California State Board of Pharmacy
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Department of Consumer Affairs
Gavin Newsom, Governor

LEGEND: Changes made to the current regulation language are shown by ~~strike-through~~ for deleted language and underline for added language. In cases where the original text contains underlined text, the underline text has been double underlined for emphasis that the original text contains underline and is not being added.

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. It ~~and~~ may be completed online, printed, initialed, signed, and readily available ~~and retained~~ in the pharmacy. Signatures and initials shall be an original handwritten signature or initial on the self-assessment form. Do not copy a previous assessment.

Notes: If a hospital pharmacy dispenses prescriptions for outpatient use, this Community Pharmacy Self-Assessment/Hospital Outpatient Pharmacy Self-Assessment must be completed in addition to the Hospital Pharmacy Self-Assessment (17M-14 Rev. ~~10/14~~ 07/18). 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~~ if any): _____ From: _____ To: _____

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

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

_____
PIC Initials

PIC: _____ RPH # _____ Exp. Date: _____

Website address (~~optional~~ if any):

Pharmacy Staff (pharmacists, intern pharmacists, pharmacy technicians):
Please use an additional sheet if necessary. ~~APP~~ APH=Advanced Practice Pharmacist, DEA =Drug Enforcement Administration.

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

PIC Initials

COMMUNITY PHARMACY SELF-ASSESSMENT /
HOSPITAL OUTPATIENT PHARMACY SELF-ASSESSMENT

All references to the California Code of Regulations (CCR) are to Title 16 unless otherwise noted. Additionally, Business and Professions Code is referenced as BPC.

Please mark the appropriate box for each item. If "NO", enter an explanation on "CORRECTIVE ACTION OR ACTION PLAN" lines at the end of the section. If more space is needed, you may add additional sheets.

1. Facility

Yes No N/A

☐☐☐ 1.1. The pharmacy has an area suitable for confidential patient consultation. (CCR 1764, 1714)

☐☐☐ 1.2. The pharmacy is secure and only a pharmacist possesses a key. The pharmacy has provisions for effective control against the theft of dangerous drugs and devices. (B&PC 4116, CCR 1714)

☐☐☐ 1.3. The pharmacy is of sufficient size and has an unobstructed area to accommodate the safe practice of pharmacy. (CCR 1714)

☐☐☐ 1.4. The pharmacy premises, fixtures, and equipment are maintained in a clean and orderly condition, properly lighted and free from rodents and insects. (CCR 1714)

☐☐☐ 1.5. The pharmacy sink has hot and cold running water. (CCR 1714)

☐☐☐ 1.6. The pharmacy has a readily accessible restroom. (CCR 1714)

☐☐☐ 1.7. Current board-issued "Notice to Consumers" is posted in public view where it can be read by the consumer, or written receipts containing the required information are provided to the consumers. A written receipt that contains the required information on the notice may be provided to consumers as an alternative to posting the notice in the pharmacy. A pharmacy may also or instead display the notice on a video screen. Additional "Notice to Consumers" in languages other than English may also be posted. (B&PC 4122, CCR ~~1707.2~~ 1707.6)

☐☐☐ 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])

☐☐☐ ~~1.8~~ 1.9. Pharmacists, interns, pharmacy technicians, and pharmacy technician trainees wear nametags, in 18-point type, that contain their name and license status. (B&PC 680, B&PC 4115.5[e], CCR 1793.7[d])

☐☐☐ ~~1.9~~ 1.10. The original board-issued pharmacy license and the current renewal are posted where they may be clearly read by the purchasing public. (B&PC 4032, 4058)

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

~~**Yes No N/A**~~

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

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

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

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

Date Last Notification Received: _____

E-mail address registered with the board: _____

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

Date Last Notification Received: _____

E-mail address registered with the board: _____

CORRECTIVE ACTION OR ACTION PLAN: _____

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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~~ The pharmacy ~~may~~ takes delivery of dangerous drugs and dangerous devices when the pharmacy is closed and no pharmacist is on duty ~~if~~ only when 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~~ is responsible for the dangerous drugs and dangerous devices delivered to the secure storage facility. The pharmacy ~~shall~~ is 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][1][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][1][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][1][A][iii])

PIC Initials

CORRECTIVE ACTION OR ACTION PLAN: _____

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3. Drug Stock

Yes No N/A

☐☐☐ 3.1. The drug stock is clean, orderly, properly stored, properly labeled and in-date. (B~~&~~PC 4342, H~~&~~SC 111255, 111335, 22 CCR 70263[q], CCR 1714[b], 21 USC sections 331, 351, 352)

☐☐☐ 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 4059.5, 4169)

- ☐ 3.2.1. Are not known or reasonably ~~are~~ should not be known to the pharmacy as ~~not~~ being adulterated.
- ☐ 3.2.2. Are not known or reasonably ~~are~~ should not be known to the pharmacy as ~~not~~ being misbranded.
- ☐ 3.2.3. Are not expired.

CORRECTIVE ACTION OR ACTION PLAN: _____

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4. Voluntary Drug Repository and Distribution Program (H&SC 150200)

Yes No N/A

☐☐☐ 4.1. Does the pharmacy donate to or operate a county-approved Voluntary Drug Repository and Distribution Program?

(If yes, complete Section ~~29~~ 30 [donate drugs] or Section 31 [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~~ license 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: _____

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PIC Initials

6. Duties of a Pharmacist

Yes No N/A

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

Only a pharmacist:

- ☐ transmits a valid prescription to another pharmacist; (BPC 4052[a][2])
- ☐ administers drugs and biological products ordered by the prescriber; (BPC 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; (BPC 4052[a][7])
- ☐ provides consultation, training and education to patients about drug therapy disease management and disease prevention; (BPC 4052[a][8])
- ☐ provides professional information and participates in multidiscipline review of patient progress; (BPC 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; (BPC 4052 [a][10], BPC 4052[a][11], BPC 4052.01, BPC 4052.3, BPC 4052.8, BPC 4052.9)
- ☐ dispenses aid-in-dying drugs; (HSC 443.5 [b][2]) and
- ☐ orders and interprets tests for monitoring and managing efficacy and toxicity of drug therapies (BPC 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; (BPC 4070 [a]), CCR 1793.1 [a])
- consults with the patient; (BPC 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. (BPC 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 only pursuant to the statewide protocol found in 16 CCR 1746. (4052.3[a][1])

☐☐☐ 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. (BPC 4052[b])

CORRECTIVE ACTION OR ACTION PLAN: _____

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7. Duties of an Advanced 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 advanced practice pharmacist has received an advanced practice pharmacist ~~recognition~~ license ~~by~~ from the board and may do the following: (B~~&~~PC 4016.5, 4210)

- ☐ ~~7.2.1~~ 7.1.1Perform patient assessments, order and interpret drug therapy-related tests, and refer patients to other health care providers; (B~~&~~PC 4052.6[a])
- ☐ ~~7.2.2~~ 7.1.2 Participate in the evaluation and management of diseases and health conditions in collaboration with other health care providers; (B~~&~~PC 4052.6[a])
- ☐ ~~7.2.3~~ 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])
- ☐ ~~7.2.4~~ 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])

☐ ~~7.2.5~~ 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])

☐ ~~7.2.6~~ 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~~s~~ ~~all~~ the functions of a pharmacist only under the direct supervision of a pharmacist. ~~A~~ The pharmacist ~~may~~ supervise~~s no more than~~ **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: _____

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9. Duties of a Pharmacy Technician

Yes No N/A

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

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

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

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

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

CORRECTIVE ACTION OR ACTION PLAN: _____

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10. Duties of Non-Licensed Personnel

Yes No N/A

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

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

CORRECTIVE ACTION OR ACTION PLAN: _____

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PHARMACY PRACTICE

11. Consultation/Patient Profile/Review of Drug Therapy

Yes No N/A

☐☐☐ 11.1. Pharmacists provide oral consultation: (~~B&PC 4052[a][7],~~ 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~~.~~; and
- ☐ 11.1.5. all of the above, 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: _____

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12. Prescription Requirements

Yes No N/A

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

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

☐☐☐ 12.3. If a prescription is orally or electronically transmitted by the prescriber's agent, the pharmacist makes a reasonable attempt to verify that the prescriber's agent is authorized to do so, and the agent's name is recorded. (B&PC 4071)

☐☐☐ 12.4. If orally transmitted, the pharmacist who received the prescription is identified by initialing the prescription, and if dispensed by another pharmacist, the dispensing pharmacist also initials the prescription. (CCR 1717, 1712)

☐☐☐ 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: _____

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13. Prescription Labeling, Furnishing and Dispensing

Yes No N/A

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

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

~~☐☐☐ 13.3. If requested by the consumer, the pharmacy provides the consumer with a prescription label that is printed in 12-point typeface. (CCR 1707.5[a])~~

~~**Yes No N/A**~~

~~☐☐☐ 13.4. The label on a drug container dispensed to a patient in California conforms to the following format: (CCR 1707.5[a])~~

~~☐ 13.4.1 The name of the patient, name of the drug and strength of the drug, the directions for use of the drug, the condition or purpose for which the drug was prescribed, if indicated on the prescription, are clustered into one area of the label and comprise at least 50 percent of the label.~~

~~☐ 13.4.2 The label is highlighted in bold typeface or color or uses blank space to set off the items in 13.4.1; (CCR 1707.5[a][2])~~

~~☐ 13.4.3 When applicable, standardized directions for use are utilized. (CCR 1707.5[a][4])~~

~~☐☐☐ 13.5. The pharmacy is exempt from the prescription label requirements in CCR 1707.5.~~

~~Exemption approved by board from: _____ to _____~~

☐☐☐ 13.~~6~~3. The ~~E~~expiration date~~s~~ of a ~~drugs'~~ 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.~~7~~4. The trade name or generic name and manufacturer of the prescription drug is accurately identified on the label and prescription record. (B&PC 4076, CCR 1717[b][2])

☐☐☐ 13.~~8~~5. Generic substitution is communicated to the patient. (B&PC 4073)

☐☐☐ 13.~~9~~6. 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.~~10~~7. The federal warning label prohibiting transfer of controlled substances is on the prescription container. (21 CFR 290.5)

☐☐☐ 13.~~11~~8. 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)

☐☐☐ 13.1~~12~~9. Patient package inserts are dispensed with all estrogen medications. (21 CFR 310.515)

☐☐☐ 13.~~13~~10. 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.~~14~~12. The pharmacy furnishes dangerous drugs in compliance with B&PC 4126.5 only to a patient pursuant to a prescription, a wholesaler from whom the dangerous drugs were purchased, a manufacturer from whom the drugs were purchased, a licensed wholesaler acting as a reverse distributor, another pharmacy to alleviate a temporary shortage with a quantity sufficient to alleviate the temporary shortage, a health care provider authorized to received drugs, or to another pharmacy of common ownership.

☐☐☐ 13.~~15~~13. The label includes a physical description of the dispensed medication, including its color, shape, and any identification code that appears on the tablets or capsules. (B&PC 4076)

Yes No N/A

☐☐☐ 13.~~16~~14. 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 in an amount, for all refills of that prescription taken together, not 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.~~17~~16.1 Where the prescription specifies an initial quantity of less than a 90-day supply followed by periodic refills; **and where:** (B&PC 4064.5[a])

☐ 13.~~17~~16.1.1 The prescriber has not indicated "no change to quantity" or words of similar meaning; (B&PC 4064.5[d])

☐ 13. ~~17~~16.1.2. The patient has completed an initial 30-day supply; (B&PC 4064.5[a][1]) (This is not required where the prescription continues the same medication as previously dispensed in a 90-day supply. B&PC 4064.5[b])

☐ 13. ~~17~~16.1.3. The total quantity dispensed does not exceed the total quantity authorized on the prescription, including refills; (B&PC 4064.5[a][2])

☐ 13. ~~17~~16.1.4. The prescriber has not specified on the prescription that dispensing the prescription in an initial amount, followed by periodic refills, is medically necessary; and (B&PC 4064.5[a][3])

☐ 13. ~~17~~16.1.5. The pharmacist is exercising his or her professional judgment. (B&PC 4064.5[a][4])

☐ 13.~~17~~16.2. The pharmacist notifies the prescriber of the increase in quantity dispensed. (B&PC 4064.5[c])

☐☐☐ 13.~~18~~17. The pharmacist includes a written label on the drug container indicating that the drug may impair a person's ability to operate a vehicle or vessel. The label may be printed on an auxiliary label affixed to the prescription container. (B&PC 4074[b], CCR 1744)

CORRECTIVE ACTION OR ACTION PLAN: _____

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14. Refill Authorization

Yes No N/A

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

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

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

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

~~**Yes No N/A**~~

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

CORRECTIVE ACTION OR ACTION PLAN: _____

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15. Quality Assurance and Medication Errors

Yes No N/A

☐☐☐ 15.1. Pharmacy has established quality assurance program that documents medication errors attributable, in whole or in part, to the pharmacy or its personnel. (B&PC 4125, CCR 1711)

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

☐☐☐ 15.3. The pharmacist communicates with the patient or patient's agent that a medication error has occurred and the steps required to avoid injury or mitigate the error. (CCR 1711[c][2][A], 1711[c][3])

☐☐☐ 15.4. When a medication error has occurred (drug was administered to or by the patient, or resulted in a clinically significant delay in therapy) the pharmacist communicates to the prescriber that a medication error has occurred. (CCR 1711[c][2][B], 1711[c][3])

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

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

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

☐☐☐ 15.7. The record of the quality assurance review is immediately retrievable in the pharmacy and is maintained in the pharmacy for at least one year from the date it was created. (CCR 1711[f])

☐☐☐ 15.8. Pharmacists are not deviating from the requirements of a prescription except upon the prior consent of the prescriber, and selection of the drug product is in accordance with B&PC 4073 (generic substitution). (CCR 1716)

CORRECTIVE ACTION OR ACTION PLAN:
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16. Erroneous or Uncertain Prescriptions / Corresponding Responsibility for Filling Controlled Substance Prescriptions

Yes No N/A

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

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

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

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

☐☐☐ 16.~~5~~ 4. Internet prescriptions for controlled substances are only dispensed if in compliance with the Ryan Haight Online Pharmacy Consumer Protection Act of 2008. (21 USC 829, 21 USC 802.)

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

CORRECTIVE ACTION OR ACTION PLAN: _____

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17. Prescription Transfer

Yes No N/A

☐☐☐ 17.1. Only pharmacists 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: _____

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18. Confidentiality of Prescriptions

Yes No N/A

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

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

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

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

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

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

CORRECTIVE ACTION OR ACTION PLAN: _____

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19. Record Keeping Requirements

Yes No N/A

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

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

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

~~**Yes No N/A**~~

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

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

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

☐ 19.4.1. Onsite, safe, hypodermic needle and syringe collection and disposal program.

☐ 19.4.2. Furnish or make available mail-back sharps containers.

☐ 19.4.3. Furnish or make available sharps containers.

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

Date Waiver Approved _____ Waiver Number _____

Address of offsite storage location: _____

☐☐☐ 19.6. The pharmacy ~~dispenses~~ 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: _____

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20. DEA Controlled Substances Inventory

Inventory:

Yes No N/A

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

☐☐☐ 20.2. Schedule II inventory is separate from Schedule III, IV and V. See also Section 21. (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:

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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 report requires: (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: _____

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~~21~~22. Oral/Electronic Transmission and ~~Fractionation~~ Partial Fill of Schedule II Controlled Substance Prescriptions

Yes No N/A

☐☐☐ 2~~1~~2.1. 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)

☐☐☐ 2~~1~~2.2. 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)

☐ 2~~1~~2.2.1. The licensed facility provides the pharmacy with a copy of the prescriber's signed order, when available.

☐ 2~~1~~2.2.2. The prescription is endorsed by the pharmacist with the pharmacy's name, license, and address.

☐ 2~~1~~2.2.3. The physician has signed the original prescription or provides a facsimile signature on the prescription.

☐ 2~~1~~2.2.4. 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)

☐☐☐ 2~~1~~2.3. 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])

☐☐☐ 2~~1~~2.4. 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 when a partial fill is requested by the patient or practitioner. (21 USC 829[f])

☐☐☐ 2~~1~~2.~~5~~6. The pharmacist, in a true emergency dispenses a Schedule II controlled substance from a prescription transmitted orally or electronically by a prescriber. If the order is written by the prescriber, the prescription is in ink, signed and dated by the prescriber. If the prescription is orally or electronically transmitted, it must be reduced to hard copy. The prescriber provides a written prescription on a controlled substance form that meets the requirements of H~~&~~SC 11162.1 by the seventh day following the transmission of the initial order. (21 CFR 1306.11[d], H~~&~~SC 11167)

☐☐☐ 2~~1~~2.~~6~~7. All prescriptions received, maintained or transmitted by the pharmacy, whether new or refill, received orally, in writing or electronically, are handled to ensure their security, integrity, authenticity and confidentiality. (CCR 1717.4)

☐☐☐ 2~~1~~2.~~7~~8. Electronic image transmission prescriptions are either received in hard copy or the pharmacy has the capacity to retrieve a hard copy facsimile of the prescription from the pharmacy's computer memory. (CCR 1717.4[e])

☐☐☐ 2~~1~~2.~~8~~9. All electronically transmitted prescriptions include the name & address of the prescriber, a telephone number for oral confirmation, date of transmission and the name of identity of the recipient. (CCR 1717.4[c])

~~Yes No N/A~~

☐☐☐ 2~~1~~2.~~9~~10. Prescriptions received into an interim storage device, in addition to the prescription information, record and maintain the date the prescription is entered into the device, the date the prescription is transmitted out of the device and the recipient of the outgoing transmission. (CCR 1717.4[d])

☐☐☐ 2~~1~~2.~~10~~11. A computer generated prescription that is not an e-script and is printed out or faxed by the practitioner to the pharmacy must be manually signed. (21 CFR 1306.05)

☐☐☐ 2~~1~~2.~~11~~12. Controlled substances written with the "11159.2 exemption" for the terminally ill are only dispensed when the original prescription is received, is tendered and partially filled within 60 days and no portion is dispensed more than 60 days from the date issued. (H~~&~~SC 11159.2, 21 CFR 1306.11[a], CCR 1745)

☐☐☐ 2~~1~~2.~~12~~13. Electronic prescriptions (e-scripts) for controlled substances that are received from the prescriber meet federal requirements. (21 CFR 1306.08, 21 CFR 1311)

CORRECTIVE ACTION OR ACTION PLAN: _____

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2~~2~~3. Automated Dispensing/Delivery Devices

Yes No N/A

☐☐☐ 2~~2~~3.1. Does the pharmacy use an automated dispensing/delivery device and/or prescription drop box? (CCR 1713)

☐☐☐ 2~~2~~3.2. The drugs in an automated ~~dispensing~~ drug delivery system ~~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 Parts 201.17, 210, 211, B~~&~~PC 4342, HSC 111355)

☐☐☐ 2~~2~~3.3. For an "automated drug delivery system" located in a skilled or intermediate care facility licensed by the Department of Public Health, the following is required:

- ☐ 2~~2~~3.3.1. Pharmacy and facility have developed policies and procedures to insure safety, accuracy, accountability, security, access, patient confidentiality, and maintenance of the quality, potency, and purity of stored drugs. (H~~&~~SC 1261.6[d][1])
- ☐ 2~~2~~3.3.2. A pharmacist reviews the order and patient's profile prior to the drug being removed. (H~~&~~SC 1261.6[e][2])
- ☐ 2~~2~~3.3.3. Stocking of the automated drug delivery system is done by a pharmacist. (H~~&~~SC 1261.6[f])

☐☐☐ 2~~2~~3.4. If the automated drug delivery system utilizes removable pockets, drawers, or similar technology, the stocking system is done outside the facility in a pharmacy and delivered to the facility:

☐ 2~~2~~3.4.1. Drugs are restocked by a pharmacist or by an intern or technician working under the supervision of a pharmacist except when statute authorizes exceptions. (H~~&~~SC 1261.6[f][1], 1261.6[g])

☐ 2~~2~~3.4.2. Removable pockets or drawers are transported between the pharmacy and the facility in a secure tamper-evident container. (H~~&~~SC 1261.1[f][2])

CORRECTIVE ACTION OR ACTION PLAN: _____

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2~~3~~4. Repackaging by the Pharmacy

Yes No N/A

☐☐☐ 2~~3~~4.1. 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)

☐☐☐ 2~~3~~4.2. A log is maintained for drugs pre-packed for future dispensing. (CCR 1751.1, 21 CFR Parts 210, 211)

☐☐☐ 2~~3~~4.3. Drugs previously dispensed are re-packaged at the patient's request in compliance with B&PC 4052.7.

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

24~~5~~. Refill Pharmacy

Yes No N/A

☐☐☐ 24~~5~~.1. Pharmacy processes refills for another California licensed pharmacy (CCR 1707.4[a])

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

☐☐☐ 24~~5~~.2. Does the pharmacy employ the use of a common electronic file? If yes, are there policies and procedures in place to prevent unauthorized disclosures? (CCR 1717.1)

☐☐☐ 24~~5~~.3. Some or all pharmacy refill orders are processed by another California licensed pharmacy. (CCR 1707.4[a])

If the answer is "yes," name of refilling pharmacy(s) _____

If the answer to both questions above is "no" or "not applicable" go to section ~~23~~26.

☐☐☐ 24~~5~~.4. Originating pharmacy and refill pharmacy have a contract outlining the refill arrangement, or the pharmacies have the same owner. (CCR 1707.4[a][1])

☐☐☐ 24~~5~~.5. Refill prescription label meets requirements of B~~&~~PC 4076 and CCR 1707.5 and shows the name and address of the refilling and or originating pharmacy. (CCR 1707.4[a][2])

☐☐☐ 24~~5~~.6. Patient is provided with written information, either on the prescription label or prescription container that describes which pharmacy to contact for questions. (CCR 1707.4[a][3])

~~**Yes No N/A**~~

☐☐☐ 24~~5~~.7. Both pharmacies maintain complete and accurate records of refill. (CCR 1707.4[a][4])

☐☐☐ 24~~5~~.8. Both pharmacies are responsible for accuracy of the refilled prescription. (CCR 1707.4[a][5])

☐☐☐ 24~~5~~.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

☐☐☐ 2~~5~~6.1. The pharmacy is a provider of blood clotting products for home use. (HSC 125286.20)

☐ 2~~5~~6.1.1. Health system pharmacy. (HSC 125286.20[j][1][B])

☐ 2~~5~~6.1.2. Pharmacy affiliated with hemophilia treatment centers. (HSC 125286.20[j][1][C])

☐ 2~~5~~6.1.3. Specialty home care pharmacy. (HSC 125286.20[j][1][D])

☐ 2~~5~~6.1.4. Retail pharmacy. (HSC 125286.20[j][1][E])

☐☐☐ 2~~5~~6.2. The pharmacy meets the following requirements:

☐ 2~~5~~6.2.1. 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])

☐ 2~~5~~6.2.2. 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])

☐ 2~~5~~6.2.3. 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])

☐ 2~~5~~6.2.4. 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])

☐ 2~~5~~6.2.5. Supplies all necessary ancillary infusion equipment and supplies with each prescription, as needed. (HSC 125286.25[e])

☐ 2~~5~~6.2.6. 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])

☐ 2~~5~~6.2.7. 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])

☐ 2~~5~~6.2.8. 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])

☐ 2~~5~~6.2.9. 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])

☐ 2~~5~~6.2.10. 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])

☐ 2~~5~~6.2.11. Provides language interpretive services over the telephone or in person, as needed by the patient. (HSC 125286.25[k])

☐ 2~~5~~6.2.12. Has a detailed plan for meeting the requirements of the Standards of Service for Providers of Blood Clotting Products for Home Use Act in the event of a natural or manmade disaster or other disruption of normal business operations. (HSC 125286.25[l])

PIC Initials

2~~6~~7. Policies and Procedures

Yes No N/A

☐☐☐ 2~~6~~7.1. 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])~~
- ☐ 2~~6~~7.1.~~2~~1. 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])
- ☐ 2~~6~~7.1.~~3~~2. 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])
- ☐ 2~~6~~7.1.~~4~~3. 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])
- ☐ 2~~6~~7.1.~~5~~4. 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])
- ☐ 2~~6~~7.1.~~6~~5. 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])
- ☐ 2~~6~~7.1.~~7~~6. 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])
- ☐ 2~~6~~7.1.~~8~~7. Compliance with Title VII of Public Law 109-177 – Combat Methamphetamine Epidemic Act of 2005;
- ☐ 2~~6~~7.1.~~9~~8. Reporting requirements to protect the public; (B&PC 4104)
- ☐ 2~~6~~7.1.~~10~~9. ~~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)
- ☐ 2~~6~~7.1.~~11~~10. 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)

PIC Initials

☐ 2~~6~~7.1.~~12~~11. 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**~~

☐☐☐ 2~~6~~7.2. 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)

☐☐☐ 2~~6~~7.3. Does your pharmacy furnish emergency contraceptives pursuant to B~~&~~PC 4052.3[a][1]? (B~~&~~PC 4052, CCR 1746) If yes, does the pharmacy

☐ 2~~6~~7.3.1. 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)

☐ 2~~6~~7.3.2. Provide the patient with a copy of the current EC Fact Sheet approved by the Board of Pharmacy? (CCR 1746)

☐ 2~~6~~7.3.3. 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)

☐ 2~~6~~7.3.4. Prior to furnishing EC, the pharmacist has completed a minimum of one hour of continuing education specific to emergency contraception. (CCR 1746)

☐ 2~~6~~7.3.5. 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)

☐ 2~~6~~7.3.6. 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])

☐ 2~~6~~7.3.7. 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)

☐ 2~~6~~7.3.8. 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)

☐☐☐ 2~~6~~7.4. 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)

☐ 2~~6~~7.4.1. 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.

☐ 2~~6~~7.4.2. 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. (BPC 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. (BPC 4052.3, CCR 1746.1)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

2~~7~~8. Compounding

Yes No N/A

☐☐☐ 2~~7~~8.1. 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~~[i]~~[k]~~)~~

2~~8~~9. Nuclear Pharmacy

Yes No N/A

☐☐☐ 2~~8~~9.1. All pharmacists handling radioactive drugs are competent in the preparation, handling, storage, receiving, dispensing, disposition and pharmacology of radioactive drugs. (CCR 1708.4)

☐☐☐ 2~~8~~9.2. 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)

☐☐☐ 2~~8~~9.3. 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: _____

~~29~~30. Pharmacies That Donate Drugs to a Voluntary County-Approved Drug Repository and Distribution Program

Yes No N/A

☐☐☐ ~~29~~30.1. The pharmacy donates medications to a county-approved drug repository and distribution program, and meets the following requirements: (H~~&~~SC 150202.5, 150204, B~~&~~PC 4169.5)

- ☐ ~~29~~30.1.1. The pharmacy is licensed by and is not on probation with the California State Board of Pharmacy, **and** (H~~&~~SC 150202.5)
- ☐ ~~29~~30.1.2. The pharmacy's primary or sole type of pharmacy practice is limited to skilled nursing facility, home health care, board and care, or mail order. (H~~&~~SC 150202.5)

☐☐☐ ~~29~~30.2. If the pharmacy utilizes a surplus medication collection and distribution intermediary, the pharmacy ensures that the intermediary is licensed by the California State Board of Pharmacy. (B~~&~~PC 4169.5)

☐☐☐ ~~29~~30.3. No controlled substances shall be donated. (H~~&~~SC 150204[c][1])

☐☐☐ ~~29~~30.4. Drugs that are donated are unused, unexpired and meet the following requirements: (H~~&~~SC 150202.5, 150204[c])

- ☐ ~~29~~30.4.1. Have not been adulterated, misbranded, or stored under conditions contrary to standards set by the USP or the product manufacturer. (H~~&~~SC 150204[c][2])
- ☐ ~~29~~30.4.2. Were received directly from a manufacturer or wholesaler. (H~~&~~SC 150202.5[a])
- ☐ ~~29~~30.4.3. Were returned from a health facility to which the drugs were originally issued, in a manner consistent with state and federal law, and where the drugs were centrally stored; were under the control of a health facility staff member; and that were never in the possession of a patient or individual member of the public. (H~~&~~C 150202.5[b], 150204[c][3])
- ☐ ~~29~~30.4.4. Are in unopened, tamper-evident packaging or modified unit dose containers with lot numbers and expiration dates affixed. (H~~&~~SC 105204[d])
- ☐ ~~29~~30.4.5. 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])

3~~0~~1. Pharmacies That Operate a Voluntary County-Approved Drug Repository and Distribution Program

Yes No N/A

☐☐☐ 3~~0~~1.1. The pharmacy conducts a county-approved drug repository and distribution program. (H~~&~~SC 150201, 150204)

☐ 3~~0~~1.1.1. The pharmacy is licensed by and is not on probation with the California State Board of Pharmacy, **and:** (H~~&~~SC 150201[a][1])

☐ 3~~0~~1.1.1.1 Is county owned (H~~&~~SC 150201[b][1]) or

☐ 3~~0~~1.1.1.2 Contracts with the county to establish a voluntary drug repository and distribution program. (H~~&~~SC 150201[b][1], 150200)

☐ 3~~0~~1.1.2. 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**~~

☐☐☐ 3~~0~~1.2. 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: _____

☐☐☐ 3~~0~~1.3. 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])

☐☐☐ 3~~0~~1.4. 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: _____

☐☐☐ 3~~0~~1.5. The pharmacy complies with the county's established written procedures. (H~~&~~SC 150204[b])

Pharmacies That Operate a Voluntary County-Approved Drug Repository and Distribution Program: Drugs and Maintenance of Drug Stock

☐☐☐ 3~~0~~1.6. 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])

☐☐☐ 3~~0~~1.7. 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])

☐☐☐ 3~~0~~1.8. 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])

☐☐☐ 3~~0~~1.9. Donated medications received are unused, unexpired and meet the following requirements: (H~~&~~SC 150202, 150202.5, 150204[c])

☐ 3~~0~~1.9.1. Are received from authorized sources. (H~~&~~SC 150202, 150203)

☐ 3~~0~~1.9.2. No controlled substances are received. (H~~&~~SC 150204[c][1])

☐ 3~~0~~1.9.3. Are not adulterated, misbranded, or stored under conditions contrary to USP standards or the product manufacturer. (H~~&~~SC 150204[c][2])

☐ 3~~0~~1.9.4. 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])

☐ 3~~0~~1.9.5. Are received in unopened, tamper-evident packaging or modified unit dose containers with lot numbers and expiration dates affixed. (H~~&~~SC 150204[d])

☐ 3~~0~~1.9.6. Are maintained in the donated packaging until dispensed to an eligible patient under the program, who presents a valid prescription. (H~~&~~SC 150204[i])

☐ 3~~0~~1.9.7. 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**~~

☐☐☐ 3~~0~~1.10. 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])

Pharmacies That Operate a Voluntary County-Approved Drug Repository and Distribution Program: Transferring Donated Drugs From One Participating Entity to Another

☐☐☐ 3~~0~~1.11. The pharmacy transfers donated medications to another participating county-owned pharmacy within an adjacent county. (H~~&~~SC 150204[g][4])

☐☐☐ 3~~0~~1.12. 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:

_____

☐☐☐ 3~~0~~1.13. Donated medication is not transferred by any participating entity more than once. (H~~&~~SC 150204[g][4][B])

☐☐☐ 3~~0~~1.14. 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])

☐☐☐ 3~~0~~1.15. 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])

Pharmacies That Operate a Voluntary County-Approved Drug Repository and Distribution Program: Dispensing to Eligible Patients

☐☐☐ 3~~0~~1.16. 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])

☐☐☐ 3~~0~~1.17. 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 by _____(date). 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 in the timeframe identified in the Pharmacist-in-Charge Certification above could result in the revocation of the pharmacy's license issued by the California State Board of Pharmacy.

Signature _____ _____ Date
Pharmacy Owner or Hospital Administrator

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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~~

PIC Initials

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: (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~~

PIC Initials

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

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