 1301.74[f])

12.15. If your business uses a common carrier to deliver controlled substances, are the shipping containers free of any outward indication that there are controlled substances within, to guard against storage or in-transit theft? (CFR 1301.74[e])

12.16. Are all Schedule II controlled substances ordered from your business using a fully completed DEA 222 order form? (CFR 1305.03, 1305.06)

Yes No N/A

- 12.17. When your business fills orders for Schedule II controlled substances, is the date filled and the number of containers filled recorded on copies 1 and 2 of DEA 222 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])
- 12.18. If a Schedule II controlled substance order cannot be filled, does your business return copy 1 and 2 of the DEA 222 order form to the buyer with a letter indicating why the order could not be filled? (CFR 1305.15)
- 12.19. When your business partially fills Schedule II controlled substances, is the balance provided within 60 days of the date of the order form? After the final partial filling, is copy 1 retained in your files and copy 2 of the completed DEA 222 order form sent to DEA by the close of that month? (CFR 1305.13[b])
- 12.20. For all Schedule II controlled substances received by your business, is copy 3 of the DEA 222 order form completed by writing in for each item received, the date received and the number of containers received? (CFR 1305.13[e])
- 12.21. Does your business use the online CSOS secure transmission system offered by the Drug Enforcement Administration in place of a paper DEA 222 Form for Schedule II controlled substances? (CFR 1305.21, 1305.22)
- 12.22. Does your business follow the procedure outlined by DEA to obtain Schedule II controlled substances when the original DEA 222 order form is lost or stolen? (CFR 1305.16(a))
- 12.23. Are all records of purchase and sale for all schedules of controlled substances for your business kept on your licensed business premises for 3 years from the making? (B&PC 4081, CCR 1718, CFR 1305.17[c], 1305.17[a] [b], and H&SC 11252, 11253, 1304.03)
- 12.24. Are records of Schedule II controlled substances stored separate from all others? (CFR 1304.04 [f][1])
- 12.25. Are records for Schedule III-V controlled substances stored so that they are easily retrievable? (CFR 1304.04 [f][2])
- 12.26. Before your business distributes carfentanil etorphine HCL and or diprenorphine, do you contact the DEA to determine the person (individual or business) is authorized to receive these drugs? (CFR 1301.75[g], 1305.16[b])
- 12.27. Do you separate records for the sale of carfentanil etorphine hydrochloride and or diprenorphine from all other records? (CFR 1305.17[d])

Yes No N/A

12.28. Does the owner of your business notify the DEA, on a DEA 106 form, of any theft or significant loss of controlled substances upon discovery of the theft? (CFR 1301.74[c])

12.29. Does the owner of your business notify the board of any loss of controlled substances within 30 days of discovering the loss? (CCR 1715.6)

CORRECTIVE ACTION OR ACTION PLAN _____

13. Policies and Procedures

13.1. Does this business maintain and adhere to policies and procedures for the following: (CCR 1780[f])

Yes No N/A

13.1.1. Receipt of drugs

13.1.2. Security of drugs

13.1.3. Storage of drugs-(including maintaining records to document proper storage)

13.1.4. Inventory of drug-(including correcting inaccuracies in inventories)

13.1.5. Distributing drugs

13.1.6. Identifying, recording and reporting theft or losses

13.1.7. Correcting errors and inaccuracies in inventories

Physically quarantining and separating:

13.1.8. returned, damaged, outdated, deteriorated, misbranded or adulterated drugs

13.1.9. drugs that have been partially used?

13.1.10. drugs where the outer or secondary seals on the container have been broken

13.1.11. drugs returned to your business, when there is doubt about the safety, identity, strength, quality, or purity of the drug

13.1.12. drugs where the conditions of return cast doubt on safety, identity, strength, quality or purity (CCR 1780[e][f])

CORRECTIVE ACTION OR ACTION PLAN _____

14. Training

Yes No N/A

- 14.1 Are training and experience provided to all employees to assure all personnel comply with all licensing requirements? (CCR 1780[f][4])

List the types of training you have provided to staff in the last calendar year and the dates of that training.

CORRECTIVE ACTION OR ACTION PLAN _____

15. Dialysis Drugs

Yes No N/A

- 15.1. Does your business provide dialysis drugs directly to patients, pursuant to a prescription? (B&PC 4054) (4059[c]) If so, please complete the next 4 questions, if not proceed to Section ~~15~~ 16.
- 15.2. Do home dialysis patients complete a training program provided by a dialysis center licensed by Department of Health Services? Prescriber must provide proof of completion of this training to your business. (B&PC 4059[d])
- 15.3. Do you have written or oral orders for authorized dialysis drugs for each dialysis patient being serviced. Are such orders received by either a designated representative or a pharmacist? Note: refill orders cannot be authorized for more than 6 months from the date of the original order. (CCR 1787[a][b][c])
- 15.4. Does your business provide an "expanded invoice" for dialysis drugs dispensed directly to the patient including name of drug, manufacturer, quantities, lot number, date of shipment, and name of the designated representative or pharmacist responsible for distribution? A copy of the invoice must be sent to the prescriber, the patient and a copy retained by this business. Upon receipt of drugs, the patient or patient agent must sign for the receipt for the drugs with any irregularities noted on the receipt. (CCR 1790)
- 15.5. Is each case or full shelf package of the dialysis drugs dispensed labeled with the patient name and the shipment? Note that additional information as required is provided with each shipment. (CCR 1791)

CORRECTIVE ACTION OR ACTION PLAN _____

16. Record Keeping Requirements

Yes No N/A

16.1. Does your business' sales record for drugs include date of sale, your business name and address, the business name and address of the buyer, and the names and quantities of the drugs sold? (B&PC 4059[b])

~~16.2.1. Does your business maintain transaction histories, transaction information, and transaction statements for products included in the Drug Supply Chain Security Act? (Title II of the DQSA Section 582[c])~~

~~16.3.2. Are purchase and sales records for all transactions retained on your licensed premises for 3 years from the date of making? (B&PC 4081[a], 4105[c], 4081, 4332, 4059.5[a]) Note: A drug pedigree is considered to be a part of the records of purchase and sale and must be retained for three years from the making.~~

16.4.3. Are all purchase and sales records retained in a readily retrievable form? (B&PC 4105[a])

16.5.4. Is a current accurate inventory maintained for all dangerous drugs? (B&PC 4081, 4332, 1718)

16.6.5. If you temporarily remove purchase or sales records from your business, does your business retain on your licensed premises at all times, a photocopy of each record temporarily removed? (B&PC 4105[b])

16.7.6. Are required records stored off-site only if a board issued written waiver has been granted?

16.8.7. If your business has a written waiver, write the date the waiver was approved and the off-site address where the records are stored below. (CCR 1707[a])

Date _____ Address _____

16.9.8. Is an off-site written waiver in place and is the storage area secure from unauthorized access? (CCR 1707[b][1])

16.10.9. If an off-site written waiver is in place, are the records stored off-site retrievable within 2 business days? (CCR 1707[b][2])

~~16.11.10. Can the records that are retained electronically be produced immediately in hard copy form by any designated representative, if the designated representative-in-charge is not present? (B & P 4105[d])~~

~~16.12.11. Are records of training provided to employees to assure compliance with licensing requirements, retained for 3 years? (CCR 1780[f][4])~~

Yes No N/A

- 16.~~13.12~~. Has this licensed premises, or the designated representative-in-charge or pharmacist, been cited, fined or disciplined by this board or any other state or federal agency within the last 3 years? If so list each incident with a brief explanation (B&PC 4162[a][4]):
-
-

- 16.~~14.13~~. Has the licensed premises received any orders of correction from this board? A copy of the order and the corrective action plan must be on the licensed premises for 3 years. (B&PC 4083)

- 16.~~15.14~~. Has this business received a letter of admonishment from this board? A copy must be retained on the premises for 3 years from the date of issue. (B&PC 4315[e])

- 16.~~16.15~~. If this business dispenses dialysis drugs directly to patients, are the prescription records retained for 3 years, including refill authorizations and expanded invoices for dialysis patients? (CCR 1787[c], 1790)

CORRECTIVE ACTION OR ACTION PLAN _____

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

17. Reporting Requirements to the Board

Yes No N/A

- 17.1. A designated representative-in-charge who terminates employment at this business, must notify the board within 30 days of the termination (B&PC 4101[b], 4305.5[c]).
- 17.2. The owner must report to the board within 30 days the termination of the designated representative-in-charge or pharmacist (B&PC 4305.5[a])
- 17.3. The owner must report to the board within 30 days of discovery, any loss of controlled substances, including amounts and strengths of the missing drugs. (CCR 1715.6)
- 17.4. The owner must notify the DEA, on a DEA form 106, any theft or significant loss of controlled substances upon discovery. (CFR 1301.74[c])

Yes No N/A

- 17.5. Do your employees know about their obligation to report any known diversion or loss of controlled substances to a responsible person within your business? (CFR 1301.91)
- 17.6. The owner must notify the board within 30 days of any change in the beneficial ownership of this business. (B&PC 4201[i], CCR 1709[b])
- 17.7. When called upon by the board, your business can report all sales of dangerous drugs or controlled substances subject to abuse. (B&PC 4164[a])
- 17.8. Effective January 1, 2006 your business will develop and maintain a tracking system for individual sales of dangerous drugs at preferential or contract prices to pharmacies that primarily or solely dispense prescription drugs to patients of long-term care facilities. Your system must:
1. identify pharmacies that primarily or solely dispense prescription drugs to patients of long term care facilities
 2. identify purchases of any dangerous drugs at preferential or contract prices
 3. identify current purchases that exceed prior purchases by 20 percent over the previous 12 calendar months. (B&PC 4164[b])
- 17.9. I understand that this wholesaler license is not transferable to a new owner. A change of ownership must be reported to this board, as soon as the parties have agreed to the sale. Before the ownership actually changes, an additional application for a temporary permit must be submitted to the board if the new owner wants to conduct business while the board is processing the change of ownership application and until the new permanent permit is issued. A company cannot transfer the ownership of the business via a contract with another individual or business, without the board's approval (B&PC 4201[g])
- 17.10. The owner of this business must immediately notify the board in writing if any assignment is made for the benefit of creditors, if the business enters into any credit compromise arrangement, files a petition in bankruptcy, has a receiver appointed, or enters into liquidation or any other arrangement that might result in the sale or transfer of drugs. (CCR 1705)
- 17.11. If this business is discontinued, the owner must notify the board in writing before the actual discontinuation of business. (CCR 1708.2). If the business holds a DEA registration, the owner must notify the DEA promptly of the discontinuation of business and all unused DEA 222 order forms must be returned to the DEA. (CFR 1301.52[a], 1305.14)

CORRECTIVE ACTION OR ACTION PLAN _____

18. Additional Licenses/Permits Required

18.1. List all licenses and permits required to conduct this business, including local business licenses, wholesale licenses held in other states, permits or licenses required by foreign countries or other entities (B&PC 4059.5[e], 4107, CFR 1305.11[a]) Use additional sheets if necessary.

DESIGNATED REPRESENTATIVE-IN-CHARGE / PHARMACIST CERTIFICATION:

I, (please print) _____, DRIC# / RPH # _____
hereby certify that I have completed the self-assessment of this wholesale business of which I am the designated representative-in-charge (DRIC) / pharmacist (RPH). I understand that all responses are subject to verification by the Board of Pharmacy. I further state under penalty of perjury that the information contained in this self-assessment form is true and correct.

Signature _____ Date _____
Designated Representative-in-Charge (DRIC) / Pharmacist (RPH)

ACKNOWLEDGEMENT BY OWNER, PARTNER OR CORPORATE OFFICER:

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

Signature _____ Date _____

Legal References

The following Legal References are used in the self-assessment form. Many of these references can be viewed on the Board of Pharmacy Web site at www.pharmacy.ca.gov (see *Laws and Regulations*), at the California State Law Library, or at other libraries or Internet Web sites:

California Code of Regulations (CCR), Title 16, unless otherwise noted

Business and Professions Code (B&PC), Chapter 9, Division 2, unless otherwise noted

Health and Safety Code (H&SC), Division 10, Uniform Controlled Substances Act

Health and Safety Code (H&SC), Division 104, Part 5, Sherman Food, Drug and Cosmetic Laws

United States Code of Federal Regulations (CFR), Title 21, Chapter II, Part 1300, Drug Enforcement Administration, Food and Drugs and Codified Controlled Substances Act (CSA)

California Board of Pharmacy

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

Board of Registered Nursing

1625 N. Market Blvd., Suite N217
Sacramento, CA 95834
Phone: (916) 322-7697
Fax: (916) 574-8637
<http://www.rn.ca.gov/>

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

~~LawTech Publishing Co.
1060 Calle Cordillera, Suite 105
San Clements, CA 92673
Phone: (800) 498-0911 Ext. 5
www.lawtechpublishing.com~~

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.ombe.ca.gov>

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>

Physician Assistant Committee

2005 Evergreen St., Suite 1100
Sacramento, CA 95815
Phone: (916) 561-8780
Fax: (916) 263-2671
<http://www.pac.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 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
Online Registration—Renewal:
www.deadiversion.usdoj.gov/drugreg/reg_apps/onlineforms.htm
Registration Changes (Forms):
http://www.deadiversion.usdoj.gov/drugreg/change_requests/index.html
Online DEA 106 Theft/Loss Reporting:
<https://www.deadiversion.usdoj.gov/webforms/app106Login.jsp>
Controlled Substance Ordering System (CSOS): <http://www.deaecom.gov/>

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

DEA—Los Angeles
255 East Temple Street, 20th Floor
Los Angeles, CA 90012
Registration: (888) 415-9822 or (213) 621-6960
Diversion or Investigation: (213) 621-6942

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

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

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

DEA—Fresno
2444 Main Street, Suite 240
Fresno, CA 93721
Registration: (888) 304-3251 or (415) 436-7900
Diversion or Investigation: (559) 487-5406

DEA—San Diego and Imperial Counties
4560 Viewridge Avenue
San Diego, CA 92123-1637
Registration: (800) 284-1152
Diversion or Investigation: (858) 616-4100

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

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

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

**Remote Dispensing
Technicians
16 CCR § 1793.9**

**Title 16. Board of Pharmacy
Proposed Text**

Add section 1793.9 in Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1793.9 Pharmacy Technician in a Remote Dispensing Site Pharmacy

A pharmacy technician must satisfy each of the following requirements before working in a remote dispensing site pharmacy:

- (a) Possess a pharmacy technician license that is in good standing.
- (b) Possess and maintain a certification issued by an approved pharmacy technician certifying program.
- (c) (1) Possess a minimum of an associate degree in pharmacy technology;
(2) Possess a minimum of a bachelor's degree in any subject; or
(3) Complete a course of training specified by the board as provided in section 1793.6.
- (d) Complete 1,000 hours of experience working as a pharmacy technician within the three years prior to first working in the remote dispensing site pharmacy.

Authority: Sections 4005 and 4132, Business and Professions Code

Reference: Sections 4005, 4026.5, 4044.3, 4052, 4115, 4132 and 4202, Business and Professions Code

**Abandonment of
Applications
16 CCR § 1706.2**

Title 16. Board of Pharmacy Proposed Text

Proposed changes to the current regulation language are shown by strikethrough for deleted language and underline for added language.

Amend section 1706.2 in Article 1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1706.2. Abandonment of Application Files.

- (a) An applicant for a premises license ~~to conduct a pharmacy, non-resident pharmacy, sterile injectable compounding pharmacy, wholesaler, out-of-state distributor, clinic, veterinary food-animal drug retailer, or to furnish hypodermic needles and syringes~~ who fails to complete all application requirements within 60 days after being notified by the board of deficiencies in his, her or its file, may be deemed to have abandoned the application and may be required to file a new application and meet all of the requirements in effect at the time of reapplication.
- ~~(b) An applicant for a pharmacy technician license or a designated representative license who fails to complete all application requirements within 60 days after being notified by the board of deficiencies in his or her file, may be deemed to have abandoned the application and may be required to file a new application and meet all of the requirements which are in effect at the time of reapplication.~~
- ~~(b-e)~~ An applicant who fails to pay the fee for licensure as a pharmacist required by subdivision ~~(f)(1)~~ of section 1749 of this Division within 12 months after being notified by the board of his or her eligibility shall be deemed to have abandoned the application and must file a new application and be in compliance with the requirements in effect at the time of reapplication.
- ~~(c-d)~~ An applicant to take the pharmacist licensure examinations who fails to take the examinations within 12 months of being deemed eligible, shall be deemed to have abandoned the application and must file a new application in compliance with all of the requirements in effect at the time of reapplication.
- ~~(d-e)~~ An applicant for an intern pharmacist license who fails to complete all application requirements within one year after being notified by the board of deficiencies in his or her file, may be deemed to have abandoned the application and may be required to file a new application and meet all of the requirements which are in effect at the time of reapplication.
- (e) An applicant for an individual license not included in subdivision (b), (c), or (d), who fails to complete all application requirements within 60 days after being notified by the board of deficiencies in his or her file, may be deemed to have abandoned the application and may be required to file a new application and meet all of the requirements which are in effect at the time of reapplication.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4022.5, 4029, 4030, ~~4034, 4034.5, 4037, 4041, 4042, 4043, 4044.3, 4045, 4053, 4110, 4112, 4115, 4120, 4127.1, 4127.15, 4141, 4160, 4161, 4180, 4190, 4200, 4201, 4202, 4202.5, 4203, 4203.5, 4204, 4205, and 4208, and 4210,~~ Business and Professions Code.

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

**Title 16. Board of Pharmacy
Proposed Text**

Proposed changes to the current regulation language are shown by strikethrough for deleted language and underline for added language.

Amend section 1702 in Article 1 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.
- (1) A pharmacist ~~s~~ shall retain for at least three years as evidence of having complied with subdivision (a) either a receipt showing that he or she has electronically transmitted his or her fingerprint images to the Department of Justice or, for those who did not use an electronic fingerprinting system, a receipt evidencing that his or her fingerprints were recorded and submitted to the board.
- (2) A pharmacist applicant for renewal shall pay the actual cost of compliance with subdivision (a).
- (3) As a condition of petitioning the board for reinstatement of a revoked or surrendered license, or for restoration of a retired license, an applicant shall comply with subdivision (a).
- (4) The board may waive the requirements of this section for licensees who are actively serving in the United States military. The board may not return a license to active status until the licensee has complied with subdivision (a).
- (b) As a condition of renewal, a pharmacist applicant shall disclose on the renewal form whether he or she has been convicted, as defined in Section 490 of the Business and Professions Code, of any violation of the law in this or any other state, the United States, or other country, since his or her last renewal. Traffic infractions 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) As a condition of renewal, a pharmacist applicant shall disclose whether he or she has complied with any continuing education requirements to renew his or her pharmacist or advanced pharmacist license as required by section 1732.2.
- (e) 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.

Note: Authority cited: Sections 4001.1 and 4005, Business and Professions Code. Reference: Sections 141, 490, 4036, 4200.5, 4207, 4231, 4300, 4301, 4301.5, 4311 and 4400, Business and Professions Code; and Sections 11105(b)(10) and 11105(e), Penal Code.

Amend section 1702.1 in Article 1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1702.1. Pharmacy Technician Renewal Requirements for Individual Licensees Other Than Pharmacists.

This section applies to the renewal of any license held by an individual other than a license as a pharmacist or an advanced practice pharmacist.

- (a) An individual licensee ~~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 January 1, 2018.
- (1) The individual ~~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) The individual ~~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~~ the individual 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 not involving alcohol, dangerous drugs, or controlled substances do not need to be disclosed.
- (c) As a condition of renewal, ~~a pharmacy technician applicant~~ the individual 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.

Note: Authority cited: Sections 4001.1 and 4005, Business and Professions Code. Reference: Sections 141, 490, 4022.5, 4022.6, 4022.7, 4038, 4115, 4202, 4207, 4300, 4301 and 4400, Business and Professions Code; and Sections 11105(b)(10) and 11105(e), Penal Code.

Repeal section 1702.2 in Article 1 of Division 17 of Title 16 of the California Code of Regulations.

~~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 January 1, 2018.~~
- ~~(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 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 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.~~

Note: Authority cited: Sections 4001.1 and 4005, Business and Professions Code. Reference: Sections 141, 490, 4022.5, 4022.7, 4053, 4207, 4300, 4301 and 4400, Business and Professions Code; and Sections 11105(b)(10) and 11105(e), Penal Code.

Amend section 1702.5 in Article 1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1702.5. Renewal Requirements for Premises or Facilities ~~Disclosure of Discipline, Renewal, Nonresident Wholesaler or Nonresident Pharmacy.~~

This section applies to a renewal application submitted by a licensed premises or facility.

- (a) As a condition of renewal, an applicant seeking renewal of a premises or facility 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 issuance or 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.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 141, 4112, 4161, 4300, 4301, 4302, 4303, 4303.1 and 4316, Business and Professions Code.

**Mail-Order Pharmacy
Consultation
16 CCR § 1707.2**

Title 16. Board of Pharmacy

Amend section 1707.2 in Article 2 of Division 17 of Title 16 California Code of Regulations to read as follows:

§ 1707.2. Duty to Consult

(a) A pharmacist shall provide oral consultation to his or her patient or the patient's agent in all ~~care~~ settings:

(1) upon request; ~~or~~

(2) whenever the pharmacist deems it warranted in the exercise of his or her professional judgment;.

~~(b) (1) In addition to the obligation to consult set forth in subsection (a), a pharmacist shall provide oral consultation to his or her patient or the patient's agent in any care setting in which the patient or agent is present:~~

~~(3A) whenever the prescription drug has not previously been dispensed to a patient; or~~

~~(4B) whenever a prescription drug not previously dispensed to a patient in the same dosage form, strength, or with the same written directions, is dispensed by the pharmacy.~~

~~(b)(12) When the patient or patient's agent is not present (including, but not limited to, a prescription drug that was shipped by mail, or delivery), a pharmacy shall ensure that ~~the patient receives written notice:~~~~

~~(A) the patient receives written notice of his or her right to request consultation; ~~and~~~~

~~(B) the patient receives written notice of ~~a~~ the hours of availability and the telephone number from which the patient may obtain oral consultation from a pharmacist who has ready access to the patient's record; and~~

~~(C) A pharmacist shall be available (i) to speak to the patient or patient's agent during any regular hours of operation, within an average of ten (10) minutes or less, unless a return call is scheduled to occur within one business hour, (ii) for no less than six days per week, and (iii) for a minimum of 40 hours per week.~~

~~(23) A pharmacist is not required by this subsection to provide oral consultation to an inpatient of a health care facility licensed pursuant to section 1250 of the Health and Safety Code, or to an inmate of an adult correctional facility or a juvenile detention facility, except upon the patient's discharge. A pharmacist is not obligated to consult about discharge medications if a health facility licensed pursuant to subdivision (a) or (b) of Health and Safety Code Section 1250 has implemented a written policy about discharge medications which meets the requirements of Business and Professions Code Section 4074.~~

(c) When oral consultation is provided, it shall include at least the following:

- (1) directions for use and storage and the importance of compliance with directions; and
- (2) precautions and relevant warnings, including common severe side or adverse effects or interactions that may be encountered.

(d) Whenever a pharmacist deems it warranted in the exercise of his or her professional judgment, oral consultation shall also include:

- (1) the name and description of the medication;
- (2) the route of administration, dosage form, dosage, and duration of drug therapy;
- (3) any special directions for use and storage;
- (4) precautions for preparation and administration by the patient, including techniques for self-monitoring drug therapy;
- (5) prescription refill information;
- (6) therapeutic contraindications, avoidance of common severe side or adverse effects or known interactions, including serious potential interactions with known nonprescription medications and therapeutic contraindications and the action required if such side or adverse effects or interactions or therapeutic contraindications are present or occur;
- (7) action to be taken in the event of a missed dose.

(e) Notwithstanding the requirements set forth in subsection (a) and (b), a pharmacist is not required to provide oral consultation when a patient or the patient's agent refuses such consultation.

Note: Authority cited: Sections 4005, 4076 and 4122, Business and Professions Code. Reference: Sections 4005, 4076, 4112 and 4122, Business and Professions Code.

Fee Schedule

16 CCR § 1749

Title 16. Board of Pharmacy Proposed Text

Proposed changes to the current regulation language are shown by strikethrough for deleted language and underline for added language.

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

1749. Fee Schedule

The application, renewal, penalties, and other fees for the issuance and renewal of licenses, certificates, and permits, and the penalties to be assessed for failure to renew in accordance with section 163.5 of the Business and Professions Code and Pharmacy Law are hereby fixed as follows:

- (a) The application and initial license fee for the issuance of any pharmacy or remote site dispensing pharmacy license is ~~five hundred twenty dollars (\$520)~~ five hundred seventy dollars (\$570). The application fee for the annual renewal of any pharmacy or remote site dispensing pharmacy license is ~~six hundred sixty five dollars (\$665)~~ nine hundred and thirty dollars (\$930). The penalty for failure to renew is one hundred fifty dollars (\$150).
- (b) The application fee for the issuance of a temporary pharmacy license is three hundred twenty-five dollars (\$325).
- (c) The application and initial license fee for the issuance of a pharmacy technician license shall be ~~one hundred and forty dollars (\$140)~~ one hundred ninety-five dollars (\$195). The application fee for the biennial renewal of a pharmacy technician license shall be ~~one hundred forty dollars (\$140)~~ one hundred ninety-five dollars (\$195). The penalty for failure to renew a pharmacy technician license is ~~seventy dollars (\$70)~~ ninety-seven dollars and fifty cents (\$97.50).
- (d) The application fee for application and examination as a pharmacist is ~~two hundred sixty dollars (\$260)~~ two hundred eighty-five dollars (\$285).
- (e) The application fee for regrading an examination is one hundred fifteen dollars (\$115).
- (f)(1) The application fee for the issuance of an original pharmacist license is ~~one hundred ninety-five dollars (\$195)~~ two hundred and fifteen dollars (\$215).
- (2) The application 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 application fee for the biennial renewal of a pharmacist's license is ~~three hundred sixty dollars (\$360)~~ five hundred five dollars (\$505). The penalty fee for failure to renew is one hundred fifty dollars (\$150).
- (2) The application 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 application and initial license fee for the issuance or renewal of a wholesaler's license or third-party logistics provider is ~~seven hundred eighty dollars (\$780)~~ eight hundred twenty dollars (\$820). The application fee for the annual renewal of wholesaler or third-party logistics provider is ~~eight hundred twenty dollars (\$820)~~ eight hundred twenty dollars (\$820). The penalty for failure to renew is one hundred fifty dollars (\$150). The application fee for a temporary license is ~~seven hundred fifteen dollars (\$715)~~ seven hundred fifteen dollars (\$715).
- (i) The application and initial license fee for the issuance of a hypodermic license is ~~one hundred seventy dollars (\$170)~~ two hundred forty dollars (\$240). The application fee for the annual renewal of a hypodermic needle license is ~~two hundred eighty dollars (\$200)~~ two hundred eighty dollars (\$280). The penalty for failure to renew is one hundred forty dollars (\$100) (\$140).
- (j) The application and initial license fee for the issuance of a license as a designated representative license pursuant to Section 4053 of the Business and Professions Code or designated representative-3PL license pursuant to Section 4053.1, or a designated representative-reverse distributor license pursuant to Section 4053.2 is ~~one hundred fifty dollars (\$150)~~ two hundred ten dollars (\$210). The application fee for the annual renewal of a license as a designated representative or designated representative-3PL, or a designated representative-reverse distributor shall be ~~two hundred and fifteen dollars (\$215)~~ three hundred dollars (\$300). The penalty for failure to renew is ~~one hundred seven dollars and fifty cents (\$107.50)~~ one hundred fifty dollars (\$150).
- (k) The application and initial license fee for the application or renewal of a license as a nonresident wholesaler or nonresident third-party logistics provider is ~~seven hundred eighty dollars (\$780)~~ eight hundred twenty dollars (\$820). The application fee for the annual renewal of a nonresident wholesaler or nonresident third-party logistics provider is ~~eight hundred twenty dollars (\$820)~~ eight hundred twenty dollars (\$820). The penalty for failure to renew is one hundred fifty dollars (\$150). The application fee for a temporary license is ~~seven hundred fifteen dollars (\$715)~~ seven hundred fifteen dollars (\$715).
- (l) The application and initial license fee for an intern pharmacist license is ~~one hundred sixty-five dollars (\$165)~~ two hundred thirty dollars (\$230). The application fee for transfer of intern hours or verification of licensure to another state is ~~thirty dollars (\$30)~~ thirty dollars (\$30).
- (m) The application 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 thirty dollars (\$100)~~ one hundred thirty dollars (\$130).
- (n) The application fee for the reissuance of any license that has been lost or destroyed or reissued due to a name change is ~~forty-five dollars (\$45)~~ forty-five dollars (\$45).
- (o) The application fee for evaluation of continuing education courses for accreditation is ~~forty dollars (\$40)~~ forty dollars (\$40) for each hour of accreditation requested.
- (p) The application and initial license fee for the issuance of a clinic license is ~~five hundred twenty dollars (\$520)~~ five hundred seventy dollars (\$570). The application fee for the annual renewal of a clinic license is ~~three hundred twenty-five dollars (\$325)~~ three hundred sixty dollars (\$360). The penalty for failure to renew is one hundred fifty dollars (\$150).

- (q) The application and initial license fee for the issuance of a nongovernmental license to compound sterile drug products or a hospital satellite compounding pharmacy is ~~one thousand six hundred forty five dollars (\$1,645)~~ two thousand three hundred five dollars (\$2,305). The application fee for the annual renewal of a nongovernmental license to compound sterile drug products or a hospital satellite compounding pharmacy is ~~one thousand three hundred twenty five dollars (\$1,325)~~ one thousand eight hundred fifty-five dollars (\$1,855). The penalty for failure to renew is one hundred fifty dollars (\$150). The application fee for a temporary license is ~~five hundred fifty dollars (\$550)~~ seven hundred fifteen dollars (\$715).
- (r) The application and initial license fee for the issuance of a nonresident sterile compounding pharmacy is ~~two thousand three hundred eighty dollars (\$2,380)~~ three thousand three hundred thirty-five dollars (\$3,335). The application fee for the annual renewal of nonresident sterile compounding pharmacy license is ~~two thousand two hundred seventy dollars (\$2,270)~~ three thousand one hundred eighty dollars (\$3,180). The penalty for failure to renew is one hundred fifty dollars (\$150). The application fee for a temporary license is ~~five hundred fifty dollars (\$550)~~ seven hundred fifteen dollars (\$715).
- (s) The application and initial license fee for the issuance of a license as a designated representative for a veterinary food-animal drug retailer is ~~one hundred fifty dollars (\$150)~~ two hundred ten dollars (\$210). The application fee for the annual renewal of a license as a designated representative is ~~two hundred fifteen dollars (\$215)~~ three hundred dollars (\$300). The penalty for failure to renew is ~~one hundred seven dollars and fifty cents (\$107.50)~~ one hundred fifty dollars (\$150).
- (t) The application and initial license fee for a veterinary food-animal drug retailer license is ~~four hundred and thirty five dollars (\$435)~~ six hundred ten dollars (\$610). The annual renewal application fee for a veterinary food-animal drug retailer is ~~three hundred thirty dollars (\$330)~~ four hundred sixty dollars (\$460). The application fee for the issuance of a temporary license is two hundred and fifty dollars (\$250). The penalty for failure to renew is one hundred fifty dollars (\$150).
- (u) The application fee for the issuance of a retired pharmacist license shall be forty-five dollars (\$45).
- (v) The application and initial license fee for the issuance of a centralized hospital packaging pharmacy license is ~~eight hundred twenty dollars (\$820)~~ one thousand one hundred fifty dollars (\$1,150). The annual renewal application fee for a centralized hospital packaging pharmacy license is ~~eight hundred five dollars (\$805)~~ one thousand one hundred twenty five dollars (\$1,125). The penalty for failure to renew is one hundred fifty dollars (\$150).
- (w) The application and initial license fee for the issuance of an outsourcing facility license is ~~two thousand two hundred seventy dollars (\$2,270)~~ three thousand one hundred eighty dollars (\$3,180). The annual renewal application fee for an outsourcing facility is ~~one thousand three hundred twenty five dollars (\$1,325)~~ one thousand eight hundred fifty-five dollars (\$1,855). The penalty for failure to renew is one hundred fifty dollars (\$150). The application fee for a temporary outsourcing facility license is seven hundred fifteen dollars (\$715).

- (x) The application and initial license fee for the issuance of a nonresident outsourcing facility license is two thousand three hundred eighty dollars (\$2,380) three thousand three hundred thirty-five dollars (\$3,335). The annual renewal application fee for a nonresident outsourcing facility is two thousand two hundred seventy dollars (\$2,270) three thousand one hundred eighty dollars (\$3,180). The penalty for failure to renew is one hundred fifty dollars (\$150). The application fee for a temporary nonresident outsourcing facility license is seven hundred fifteen dollars (\$715).
- (y) The application and initial license fee of a correctional clinic that is not owned by the state is five hundred twenty dollars (\$520). The annual renewal application fee for a correctional clinic license is three hundred twenty-five dollars (\$325). The penalty for failure to renew is one hundred fifty dollars (\$150).
- (z) The application and initial license fee of an EMSADDS is one hundred dollars (\$100). The application fee for the annual renewal of an EMSADDS is one hundred dollars (\$100). The penalty for failure to renew is thirty-five dollars (\$35).
- (aa) The application and initial license fee of a co-location clinic license is seven hundred fifty dollars (\$750).
- (ab) The application and initial license fee of a designated paramedic license is one hundred and forty dollars (\$140). The application fee for the biennial renewal of a designated paramedic license is one hundred forty dollars (\$140). The penalty for failure to renew a designated paramedic license is sixty-five dollars (\$65).

Note: Authority cited: Sections 4005 and 4400, Business and Professions Code.
Reference: Sections 163.5, 4005, 4044.3, 4053, 4053.1, 4110, 4112, 4119.01, 4120, 4127.1, 4127.15, 4127.2, 4128.2, 4129.1, 4129.2, 4130, 4160, 4161, 4180, 4180.5, 4187, 4190, 4196, 4200, 4202, 4202.5, 4203, 4208, 4210, 4304, 4400, 4401 and 4403, Business and Professions Code.