California State Board of Pharmacy
2720 Gateway Oaks Drive, Ste. 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

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 may be completed online, printed, signed, and readily available in the pharmacy. Signatures and initials shall be an original handwritten signature or initial in ink on the self-assessment form. Scanned copies of original signatures and initials may be maintained as file copy for the pharmacy. 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. 03/19). 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) _____

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

Licensed Sterile Compounding License# _____ Expiration:

Accredited by (if any): _____ From: _____ To: _____

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

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

PIC: _____ RPH # _____ Exp. Date: _____

Website address (if any): _____

_____
PIC Initials

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

1. _____ RPH # _____ Exp. Date: _____
   APH# _____ Exp. Date: _____
   DEA # _____ Exp. Date: _____

2. _____ RPH # _____ Exp. Date: _____
   APH # _____ ___ Exp. Date: _____
   DEA # _____ Exp. Date: _____

3. _____ RPH # _____ Exp. Date: _____
   APH # _____ ___ Exp. Date: _____
   DEA # _____ Exp. Date: _____

4. _____ RPH # _____ Exp. Date: _____
   APH # _____ __ Exp. Date: _____
   DEA # _____ Exp. Date: _____

5. _____ RPH # _____ Exp. Date: _____
   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.

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. (BPC 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 in lieu of the poster. Additional "Notice to Consumers" in languages other than English may also be posted. (BPC 4122, CCR 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])
☐	☐	☐	1.9. Pharmacists, interns, pharmacy technicians, and pharmacy technician trainees wear nametags, in 18-point type, that contain their name and license status. (BPC 680, BPC 4115.5[e], CCR 1793.7[d])
☐	☐	☐	1.10. The original board-issued pharmacy license and the current renewal are posted where they may be clearly read by the purchasing public. (BPC 4032, 4058)
☐	☐	☐	1.11. Does the pharmacy compound sterile drugs? (If yes, complete section 27 – "Compounding.")

Yes No N/A

☐☐☐ 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. (BPC 4104[a])

☐☐☐ 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. (BPC 4104[b])

☐☐☐ 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. (BPC 4104[c])

☐☐☐ 1.15. The pharmacy is subscribed to the board's e-mail notifications. (BPC 4013)

Date Last Notification Received: _____

E-mail address registered with the board:_____ _____

☐☐☐ 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. (BPC 4013[c])

Date Last Notification Received: _____

E-mail address registered with the board:_____ _____

☐☐☐ 1. 17. The pharmacy informs the customer at the point of sale for a covered prescription drug whether the retail price is lower than the applicable cost-sharing amount for the prescription drug unless the pharmacy automatically charges the customer the lower price. Additionally, the pharmacy submits the claim to the health care service plan or insurer. (BPC 4079, BPC 4079.5)

☐☐☐ 1.18. A pharmacy that dispenses controlled substances shall display safe storage products (a device made with the purpose of storing prescription medications with a locking or secure mechanism for access by the patient i.e. medicine lock box, locking medicine cabinet, locking medication bags, prescription locking vials, etc.) in a place on the premise that is located close to the pharmacy unless the pharmacy is owned and managed by pharmacists and owns 4 or less pharmacy. (BPC 4106.5)

_____
PIC Initials

Yes No N/A

☐☐☐ 1.19. A community pharmacy does not require a pharmacist employee to engage in practice of pharmacy at any time the pharmacy is open to the public unless either another employee at the establishment is made available to assist the pharmacist at all times unless the pharmacy is exempted. (BPC 4113.5)

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. (BPC 4059.5[a], HSC 1120~~{~~[a]~~}~~)

☐☐☐ 2.2. The pharmacy takes delivery of dangerous drugs and dangerous devices when the pharmacy is closed and no pharmacist is on duty only when all of the following requirements are met: (BPC 4059.5[f]):

- ☐ 2.2.1. The drugs are placed in a secure storage facility in the same building as the pharmacy (BPC 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 (BPC 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 (BPC 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 (BPC 4059.5[f][4]); and
- ☐ 2.2.5. The agent delivering dangerous drugs and dangerous devices leaves documents indicating the name and amount of each dangerous drug or dangerous device delivered in the secure storage facility. The pharmacy is responsible for the dangerous drugs and dangerous devices delivered to the secure storage facility. The pharmacy is also being responsible for obtaining and maintaining records relating to the delivery of dangerous drugs and dangerous devices to a secure storage facility. BPC 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])

Yes No N/A

☐☐☐ 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])

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. (BPC 4342, HSC 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, warehoused, distributed or transferred with an entity licensed with the board as a wholesaler, third-party logistics provider, pharmacy, or manufacturer, and provided the dangerous drugs and devices: (BPC 4059.5, 4169)

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

☐☐☐ 3.3. If the pharmacy has reasonable cause to believe a dangerous drug or dangerous device in, or having been in its possession is counterfeit or the subject of a fraudulent transaction, the pharmacy will notify the board within 72 hours of obtaining that knowledge. (BPC 4107.5)

☐☐☐ 3.4. The pharmacy does not furnish dangerous drugs or dangerous devices to an unauthorized person. (BPC 4163)

☐☐☐ 3.5. The pharmacy is aware, effective November 27, 2020, pharmacies are required by the Drug Quality and Security Act (DQSA), to have pharmacy lot-level traceability and by November 27, 2023, unit-level traceability. (Drug Supply Chain Security Act)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

4. Voluntary Drug Repository and Distribution Program (HSC 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 30 [donate drugs] or Section 31 [operate program] of this Self-Assessment.)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

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. (BPC 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 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. (BPC 4101, 4113)
☐	☐	☐	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. (HSC 1206, 1265)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

6. Duties of a Pharmacist

Yes	No	N/A	
☐	☐	☐	6.1. 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]).

Yes No N/A

☐☐☐ 6.2. 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. (BPC 4052, 4052.1, 4052.2, 4052.3, 4052.4)

Yes No N/A

☐☐☐ 6.4. Pharmacists have obtained approval to access the CURES Prescription Drug Monitoring Program (PDMP). (HSC 11165.1)

☐☐☐ 6.5. The pharmacist dispenses emergency contraceptive only 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.) (BPC 1206.6)

☐☐☐ 6.7. Only a pharmacist performs CLIA waived clinical laboratory tests, where the pharmacy is registered with CDPH to perform such services. (BPC 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])

☐☐☐ 6.9. All pharmacists have joined the board's email notification list. (BPC 4013)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

7. Duties of an Advanced Practice Pharmacist

Yes No N/A

☐☐☐ 7.1. The advanced practice pharmacist has received an advanced practice pharmacist license from the board and may do the following: (BPC 4016.5, 4210)

- ☐ 7.1.1. Perform patient assessments, order and interpret drug therapy-related tests, and refer patients to other health care providers; (BPC 4052.6[a])
- ☐ 7.1.2. Participate in the evaluation and management of diseases and health conditions in collaboration with other health care providers; (BPC 4052.6[a])
- ☐ 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; (BPC 4052.6[b])
- ☐ 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; (BPC 4052.6[b])

☐ 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; (BPC 4052.6[d])

☐ 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. (BPC 4052.6[e])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

8. Duties of an Intern Pharmacist

Yes No N/A

☐☐☐ 8.1. The intern pharmacist performs the functions of a pharmacist only under the direct supervision of a pharmacist. The pharmacist supervises no more than **two interns** at any one time. (BPC 4114, 4023.5, CCR 1726)

☐☐☐ 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 or the pharmacist-in-charge at the pharmacy while the intern pharmacist obtained the experience, when applicable. (BPC 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])

☐☐☐ 8.5. All intern pharmacists have joined the board's email notification list. (BPC 4013)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

9. Duties of a Pharmacy Technician

Yes No N/A

☐☐☐ 9.1. Pharmacy technicians only perform packaging, manipulative, repetitive, or other nondiscretionary tasks, while assisting and under the direct supervision and control of a pharmacist. The pharmacist is responsible for the duties performed by the pharmacy technician under the pharmacist's supervision. (BPC 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. (BPC 4038, 4115, CCR 1793.7[f])

Yes No N/A

☐☐☐ 9.3. A pharmacy technician or pharmacy technician trainee wears identification, in 18-point type, that identifies himself or herself as a pharmacy technician or pharmacy technician trainee. (BPC 680, BPC 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. (BPC 4115.5)

☐☐☐ 9.6. All pharmacy technicians have joined the board's email notification list. (BPC 4013)

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: (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;

_____
PIC Initials

☐ 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.

Yes No N/A

☐☐☐ 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. (BPC 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. (BPC 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. (BPC 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. (BPC 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. (BPC 4070[c], CCR 1717.4[h])

☐☐☐ 12.6. Facsimile prescriptions are received only from a prescriber's office. (BPC 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. (BPC 2290.5, 2242, 2242.1, 4067[a])

Yes No N/A

☐☐☐ 12.8. With the exception of those prescriptions written under HSC 11159.2 and HSC 11167.5, all written controlled substances prescriptions (Schedules II – V) are on California Security Prescription forms. (HSC 11164[a], HSC 11167.5)

☐☐☐ 12.9. All controlled substance prescriptions are valid for six months and are signed and dated by the prescriber. (HSC 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. (BPC 4076)

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

☐☐☐ 13.3. The expiration date of a drug's effectiveness is accurately identified on the label. (BPC 4076)

☐☐☐ 13.4. The trade name or generic name and manufacturer of the prescription drug is accurately identified on the label and prescription record and includes the statement "generic for _____" where the brand name is inserted, and the name of the manufacturer. In the professional judgment of the pharmacist, if the brand name is no longer widely used, the label may list only the generic name of the drug and the manufacturer's name may be listed outside the patient-centered area. (BPC 4076, CCR 1717[b][2], CCR 1707.5[a][1][B])

☐☐☐ 13.5. Generic substitution is communicated to the patient. (BPC 4073)

☐☐☐ 13.6. When a biological product is substituted with an alternative biological product, all the requirements of BPC 4073.5 are met. (BPC 4073.5)

☐☐☐ 13.7. If the prescription is filled by a pharmacy technician or a pharmacy technician trainee, before dispensing, the prescription is checked for accuracy by a licensed pharmacist and that pharmacist initials the prescription label or by recording the identity of the reviewing pharmacist in a computer system by a secure means. (BPC 4115, 4115.5, CCR 1793.7, CCR 1712)

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

☐☐☐ 13.9. Prescriptions are dispensed in a new and child-resistant container, or senior-adult ease-of-opening tested container, or in a non-complying package only pursuant to the prescriber or when requested by the purchaser. (15 USC 1473[b], 16 CFR 1700.15, CCR 1717)

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

_____
PIC Initials

Yes No N/A

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

☐☐☐ 13.12. Medication guides are provided on required medications. (21 CFR, Part 208, Section 208.24[e])

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

☐☐☐ 13.14. The label includes a physical description of the dispensed medication, including its color, shape, and any identification code that appears on the tablets or capsules. (BPC 4076)

☐☐☐ 13.15. Controlled substance prescriptions are not filled or refilled more than six months from the date written. (HSC 11200[a])

☐☐☐ 13.16. 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. (HSC 11200[b])

☐☐☐ 13.17. The pharmacy dispenses not more than a 90-day supply of a dangerous drug, excluding controlled substances, psychotropic medications and self-administered hormonal contraception, under the following provisions: (BPC 4064.5)

- ☐ 13.17.1 Where the prescription specifies an initial quantity of less than a 90-day supply followed by periodic refills; **and where:** (BPC 4064.5[a])
- ☐ 13.17.1.1 The prescriber has not indicated “no change to quantity” or words of similar meaning; (BPC 4064.5[d])
- ☐ 13.17.1.2. The patient has completed an initial 30-day supply; (BPC 4064.5[a][1]) (This is not required where the prescription continues the same medication as previously dispensed in a 90-day supply. BPC 4064.5[b])
- ☐ 13.17.1.3. The total quantity dispensed does not exceed the total quantity authorized on the prescription, including refills; (BPC 4064.5[a][2])
- ☐ 13.17.1.4. The prescriber has not specified on the prescription that dispensing the prescription in an initial amount, followed by periodic refills, is medically necessary; and (BPC 4064.5[a][3])
- ☐ 13.17.1.5. The pharmacist is exercising his or her professional judgment. (BPC 4064.5[a][4])
- ☐ 13.17.2. The pharmacist notifies the prescriber of the increase in quantity dispensed. (BPC 4064.5[c])
- ☐ 13.17.3. When requested by the patient, the pharmacist dispenses up to a 12-month supply of an FDA-approved, self-administered hormonal contraceptive pursuant to a

valid prescription that specifies an initial quantity followed by periodic refills. (BPC 4064.5)

☐ 13.17.4. When a pharmacist furnishes a self-administered hormonal contraceptive pursuant to BPC 4052.3 under protocols developed by the Board of Pharmacy, the pharmacist may furnish, at the patient's request, up to a 12-month supply at one time. (BPC 4064.5)

Yes No N/A

☐☐☐ 13.18. The pharmacist includes a written label on the drug container indicating that the drug may impair a person's ability to operate a vehicle or vessel. The label may be printed on an auxiliary label affixed to the prescription container. (BPC 4074[a][b], BPC 4076.7, CCR 1744[a])

☐☐☐ 13.19. The pharmacist includes a written label on the drug container to alert the patient about possible potentiating effects when taken in combination with alcohol. The label may be printed on an auxiliary label affixed to the prescription container. (BPC 4074[a], CCR 1744[b])

☐☐☐ 13.20. Whenever an opioid prescription drug is dispensed to patient for outpatient use, the pharmacy prominently displays on the label or container or by a flag or other notification to the container, a notice that states, "Caution: Opioid. Risk of overdose and addiction." (BPC 4076.7)

☐☐☐ 13.21. When requested by a patient or patient representative, the pharmacy provides translated directions for use, printed on the prescription container, label, or on a supplemental document. If the translated directions for use appears on the prescription container or label, the English-language version of the directions for use also appears on the container or label, whenever possible, and may appear on other areas of the label outside the patient-centered area. If the English-language directions is not possible to appear on the container or label, the English-language directions is provided on a supplemental document. (BPC 4076.6)

☐☐☐ 13.22. When a pharmacist furnishes naloxone pursuant to the board of pharmacy's approved protocol, the pharmacist complies to all the requirements listed in CCR 1746.3.

☐☐☐ 13.23. When the pharmacy furnished naloxone or another opioid antagonist to a school district, county office of education, or charter school pursuant to Section 49414.3 of the Education Code, it is furnished exclusively for use at a school district school site, county office of education school site, or charter school, and a physician or surgeon provides a written order specifying the quantity to be furnished. (BPC 4119.8)

☐☐☐ 13.24. The pharmacy furnishes naloxone hydrochloride or other opioid antagonist to a law enforcement agency if the furnished exclusively for use by trained employees of the law enforcement agency and the records of acquisition and disposition of naloxone hydrochloride or other opioid antagonists furnished shall be maintained by the law enforcement agency for 3 years. (BPC 4119.9)

☐☐☐ 13.25. For each vaccine administered by a pharmacist, a patient vaccine administration record is maintained in an automated data processing or manual record mode such that information required under section 300aa-25 of Title 42 of the United States Code is readily retrievable during the pharmacy's normal operating hours, provides each patient with a vaccine administration record, and reports to the immunization registry, in accordance with BPC 4052.8(b)(3), the information described in HSC 120440(c) within 14 days of the administration of

any vaccine (includes informing each patient or patient's guardian of immunization record sharing preferences detailed in HSC 120440(e). (CCR 1746.4)

☐☐☐ 13.26. The pharmacy furnishes epinephrine auto-injectors to an authorized entity for the purpose of rendering emergency care in accordance with HSC 1797.197(a), and is furnished exclusively for use by, or in connection with, an authorized entity and an authorized health care provider provides a prescription specifying the quantity of the epinephrine auto-injectors to be furnished to the authorized entity. A new prescription is obtained for any additional epinephrine auto-injector required for use. The pharmacy complies with the requirements for labeling and records maintained pursuant to BPC 4119.4.

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. (BPC 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. (BPC 4064)

☐☐☐ 14.4. Refills for Schedule II controlled substances are prohibited. (HSC 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. (BPC 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])

Yes No N/A

☐☐☐ 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 BPC 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. (HSC 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 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.)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

_____
PIC Initials

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])

☐☐☐ 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. All completed pharmacy self-assessments 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. Any record maintained electronically, the pharmacist-in-charge or pharmacist on duty is able to produce a hardcopy and electronic copy of all records of acquisition or disposition or other drug or dispensing-related records maintained electronically. These records include (BPC 4081, 4105, 4169, 4333):

- ☐ 19.2.1. Prescription records (BPC 4081[a])
- ☐ 19.2.2. Purchase Invoices for all prescription drugs (BPC 4081[b])
- ☐ 19.2.3. Purchase Invoices and sales records for non-prescription diabetic test devices dispensed pursuant to a prescription (BPC 4081[d])
- ☐ 19.2.4. Biennial controlled substances inventory (21 CFR 1304.11, CCR 1718)
- ☐ 19.2.5. U.S. Official Order Forms (DEA Form 222) (21 CFR 1305.13)
- ☐ 19.2.6. Power of Attorney for completion of DEA 222 forms (21 CFR 1305.07)
- ☐ 19.2.7. Theft and Loss Reports (DEA Form 106) (21 CFR 1301.74[c])
- ☐ 19.2.8. Record documenting return of drugs to wholesaler or manufacturer (BPC 4081)
- ☐ 19.2.9. Record documenting transfers or sales to other pharmacies, licensees, prescribers, and reverse distributors (BPC 4081, 4105, CCR 1718)
- ☐ 19.2.10. Records of receipt and shipment (BPC 4081)

☐☐☐ 19.3. Hypodermic needle and syringe sales by a pharmacist to a person without a prescription are limited to: (BPC 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. (HSC 121285, BPC 4145.5)
- ☐ 19.3.4. For industrial use, as determined by the board. (BPC 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 hypodermic needles and syringes for human use to a person 18 years of age or older for personal use. (BPC 4145.5)

☐☐☐ 19.4. When hypodermic needles and syringes are furnished by a pharmacy 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: (BPC 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.

Yes No N/A

☐☐☐ 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, BPC 4105)

Date Waiver Approved _____ Waiver Number _____

Address of offsite storage location: _____

☐☐☐ 19.6. The pharmacy furnishes an epinephrine auto-injector to a school district, county office of education, or charter school pursuant to Section 49414 of the Education Code if all of the following are met:

☐ 19.6.1. The epinephrine auto-injectors are furnished for use at a school district site, county office or education, or charter school (BPC 4119.2 [a][1]).

☐ 19.6.2. A physician and surgeon provide a written order that specifies the quantity of epinephrine auto-injectors to be furnished (BPC 4119.2 [a][2]).

☐☐☐ 19.7. The pharmacy furnishes an epinephrine auto-injector to an authorized entity for the purpose of rendering emergency care in accordance with HSC 1797.197a. (BPC 4119.3, 4119.4)

☐ 19.7.1. An authorized healthcare provider provides a written order that specifies the quantity of epinephrine auto-injectors to be dispensed. (BPC 4119.3[a][1], 4119.4[a][2])

☐ 19.7.2. 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. (BPC 4119.3[a][1], 4119.4[b])

☐ 19.7.3. Each dispensed prescription includes the manufacturer’s product information sheet for epinephrine auto-injectors. (BPC 4119.3[a][2], 4119.4[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

_____

PIC Initials

20. DEA Controlled Substances Inventory

Inventory:

Yes No N/A

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

☐☐☐ 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 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~~1])

☐☐☐ 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, 1305.13, 1305.21, 1305.22[g])

☐☐☐ 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)

☐☐☐ 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], Drug Supply Chain Security Act. BPC 4160)

Yes No N/A

☐☐☐ 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. (HSC 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 within one business day of 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], 1717[f])

☐☐☐ 20.17. All Schedule II through IV controlled substance dispensing data is successfully transmitted to CURES weekly. (HSC 11165[d])

☐☐☐ 20.18. Furnishing of dangerous drugs and controlled substances for physician office use is done under sales and purchase records that correctly give the date, names and addresses of supplier and buyer, the drug or device and its quantity. The prescription may not be used for obtaining dangerous drugs or controlled substances for supplying a practitioner for the purpose of dispensing to patients. (21 CFR 1306.04[b], HSC 11250)

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 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])

Yes No N/A

☐☐☐ 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: _____

_____

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

Yes No N/A

☐☐☐ 22.1. 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], HSC 11164)

☐☐☐ 22.2. 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], HSC 11167.5)

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

☐ 22.2.2. The prescription is endorsed by the pharmacist with the pharmacy's name, license, and address.

☐ 22.2.3. The physician has signed the original prescription or provides a facsimile signature on the prescription.

☐ 22.2.4. 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], HSC 11167.5)

Yes No N/A

☐☐☐ 22.3. 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. The pharmacist shall notify the prescriber if the remaining portion of the prescription is not filled within 72 hours. (21 CFR 1306.13[a], CCR 1745[d])

☐☐☐ 22.4. The pharmacist maintains records (in a readily retrievable form or on the original prescription) 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. The pharmacist shall report to CURES only the actual amounts of drug dispensed. The total dispensed shall not exceed the prescribed quantity. (21 USC 829[f], BPC 4052.10)

☐☐☐ 22.6. 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. (HSC 11159.2, 21 CFR 1306.11[a], CCR 1745)

☐☐☐ 22.7. 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 HSC 11162.1 by the seventh day following the transmission of the initial order. (21 CFR 1306.11[d], HSC 11167)

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

Yes No N/A

☐☐☐ 22.9. 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])

☐☐☐ 22.10. 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])

☐☐☐ 22.11. 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])

☐☐☐ 22.12. 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)

☐☐☐ 22.13. 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: _____

_____

23. Automated Drug Delivery Systems

Yes No N/A

☐☐☐ 23.1. Does the pharmacy use an automated drug delivery system, automated patient dispensing system and/or automated unit dose system? (CCR 1713)

If yes, complete the annual self-assessment for automated drug delivery systems.

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

24. Repackaging by the Pharmacy

Yes No N/A

☐☐☐ 24.1. 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], BPC 4342, HSC 110105, 111430)

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

Yes No N/A

☐☐☐ 24.3. Drugs previously dispensed by another pharmacy are re-packaged at the patient's request and includes the name and address of both pharmacies and complies with the other requirements of BPC 4052.7.

☐☐☐ 24.4. The pharmacy only repackages and furnishes a reasonable quantity of dangerous drugs and devices for prescriber office use. (BPC 4119.5 [b])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

25. Policies and Procedures

Yes No N/A

☐☐☐ 25.1. There are written policies and procedures in place for:

- ☐ 25.1.1. 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; (BPC 4104[a],[c])
- ☐ 25.1.2. 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; (BPC 4104[b],[c])
- ☐ 25.1.3. Oral consultation for discharge medications to an inpatient of a health care facility licensed pursuant to HSC 1250, or to an inmate of an adult correctional facility or juvenile detention facility; (BPC 4074, CCR 1707.2[b][3])
- ☐ 25.1.4. 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])
- ☐ 25.1.5. 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])
- ☐ 25.1.6. 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; (BPC 4059.5[f][1])
- ☐ 25.1.7. Compliance with Title VII of Public Law 109-177 – Combat Methamphetamine Epidemic Act of 2005;
- ☐ 25.1.8. Reporting requirements to protect the public; (BPC 4104)
- ☐ 25.1.9. A policy to establish how a patient will receive a medication when a pharmacist has a conscientious objection. (BPC 733)

☐ 25.1.10. 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 (BPC 733)

☐ 25.1.11. 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)

☐ 25.1.12. Inventory reconciliation reporting requirements. (CCR 1715.65[b])

Yes No N/A

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

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

☐☐☐ 25.3. Does your pharmacy furnish emergency contraceptives pursuant to BPC 4052[a][10][A][1], BPC 4052, CCR 1746? If yes, does the pharmacy:

☐ 25.3.1. 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)

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

☐ 25.3.3. 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)

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

☐ 25.3.5. 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)

☐ 25.3.6. 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? (BPC 733[b])

☐ 25.3.7. 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? (BPC 733[b], BPC 4052.3)

☐☐☐ 25.4. 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. (BPC 4052.01[a], CCR 1746.3)

☐ 25.4.1. 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.

☐ 25.4.2. 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.

☐ 25.4.3. The pharmacy furnishes naloxone hydrochloride or other opioid antagonist to a law enforcement agency if the furnished exclusively for use by trained employees of the law enforcement agency and the records of acquisition and disposition of naloxone hydrochloride or other opioid antagonists furnished shall be maintained by the law enforcement agency for 3 years. (BPC 4119.9)

Yes No N/A

☐☐☐ 25.5. 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)

☐☐☐ 25.6. Furnishes Self-Administered 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. A pharmacist may furnish at the patient's request up to a 12month supply at one time. (BPC 4052.3, BPC 4064.5[f][2], CCR 1746.1)

☐☐☐ 25.7. Does your pharmacy furnish travel medications not requiring a diagnosis that are recommended by the federal Center for Disease Control and Prevention (CDC) for individuals traveling outside the 50 states and the District of Columbia pursuant to section BPC 4052(a)(10)(A)(3)? If yes, does the pharmacy do the following: (CCR 1746.5[a][c])

☐ 25.7.1. Keep documentation on site and available for inspection by the board, pharmacist(s) completion of an immunization training program that meets the requirements on BPC 4052.8(b)(1), completion of a travel medicine training program, consisting of at least 10 hours of training and cover each element of the International Society of Travel Medicine's Body of Knowledge for the Practice of Travel Medicine (2012), and incorporate by reference, completion of the CDC Yellow Fever Vaccine Course and current basic life support certification. (CCR 1746.5[c])

☐ 25.7.2. Pharmacist complete two hours of ongoing continuing education focused on travel medicine, separate from continuing education in immunization and vaccines, from an approved provider once every two years. (CCR 1746.5[d])

☐ 25.7.3. Prior to furnishing travel medications, the pharmacist performs a good faith evaluation of the patient, including evaluation of the patient's travel history using destination-specific travel criteria. The travel history includes all the information necessary for a risk assessment during pre-travel consultation, as identified in the CDC Yellow Book. (CCR 1746.5[e])

☐ 25.7.4. The pharmacist notifies the patient's primary care provider of any drugs or devices furnished to the patient within 14 days of the date of furnishing, or enter the appropriate information in the patient record system shared with the primary care provider, as permitted by the primary care provider. If the patient does not have a primary care provider, or is unable to provide contact information for his or her primary care provider, the pharmacist provides the patient with written record of the drugs or devices furnished and advise the patient to consult a physician of the patient's choice. (CCR 1746.5[f])

☐ 25.7.5. A patient medication record is maintained and securely stored in a physical or electronic manner for each travel medication furnished, such that the information required under section 300aa-25 of title 42 of the United States Code is readily retrievable during the pharmacy or facility's normal operating hours and the pharmacist provides the patient with written documentation that reflects the clinical assessment and travel medication plan. (CCR 1746.5[g])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

26. Refill Pharmacy

Yes	No	N/A	
☐	☐	☐	26.1. Pharmacy processes refills for another pharmacy within this state (CCR 1707.4[a]) If the answer is "yes", name the pharmacy or pharmacies _____
☐	☐	☐	26.2. 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)
☐	☐	☐	26.3. 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 27.

☐	☐	☐	26.4. Originating pharmacy and refill pharmacy have a contract outlining the refill arrangement, or the pharmacies have the same owner. (CCR 1707.4[a][1])
☐	☐	☐	26.5. Refill prescription label meets requirements of BPC 4076 and CCR 1707.5 and shows the name and address of the refilling and or originating pharmacy. (CCR 1707.4[a][2])
☐	☐	☐	26.6. 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])
☐	☐	☐	26.7. Both pharmacies maintain complete and accurate records of refill. (CCR 1707.4[a][4])
☐	☐	☐	26.8. Both pharmacies are responsible for accuracy of the refilled prescription. (CCR 1707.4[a][5])
☐	☐	☐	26.9. 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: _____

_____

27. Compounding

Yes No N/A

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

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

28. Nuclear Pharmacy

Yes No N/A

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

☐☐☐ 28.2. A pharmacist qualified under CCR 1708.4 to furnish radioactive drugs is in the pharmacy whenever the furnishing of radioactive drugs occurs. All personnel involved in the furnishing of radioactive drugs are under the immediate and direct supervision of such a qualified pharmacist. (CCR 1708.5)

☐☐☐ 28.3. The pharmacy possesses a current Sterile Compounding Permit (BPC 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. Telepharmacy Systems and Remote Dispensing Site Pharmacies

Yes No N/A

☐☐☐ 29.1. Pharmacy provides tele-pharmacy services and acts as a supervising pharmacy for only **one** remote dispensing site pharmacy and has obtained a remote dispensing site pharmacy license from the board. (BPC 4130 [b][e], BPC 4044.6, BPC 4044.3[a])

If the answer is "yes", name the remote dispensing site pharmacy and license number:

Name:_____ License No.:_____

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

☐☐☐ 29.2. The supervising pharmacy uses a telepharmacy system for the dispensing of prescription drugs and providing related drug regimen review and patient counseling services at the remote dispensing site pharmacy. (BPC 4031[a], BPC 4044.7)

☐☐☐ 29.3. The remote dispensing site pharmacy is located in a medically underserved area unless otherwise approved by the board. (BPC 4130 [c])

Yes No N/A

☐☐☐ 29.4. The remote dispensing site pharmacy is staffed by pharmacists or pharmacy technicians, or both, but does not employ any unlicensed personnel. (BPC 4130 [d])

☐☐☐ 29.5. The supervising pharmacy has only obtained one remote dispensing site pharmacy license. (BPC 4130 [e])

☐☐☐ 29.6. The remote dispensing site pharmacy is not operated by the state and is not located in any state facility, including, but not limited to, correctional facilities, state hospitals, or developmental centers. (BPC 4130 [f])

☐☐☐ 29.7. The remote dispensing site pharmacy will cease to be a remote dispensing site pharmacy and will become a full-service pharmacy licensed under Section 4110 with a pharmacist onsite if it meets all the requirements for licensure for a pharmacy, if the remote dispensing pharmacy dispenses more than 225 prescriptions per day, calculated each calendar year. (BPC 4130 [h])

☐☐☐ 29.8. The supervising pharmacy provides telepharmacy services for only one remote dispensing site pharmacy. (BPC 4131[a])

☐☐☐ 29.9. The supervising pharmacy is not located greater than 150 road miles from the remote dispensing site pharmacy, unless otherwise approved by the board. (BPC 4131 [b])

☐☐☐ 29.10. The supervising pharmacy and the remote dispensing site pharmacy are under common ownership. (BPC 4131 [c])

☐☐☐ 29.11. The remote dispensing site pharmacy is staffed by a pharmacist, or at least one registered pharmacy technician meeting the qualifications of Section 4132 (BPC 4131[d]).

☐☐☐ 29.12. Pharmacy technicians working at a remote dispensing site pharmacy remain under the direct supervision and control of a pharmacist at the supervising pharmacy at all times that the remote dispensing site pharmacy is operational. (BPC 4131[d])

☐☐☐ 29.13. The supervising pharmacists utilizes a telepharmacy system to supervise operations through audio and visual technology from the supervising pharmacy. (BPC 4131[d])

☐☐☐ 29.14. The designated pharmacist-in-charge of the supervising pharmacy is also the pharmacist-in-charge at the remote dispensing site pharmacy. (BPC 4131[e])

☐☐☐ 29.15. The pharmacist -in-charge of the remote dispensing site pharmacy and the pharmacist-on-duty at the supervising pharmacy are responsible to ensure that both the supervising pharmacy and the remote dispensing site pharmacy are sufficiently staffed to allow for appropriate supervision, which is supervision that would not be reasonably expected to result in an unreasonable risk of harm to public health, safety, or welfare. (BPC 4131[f])

☐☐☐ 29.16. In addition to the requirements of 4204, at least one pharmacy technician working at the remote dispensing site pharmacy has met the qualifications promulgated by the board. (BPC 4132[a]). The regulations developed by the board only apply to pharmacy technicians working at remote dispensing sites.

Yes No N/A

☐☐☐ 29.17. Registered pharmacy technicians may perform order entry, packaging, manipulative, repetitive, and other nondiscretionary tasks at the remote dispensing site pharmacy under the supervision of a pharmacist at the supervising pharmacy using a telepharmacy system. (BPC 4132[b])

☐☐☐ 29.18. Pharmacy technicians at the remote dispensing site pharmacy do not do any of the following:

- ☐ 29.18.1. Receive a new prescription order orally from a prescriber or other person authorized to prescribe by law. (BPC 4132[c][1])
- ☐ 29.18.2. Consult with a patient or his or her agent regarding a prescription, either prior to or after dispensing, or regarding any medical information contained in a patient medication record system or patient chart. (BPC 4132[c][2])
- ☐ 29.18.3. Identify, evaluate, or interpret a prescription. (BPC 4132[c][3])
- ☐ 29.18.4. Interpret the clinical data in a patient medication record system or patient chart. (BPC 4132[c][4])
- ☐ 29.18.5. Consult with any prescriber, nurse, or other health care professional or authorized agent thereof. (BPC 4132[c][5])
- ☐ 29.18.6. Supervise the packaging of drugs and check the packaging procedures and product upon completion. (BPC 4132[c][6])
- ☐ 29.18.7. Perform any function that requires the professional judgment of a licensed pharmacist. (BPC 4132[c][7])
- ☐ 29.18.8. Compound drug preparations. (BPC 4132[c][8])

☐☐☐ 29.19. A pharmacist at the supervising pharmacy supervises no more than two pharmacy technicians at each remote dispensing site pharmacy. The pharmacist may also supervise pharmacy technicians at the supervising pharmacy. (BPC 4132[d])

☐☐☐ 29.20. The supervising pharmacy's telepharmacy system maintains a video and audio communication system that provides for effective communication between the supervising pharmacy and the remote dispensing site pharmacy's personnel and patients. (BPC 4133[a])

☐☐☐ 29.21. The telepharmacy system facilitates adequate pharmacist supervision and allows the appropriate exchange of visual verbal, and written communications for patient counseling and other matters involved in the lawful dispensing of drugs. (BPC 4133[b])

☐☐☐ 29.22. Patient counseling is provided using audio-visual communication prior to all prescriptions being dispensed from the remote dispensing site pharmacy. (BPC 4133[c])

☐☐☐ 29.23. The telepharmacy system is able to do all of the following:

- ☐ 29.23.1. Identify and record the pharmacy technician preparing each prescription and the supervising pharmacist who reviewed and authorized the dispensing of the prescription. (BPC 4133[d][1])

☐ 29.23.2. Require a pharmacist to review and compare the electronic image of any new prescription presented at the remote dispensing site pharmacy with the data entry record of the prescription. (BPC 4133[d][2])

☐ 29.23.3. Require the pharmacy technician to use barcode technology to verify the accuracy of the drug to be dispensed. (BPC 4133[d][3])

☐ 29.23.4. Require remote visual confirmation by a pharmacist at the supervising pharmacy of the drug stock bottle and the drug to be dispensed prior to dispensing. (BPC 4133[d][4])

☐ 29.23.5. Ensure that a prescription is not sold or delivered to a patient prior to a pharmacist performing final verification of the accuracy of the prescription and releasing the prescription for sale and delivery. (BPC 4133[d][5])

Yes No N/A

☐☐☐ 29.24. The video and audio communication system used to counsel and interact with each patient or patient's caregiver shall be secure and compliant with the federal Health Insurance Portability and Accountability Act (Public Law 104-191). (BPC 4133[e])

☐☐☐ 29.25. All records of prescriptions dispensed including the records of the actions performed through the telepharmacy system shall be maintained at the remote dispensing site pharmacy and shall be maintained for three years after the filling of the prescription. (BPC 4133[f])

☐☐☐ 29.26. A pharmacist from the supervising pharmacy completes a monthly in-person, self-inspection of each remote dispensing site pharmacy using the form designated by the board and retains all inspection reports. (BPC 4134[a])

☐☐☐ 29.27. A perpetual inventory is kept for all controlled substances stored at the remote dispensing site pharmacy. (BPC 4134[b])

☐☐☐ 29.28. All controlled substances stored at the remote dispensing site pharmacy are stored in a secure cabinet or safe that is locked. (BPC 4134[c])

☐☐☐ 29.29. A pharmacist from the supervising pharmacy performs inventory and inventory reconciliation functions at the remote dispensing site pharmacy to detect and prevent the loss of any controlled substances. (BPC 4134[d])

☐☐☐ 29.30. The pharmacist-in-charge of the remote dispensing site pharmacy reviews all inventory and inventory reconciliation reports taken and establishes and maintains secure methods to prevent losses of any controlled substances. (BPC 4134[e])

☐☐☐ 29.31. A pharmacist from the supervising pharmacy compiles an inventory reconciliation report of all Schedule II controlled substances at the remote dispensing site pharmacy at least once every three months. This compilation shall include the following:

☐ 29.31.1. 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; (BPC 4134[f][1])

☐ 29.31.2. A review of all acquisitions and dispositions of federal Schedule II controlled substances since the last inventory reconciliation report; (BPC 4134[f][2])

☐ 29.31.3. A comparison of the two above-mentioned items to determine if there are any variances; (BPC 4134[f][3])

☐ 29.31.4. 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 (BPC 4134[f][4])

Yes No N/A

☐☐☐ 29.32. The remote dispensing site pharmacy reports in writing, any identified losses of controlled substances and possible causes of losses 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 remote dispensing site 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. (BPC 4134[g])

☐☐☐ 29.33. Possible causes of overages are identified in writing and incorporated into the inventory reconciliation report. (BPC 4134[h])

☐☐☐ 29.34. The inventory reconciliation report is dated and signed by the individual(s) performing the inventory, and countersigned by the pharmacist-in-charge of the remote dispensing site pharmacy, 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. (BPC 4134 [i])

☐☐☐ 29.35. While closed, the remote dispensing site pharmacy utilizes an alarm or other comparable monitoring system. (BPC 4135[a])

☐☐☐ 29.36. The remote dispensing site pharmacy is not open or its employees are not allowed access at times when the supervising pharmacy is closed. (BPC 4135[b])

☐☐☐ 29.37. The remote dispensing site pharmacy's security system tracks entries into the remote dispensing site pharmacy and the pharmacist-in-charge periodically review the record of entries. (BPC 4135[b])

☐☐☐ 29.38. Pharmacy services are not provided at the remote dispensing site pharmacy if the telepharmacy system is unavailable. (BPC 4135[b])

☐☐☐ 29.39. The remote dispensing site pharmacy retains a recording of facility surveillance excluding patient communications, for a minimum of 120 days. (BPC 4135[c])

☐☐☐ 29.40. Dangerous drugs and devices and controlled substances ordered by the remote dispensing site pharmacy are signed for and received by a pharmacist or a registered pharmacy technician, who meets the qualifications of Section 4132. (BPC 4059.5[q])

☐☐☐ 29.41. A controlled substance signed for by a pharmacy technician under this section is stored separately from existing inventory until the time the controlled substance is reviewed and countersigned by a pharmacist. (BPC 4059.5[q])

Yes No N/A

☐☐☐ 29.42. Any receipt and storage of a controlled substance by a pharmacy technician pursuant to this section is captured on video, and the video is accessible to the supervising pharmacy and maintained by the remote dispensing site pharmacy for 120 days. (BPC 4059.5[q])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

30. Prescription Drug Take-Back Services

Yes No N/A

☐☐☐ 30.1. Does the pharmacy participate in a Prescription Drug Take-Back Program and adheres to the federal, state and local requirements governing the collection and destruction of dangerous drugs? (CCR 1776, 1776.1)

If yes, check off below the type of prescription drug take-back program the pharmacy offers and complete the sections that applies to the type of program(s):

- ☐ Mail back envelopes or package service. (CCR 1776.2)
- ☐ Collection receptacles in the pharmacy. (CCR 1776.3)
- ☐ Drug take-back services in the Skilled Nursing Facilities. (CCR 1776.4, HSC 1250[c])

☐☐☐ 30.2. Only prescription drugs that have been dispensed by any pharmacy or practitioner to a consumer are eligible for collection as part of drug take-back services maintained by the pharmacy. (CCR 1776.1[e])

☐☐☐ 30.3. Dangerous drugs that have not been dispensed to consumers for use (such as outdated drug stock, drug samples provided to medical practitioners or medical waste) is not collected as part of the pharmacy's drug take-back service. (CCR 1776.1[f])

☐☐☐ 30.4. The pharmacy does not accept or possess prescription drugs from skilled nursing facilities, residential care homes, health care practitioners or any other entity as part of its drug take-back services. (CCR 1776.1[g][2])

☐☐☐ 30.5. Quarantined, recalled or outdated prescription drugs from the pharmacy stock are not disposed as part of the pharmacy's drug take-back services. (CCR 1776.1[g][3])

Pharmacies Offering Mail Back Envelopes or Package Services (CCR 1776.1, 1776.2)

Yes No N/A

☐☐☐ 30.6. The pharmacy provides prescription drug take-back preaddressed mailing envelopes or packages to consumers to return prescription drugs to an authorized destruction location. (CCR 1776.2[a])

☐☐☐ 30.7. All drug take-back envelopes and packages made available to the public are preaddressed to a location registered with the DEA as a collector. (CCR 1776.2[b])

Yes No N/A

☐☐☐ 30.8. The preaddressed envelopes and packages are water and spill proof, tamper evident, tear resistant and sealable. The exterior is nondescript and has no markings indicating the envelope or package contains prescription drugs. Postage is prepaid on each envelope or package. (CCR 1776.2[c])

☐☐☐ 30.9. The preaddressed envelope and package contains a unique identification number for each envelope and package, and the instructions for users indicates the process to mail back the drugs. (CCR 1776.2[d])

☐☐☐ 30.10. The pharmacy does not accept any mail back packages or envelopes containing drugs unless the pharmacy is registered as a collector and has an onsite method of destruction that complies with DEA requirements. The consumer is directed to mail the envelopes or packages. (CCR 1776.2[e])

If the answer is no and the pharmacy is registered with DEA as a collector with an onsite method of destruction that complies with DEA requirements, list the following (21 CFR 1317.40):

DEA Collector Registration Number: _____ Expiration Date: _____

☐☐☐ 30.11. Once drugs are deposited into a mail back envelope or package by the consumer, the pharmacy does not remove, count, sort or individually handle any prescription drugs from the consumer. (CCR 1776.1[d], [g])

Pharmacies with Collection Receptacles in the Pharmacy (CCR 1776.1, 1776.3)

Yes No N/A

☐☐☐ 30.12. The pharmacy is registered with DEA as a collector for purposes of maintaining a prescription drug take-back collection receptacle. (21 CFR 1317.30, 1317.40)

☐☐☐ 30.13. The pharmacy notified the board in writing within 30 days of establishing the collection program. (CCR 1776.1[i])

Date the board was notified: _____

☐☐☐ 30.14. When the pharmacy renewed its pharmacy license, the pharmacy identified and disclosed to the board all the locations where its collection receptacles are located. (CCR 1776.1[i][2])

☐☐☐ 30.15. The pharmacy is aware, any tampering with a collection receptacle or theft of deposited drugs and any tampering, damage or theft of the removed liner are reported to the board in writing within 14 days. (CCR 1776.1[i][3][4])

List the dates the board was notified of any tampering or theft from the collection receptacle and/or tampering, damage or theft of the removed liner:

Date reported: _____

☐☐☐ 30.16. The pharmacy is not on probation with the board. (CCR 1776.1[l])

If answered NO, meaning the pharmacy is on probation, the pharmacy cannot maintain a drug take back collection receptacle and must cease and notify the board in writing within 30 days and notify the DEA within 30 days.

_____
PIC Initials

Yes No N/A

☐☐☐ 30.17. Once drugs are deposited into a collection receptacle by the consumer, the pharmacy does not remove, count, sort or individually handle any prescription drugs from the consumer. (CCR 1776.1[d], 1776.3[e])

☐☐☐ 30.18. The collection receptacle is substantially constructed with a permanent outer container, removable inner liner, and is locked at all times to prevent access to the inner liner. (CCR 1776.3[d])

☐☐☐ 30.19. The collection receptacle is securely fastened to a permanent structure so it cannot be removed and is installed in an inside location. (CCR 1776.3[b])

Yes No N/A

☐☐☐ 30.20. The receptacle is visible to the pharmacy and DEA registrant employees, but not located in or near emergency areas, nor behind the pharmacy's counter. (CCR 1776.3[b])

☐☐☐ 30.21. The receptacle includes a small opening that allows deposit of drugs into the inside of the receptacle directly into the inner liner, but does not allow for an individual to reach into the receptacle's contents. When the pharmacy is closed, the collection receptacle is not accessible to the public for deposit of drugs. The pharmacy locks the deposit opening on the collection receptacle. (CCR 1776.3[d])

☐☐☐ 30.22. The pharmacy directs consumers to directly deposit the drugs into the collection receptacle. (CCR 1776.3[e])

☐☐☐ 30.23. The inner liner used is made of material that is certified by the manufacturer to meet the ASTM D179 standard test for impact resistance of 165 grams (drop dart test) and the ASTM D1922 standards for tear resistance of 480 grams in both parallel and perpendicular planes. (CCR 1776.3[f])

- ☐ 30.23.1 The liner is waterproof, tamper evident, tear resistant, and opaque to prevent viewing or removal of any contents once the liner has been removed from the collection receptacle.
- ☐ 30.23.2. The liner is clearly marked to display the maximum contents (for example, in gallons). (CCR 1776.3[f][2]
- ☐ 30.23.3. The liner bears a permanent, unique identification number established by the pharmacy or pre-entered onto the liner by the liner's manufacturer or distributor. (CCR 1776.3[f][2])
- ☐ 30.23.4. The liner is removable as specified pursuant to CCR 1776.3.

☐☐☐ 30.24. The receptacle allows the public to deposit prescription drugs into the receptacle for containment into the inner liner, without permitting access to or removal of prescription drugs already deposited into the collection receptacle and liner. Once the prescription drugs or any other item is placed in the collection receptacle, the prescription drug or item cannot be removed, counted, sorted, or otherwise individually handled. (CCR 1776.3[d],[e],[g])

☐☐☐ 30.25. If the liner is not already itself rigid or already inside of a rigid container when it is removed from the collection receptacle, the liner is immediately, without interruption, placed in a rigid container for storage, handling and transport. (CCR 1707.3[h])

Yes No N/A

☐☐☐ 30.26. The liner is removed from a locked collection receptacle only by or under the supervision of two employees of the pharmacy. Upon removal, the liner is immediately, without interruption, sealed and the pharmacy employees record, in a log, their participation in the removal of each liner from the collection receptacle. Liners and their rigid containers are not opened, x-rayed, analyzed, or penetrated at any time by the pharmacy or pharmacy personnel. (CCR 1776.3[i])

☐☐☐ 30.27. Liners and their rigid containers that are filled and removed from the collection receptacle is stored in a secured, locked location in the pharmacy no longer than 14 days. (CCR 1776.3[j])

☐☐☐ 30.28. The pharmacy maintain records for collected unwanted drugs from consumers for three years, including the following records for each liner: (CCR 1776.3[k], 1776.6[a])

☐☐☐ 30.29. The pharmacy seals the inner liners and their contents are shipped to a reverse distributor's registered location by common or contract carrier (such as UPS, FEDEX, USPS) or by a licensed reverse distributor pick up at the licensed pharmacy's premise. (CCR 1776.3[l])

☐☐☐ 30.30. The collection receptacle has a signage that includes: (1) the name and phone number of the responsible pharmacy, (2) medical sharps and needles (e.g. insulin syringes) is not to be deposited, (3) consumers may deposit prescription drugs including Schedule II-V controlled substance. (CCR 1776.1[e], 1776.3[m])

Pharmacies with Drug Take-Back Services in Skilled Nursing Facilities

Yes No N/A

☐☐☐ 30.31. The pharmacy provides mail back envelopes or packages to skilled nursing facility employees or person lawfully entitled to dispose of resident decedent's property of unwanted or unused prescription drugs. (CCR 1776.4[a])

☐☐☐ 30.32. If the pharmacy provides mail back envelopes or packages to skilled nursing facilities, the skilled nursing facility employees keeps a record noting the specific quantity of each prescription drug mailed back, the unique identification number of the mail back package and the preaddressed location to which the mail back envelope is sent. (CCR 1776.4[a])

☐☐☐ 30.33. If the pharmacy is onsite at a skilled nursing facility, has the pharmacy established a collection receptacle in the skilled nursing facility for the collection and ultimate disposal of unwanted prescription drugs. (CCR 1776.4[b])

If no, answer N/A to the remaining questions in this section.

If yes, continue answering the questions in this section.

List the location(s) of the collection receptacle:

_____

_____

_____

☐☐☐ 30.34. Was the board notified in writing within 30 days of establishing a collection receptacle? (CCR 1776.4[b][2])

Yes No N/A

☐☐☐ 30.35. Has there been any tampering of the collection receptacle, theft of the deposited drugs and/or tampering, damage or theft of the removed liner? (CCR 1776.4[b][4], [5])

☐ If yes, was the board notified in writing within 14 days of any tampering of the collection receptacles and/or liner?

☐☐☐ 30.36. When the pharmacy license was renewed, did the pharmacy provide the list a current list of collection receptacles? (CCR 1776.4[b][6])

☐☐☐ 30.37. The skilled nursing facility places patient's unneeded prescription drugs into a collection receptacle within three business days after the permanent discontinuance of use of a medication by a prescriber, as a result of the resident's transfer to another facility or as a result of death. Records of such deposit is made in the patient's records, with the name and signature of the employee discarding the drugs. (CCR 1776.4[d])

☐☐☐ 30.38. Is the collection receptacle located in a secured area regularly monitored by the skilled nursing facility employees, securely fastened to a permanent structure so it cannot be removed, have a small opening that allows deposit of drugs into the inside of the collection receptacle and directly into the inner liner, but does not allow for an individual to reach into the receptacle's contents, securely locked and substantially constructed with a permanent outer container and a removable inner liner? (CCR 1776.4[e][f][g])

☐☐☐ 30.39. The liner certified by the manufacturer to meet the American Society for Testing Materials (ASTM) D1709 standard test for impact resistance of 165 grams (drop dart test), the ASTM D1922 standards for tear resistance of 480 grams in both parallel and perpendicular planes, waterproof, tamper evident, tear resistant, opaque to prevent viewing and discourage removal of any contents once the liner is removed from the collection receptacle, marked to display the maximum contents, and bear a permanent, unique identification number. (CCR 1776.4[h])

☐☐☐ 30.40. The receptacle allows the deposit of prescription drugs into the receptacle for containment into the inner liner, without permitting access to or removal of prescription drugs already deposited into the collection receptacle and liner. Once a prescription drug or item is placed in the collection receptacle, the prescription drug or item cannot be removed, sorted, counted, or otherwise individually handled. (CCR 1776.4[g][1])

☐☐☐ 30.41. If the liner is not already itself rigid or already inside a rigid container when it is removed from the collection receptacle, the liner is immediately placed in a rigid container for storage, handling and transport. (CCR 1776.4[g][2])

☐☐☐ 30.42. The rigid container is either disposable, reusable, or recyclable. The rigid container is leak resistant, have sealable tight fitting covers and kept clean and in good repair. (CCR 1776.4[g][2])

☐☐☐ 30.43. The collection receptacle contains signage with (1) the name and phone number of the pharmacy, (2) medical sharps and needles (e.g. insulin syringes) cannot be deposited, and (3) consumers may deposit prescription drugs including Schedule II-V controlled substances. (CCR 1776.4[i])

Yes No N/A

☐☐☐ 30.44. Once deposited, the prescription drugs are not counted, sorted, or otherwise individually handled. (CCR 1776.4[j])

☐☐☐ 30.45. The installation, removal, transfer, and storage of inner liners is performed only by (1) one employee of the authorized collector pharmacy and one supervisory level employee of the long-term care facility (e.g. charge nurse or supervisor) designated by the authorized collector or (2) by or under the supervision of two employees of the authorized collector pharmacy. (CCR 1776.4[k])

☐☐☐ 30.46. Sealed inner liners placed in a container is stored at the skilled nursing facility up to three business days in a securely locked, substantially constructed cabinet or a securely locked room with controlled access until transfer to a reverse distributor for destruction. (CCR 1776.4[l])

☐☐☐ 30.47. Liners housed in a rigid container is delivered to a reverse distributor for destruction by a common or contract carrier or by a reverse distributor picked up at the skilled nursing facility. (CCR 1776.4[m])

Record Keeping Requirements for Board Licensees Providing Drug Take Back Services

Yes No N/A

☐☐☐ 30.48. Records required for drug take back services are maintained for three years. (CCR 1776.6)

☐☐☐ 30.49. The pharmacy makes and keeps the following records for each liner: (CCR 1776.6[a])

- ☐ 30.49.1. The date each unused liner is acquired, its unique identification number and size (e.g. 5 gallon, 10 gallon). If the liner does not already contain a unique identification number, the pharmacy assigns the unique identification number. (CCR 1776.6[a][1])
- ☐ 30.49.2. The date each liner is installed in a collection receptacle, the address of the location where each liner is installed, the unique identification number and size (e.g., 5 gallon, 10 gallon), the registration number of the collector pharmacy, and the names and signatures of the two employees that witnessed each installation. (CCR 1776.6[a][2])
- ☐ 30.49.3. The date each inner liner is removed and sealed, the address of the location from which each inner liner is removed, the unique identification number and size (e.g. 5 gallon, 10 gallon) of each inner liner removed, the registration number of the collector pharmacy, and the names and signatures of the two employees that witnessed the removal and sealing. (CCR 1776.6[a][3])
- ☐ 30.49.4. The date each sealed inner liner is transferred to storage, the unique identification number and size (e.g., 5 gallon, 10 gallon) of each inner liner stored, and the names and signatures of the two employees that transferred each sealed inner liner to storage. (CCR 1776.6[a][4])
- ☐ 30.49.5. The date each sealed inner liner is transferred for destruction, the address and registration number of the reverse distributor or distributor to whom each sealer inner liner was transferred, the unique identification number and size (e.g., 5 gallon, 10 gallon) of each liner transferred, and the names and signatures of the two employees who transferred each sealed inner liner to the reverse distributor or distributor, or the common carrier who delivered it, the company used, and any related paperwork (invoice, bill of lading). (CCR 1776.6[a][5])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

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

Yes No N/A

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

- ☐ 31.1.1. Health system pharmacy. (HSC 125286.20[j][1][B])
- ☐ 31.1.2. Pharmacy affiliated with hemophilia treatment centers. (HSC 125286.20[j][1][C])
- ☐ 31.1.3. Specialty home care pharmacy. (HSC 125286.20[j][1][D])
- ☐ 31.1.4. Retail pharmacy. (HSC 125286.20[j][1][E])

☐☐☐ 31.2. The pharmacy meets the current requirements of HSC 125286.25 including knowledge of bleeding disorders, access to providers with clinical clotting factor experience, maintaining 24 hour 7 day a week on call service with knowledgeable pharmacy staffing, ability to obtain all FDA approved brands of blood clotting products, supplying all necessary infusion equipment and supplies with each prescription, storing and shipping or delivering blood clotting products in conformity with state and federal standards (and per the product's package insert), shipping authorized nonemergency prescription blood clotting products and equipment within two business days, shipping authorized emergency prescription blood clotting products and supplies within 12 hours for patient living within 100 miles (from major metropolitan airport) and within one day if the patient lives more than 100 miles (from a major metropolitan airport), providing patients a designated contact telephone number for reporting delivery problems and responding to calls within a reasonable time period, notifying patients of Class 1 and 2 recalls and withdrawals of blood clotting products or equipment within 24 hours of receiving such notice, participating in National Patient Notification System for blood clotting recalls, providing language interpretive services and has a detailed disaster plan for the requirements of Standards of Service for Providers of Blood Clotting Products for Home Use Act or other disruptions of normal business operation.

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

Yes No N/A

☐☐☐ 32.1. The pharmacy donates medications to a county-approved drug repository and distribution program, and meets the following requirements: (HSC 150202.5, 150204, BPC 4169.5)

- ☐ 32.1.1. The pharmacy is licensed by and is not on probation with the California State Board of Pharmacy, **and** (HSC 150202.5)
- ☐ 32.1.2. 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. (HSC 150202.5)

☐☐☐ 32.2. 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. (BPC 4169.5)

Yes No N/A

☐☐☐ 32.3. No controlled substances shall be donated. (HSC 150204[c][1])

☐☐☐ 32.4. Drugs that are donated are unused, unexpired and meet the following requirements: (HSC 150202.5, 150204[c])

- ☐ 32.4.1. Have not been adulterated, misbranded, or stored under conditions contrary to standards set by the USP or the product manufacturer. (HSC 150204[c][2])
- ☐ 32.4.2. Were received directly from a manufacturer or wholesaler. (HSC 150202.5[a])
- ☐ 32.4.3. 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])
- ☐ 32.4.4. Are in unopened, tamper-evident packaging or modified unit dose containers with lot numbers and expiration dates affixed. (HSC 105204[d])
- ☐ 32.4.5. 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. (HSC 150204[m])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

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

Yes No N/A

☐☐☐ 33.1. The pharmacy conducts a county-approved drug repository and distribution program. (HSC 150201, 150204)

- ☐ 33.1.1. The pharmacy is licensed by and is not on probation with the California State Board of Pharmacy, **and:** (HSC 150201[a][1])
  - ☐ 33.1.1.1. Is county owned (HSC 150201[b][1]) or
  - ☐ 33.1.1.2. Contracts with the county to establish a voluntary drug repository and distribution program. (HSC 150201[b][1], 150200)
- ☐ 33.1.2. 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. (HSC 150201[a][2])

☐☐☐ 33.2. 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. (HSC 150204[a][5])

Issued By: _____ Date: _____

_____
PIC Initials

Yes No N/A

☐☐☐ 33.3. Date that the county health department confirmed receipt of the pharmacy's "notice of intent" to participate in the program: _____ (HSC 150204[a][3])

☐☐☐ 33.4. The pharmacy provides the county health department on a quarterly basis the name and location of all sources of donated medication it receives. (HSC 150204[a][4][A])

Date last quarterly report was submitted: _____

☐☐☐ 33.5. The pharmacy complies with the county's established written procedures. (HSC 150204[b])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

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

Yes No N/A

☐☐☐ 33.6. Donated medications are segregated from the participating entity's other drug stock by physical means, for purposes that include inventory, accounting and inspection. (HSC 150204[j])

☐☐☐ 33.7. Records of acquisition and disposition of donated medications are kept separate from the participating entity's other drug acquisition and disposition records. (HSC 150204[k])

☐☐☐ 33.8. 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. (HSC 150204[n])

☐☐☐ 33.9. Donated medications received are unused, unexpired and meet the following requirements: (HSC 150202, 150202.5, 150204[c])

- ☐ 33.9.1. Are received from authorized sources. (HSC 150202, 150203)
- ☐ 33.9.2. No controlled substances are received. (HSC 150204[c][1])
- ☐ 33.9.3. Are not adulterated, misbranded, or stored under conditions contrary to USP standards or the product manufacturer. (HSC 150204[c][2])
- ☐ 33.9.4. 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. (HSC 150204[c][3])
- ☐ 33.9.5. Are received in unopened, tamper-evident packaging or modified unit dose containers with lot numbers and expiration dates affixed. (HSC 150204[d])
- ☐ 33.9.6. Are maintained in the donated packaging until dispensed to an eligible patient under the program, who presents a valid prescription. (HSC 150204[i])
- ☐ 33.9.7. 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. (HSC 150204[m])

Yes No N/A

☐☐☐ 33.10. The pharmacy exists solely to operate the repository and distribution program. (HSC 150204(i). If yes:

- ☐ 33.10.1. The pharmacy repackages a reasonable quantity of donated medicine in anticipation of dispensing the medicine to its patient population.
- ☐ 33.10.2. The pharmacy has policies and procedures in place for identifying and recalling medications.
- ☐ 33.10.3. Repackaged medications are repackaged with the earliest expiration date.

☐☐☐ 33.11. 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. (HSC 150204[d], 150204[h])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

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

Yes No N/A

☐☐☐ 33.12. The pharmacy transfers donated medications to another participating county-owned pharmacy within an adjacent county. (HSC 150204[g][4])

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

Adjacent counties to which donated medications are transferred:

_____

☐☐☐ 33.14. Donated medication is not transferred by any participating entity more than once. (HSC 150204[g][4][B])

☐☐☐ 33.15. 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. (HSC 150204[g][4][C])

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

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

☐☐☐ 33.17. 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. (HSC 150204[i])

Yes No N/A

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

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

34. Emergency Medical Services Automated Drug Delivery Systems

Yes No N/A

☐☐☐ 34.1 The pharmacy restocks dangerous drugs and dangerous devices into emergency medical services automated drug delivery systems (EMSADDS) in compliance with section BPC 4119.01, BPC 4034.5

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

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 _____. 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 _____ _____
(Pharmacist-in-Charge) Date

ACKNOWLEDGEMENT BY OWNER OR HOSPITAL ADMINISTRATOR:

I, (please print) _____, hereby certify under penalty of perjury of the laws of the State of California that I have read and reviewed this completed self-assessment. I understand that failure to correct any deficiency identified in this self-assessment 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

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