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

HOSPITAL PHARMACY SELF-ASSESSMENT

Title 16 of the California Code of Regulations section 1715 requires the pharmacist-in-charge of each pharmacy licensed under section 4037 or 4029 of the Business and Professions Code to complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. **The assessment shall be performed before July 1 of every odd-numbered year. The pharmacist-in-charge must also complete a self-assessment within 30 days whenever (1) a new pharmacy permit has been issued, or (2) there is a change in the pharmacist-in-charge. The primary purpose of the self-assessment is to promote compliance through self-examination and education.**

The self-assessment must be completed in its entirety. 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 dispensing prescriptions for outpatient use, a Community Pharmacy Self-Assessment/Hospital Outpatient Pharmacy Self-Assessment (17M-13, Rev. 03/19) must be completed also. A hospital that compounds drug products must also complete the Compounding Self-Assessment (17M-39 Rev. 02/12).

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

Pharmacy Name: _____

Address: _____ Phone: _____

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

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

Licensed Sterile Compounding License #_____ Expiration: _____

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

Centralized Hospital Packaging#: _____ Exp. Date: _____

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

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

PIC: _____ RPH # _____ Exp. Date: _____

Website address (if any): _____

_____
PIC Initials

Pharmacy staff (pharmacists, interns, technicians):
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. _____	RPH # _____	Exp. Date: _____
	APH # _____ _	Exp. Date: _____
	DEA # _____	Exp. Date: _____
7. _____	RPH # _____	Exp. Date: _____
	APH # _____ _	Exp. Date: _____
	DEA # _____	Exp. Date: _____
8. _____	RPH # _____	Exp. Date: _____
	APH # _____ _	Exp. Date: _____
	DEA # _____	Exp. Date: _____
9. _____	INT # _____	Exp. Date: _____
10. _____	INT # _____	Exp. Date: _____
11. _____	INT # _____	Exp. Date: _____
12. _____	INT # _____	Exp. Date: _____
13. _____	TCH # _____	Exp. Date: _____
14. _____	TCH # _____	Exp. Date: _____
15. _____	TCH # _____	Exp. Date: _____
16. _____	TCH # _____	Exp. Date: _____

HOSPITAL PHARMACY SELF-ASSESSMENT

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

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

1. Pharmacy

Yes No N/A

☐☐☐ 1.1. The pharmacy is secure and has provisions for effective control against the theft of dangerous drugs and devices. (BPC 4116, 4117, CCR 1714)

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

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

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

☐☐☐ 1.5. The pharmacy maintains "night stock" medications which are accessible without entering the pharmacy during hours when the pharmacy is closed, and the pharmacist is not available. Access is limited to designated registered nurses. (22 CCR 70263[n])

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

☐☐☐ 1.7. The pharmacy premises**,** fixtures**,** and equipment are maintained in a clean and orderly condition. (CCR 1714)

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

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

Yes No N/A

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

☐☐☐ 1.11. Pharmacists, interns, pharmacy technicians, and pharmacy technician trainees wear nametags, in 18-point type, that contain their name and license status. (BPC 680, BPC 4115.5[e], CCR 1793.7[c])

☐☐☐ 1.12. Does the pharmacy compound sterile drugs?
(If yes, complete Compounding Self-Assessment Form 17M-39, Rev. 10/12)

☐☐☐ 1.13. The pharmacy is subscribed to the board's e-mail notifications. (BPC 4013)
Date Last Notification Received: _____

E-mail address registered with the board: _____

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

Date Last Notification Received: _____

E-mail address registered with the board:_____

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

2. Nursing Stations

Yes No N/A

☐☐☐ 2.1. Adequate space is available at ward or nursing station for the storage of drugs and preparation of medication doses. All such spaces and areas can be locked and are accessible to authorized personnel only. (22 CCR 70269)

☐☐☐ 2.2. The pharmacist, intern pharmacist, or pharmacy technician completes the monthly inspections of all floor stock and drugs maintained in nursing stations. Any irregularities are reported to the director of nursing services, and as required by hospital policy. (BPC 4119.7[c], 4115[j], 22 CCR 70263[q][10])

☐ 2.2.1. An intern shall report any irregularities to the pharmacist. (BPC 4119.7[c])

☐ 2.2.2. A pharmacy technician shall report any irregularities to the pharmacist-in-charge and to the director of the health care facility within 24 hours. (BPC 4115[i][3])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

3. Delivery of Drugs

Yes No N/A

☐☐☐ 3.1. Delivery to the pharmacy of dangerous drugs and dangerous devices are only delivered to the licensed premise and signed for and received by a pharmacist. (BPC 4059.5[a])

☐☐☐ 3.2. Deliveries to a hospital pharmacy may be made to a central receiving location within the hospital. However, the dangerous drugs or dangerous devices shall be delivered to the licensed pharmacy premise within one working day following receipt by the hospital, and the pharmacist on duty at that time shall immediately inventory the drugs or devices. (BPC 4059.5[c])

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

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

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

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

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

☐☐☐ 3.7. 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. Drug Stock

Yes No N/A

☐☐☐ 4.1. The drug stock is clean, orderly, properly stored, properly labeled and in-date. (BPC 4342, HSC 111255, 111335, CCR 1714 (b), 22 CCR 70263[q], 21 USC sections 331, 351, 352)

☐☐☐ 4.2. All ward/floor drug stock and drug supplies that are maintained for access when the pharmacist is not available are properly labeled and stored. (22 CCR 70263[n])

☐☐☐ 4.3. Preferentially priced drugs are furnished solely or predominately to inpatients in accordance with provisions of the Nonprofit Institutions Act (15 USC 13c). Such drugs also may be dispensed pursuant to prescriptions for inpatients at the time of discharge, for employees of the hospital, or on an emergency basis for a walk-in customer (provided that sales to walk-ins do not exceed one percent of the pharmacy's total prescription sales). (BPC 4380, CCR 1710[a])

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

☐☐☐ 4.5. All drugs are maintained in accordance with national standards regarding the storage area and refrigerator or freezer temperature and manufacturer's guidelines. (BPC 4119.7[b]

☐☐☐ 4.6. Dangerous drugs or dangerous devices are purchased, traded, sold or transferred with an entity licensed with the board as a wholesaler, third-party logistics provider, pharmacy or a manufacturer, and provided the dangerous drugs and devices: (BPC 4059.5, 4169)

- ☐ 4.6.1. Are not known or reasonably should not be known to the pharmacy as being adulterated.
- ☐ 4.6.2. Are not known or reasonably should not be known to the pharmacy as being misbranded.
- ☐ 4.6.3. Are not expired.

☐☐☐ 4.7. If the pharmacy reasonably has 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)

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

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

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

Yes No N/A

☐☐☐ 5.1. The hospital pharmacy donates medications to a county-approved drug repository and distribution program, and meets the following requirements: (HSC 150202, 150202.5, 150204)

- ☐ 5.1.1. The hospital pharmacy is licensed by and is not on probation with the California State Board of Pharmacy, **and** (HSC 150202.5)
- ☐ 5.1.2. The hospital pharmacy's primary or sole type of pharmacy practice is limited to skilled nursing facility, home health care, board and care, or mail order. (HSC 150202.5)

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

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

- ☐ 5.3.1. Have not been adulterated, misbranded, or stored under conditions contrary to standards set by the USP or the product manufacturer. (HSC 150204[c][2])
- ☐ 5.3.2. Were received directly from a manufacturer or wholesaler. (HSC 150202.5[a])
- ☐ 5.3.3. Were centrally stored and under the control of a health facility staff member, and were never in the possession of a patient or individual member of the public. (HSC 150202.5[b], 150204[c][3])
- ☐ 5.3.4. Are in unopened, tamper-evident packaging or modified unit dose containers with lot numbers and expiration dates affixed. (HSC 105204[d])
- ☐ 5.3.5. For donated medications that require refrigeration, are medications that are stored, packaged and transported at appropriate temperatures and in accordance with USP standards and pharmacy law. (HSC 150204[m])

☐☐☐ 5.4. The hospital pharmacy follows the same procedural drug pedigree requirements for donated drugs as it does for drugs purchased from a wholesaler or directly from a drug manufacturer. (HSC 150204[n])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

6. Pharmacist-in-Charge (PIC)

Yes No N/A

☐☐☐ 6.1. The pharmacy has a PIC who is responsible for the daily operation of the pharmacy. (BPC 4101, 4113, 4305, 4330, CCR 1709, 1709.1)

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

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

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

If yes, name of other pharmacy _____

Yes No N/A

☐☐☐ 6.4. Any change of PIC is reported by the pharmacy and the departing PIC to the board in writing within 30 days. (BPC 4101, 4330)

☐☐☐ 6.5. The PIC is not concurrently serving as the designated representative-in-charge for a wholesaler or veterinary food-animal drug retailer. (CCR 1709.1[d])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

7. Duties of a Pharmacist

Yes No N/A

☐☐☐ 7.1. Only a pharmacist: (BPC 4019, BPC 4051, BPC 4052, BPC 4052.2, CCR 1717[c], CCR 1793.1, CCR 1793.7)

- ☐ 7.1.1. The pharmacist receives a chart order for an inpatient; (BPC 4019, BPC 4051 [b], BPC 4052, BPC 4052.2, CCR 1717, CCR 1793.1[a])
- ☐ 7.1.2. Identifies, evaluates and interprets the chart order; (CCR 1717[c], CCR 1793.1[c])
- ☐ 7.1.3. Reviews patient's drug regimen and interprets the clinical data in the patient's medication record; (BPC 4052.1[a][4], BPC 4052.2[a][4], CCR 1793.1[d])
- ☐ 7.1.4. Consults with any prescriber, nurse or health care professional; (CCR 1793.1[e])
- ☐ 7.1.5. Calculates drug doses; (BPC 4052 [a][3], BPC 4052.2 [a][3], BPC 4052.2 [a][4])
- ☐ 7.1.6. Supervises the packaging of drugs and checks the packaging procedures and products upon completion; (CCR 1793.1[f])
- ☐ 7.1.7. Is responsible for all activities of pharmacy technicians, interns and clerks related to the furnishing of drugs to ensure that all such activities are performed completely, safely and without risk of harm to patients; (CCR 1793.7[e])
- ☐ 7.1.8. Performs any other duty which federal or state law or regulation authorizes only a registered pharmacist to perform; and performs all functions which require professional judgment. (BPC 4052, BPC 4052.2, CCR 1793.1[g])

☐☐☐ 7.2 Pharmacists in a licensed health care facility who are performing the following functions are doing so in accordance with the hospital's policies, procedures and protocols which have been developed by health professionals including physicians, pharmacists, and registered nurses, with the concurrence of the facility administrator: (BPC 4027, 4051, 4052, 4052.2)

- ☐ 7.2.1. Ordering or performing routine drug therapy-related patient assessment procedures; (BPC 4052.1[a][1]; 4052.2[a][1])
- ☐ 7.2.2. Ordering drug therapy-related laboratory tests; administering drugs or biologicals by injection; (BPC 4052.1[a][2], [3]; 4052.2[a][2], [3])
- ☐ 7.2.3. Initiating or adjusting the drug regimen of a patient; (BPC 4052.1[a][4], BPC 4052.2[a][4])
- ☐ 7.2.4. Performing moderate or waived laboratory tests. (Prior to performing any of these functions, the pharmacist must have either (1) successfully completed clinical residency

training, or (2) demonstrated clinical experience in direct patient care delivery as specified in BPC section 4052.2[d]. (BPC 4052.4)

Yes No N/A

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

☐☐☐ 7.4. All pharmacists have submitted an application to the Department of Justice to obtain approval to access information online regarding the controlled substance history of a patient. (HSC 11165.1)

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

☐☐☐ 7.6 The hospital pharmacist (or pharmacy technician or an intern pharmacist if both requirements of BPC 4118.5 (b) 1 and 2 are met) shall obtain an accurate medication profile or list for each high-risk patient upon admission of the high-risk patients if the hospital has more than 100 beds, the accurate medication profile is acquired during hospital pharmacy's hours of operation. (BPC 4118.5)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

8. Duties of an Advanced Practice Pharmacist

Yes No N/A

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

- ☐ 8.1.1 Perform patient assessments, order and interpret drug therapy-related tests, and refer patients to other health care providers; (BPC 4052.6[a])
- ☐ 8.1.2 Participate in the evaluation and management of diseases and health conditions in collaboration with other health care providers; (BPC 4052.6[a])
- ☐ 8.1.3 Initiate drug therapy and promptly transmit written notification to, or enter the appropriate information into a patient record system shared with the patient's primary care provider or diagnosing provider; (BPC 4052.6[b])
- ☐ 8.1.4 Adjust or discontinue drug therapy and promptly transmit written notification to the patient's diagnosing prescriber or enters the appropriate information in a patient's record system shared with the prescriber; (BPC 4052.6[b])
- ☐ 8.1.5 Prior to initiating or adjusting a controlled substance therapy, the advance practice pharmacist is personally registered with the federal Drug Enforcement Administration; (BPC 4052.6[d])
- ☐ 8.1.6 Ordering of tests is done in coordination with the patient's primary care provider or diagnosing prescriber, including promptly transmitting written notification to the prescriber or entering information in a patient record system shared with the prescriber. (BPC 4052.6[e])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

9. Duties of an Intern Pharmacist

Yes No N/A

☐☐☐ 9.1. Intern pharmacists are performing all the functions of a pharmacist only under the direct supervision of a pharmacist, and the pharmacist is supervising no more than **two interns** at any one time. (BPC 4023.5, 4030, 4114, 4119.6, 4119.7, CCR 1726)

- ☐ 9.1.1 Stock, replenish and inspect the emergency pharmaceutical supply container and the emergency medical system supplies. (BPC 4119.6)
- ☐ 9.1.2. Inspect the drugs maintained in the health care facility at least once per month. (BPC 4119.7[c])

☐☐☐ 9.2. All prescriptions filled or refilled by an intern are initialed or documented by secure computer entry by a pharmacist prior to dispensing. (CCR 1712[a], 1717[b][1])

☐☐☐ 9.3. During a temporary absence of a pharmacist for a meal period or duty free break, an intern pharmacist does not perform any discretionary duties or act as a pharmacist. (CCR 1714.1[d])

☐☐☐ 9.4. The intern hours affidavits are signed by the pharmacist under whom the experience was earned, or by the pharmacist-in-charge at the pharmacy while the intern pharmacist obtained the experience, when applicable. (BPC 4209[b], [c], [d]; CCR 1726)

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

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

10. Duties of a Pharmacy Technician

Yes No N/A

☐☐☐ 10.1. Registered pharmacy technicians are performing packaging, manipulative, repetitive, or other nondiscretionary tasks related to the furnishing of drugs, while assisting and under the direct supervision and control of a pharmacist. The pharmacist is responsible for the duties performed by the pharmacy technician under the pharmacist's supervision. (BPC 4023.5, 4038, 4115, CCR 1793.2, CCR 1793.7)

☐☐☐ 10.2. The ratio is no less than one pharmacist to two technicians. (BPC 4115[f], CCR 1793.7[f])

☐☐☐ 10.3. When prescriptions are dispensed to discharge patients with only one pharmacist, there is no more than one technician performing the tasks as defined in BPC 4115(a). The ratio of pharmacy technicians performing those tasks for additional pharmacists does not exceed 2:1. (BPC 4038, 4115[f], CCR 1793.7[f])

☐☐☐ 10.4. Any function performed by a technician in connection with the dispensing of a prescription or chart order, including repackaging from bulk and storage of pharmaceuticals is verified and

documented in writing by a pharmacist or documented by a pharmacist using secure computer entry. (CCR 1712, 1793.7)

Yes No N/A

☐☐☐ 10.5. 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])

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

☐☐☐ 10.7. During a temporary absence of a pharmacist for a meal period or duty free break, a pharmacy technician may, at the discretion of the pharmacist, remain in the pharmacy but may only perform nondiscretionary tasks. Any task performed by the pharmacy technician during the pharmacist's temporary absence is reviewed by the pharmacist. (BPC 4115[g], CCR 1714.1[c])

☐☐☐ 10.8. The general acute-care hospital has an ongoing clinical pharmacy program and allows specially trained pharmacy technicians to check the work of other pharmacy technicians when the following conditions are met: (CCR 1793.8)

- ☐ 10.8.1. Pharmacists are deployed to the inpatient care setting to provide clinical services.
- ☐ 10.8.2. Compounded or repackaged products are previously checked by a pharmacist, then used by the technician to fill unit dose distribution and floor and ward stock.
- ☐ 10.8.3. The overall operations are the responsibility of the pharmacist-in-charge.
- ☐ 10.8.4. The pharmacy technician checking technician program is under the direct supervision of the Pharmacist as specified in the policies and procedures.
- ☐ 10.8.5. There is an ongoing evaluation of the program that uses specialized and advanced trained pharmacy technicians to check the work of other pharmacy technicians.

☐☐☐ 10.9. Pharmacy technician duties include the following:

- ☐ 10.9.1. Package emergency supplies for use in the health care facility and the hospital's emergency medical system. (BPC 4119, 4115[i])
- ☐ 10.9.2. Seal emergency containers for use in the health care facility. (BPC 4115[i])
- ☐ 10.9.3. Perform monthly checks of the drug supplies stored throughout the health care facility and report any irregularities within 24 hours to the pharmacist-in-charge and to the director or chief executive officer. (BPC 4115[i])

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

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

11. Duties of Non-Licensed Personnel

Yes No N/A

☐☐☐ 11.1. A non-licensed person (clerk/typist) is permitted to type a prescription label or otherwise enter prescription information into a computer record system, and at the direction of a pharmacist, may request and receive refill authorization. (BPC 4007, CCR 1793.3)

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

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

PHARMACY PRACTICE

12. Pharmaceutical Service Requirements

Yes No N/A

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

- ☐ 12.1.1. Basic information concerning investigational drugs and adverse drug reactions;
- ☐ 12.1.2. Repackaging and compounding records;
- ☐ 12.1.3. Physician orders;
- ☐ 12.1.4. Wards, nursing stations and night stock medications;
- ☐ 12.1.5. Drugs brought into the facility by patients for storage or use;
- ☐ 12.1.6. Bedside medications;
- ☐ 12.1.7. Emergency drug supply;
- ☐ 12.1.8. Pass medications;
- ☐ 12.1.9. Inspection of ward stock, nursing stations and night lockers no less frequently than every 30-days\\Outdated drugs;
- ☐ 12.1.10. Routine distribution of inpatient medications;
- ☐ 12.1.11. Preparation, labeling and distribution of IV admixtures and cytotoxic agents;
- ☐ 12.1.12. Handling of medication when pharmacist not on duty; and
- ☐ 12.1.13. Use of electronic image and data order transmissions.

☐☐☐ 12.2. The pharmacy complies with the requirements of 22 CCR 70263, addressing the following areas:

- ☐ 12.2.1. Destruction of controlled substances; and
- ☐ 12.2.2. Development and maintenance of the hospital's formulary. (22 CCR 70263, CCR 1751, CCR 1751.8)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

13. Medication/Chart Order

Yes No N/A

☐☐☐ 13.1. The pharmacy receives the original, the electronic transmission, or a copy of the medication order. Faxed copies, tele-autograph copies, or transmissions between computers are permissible. (BPC 4019, 4040, CCR 1717.4)

☐☐☐ 13.2. The chart or medical record of the patient contains all of the information required by BPC 4040 and the chart order is signed by the practitioner authorized by law to prescribe drugs if present or, if not present, within a specified time frame not exceeding 48 hours. (BPC 4019, 4040, 22 CCR 70263[g])

☐☐☐ 13.3. A copy of the chart order is maintained on the premises for three years. (BPC 4081, 4105, 4333)

☐☐☐ 13.4. The pharmacy furnishes dangerous drugs or dangerous devices pursuant to preprinted or electronic standing orders, order sets and protocols established under policies and procedures. (BPC 4119.7)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

14. Labeling and Distribution

Yes No N/A

☐☐☐ 14.1. Unit dose medication are properly labeled and include the information as required by BPC 4076, or the information is otherwise readily available at the time of drug administration. (BPC 4076[b])

☐☐☐ 14.2. The pharmacist is responsible for the proper labeling, storage and distribution of investigational drugs pursuant to the written order of the investigator. (22 CCR 70263[o]).

☐☐☐ 14.3. This pharmacy furnishes dangerous drugs in compliance with 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 receive drugs, to another pharmacy of common ownership, or to a patient or to another pharmacy pursuant to a prescription. (BPC 4126.5)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

15. Duration of Drug Therapy

Yes No N/A

☐☐☐ 15.1. The hospital has policies limiting the duration of drug therapy in the absence of the prescriber's specific indication of duration of drug therapy or under other circumstances recommended by the pharmacy and therapeutics committee or its equivalent and approved by the executive committee of the medical staff. Limitations are established for classes of drugs and/or individual drug entities. (22 CCR 70263[j])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

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

Yes No N/A

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

☐☐☐ 16.2. Patient medical information, all prescriptions (chart orders, patient discharge and employee prescriptions) are confidential and are not disclosed unless authorized by law. (BPC 4040, CCR 1764, Civil Code 56 et seq.)

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

☐☐☐ 16.4. The pharmacy ensures electronically transmitted prescriptions (chart orders, discharge patient or employee prescriptions) are received, maintained and transmitted in a secure and confidential manner. (CCR 1717.4)

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

Date Waiver Approved _____ Waiver Number _____

Address of offsite storage location: _____

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

17. Quality Assurance and Medication Errors

Yes No N/A

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

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

☐☐☐ 17.3. When a medication error has occurred (drug was administered to or by the patient, or resulted in a clinically significant delay in therapy) the pharmacist communicates with the patient or patient's agent that a medication error has occurred and the steps required to avoid injury or mitigate the error. (CCR 1711[c][2][A], 1711 [c][3])

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

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

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

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

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

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

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

18. Record Keeping Requirements

Yes No N/A

☐☐☐ 18.1. All completed pharmacy self-assessments are on file in the pharmacy and are maintained for three years. (CCR 1715)

☐☐☐ 18.2. 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 and disposition or other drug or dispensing-related records maintained electronically. These records include:

- ☐ 18.2.1. Prescription records (BPC 4081[a])

- ☐ 18.2.2. Purchase Invoices and sales records for all prescription drugs (BPC 4081[b])
- ☐ 18.2.3. Biennial controlled substances inventory (21 CFR 1304.11)
- ☐ 18.2.4. U.S. Official Order Forms (DEA Form- 222) (21 CFR 1305.13)
- ☐ 18.2.5. Power of Attorney for completion of DEA 222 forms (21 CFR 1305.07)
- ☐ 18.2.6. Theft and Loss Reports (DEA Form 106) (21 CFR 1301.74[c])
- ☐ 18.2.7. Record documenting return of drugs to wholesaler or manufacturer (BPC 4081)
- ☐ 18.2.8. Record documenting transfers or sales to other pharmacies, prescribers, and reverse distributors. (BPC 4059, 4081, 4105, 4332, CCR 1718)
- ☐ 18.2.9. Centrally stored unused medications donated to a drug repository and distribution program. (HSC 150200, 150202[a][1]), 150204[k], BPC 4105[c].

Yes No N/A

☐☐☐ 18.3. Transfers or sales to other pharmacies and prescribers do not exceed five percent of the pharmacy's total annual purchases of dangerous drugs or devices. If more than five percent, registration with the board as a wholesaler has been obtained. (21 CFR 1307.11, Drug Supply Chain Security Act (DSCSA), BPC 4160)

☐☐☐ 18.4. If sales or distributions of controlled substances to other hospitals, pharmacies, or prescribers exceed five percent of the total number of controlled substances dosage units (that are furnished to the inpatients or dispensed on prescriptions to discharge patients or employees) per calendar year, the following have been obtained: a separate DEA distributor registration and a wholesaler's permit from the board. (21 CFR 1307.11, DSCSA, BPC 4160)

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

Date completed: _____ (21 CFR 1304.11)

☐☐☐ 18.6. All completed controlled substances inventories are available for inspection for three years. (CCR 1718)

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

☐☐☐ 18.8. Inventories and records for Schedule III-V controlled substances are filed separately or maintained in a readily retrievable manner that distinguishes them from other ordinary business records. (21 CFR 1304.04)

☐☐☐ 18.9. DEA Forms 222 are properly executed. (21 CFR 1305.12)

☐☐☐ 18.10. When the pharmacy distributes Schedule II controlled substances to other DEA registrants, Copy 2 of the DEA Form 222, properly completed, are submitted at the end of each month to the DEA Regional Office. (21 CFR 1305.13)

☐☐☐ 18.11. Any controlled substances drug loss is reported upon discovery to the DEA and to the Board of Pharmacy within 30 days. (21 CFR 1301.74[c], CCR 1715.6)

☐☐☐ 18.12. Records stored off-site (only for pharmacies who have obtained a waiver from the Board of Pharmacy to store records off-site) are secure and retrievable within two business days. Records for non-controlled substances are maintained on the licensed premises for at least one year from

the date of dispensing. Controlled substances are maintained on the licensed premises for at least two years from the date of dispensing. (CCR 1707)

Yes No N/A

☐☐☐ 18.13. Do pharmacy staff hand initial prescription records and prescription labels, OR does the pharmacy comply with the requirement for a pharmacist to initial or sign a prescription record or prescription label by recording the identity of the reviewing pharmacist in a computer system by a secure means. This computer does not permit the record to be altered after made and the record of the pharmacist's identity made in the computer system is immediately retrievable in the pharmacy. (CCR 1712)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

19. Inventory Reconciliation Report of Controlled Substances

Yes No N/A

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

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

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

- ☐ 19.3.1 A physical count, not an estimate, of all quantities of federal Schedule II controlled substances. The biennial inventory of controlled substances required by federal law may serve as one of the mandated inventories under this section in the year where the federal biennial inventory is performed, provided the biennial inventory was taken no more than three months from the last inventory required by this section; (CCR 1715.65[c][1])
- ☐ 19.3.2 A review of all acquisitions and dispositions of federal Schedule II controlled substances since the last inventory reconciliation report; (CCR 1715.65[c][2])
- ☐ 19.3.3 A comparison of the two above-mentioned items to determine if there are any variances; (CCR 1715.65[c][3])
- ☐ 19.3.4 All records used to compile each inventory reconciliation report shall be maintained in the pharmacy or clinic for at least three years in a readily retrievable form; and (CCR 1715.65[c][4])
- ☐ 19.3.5 Possible causes of overages shall be identified in writing and incorporated into the inventory reconciliation report. (CCR 1715.65[c][5])

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

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

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

Yes No N/A

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

☐☐☐ 19.7 A separate quarterly inventory reconciliation report shall be required for federal Schedule II controlled substances stored within the pharmacy and for each pharmacy satellite location. (CCR 1715.65 [g])

☐☐☐ 19.8 The pharmacist-in-charge of an inpatient hospital pharmacy or of a pharmacy servicing onsite or offsite automated drug delivery systems shall ensure that:

- ☐ 19.8.1 All controlled substances added to an automated drug delivery system are accounted for;
- ☐ 19.8.2 Access to automated drug delivery systems is limited to authorized facility personnel;
- ☐ 19.8.3 An ongoing evaluation of discrepancies or unusual access associated with controlled substances is performed; and
- ☐ 19.8.4 Confirmed losses of controlled substances are reported to the board.

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

20. After-Hours Supply of Medication

Yes No N/A

☐☐☐ 20.1 The pharmacy has a system assuring the prescribed medications are available in the hospital 24 hours a day. (22 CCR 70263[e])

☐☐☐ 20.2. The pharmacy maintains a record of the drugs taken from the after-hours supply of medications and the pharmacist is notified of such use. The record includes the name and strength of the drug, the amount taken, the date and time, the name of the patient to whom the drug was administered and the signature of the registered nurse. (22 CCR 70263[n])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

21. Drug Supplies for Use in Medical Emergencies

Yes No N/A

☐☐☐ 21.1. A supply of drugs for use in medical emergencies only is immediately available at each nursing unit or service area as required. (22 CCR 70263[f])

Yes No N/A

☐☐☐ 21.2. Written policies and procedures have been developed that establish the contents of the supply, procedures for use, restocking and sealing of the emergency drug supply. (22 CCR 70263[f][1], BPC 4115[i][3], BPC 4119.6)

☐☐☐ 21.3. The emergency drug supply is stored in a clearly marked portable container which is sealed by the pharmacist in such a manner that a seal must be broken to gain access to the drugs. The contents of the container are listed on the outside cover and include the earliest expiration date of any drugs within. (22 CCR 70263[f][2])

☐☐☐ 21.4. The pharmacist is responsible for inspection of the drug supply at periodic intervals (no less frequently than every 30 days) specified in the writ-ten policies. Records of the inspection are kept for at least three years. The inspection can be done by a pharmacy technician or pharmacy intern as defined in the pharmacy's written inspection policies and procedures. (22 CCR 70263[f][3], BPC 4115[i][3], BPC 4119.7[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

22. Schedule II-V Controlled Substances Floor Stock Distribution Records

Yes No N/A

☐☐☐ 22.1. Records for the distribution of Schedule II-V controlled substances floor stock are open to inspection by authorized officers of the law and are preserved for at least three years from the date of making. (BPC 4081)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

23. Emergency Room Dispensing

Yes No N/A

☐☐☐ 23.1. A prescriber may dispense a dangerous drug, including a controlled substance, to an emergency room patient if all of the following apply: (BPC 4068[a])

- ☐ 23.1.1. The hospital pharmacy is closed and there is no pharmacist available in the hospital;
- ☐ 23.1.2. The dangerous drug is acquired by the hospital pharmacy;
- ☐ 23.1.3. The dispensing information is recorded and provided to the pharmacy when the pharmacy reopens;
- ☐ 23.1.4. The hospital pharmacy retains the dispensing information and, if the drug is a schedule II, III or IV controlled substance, reports the dispensing information to the Department of Justice pursuant to Section 11165 of the Health and Safety Code;
- ☐ 23.1.5. The prescriber determines that it is in the best interest of the patient that a particular drug regimen be immediately commenced or continued, and the prescriber reasonably

believes that a pharmacy located outside the hospital is not available and accessible at the time of dispensing to the patient; and

☐ 23.1.6. The quantity of drugs dispensed to any patient pursuant to this section are limited to that amount necessary to maintain uninterrupted therapy during the period when pharmacy services outside the hospital are not readily available or accessible, but shall not exceed a 72-hour supply;

Yes No N/A

☐☐☐ 23.2. The prescriber shall ensure that the label on the drug contains all the information required by Section 4076. (BPC 4068[a][7])

☐☐☐ 23.3. The prescriber shall be responsible for any error or omission related to the drugs dispensed. (BPC 4068[b])

☐☐☐ 23.4. The brand name or generic name and manufacturer of the prescription drug is accurately identified on the label and prescription record. (BPC 4076, CCR 1717)

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

☐☐☐ 23.6. Prescriptions are dispensed in new, senior-adult ease –of-opening tested, and child-resistant containers or in a noncomplying package, only pursuant to the prescription or when requested by the purchaser. (15 USC 1473 section 4[b], 16 CFR 1700.15., CCR 1717)

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

☐☐☐ 23.8. The pharmacy provides patients with required Black Box Warning Information. (21 CFR 201.57[c])

☐☐☐ 23.9. Medication guides are provided on required medications. (21 CFR Part 208)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

24. Discharge Medication/Consultation Services

Yes No N/A

☐☐☐ 24.1. Patients receive information regarding each medication given at the time of discharge. The information includes the use and storage of each medication, the precautions and relevant warnings and the importance of compliance with directions. A written policy has been developed in collaboration with a physician and surgeon, a pharmacist, and a registered nurse and approved by the medical staff that ensures that each patient receives the medication consultation. (BPC 4074, CCR 1707.2)

☐☐☐ 24.2. Prescriptions are transmitted to another pharmacy as required by law. (BPC 4072, CCR 1717[f], 1717.4)

Yes No N/A

☐☐☐ 24.3. The prescription label contains all the required information and is formatted in accordance with CCR 1707.5 including Patient Centered Labels in at least 12-point sans serif typeface for the 4 required items in the required order. (BPC 4076, CCR 1707.5)

☐☐☐ 24.4. 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 (BPC 4074 [a][b], CCR 1744[a]), BPC 4076.7

☐☐☐ 24.5 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]).

☐☐☐ 24.6. The trade name or generic name and manufacturer of the prescription drug is accurately identified in the prescription record. (CCR 1717)

☐☐☐ 24.7. Generic substitution for discharge medications is communicated to the patient, and the name of the dispensed drug product is indicated on the prescription label. (BPC 4073)

☐☐☐ 24.8. If the prescription is filled by a pharmacy technician, the pharmacist's initials are on the prescription label to document the pharmacist's verification of the product or can be satisfied by recording the identity of the reviewing pharmacist in a computer system by a secure means and is immediately retrievable in the pharmacy. (BPC 4115[f], CCR 1793.7, CCR 1712)

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

☐☐☐ 24.10. Prescriptions are dispensed in a new and child-resistant container, or senior-adult ease-of-opening tested container, or in a non-complying package only pursuant to the prescriber or when requested by the purchaser. (~~25~~ 15 USC 1473 ~~section 4[b]~~, 16 CFR 1700.15, CCR 1717)

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

☐☐☐ 24.12. The pharmacy provides patients with required Black Box Warning. (21 CFR 201.57[c])

☐☐☐ 24.13. Medication guides are provided on required medications. (21 CFR Part 208)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

25. Central Filling of Patient Cassettes For Other Hospital Pharmacies

Yes No N/A

☐☐☐ 25.1. Pharmacy processes orders for the filling of patient cassettes for another hospital or Pharmacy within this state receives filled medication orders or patient cassettes from another hospital. (CCR 1710[b])

If the answer is "yes," name of hospital: _____

☐☐☐ 25.2. Pharmacy receives filled medication containers or cassettes from another pharmacy. (CCR 1710[b])

If the answer is "yes," name of supplying pharmacy: _____

If the answer to this and the previous question is "no" or "not applicable" go to Section 26.

Yes No N/A

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

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

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

☐☐☐ 25.6. Each cassette or container meets the requirements of Business and Professions Code section 4076. (CCR 1710[b][3], BPC 4076[b], BPC 4076[c], BPC 4076[d])

☐☐☐ 25.7. Complete and accurate records are maintained of each cassette fill transaction, including the name of the pharmacist checking the cassettes at each pharmacy. (CCR 1710[b][5])

26. Centralized Hospital Packaging Pharmacy

Yes No N/A

☐☐☐ 26.1 Prior to engaging in centralized hospital packaging, the pharmacy in addition to the hospital pharmacy license, has obtained a Centralized Hospital Packaging specialty license from the Board (BPC 4128.2a)

License Number: _____

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

☐☐☐ 26.2. The pharmacy prepares medications, by performing the following specialize functions, for administration only to inpatients within its own general acute care hospital and one or more general acute care hospitals under common ownership and located within a 75-mile radius: (BPC 4128)

Hospitals to which central packaged unit dose medications are provided:

- ☐ 26.2.1. _____ Distance (miles): _____
- ☐ 26.2.2. _____ Distance (miles): _____
- ☐ 26.2.3. _____ Distance (miles): _____
- ☐ 26.2.4. _____ Distance (miles): _____
- ☐ 26.2.5 Prepares unit dose packages for single administration to inpatients from bulk containers, if each unit dose package is barcoded pursuant to BPC 4128.4.
- ☐ 26.2.6 Prepares sterile compounded unit dose drugs for administration to inpatients, if each unit dose drug is barcoded pursuant to BPC 4128.4.
- ☐ 26.2.7 Prepares compounded unit dose drugs for administration to inpatients, if each unit dose package is barcoded pursuant to BPC 4128.4.

Yes No N/A

☐☐☐ 26.3. The pharmacy prepares and stores limited quantities of unit-dose drugs in advance of a patient-specific prescription in amounts necessary to ensure continuity of care. (BPC 4128.3)

☐☐☐ 26.4. Any unit dose medications produced by a centralized hospital packaging pharmacy are barcoded to be machine readable at the inpatient's bedside using barcode medication administrative software. (BPC 4128.4[a])

- ☐ The barcode medication administration software permits health care practitioners to ensure that before a medication is administered to an inpatient, it is the right medication, for the right inpatient, in the right dose, and via the right route of administration. The software verifies that the medication satisfies these criteria by reading the barcode on the medication and comparing the information retrieved to the electronic medical record of the inpatient. (BPC 4128[b])

☐☐☐ 26.5. Any label for each unit dose medication produced by a centralized hospital packaging pharmacy displays a human-readable label that contains the following: (BPC 4128.5[a])

- ☐ 26.5.1 The date the medication was prepared.
- ☐ 26.5.2 The beyond-use date
- ☐ 26.5.3 The established name of the drug.
- ☐ 26.5.4 The quantity of each active ingredient.
- ☐ 26.5.5 The lot number or control number assigned by the centralized hospital packaging pharmacy.
- ☐ 26.5.6 Special storage or handling requirements.
- ☐ 26.5.7 The name of the centralized hospital packaging pharmacy.

☐☐☐ 26.6 The pharmacist is able to retrieve all of the following information using the lot number or control number: (BPC 4128.5[b])

- ☐ 26.6.1 The components used in the drug product.
- ☐ 26.6.2 The expiration date of each of the drug's components.
- ☐ 26.6.3 The National Drug Code Directory number.

☐☐☐ 26.7. The centralized hospital packaging pharmacy and the pharmacists working in the pharmacy are responsible for the integrity, potency, quality, and labeled strength of any unit dose drug product prepared by the centralized hospital packaging pharmacy. (BPC 4128.7)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

27. Policies and Procedures

Yes No N/A

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

- ☐ 27.1.1. Oral consultation for discharge medication to an inpatient of a health care facility licensed pursuant to HSC 1250. The assurance that each patient received information regarding each medication given at the time of discharge. (BPC 4074[e], CCR 1707.2 [b][3])
- ☐ 27.1.2. Action to be taken to protect the public when a licensed individual employed by or with the pharmacy is known to be chemically, mentally, or physically impaired to the extent that it effects his or her ability to practice the profession or occupation authorized by his or her license. (BPC 4104[a])
- ☐ 27.1.3. Action to be taken to protect the public when a licensed individual employed by or with the pharmacy is known to have engaged in the theft or diversion or self-use of prescription drugs belonging to the pharmacy. (BPC 4104[b])
- ☐ 27.1.4. Addressing chemical, mental, or physical impairment, as well as, theft, diversion, or self-use of dangerous drugs, among licensed individual employees by or with the pharmacy. (BPC 4104[b])
- ☐ 27.1.5. Reporting to the board within 14 days of the receipt or development of information as specified in BPC 4104[c][1-6].
- ☐ 27.1.6. 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])
- ☐ 27.1.7. 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])
- ☐ 27.1.8. 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)
- ☐ 27.1.9. Inventory reconciliation reporting requirements. (CCR 1715.65)
- ☐ 27.1.10. Pharmacy technician performing monthly checks of the drug supplies stored throughout the health care facility and reporting irregularities within 24 hours to the pharmacist-in-charge and the director or chief executive officer of the health care facility. (BPC 4115[i][3])
- ☐ 27.1.11. Intern pharmacist under the direct supervision and control of a pharmacist may inspect the drugs maintained in the health care facility at least once per month. (BPC 4119.7[c])
- ☐ 27.1.12. Furnishing dangerous drug or dangerous device pursuant to preprinted or electronic standing orders, order sets, and protocol, if the order is dated, timed, and authenticated in the medical record of the patient to whom the dangerous drug or dangerous device is provided. (BPC 4119.7[c])
- ☐ 27.1.13. Storing and maintaining drugs in accordance with national standards regarding storage areas, refrigerator or freezer temperature, and otherwise pursuant to the manufacturer's guidelines. (BPC 4119.7[b], 22 CCR 70263 [q] Part 6)

☐ 27.1.14. Written policies and procedures for establishing the supply contents, procedure for use, restocking and sealing of emergency drug supply. (CCR 70263[f][1])

☐ 27.1.15. If applicable, written policies and procedures addressing for dispensing, storage and records of use if bedside medications are allowed. No controlled substances shall be left at bedside. (CCR 70262[l])

☐ 27.1.16. Policies regarding the use of investigational drugs. Basic information concerning the dosage form, route of administration, strength, actions, uses, side effects, adverse effects, interaction and symptoms of toxicity shall be available in the pharmacy and the nursing station. The pharmacist is responsible for the proper labeling, storage and distribution of such drug pursuant to the investigator's written orders. (CCR 70263[o]).

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

28. Compounding

Yes No N/A

☐☐☐ 28.1. 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)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

29. Automated Drug Delivery Systems

Yes No N/A

☐☐☐ 29.1. Prior to July 1, 2019: The hospital pharmacy operates automated drug delivery systems (ADDS) for doses administered at the facility and approved services listed on the hospital's license and is exempt from registration with the Board. (BPC 4105.5[e])

☐☐☐ 29.2. Prior to July 1, 2019: The hospital pharmacy operates automated drug delivery system (ADDS) for doses dispensed to patients that are registered with the Board. (BPC 4105.5[b])

☐☐☐ 29.3. Prior to July 1, 2019: The hospital pharmacy operates automated drug delivery system (ADDS) for doses dispensed to patients that are registered with the Board. (BPC 4105.5[b])

☐☐☐ 29.4. Prior to July 1, 2019: The hospital pharmacy is in compliance with the following:

☐ 29.4.1. The ADDS is consistent with legal requirements. (BPC 4105.5[c][1])

☐ 29.4.2. The pharmacy has policies and procedures related to the ADDS including appropriate security measures and monitoring of the inventory to prevent theft and diversion. (BPC 4105.5[c][2])

☐ 29.4.3. Reports drug losses from the ADDS to the board as required by law. (BPC 4105.5[c][3])

☐ 29.4.4. The pharmacy license is unexpired and not subject to disciplinary conditions. (BPC 4105.5[c][4]

Yes No N/A

☐☐☐ 29.5. July 1, 2019 and thereafter: The hospital pharmacy operates automated drug delivery systems (ADDS) that are automated unit dose systems (AUDS) for doses administered at the facility and approved services listed on the hospital's license and the ADDS is/are exempt from licensure with the Board. (BPC 4427.2[i])

☐☐☐ 29.6. July 1, 2019 and thereafter: The hospital pharmacy operates automated drug delivery system (ADDS) that are automated patient delivery dispensing systems (APDS) for doses dispensed to patients at the facility and approved services listed on the hospital's license and the ADDS is/are licensed with the Board. (BPC 4427.2[a])

Effective July 1, 2019, all pharmacies, including hospital pharmacies are required to complete the Automated Drug Delivery System Self-Assessment by July 1st annually and within 30 days whenever a new pharmacy permit is issued, there is a change in the pharmacist-in-charge and he/she becomes the new pharmacist-in-charge of the pharmacy, and there is a change in the licensed location of the pharmacy to a new address. (BPC 4427.7, CCR 1715)

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])

Yes No N/A

☐☐☐ 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])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

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])

☐☐☐ 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])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

Pharmacies with Collection Receptacles in the Pharmacy/Hospital (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.

☐☐☐ 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 fasten to a permanent structure so it cannot be removed and is installed in an inside location. (CCR 1776.3[b])

☐☐☐ 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 or is located in an area that is regularly monitored by pharmacy or DEA registrant employees and not in the proximity of any emergency or urgent care areas. When no pharmacy or DEA registrant employees are present, the collection receptacle is locked so that drugs are not deposited into the collection receptacle. (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])

Yes No N/A

☐☐☐ 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])

☐☐☐ 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])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

Onsite 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])

☐☐☐ 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])

Yes No N/A

☐☐☐ 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) can not be deposited, and (3) consumers may deposit prescription drugs including Schedule II-V controlled substances. (CCR 1776.4[i])

☐☐☐ 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])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

Record Keeping Requirements for Board Licensees Providing Drug Take Back Services

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

Yes No N/A

☐☐☐ 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: _____

_____

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 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 2, Chapter 1 – General Provisions
BPC, Division 2, Chapter 9 – Pharmacy
California Code of Regulation (CCR), Title 16, Division 17 – California State Board of Pharmacy
CCR, Title 22, Division 5, Chapter 1 – General Acute Care Hospitals
Civil Code, Division 1, Part 2.6, Chapter 2 – Disclosure of Medical Information by Providers
Code of Federal Regulations (CFR), Title 16, Chapter II, Subchapter E, Part 1700 – Poison Prevention Packaging
CFR, Title 21, Chapter I, Subchapter C, Part 201, Subpart B – Labeling Requirements for Prescription Drugs and/or Insulin
CFR, Title 21, Chapter I, Subchapter C, Part 208 – Medication Guides for Prescription Drug Products
CFR, Title 21, Chapter I, Subchapter C, Part 290 – Controlled Drugs
CFR, Title 21, Chapter I, Subchapter D, Part 310, Subpart E – Requirements for Specific New Drugs and Devices
CFR, Title 21, Chapter II - Drug Enforcement Administration, Department of Justice
Health and Safety Code (HSC), Division 10 – Uniform Controlled Substances Act
HSC, Division 104, Part 5 (Sherman Food, Drug, and Cosmetics Law), Chapter 2 – Administration
HSC, Division 116 – Surplus Medication Collection and Distribution
United States Code (USC), Title 15, Chapter 39A – Special Packaging of Household Substances for Protection of Children
USC, Title 21, Chapter 9, Subchapter V, Part H – Pharmaceutical Distribution Supply Chain (Drug Supply Chain Security Act)