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

Enforcement and Compounding Committee Report

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Jignesh Patel, Licensee Member, Vice-Chair
Renee Barker, Licensee Member
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Seung Oh, Licensee Member, President
Ricardo Sanchez, Public Member

The Board will review a summary of the committee's work at its January 23, 2023, Enforcement and Compounding Committee Meeting as well as updates for discussion and action as necessary.

a. Discussion and Consideration of Regulation of Self-Assessment Forms

- **I. Community Pharmacy/Hospital Outpatient Self-Assessment (17M-13)**
- **II. Hospital Pharmacy Self-Assessment (17M-14)**
- **III. Wholesaler/Third Party Logistics Provider Self-Assessment (17M-26)**
- **IV. Automated Drug Delivery System Self-Assessment (17M-112)**

Background

Under the law, Board licensees are required to perform self-assessments of its operations to evaluate for compliance with Pharmacy Law, its regulations, and other provisions of state and federal law that govern the practice of pharmacy. As Pharmacy law is dynamic, it is important to maintain current self-assessment forms to assist licensees in remaining compliant.

As these forms are incorporated by reference in the various regulation sections, rulemakings are necessary to permanently update these forms. As a matter of practice, upon approval of the Board, updated draft forms are posted on the Board's website in advance of the formal rulemaking. To fulfill legal requirements, the Board will accept completion of either the current draft version of the self-assessment form or the version incorporated by reference in the regulation; however, staff typically recommend completion of the most recent draft version as it provides for more meaningful self-assessment.

With recent changes to the regulation language included in CCR sections 1714 and 1784, staff believe it is possible the self-assessment forms may be updated through a streamlined rulemaking process referred to as a "Section 100" process. This process is limited to changes without regulatory effect.

Summary of Committee Discussion and Action

During the meeting members reviewed the draft updates to the self-assessment forms. The committee agreed with the Community Pharmacy/Hospital Outpatient Self-Assessment, Hospital Self-Assessment and Wholesaler/Third-Party Logistics Provider Self-Assessment updated being facilitated though the executive officer's delegated authority to use a streamlined Section 100 regulation process. Changes in the forms are detailed below. The committee is offering a recommendation for the Automated Drug Delivery Systems Self-Assessment only.

Community Pharmacy/Hospital Outpatient Self-Assessment (17M-13)

The community pharmacy/hospital outpatient self-assessment has been updated to make the following changes:

- Add the requirement for the pharmacy to update their email address with 30 days of any change, as required by CCR 1704.
- Remove the requirement to display safe storage products, because of the repeal of the requirement.
- Add the new electronic data transmission requirements and the exceptions, as established by BPC 688.
- Add the quota chain store prohibition, as established by BPC 4113.7.
- Add the requirement to disclose any disciplinary action on the annual facility renewal, as required by CCR 1702.5.
- Add the requirement for a pharmacy to notify the Board of a temporary closure, exceeding three consecutive calendar days, as required by CCR 1708.1.
- Consolidated the voluntary drug repository requirements by listing the legal codes in section. The voluntary drug repository has limited participation, so by consolidating the information into one question, it will reduce the overall length of the self-assessment form. The legal statutes are provided as a reference for those pharmacies that participate in the program.
- Add the requirement that restricts remote processing to a pharmacist, per BPC 4019. Absent the emergency waiver, only a pharmacist can enter a prescription remotely.
- Add the requirement that a pharmacy technician must be licensed by the Board and a certificate is not equivalent to licensure for clarity, per BPC 4115(e).
- Amended the inventory reconciliation requirements as a result of the changes to CCR 1715.65.
- Consolidated the Standards of Service for Providers of Blood Clotting Products for Home Use requirements by listing the legal codes in section. The providers of blood clotting products for home use are limited participation, so by consolidating the information into one question, it will reduce the overall length of the self-assessment form. The legal statutes are provided as a reference for those pharmacies that participate in the program.
- Consolidated the Telepharmacy Systems and Remote Dispensing Site Pharmacy

requirements by listing the legal codes in section. There are few licensing remote dispensing site pharmacies, so by consolidating the information into a few questions, it will reduce the overall length of the self-assessment form. The legal statutes are provided as a reference for those pharmacies that are licensed.

Hospital Pharmacy Self-Assessment (17M-14)
The hospital pharmacy self-assessment has been updated to make the following changes:

- Add the requirement for medicinal cannabis storage as required by HSC 1649.1.
- Add the requirement for lot level traceability and unit level traceability as required by the Drug Quality and Security Act (DQSA).
- Consolidated the voluntary drug repository requirements by listing the legal codes in section. The voluntary drug repository has limited participation, so by consolidating the information into one question, it will reduce the overall length of the self-assessment form. The legal statutes are provided as a reference for those pharmacies that participate in the program.
- Add the requirement for the pharmacist to report medication error quality assurance review reports to the Board at the time of renewal, as required by CCR 1711(f).
- Amended the inventory reconciliation requirements as a result of the changes to CCR 1715.65, including the requirement for inpatient hospital pharmacies to include satellite locations and drug storage areas in the hospital.
- Add the requirement that an ADDS located in an emergency room, used for dispensing to patients upon discharge be licensed by the Board, as required by BPC 4427.2(i). Additionally, added the requirement that automated unit dose delivery systems (AUDS) to comply with the requirements of Article 25 for clarity.

Wholesaler/Third-Party Logistics Provider Self-Assessment (17M-26)
The wholesaler/Third-Party Logistics Provider self-assessment has been updated to make the following changes:

- Add the requirement for the designated representative-in-charge/responsible manager to update their email address with 30 days of any change, as required by CCR 1704.
- Add the requirement for a facility to notify the Board of a temporary closure, exceeding three consecutive calendar days, as required by CCR 1708.1.

Automated Drug Delivery System Self-Assessment (17M-112)
Note: As this form is currently undergoing rulemaking, the new proposed changes to this self-assessment are reflected as follows: *new text* and ~~*deleted text*~~.
The automated drug delivery system self-assessment has been updated to make the following changes:

- Add the notes to the first page addressing the requirement of a non-licensed ADDS in a hospital to complete the self-assessment form, pursuant to BPC 4427.7(a).

- Removed the requirements of the self-assessment form from the self-assessment as they are redundant.
- Amended the inventory reconciliation requirements as a result of the changes to CCR 1715.65.
- Updated the form to include when a quality assurance review must be initiated.

Committee Recommendation: Recommend approval of the proposed amendments to self-assessment form 17M-112 and incorporate the proposed amendments into the rulemaking package and initiate a 15-day comment period, authorize the Executive Officer to take all steps necessary to complete the rulemaking, make any non-substantive changes to the package, and adopt self-assessment form 17M-112.

Attachment 1 includes copies of the self-assessment forms.

b. Discussion and Consideration of Barriers to Timely Case Resolutions

Relevant Law

BPC Section 4008 provides the Board with the authority to employ inspectors to inspect, during business hours all pharmacies, wholesalers, dispensaries, stores, or other places where drugs or devices are compounded, prepared, furnished, dispensed or stored.

BPC Section 4011 provides that the Board shall administer and enforce Pharmacy Law and the Uniform Controlled Substances Act.

BPC 4080 provides that all stock of dangerous drug or dangerous device or of shipments through a customs broker or carrier shall be, at all times during business hours, open to inspection by authorized officers of the law.

BPC 4081 generally provides that all records of manufacture and of sale and disposition shall at all times during business hours be open to inspection.

BPC 4105 generally provides that all records of acquisition and disposition in a readily retrievable form. Further this section requires that then requested by an authorized officer of the law, an entity licensed by the board shall provide the board with the request records within three business days of the time the request was made and provides provisions to request and extension.

Background

Included as part of the Board's strategic plan is an objective to determine and reduce barriers to timely case resolutions to improve consumer protection. Case resolution includes all steps from receipt and assignment of the matter through case closure. Generally, the more egregious cases have longer case resolution times as they typically are resolved through the formal discipline through the Office of the Attorney General.

When evaluating opportunities to reduce case resolution times, staff have identified some barriers to investigation that if removed, could result in reductions in investigation timeframes. As pharmacy law provisions have changed and new requirements for pharmacy operations are established, (e.g., staffing requirements, quota prohibitions, etc.) investigations require access to records that historically would not have been sought by Board staff on a routine basis. Regrettably, through the investigation process staff are experiencing resistance to records requests for information necessary to assess if violations of pharmacy law have occurred. Below are some recommendations:

1. Amend BPC 4081 to require maintenance and release of staffing schedules, job duty statements, consultant reports, and policies and procedures related to pharmacy personnel and pharmacy operations as part of the records that must be maintained.
2. Amend BPC 4105 to require maintenance and release of staffing schedules, job duty statements, consultant reports, and policies and procedures related to pharmacy personnel and pharmacy operations as part as part of the records that must be readily retrievable.

Summary of Committee Discussion and Action
During the meeting members discussed recommendations offered by staff. Members spoke in support of the changes. No public comments were received.

The committee will consider statutory language at a future meeting.

c. Overview of Federal Requirements for Compounding under the Provisions of 503A

Relevant Law
Drugs compounding in accordance with all conditions of Section 503A are subject to ALL provisions of the FD&C Act that apply to conventionally manufactured drugs, except:

- Current good manufacturing practice requirements (section 501(a)(2)(B))
- Labeling with adequate directions for use (section 502(f)(1)
- Premarket approval requirements (section 505)

Generally, Section 503A describes the federal requirements that must be satisfied for drug products compounded by a licensed pharmacist or licensed physician to be exempted for the above stated provisions. As included in the FDA released Guidance Document, "Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act" on June 2016 Revision 2, all other applicable provisions of the FD&C Act remain in effect for compounded drugs, even if the conditions of section 503A are met.

Background

As provided by the FDA, compounded drugs are not FDA-approved, meaning the FDA does not review the drugs to evaluate their safety, effectiveness, or quality before they reach patients. Similar to the board, the FDA has reported on investigations of cases of serious patient injury linked to poor quality compounded drug preparations.

In response, in part to a 2012 fungal meningitis outbreak, Congress passed the Drug Quality and Security Act (DQSA), making updates to the Federal Food, Drug and Cosmetic Act regarding human drug compounding. Since its enactment, FDA has worked to issue draft and final policy documents to implement the law.

To comply with all legal requirements governing compounding, licensees must be mindful of all state and federal laws to ensure a full understanding of the legal requirements in addition to any relevant practice standard that must also be followed.

Summary of Committee Discussion
Members received an overview on the federal requirements for compounding. The presentation provided an overview of the requirements for an authorized individual to qualify for some exemptions to federal law under provisions for section 503A. Attendees were reminded that licensees performing compounding must comply with federal and state laws.

A copy of the presentation slides is provided in **Attachment 2**.

d. Presentation on USP General Chapter 825, Regarding Radiopharmaceuticals

USP Chapter 825 provides standards for the preparation, compounding, dispensing, and repackaging of radiopharmaceuticals, including all sterile radioactive material that must maintain sterility through manipulations prior to administration. Consist with action taken by the USP Compounding Expert Committee, USP Chapter 825 shall become official on November 1, 2023.

To assist with implementation, USP has published FAQ's on the Chapter available on its website.

Summary of Committee Discussion
During the meeting members received a presentation on the provisions of USP 825.

A copy of the presentation slides is provided in **Attachment 3**.

e. Discussion and Consideration of Proposed Addition to Title 16, California Code of Regulations Section 1738 related to Radiopharmaceuticals

Relevant Law
Business and Professions Code (BPC) section 4126.8 generally provisions that compounding of drug preparations shall be consistent with standards established in the pharmacy compounding chapters of the current version of the United-States

Pharmacopeia-National Formulary, including relevant testing and quality assurance. Further the Board may adopt regulations to impose additional standard for compounding drug preparations.

BPC section 4341 provides authority for the board to institute any action or actions as may be provided by law and that, in its discretion, are necessary, to prevent the sale of pharmaceutical preparations and drugs that do not conform to the standard and tests as to quality and strength, provided in the latest edition of the United States Pharmacopeia or the National Formulary, or that violate any provision of the Sherman Food, Drug, and Cosmetic Act.

Background

In anticipation of the upcoming official date of Chapter 825, it is appropriate to review the Board's regulations to determine, in the interest of patient safety, where changes are appropriate.

Summary of Committee Discussion and Action

During the meeting members reviewed draft regulation language developed by staff to replace existing regulations. Members reviewed each of the sections of the proposed language and provided an opportunity for public comment.

Following completion of the Committee's work and consideration of compounding chapters and related regulations, the Committee will present all compounding regulations to the Board for consideration to initiate a rulemaking.

A copy of the regulation language considered and modified by the committee is provided in **Attachment 4**.

f. Review and Discussion of Enforcement Statistics

Since July 1, 2022, the Board has received 1,839 complaints and has closed 1,459 investigations. The Board has issued 92 letters of admonishment, 499 citations with or without a fine, and referred 104 cases to the Office of the Attorney General. The Board has secured 3 interim suspension orders, 2 automatic suspension orders, and been granted 4 Penal Code 23 restrictions. Further, the Board has revoked 23 licenses, accepted the disciplinary surrender of 26 licenses, denied 3 applications, and imposed other levels of discipline against 45 licensees and/or applicants. A copy of the current statistics is provided in **Attachment 5**.

As of January 1, 2023, the Board had 1,450 field investigations pending. Below is a breakdown providing more detail in the various investigation process:

	Jan. 3, 2022	Apr. 1, 2022	Jul. 1, 2022	Oct. 1, 2022	Jan. 1, 2023

	Vol.	Avg. Days	Vol.	Avg. Days	Vol.	Avg. Days	Vol.	Avg. Days	Vol.	Avg. Days
Awaiting Assignment	43	29	43	6	24	6	110	6	80	12
Cases Under Investigation	626	136	738	122	793	118	749	125	853	129
Pending Supervisor Review	135	41	173	30	171	39	223	46	199	85
Pending Second Level Review	135	41	94	56	97	58	205	36	226	55
Awaiting Final Closure	66	60	50	15	127	10	113	42	92	35

Attachment 1A

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

17M-13 (Rev. 1/23)

California State Board of Pharmacy
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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, initialed, signed, and readily available in the pharmacy. Signatures and initials shall be an original handwritten signature or initial on the self-assessment form. Do not copy a previous assessment.

Notes: If a hospital pharmacy dispenses prescriptions for outpatient use, this Community Pharmacy Self-Assessment/Hospital Outpatient Pharmacy Self-Assessment must be completed in addition to the Hospital Pharmacy Self-Assessment (17M-14 pursuant to 16 CCR 1715). Any pharmacy that compounds drug products must also complete the Compounding Self-Assessment (17M-39 pursuant to 16 CCR 1735.2[k]).

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# _____ Exp Date: _____

Licensed Remote Dispensing Site Pharmacy License # _____ 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, 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: _____

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

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

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

1. Facility

Yes No N/A

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

☐☐☐ 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[b], [d])

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

☐☐☐ 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[c])

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

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

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

☐☐☐ 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)

Yes No N/A

PIC Initials

☐☐☐ 1.11. Does the pharmacy compound sterile drugs? (If yes, complete the Compounding Self-Assessment as required by CCR 1735.2(k).)

☐☐☐ 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 their ability to practice the profession or occupation authorized by their 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 their 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 their 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 their 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 In addition to the email notification, the pharmacy has provided to the Board the electronic mail address and must notify the Board within 30 days of any change in the electronic mail address. (CCR 1704)

☐☐☐ 1.16~~7~~. 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~~8~~. 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[a], [b])

Yes No N/A

☐☐☐ ~~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 boxes, locking medicine cabinets, 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 who owns 4 or less pharmacy. (BPC 4106.5[a], [b])~~

☐☐☐ 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)

- ☐ 1.19.1. The pharmacy has designated the name(s) of personnel who will be available to assist the pharmacist; (CCR 1714.3[a][1])
- ☐ 1.19.2. Designated personnel are able, at a minimum, to perform the duties of non-licensed pharmacy personnel as specified in section 1793.3, and is qualified to have access to controlled substances; (CCR 1714.3[a][2], [3])
- ☐ 1.19.3. Designated personnel respond and are able to assist the pharmacist within five minutes after the pharmacist's request; (CCR 1714.3[a][4])
- ☐ 1.19.4. The pharmacy has policies and procedures in compliance with CCR 1714.3; (CCR 1714.3[b])
- ☐ 1.19.5. All impacted pharmacy employees and designated persons have read and signed a copy of the policies and procedures. (CCR 1714.3[c])

☐☐☐ <u>1.20. The pharmacy has the capability to receive an electronic data transmission prescription on behalf of a patient. (BPC 688[b])</u>

- ☐ <u>1.20.1 The pharmacy shall not refuse to dispense or furnish an electronic data transmission prescription solely because the prescription was not submitted via, or is not compatible with, the proprietary software of the pharmacy. (BPC 688[b][2])</u>
- ☐ <u>1.20.2 The pharmacy's staff is aware they may continue to dispense the medication from a legally valid written, oral or fax prescription and are not required to verify the prescription properly falls under one of the exceptions. (BPC 688[i])</u>

☐ 1.20.~~1~~3. For prescriptions for controlled substances, as defined by BPC section 4021 generation and transmission of the electronic data transmission prescription complies with Parts 1300, 1304, and 1311 of Title 21 of the Code of Federal Regulations. (BPC 688[c])

☐ 1.20.~~2~~4. At the request of the patient or person authorized to make a request on behalf of the patient, the pharmacy immediately transfers or forwards an electronic data transmission prescription, that was received but not dispensed to the patient, to an alternative pharmacy designated by the requester, unless the action would result in a violation of any state or federal law or the action is not supported by the latest version of NCPDP SCRIPT standard. (BPC 688[g]) ~~Unfulfilled controlled substance prescriptions are transferred or forwarded in compliance with Federal Law~~. (21 CFR 1300, 1304, 1306, 1311, BPC 688[g])

☐ 1.20.3. If ~~the~~ pharmacy staff~~, or its staff~~, is aware that an attempted transmission of an electronic data transmission prescription failed, is incomplete, or is otherwise not appropriately received, pharmacy staff immediately notifies the prescribing health care practitioner. (BPC 688[h])

Yes No N/A

☐☐☐ 1.21. The pharmacy performs FDA approved or authorized tests that are classified as CLIA waived. (BPC 4119.10)

☐ 1.21.1. The pharmacy is appropriately licensed as a laboratory under Section 1265 of the Health and Safety Code. (BPC 4119.10[a])

CDPH (CLIA) Registration #:_____ Expiration: _____

☐ 1.21.2. The pharmacy maintains policies and procedures as specified in. (BPC 4119.10[b])

☐ 1.21.3. The tests are authorized to be administered by a pharmacist pursuant to BPC 4052.4(b)(1). (BPC 4119.10[c])

☐ 1.21.4. The pharmacist-in-charge reviews the policies and procedures annually, assesses compliance with its policies, documents corrective actions to be taken when noncompliance is found, and maintains documentation of the annual review and assessment in a readily retrievable format for a period of three years. (BPC 4119.10[d])

☐ 1.21.5. The pharmacy maintains documentation related to performing tests, including the name of the pharmacist performing the test, the results of the test, and communication of results to the patient's primary medical provider, and is maintained in a readily retrievable format for a period of three years. (BPC 4119.10[e])

☐☐☐ 1.22 If the pharmacy qualifies as a chain store as defined in BPC 4001, the chain community pharmacy does not establish a quota. (BPC 4113.7, BPC 4317)

☐☐☐ 1.23 The pharmacy must report to the board any disciplinary action taken by any government agency since its last license issuance or last renewal. (CCR 1702.5)

Yes No N/A

☐☐☐ 1.24 When the pharmacy temporarily closes, the pharmacy must notify the board of the temporary closure as soon as closure exceeds three consecutive calendar days. A temporary closure does not include a routine closure (including weekends or state and federal holidays), unless that closure exceeds four consecutive calendar days. (CCR 1708.1)

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 ~~if~~ 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; and (BPC 4059.5[f][4])
- ☐ 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 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])

Yes No N/A

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

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

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

CORRECTIVE ACTION OR ACTION PLAN: _____

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3. Drug Stock

Yes No N/A

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

☐☐☐ 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[b], 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.

Yes No N/A

☐☐☐ 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 that 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. (21 USC 360eee-1[d][2], [g][1])

CORRECTIVE ACTION OR ACTION PLAN: _____

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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.)~~

☐☐☐ 4.2 The pharmacy that donates medications to or operates a voluntary county approved drug repository and distribution program meets all the requirements as specified in law. (HSC 150200, 150201, 150202, 150202.5, 150203, 150204, 150204.5, 150204.6, 150205, BPC 4169.5)

CORRECTIVE ACTION OR ACTION PLAN: _____

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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[a], 4113[d])

☐☐☐ 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. (BPC 1206.~~5~~6, 1209, 1265)

CORRECTIVE ACTION OR ACTION PLAN: _____

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PIC Initials _____

6. Duties of a Pharmacist

Yes No N/A

☐☐☐ 6.1. 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, HIV preexposure prophylaxis, HIV postexposure prophylaxis pursuant to a protocol; (BPC 4052 [a][10], 4052[a][11], 4052.01, 4052.02, 4052.03, 4052.3, 4052.8, 4052.9)
- ☐ dispenses aid-in-dying drugs; (HSC 443.5 [b][2])
- ☐ orders and interprets tests for monitoring and managing efficacy and toxicity of drug therapies; (BPC 4052 [a][12])
- ☐ initiate, adjust, or discontinue drug therapy for a patient under a collaborative practice agreement with any health care provider with prescriptive authority; and (BPC 4052 [a][13])
- ☐ provide medication-assisted treatment pursuant to a state protocol, to the extent authorized by federal law. (BPC 4052 [a][14])

Yes No N/A

☐☐☐ 6.2. In addition, a pharmacist:

- ☐ receives a new prescription order from the prescriber; (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, 4052.02, 4052.03, 4052.1, 4052.2, 4052.3, 4052.4, CCR 1793.1 [g])

Yes No N/A

☐☐☐ 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)

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

☐☐☐ 6.5. The pharmacist dispenses emergency contraception only pursuant to the statewide protocol found in CCR 1746. (BPC 4052.3[b][1])

☐☐☐ 6.6. Only a pharmacist performs blood glucose, hemoglobin A1c, or cholesterol tests that are waived under CLIA. (BPC 1206.6)

☐☐☐ 6.7. Only a pharmacist performs FDA-approved or authorized CLIA waived clinical laboratory tests as specified in law. ~~in BPC 4052.4~~ (BPC 4052.4, BPC 1206.6, BPC 4119.10)

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. ~~Effective July 1, 2022, a~~ A pharmacist who is authorized to initiate or adjust a Schedule II Controlled substance shall have completed an education course on the risks of addiction associated with the use of Schedule II drugs. (BPC 4232.5[a])

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

☐☐☐ 6.11. Only a pharmacist may electronically enter a prescription or an order, as defined in BPC 4019, into a pharmacy's or hospital's computer from any location outside of the pharmacy or hospital with the permission of the pharmacy or hospital. This does not apply to prescriptions for Schedule II, III, IV or V controlled substances, except as permitted pursuant to HSC 11164.5. (BPC 4071.1)

CORRECTIVE ACTION OR ACTION PLAN: _____

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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][1]-[3])
- ☐ 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][4])
- ☐ 7.1.3. 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[a][5], [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[a][5], [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: _____

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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 by the pharmacist-in-charge at the pharmacy while the intern pharmacist obtained the experience, when applicable. (BPC 4209[b], 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: _____

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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[a], [f][1], CCR 1793.7[f])

☐☐☐ 9.3. A pharmacy technician or pharmacy technician trainee wears identification, in 18-point type, that identifies them as a pharmacy technician or pharmacy technician trainee. (BPC 680[a], 4115.5[e], CCR 1793.7[c])

☐☐☐ 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[d])

☐☐☐ 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 140 hours. (BPC 4115.5)

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

☐☐☐ 9.7 A person shall not act as a pharmacy technician without first being licensed by the board as a pharmacy technician. A certification only is not equivalent to being licensed by the board as a pharmacy technician. (BPC 4115[e])

CORRECTIVE ACTION OR ACTION PLAN: _____

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10. Duties of Non-Licensed Personnel

Yes No N/A

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

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

CORRECTIVE ACTION OR ACTION PLAN: _____

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PHARMACY PRACTICE

11. Consultation/Patient Profile/Review of Drug Therapy

Yes No N/A

☐☐☐ 11.1. Pharmacists provide oral consultation: (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;
- ☐ 11.1.4. whenever the pharmacist deems it is warranted in the exercise of their professional judgment; and
- ☐ 11.1.5. all of the above, unless a patient or patient's agent declines the consultation directly to the pharmacist.

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

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

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

☐☐☐ 11.5. Appropriate drug warnings are provided orally or in writing. (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: _____

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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[c])

Yes No N/A

☐☐☐ 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[c], 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 for 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])

☐☐☐ 12.8. With the exception of those prescriptions written under HSC 11159.2 (terminally ill exemption), 11159.3 (declared emergency exemption) and 11167.5 (SNF, ICF, licensed home health agency and licensed hospice exemption), all written controlled substances prescriptions (Schedules II – V) are on California Security Prescription forms. (HSC 11164[a], 11167.5, 11162.1, 11159.2, 11159.3)

☐☐☐ 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 parts 1300, 1306, 1311)

CORRECTIVE ACTION OR ACTION PLAN: _____

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13. Prescription Labeling, Furnishing and Dispensing

Yes No N/A

☐☐☐ 13.1. The prescription label contains all the required information. (BPC 4076)

☐☐☐ 13.2. The prescription label is formatted in accordance with patient centered labeling requirements. (CCR 1707.5)

☐☐☐ 13.3. The expiration dates of a drug's effectiveness is accurately identified on the label. (BPC 4076[a][9])

☐☐☐ 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[a][1], CCR 1707.5[a][1], 1717[b][2])

☐☐☐ 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 the identity of the reviewing pharmacist is recorded in a computer system by a secure means. (BPC 4115, 4115.5[b][3], 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[a])

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

☐☐☐ 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 208.24[e])

☐☐☐ 13.13. The pharmacy furnishes dangerous drugs in compliance with:

- ☐ BPC 4119(b) to an approved service provider within an emergency medical services system for storage in a secured emergency pharmaceutical supplies container, in accordance with the policies and procedures of the local emergency medical services agency. (BPC 4119)
- ☐ BPC 4126.5(a) 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[a][11])

☐☐☐ 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 their professional judgment. (BPC 4064.5[a][4])
  - ☐ 13.17.1.6. The pharmacist notifies the prescriber of the increase in quantity dispensed. (BPC 4064.5[c])

☐ 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[f][1])

☐ 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[f][2])

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], 4076.7, CCR 1744)

☐☐☐ 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 it is not possible for the English-language directions to appear on the container or label, the English-language directions are provided on a supplemental document. (BPC 4076.6[a])

Yes No N/A

☐☐☐ 13.22. When a pharmacist furnishes ~~naloxone~~ federal FDA-approved opioid antagonists pursuant to the board of pharmacy's approved protocol, the pharmacist complies with all the requirements listed in BPC 4052.01 and CCR 1746.3.

☐☐☐ 13.23. When the pharmacy furnishes 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 exclusively for use by employees of the law enforcement agency, who have completed training provided by the law enforcement agency, in administering naloxone hydrochloride or other opioid antagonists, 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 the information required under section 300aa-25 of Title 42 of the United States Code is readily retrievable during the pharmacy's normal operating hours. A pharmacist 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. A pharmacist informs each patient or patient's guardian of immunization record sharing preferences detailed in HSC 120440(e). At the request of a patient, the pharmacist shall notify each patient's primary care provider or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by the primary care provider. The pharmacist shall also notify each pregnant patient's prenatal care provider, if known, of any vaccine administered to the patient within 14 days. (CCR 1746.4[d][e], [f])

☐☐☐ 13.26. The pharmacy furnishes epinephrine auto-injectors to an authorized entity for the purpose of rendering emergency care in accordance with HSC 1797.197a, 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 pursuant to BPC 4119.4.

☐☐☐ 13.27. When a pharmacist initiates and furnishes HIV preexposure prophylaxis, the pharmacist does so in compliance with all the requirements of BPC 4052.02. (BPC 4052.02, CCR 1747)

☐☐☐ 13.28. When a pharmacist initiates and furnishes HIV postexposure prophylaxis, the pharmacist does so in compliance with all the requirements of BPC 4052.03. (BPC 4052.03, CCR 1747).

☐☐☐ 13.29. When a pharmacist receives a prescription, which include the words "expedited partner therapy" or the letters "EPT" pursuant to HSC 120582, the pharmacists labels the drug without the name of the individual for whom the drug is intended (BPC 4076 [a], [f]).

Yes No N/A

☐☐☐ 13.30. When a pharmacist provides EPT the pharmacist provides written notification that describes the right of an individual who receives EPT to consult with a pharmacist about the medication dispensed and additional information regarding possible drug interactions. (BPC 4076[a], [h]).

CORRECTIVE ACTION OR ACTION PLAN: _____

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14. Refill Authorization

Yes No N/A

☐☐☐ 14.1. Refill authorization from the prescriber is obtained before refilling a prescription. (BPC 4063)

☐☐☐ 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[a])

☐☐☐ 14.4. Refills for Schedule II controlled substances are prohibited. (HSC 11200)

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

CORRECTIVE ACTION OR ACTION PLAN: _____

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15. Auto-Refill Program

Yes No N/A

☐☐☐ 15.1. The pharmacy offers a program to automatically refill prescriptions (CCR 1717.5). The pharmacy is aware ~~that effective July 1, 2022,~~ the following actions are required:

- ☐ 15.1.1. The pharmacy has policies and procedures describing the program. (CCR 1717.5[a][1])
- ☐ 15.1.2. Before a patient enrolls, the pharmacy provides a written or electronic notice summarizing the program to the patient or patient's agent. (CCR 1717.5[a][2])
- ☐ 15.1.3. The pharmacy obtains an annual renewal of each prescription from the patient or patient's agent for each prescription refilled through the program. (CCR 1717.5[a][3])
- ☐ 15.1.4. The pharmacy maintains a copy of the written or electronic consent to enroll on file for one year from date of dispensing. (CCR 1717.5[a][4])
- ☐ 15.1.5. The pharmacy completes a drug regimen review for each prescription refilled through the program at the time of refill. (CCR 1717.5[a][5])
- ☐ 15.1.6. Each time a prescription is refilled through the program, the pharmacy provides the patient or patient's agent with a written or electronic notice that a prescription was refilled through the program. (CCR 1717.5[a][6])

☐ 15.1.7. The pharmacy documents and maintains records of patient withdrawal or disenrollment for one year from the date of withdrawal or disenrollment and provides confirmation to the patient or patient's agent. (CCR 1717.5[a][7])

☐ 15.1.8. The pharmacy provides a full refund to the patient, patient's agent or payer for any prescription refilled through the program if the pharmacy was notified that the patient did not want the refill, regardless of the reason, or the pharmacy had been notified of withdrawal or disenrollment from the program prior to dispensing the prescription medication. (CCR 1717.5[a][8])

☐ 15.1.9. The pharmacy makes available any written or electronic notification required by this section in alternate languages as required by state or federal law. (CCR 1717.5[a][9])

CORRECTIVE ACTION OR ACTION PLAN: _____

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16. Quality Assurance and Medication Errors

Yes	No	N/A	
☐	☐	☐	16.1. 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)
☐	☐	☐	16.2. Pharmacy quality assurance policies and procedures are maintained in the pharmacy and are immediately retrievable. (CCR 1711[c])
☐	☐	☐	16.3. 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], [c][3])
☐	☐	☐	16.4. 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])
☐	☐	☐	16.5. Investigation of pharmacy medication errors is initiated within two business days from the date the medication error is discovered. (CCR 1711[d])

Yes	No	N/A	
☐	☐	☐	16.6. The record for quality assurance review for a medication error contains: (CCR 1711[e])

☐ 16.6.1. Date, location, and participants in the quality assurance review;

☐ 16.6.2. Pertinent data and other information related to the medication error(s) reviewed;

☐ 16.6.3. Findings and determinations; and

☐ 16.6.4. Recommended changes to pharmacy policy, procedure, systems or processes, if any.

☐☐☐ 16.7. 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])

☐☐☐ 16.8. 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: _____

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

Yes No N/A

☐☐☐ 17.1. 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])

☐☐☐ 17.2. 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)

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

☐☐☐ 17.4. 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: _____

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18. Prescription Transfer

Yes No N/A

☐☐☐ 18.1. Only pharmacists transfer prescriptions from pharmacy to pharmacy, and records of prescription transfers are kept as required. (CCR 1717 [e])

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

☐☐☐ 18.3. For electronic data transmission prescriptions, at the request of the patient or person authorized to make a request on behalf of the patient, the pharmacy immediately transfers or forwards an electronic data transmission prescription, that was received but

not dispensed to the patient, to an alternative pharmacy designated by the requester (BPC 688 (g)), unless the action would result in a violation of any state or federal law or the action is not supported by the latest version of NCPDP SCRIPT standard. ~~Unfulfilled controlled substance prescriptions received as electronic data transmission prescriptions are transferred or forwarded in compliance with Federal Law.~~ (21 CFR 1300, 1304, 1306, and 1311)

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

☐☐☐ 18.4. 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. (21 CFR 1306.25, CCR 1717[e])

☐☐☐ 18.5. 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], 21 CFR 1306.25)

CORRECTIVE ACTION OR ACTION PLAN: _____

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19. Confidentiality of Prescriptions

Yes No N/A

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

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

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

☐☐☐ 19.4. 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])

Yes No N/A

☐☐☐ 19.5. If the 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)

☐☐☐ 19.6. Destruction or disposal of patient records preserves the confidentiality of the information contained therein. (Civil Code 56.101[a])

CORRECTIVE ACTION OR ACTION PLAN: _____

20. Record Keeping Requirements

Yes No N/A

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

☐☐☐ 20.2. 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. These records include (BPC 4081, 4105, 4169, 4333):

- ☐ 20.2.1. Prescription records (BPC 4081[a])
- ☐ 20.2.2. Purchase Invoices for all prescription drugs (BPC 4081[a])
- ☐ 20.2.3. Purchase Invoices and sales records for non-prescription diabetic test devices dispensed pursuant to a prescription (BPC 4081[d])
- ☐ 20.2.4. Biennial controlled substances inventory (21 CFR 1304.11[c], CCR 1718)
- ☐ 20.2.5. U.S. Official Order Forms (DEA Form 222) (21 CFR 1305.13)
- ☐ 20.2.6. Power of Attorney for completion of DEA 222 forms (21 CFR 1305.05~~7~~)
- ☐ 20.2.7. Theft and Loss Reports (DEA Form 106) (21 CFR 1301.74[c])
- ☐ 20.2.8. Record documenting return of drugs to wholesaler or manufacturer (BPC 4081[a])
- ☐ 20.2.9. Record documenting transfers or sales to other pharmacies, licensees, prescribers, and reverse distributors (BPC 4081, 4105, CCR 1718)
- ☐ 20.2.10. Records of receipt and shipment (BPC 4081)

☐☐☐ 20.3. A pharmacist may sell hypodermic needles and syringes to a person without a prescription is limited to: (BPC 4145.5)

- ☐ 20.3.1. Persons known to the pharmacist and when the pharmacist has previously been provided with a prescription or other proof of legitimate medical need; (BPC 4145.5[a])
- ☐ 20.3.2. Use on animals, provided the person is known to the pharmacist or the person's identity can be properly established. (BPC 4145.5[c])
- ☐ 20.3.3. For industrial use, as determined by the board. (BPC 4144.5)
- ☐ 20.3.4. 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[b])

Yes No N/A

☐☐☐ 20.4. 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])

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

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

☐ 20.4.3. Furnish or make available sharps containers.

☐☐☐ 20.5. 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[e])

Date Waiver Approved _____ Waiver Number _____

Address of offsite storage location: _____

☐☐☐ 20.6. 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:

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

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

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

☐ 20.7.1. 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])

☐ 20.7.2. 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; and. (BPC 4119.3[a], 4119.4[b])

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

CORRECTIVE ACTION OR ACTION PLAN: _____

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21. DEA Controlled Substances Inventory

Inventory:

Yes No N/A

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

☐☐☐ 21.2. Schedule II inventory is separate from Schedule III, IV and V. See also Section 22. (21 CFR 1304.04[h][1])

☐☐☐ 21.3. All completed inventories are ~~is~~ available for inspection for three years. (CCR 1718)

☐☐☐ 21.4. 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])

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

☐☐☐ 21.6. 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][4])

☐☐☐ 21.7. 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)

☐☐☐ 21.8. 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 Form 222. (21 CFR 1305.03, 1305.12, 1305.13, 1305.21, 1305.22[g])

☐☐☐ 21.9. When a pharmacy distributes Schedule II controlled substances to a DEA registrant (pharmacies, wholesales, manufacturers, prescribers) a DEA Form 222 is prepared by the purchasing registrant and provided to the pharmacy selling the schedule II controlled substances. (21 CFR 1305.12)

Yes No N/A

☐☐☐ 21.10. When the pharmacy distributes Schedule II controlled substances to other DEA registrants, such as those listed above, a copy of the DEA Form 222, is properly completed by the pharmacy selling the controlled substances and that copy is submitted at the end of each month to the DEA regional office. (21 CFR 1305.13)

☐☐☐ 21.11. 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[a][1][iv]], Drug Supply Chain Security Act, BPC 4160)

☐☐☐ 21.12. 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 Department of Justice within 144 hours of the failure to provide prescription. (HSC 11167[c], [d])

☐☐☐ 21.13. 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.

☐☐☐ 21.14. ~~Any c~~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 the discovery of any loss of controlled substances in one of the following categories that causes the aggregate amount of unreported losses discovered in that category, on or after the same day of the previous year, to equal or exceed: ~~for the following:~~
(21 CFR 1301.74[c], CCR 1715.6)

21.14.1 Tablets, capsules, or other oral medication, 99 dosage units

21.14.2. Single-dose injectable medications, lozenges, film, such as oral, buccal and sublingual, suppositories, or patches, 10 dosage units.

21.14.3 Injectable multi-dose medications, medications administered by continuous infusion, or any other multi-dose unit not described, two or more multi-dose vials, infusion bags or other containers.

☐☐☐ 21.15. Do pharmacy staff hand initial prescription records or prescription labels, or (CCR 1712, 1717[b][1])

☐☐☐ 21.16. 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])

☐☐☐ 21.17. All Schedule II through IV controlled substance dispensing data is successfully transmitted to CURES within one working day from the date the controlled substance is released to be patient. (HSC 11165[d])

☐☐☐ 21.18. 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, BPC 4059)

☐☐☐ 21.19. The pharmacy has designed and operates a system to identify suspicious orders and ensures the system complies with applicable Federal and State privacy laws. Upon

discovering a suspicious order or series of orders, notify the DEA and the Special Agent in charge of DEA in their area. (21 USC 832[a]).

CORRECTIVE ACTION OR ACTION PLAN: _____

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22. Inventory Reconciliation Report of Controlled Substances

Yes No N/A

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

☐☐☐ 22.2. 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])

☐☐☐ 22.3. 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])

- ☐ 22.3.1. 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])
- ☐ 22.3.2. A review of all acquisitions and dispositions of federal Schedule II controlled substances since the last inventory reconciliation report; (CCR 1715.65[c][2])
- ☐ 22.3.3. A comparison of the two above-mentioned items to determine if there are any variances; (CCR 1715.65[c][3])
- ☐ 22.3.4. 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])
- ☐ 22.3.5. Possible causes of overages shall be identified in writing and incorporated into the inventory reconciliation report. (CCR 1715.65[c][5])
- ☐ 22.3.6 In addition to Schedule II controlled substance, the pharmacy is performing an inventory reconciliation of alprazolam 1mg, alprazolam 2mg, tramadol 50mg, and promethazine with codeine 6.25mg/10mg/5ml at least every 12 months. (CCR 1715.65[a][2])
- ☐ 22.3.7 An inventory reconciliation report must be prepared for any identified controlled substances lost no later than three months after discovery of the reportable loss. (CCR 1715.65)

☐ 22.3.8 Inventory activities for all other controlled substances must be performed at least once every two years from the performance of the last inventory activities. (CCR 1715.65[a][3][B])

☐ 22.3.9 The inventory reconciliation report may use a digital or electronic signature or biometric identifier in lieu of a physical signature if, in addition, the individual physically signs a printed statement confirming the accuracy of the inventory or report. The signature shall be dated, and the signed and dated statement shall be retained on file. (CCR 1715.65[e][1])

☐☐☐ 22.4. 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])

☐☐☐ 22.5. 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

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

CORRECTIVE ACTION OR ACTION PLAN: _____

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

Yes No N/A

☐☐☐ 23.1. 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)

☐☐☐ 23.2. 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)

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

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

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

☐ 23.2.4. 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)

☐☐☐ 23.3. 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])

☐☐☐ 23.4. 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)

☐☐☐ 23.5 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)

☐☐☐ 23.6. 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)

☐☐☐ 23.7. 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)

☐☐☐ 23.8. 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[h])

☐☐☐ 23.9. 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])

☐☐☐ 23.10. 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])

☐☐☐ 23.11. 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])

☐☐☐ 23.12. 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[d])

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

☐☐☐ 23.14. Controlled substance prescriptions with the 11159.3 exemption during a declared local, state, or federal emergency, noticed by the board, may be dispensed if the following are met: (HSC 11159.3)

- ☐ The prescription contains the information specified in HSC 11164(a), indicates that the patient is affected by a declared emergency with the words "11159.3 exemption" or a similar statement, and is written and dispensed within the first two weeks of notice issued by the board.
- ☐ When the pharmacist fills the prescription, the pharmacist exercises appropriate professional judgment, including reviewing the patient's activity report from the CURES PDMP before dispensing the medication.
- ☐ If the prescription is a Schedule II controlled substance, the pharmacist dispenses no greater than the amount needed for a seven-day supply.
- ☐ The patient first demonstrates, to the satisfaction of the pharmacist, their inability to access medications, which may include, but not limited to, verification of residency within an evacuation area.

CORRECTIVE ACTION OR ACTION PLAN: _____

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24. Automated Drug Delivery Systems

Yes No N/A

☐☐☐ 24.1. 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 biennial self-assessment for automated drug delivery systems.

Note: An ADDS license is not required for technology installed within the secured licensed premises area of a pharmacy, used in the selecting, counting, packaging, and labeling of dangerous drugs and devices. (BPC 4427.2[j]) or exempt AUDS operated by a licensed hospital pharmacy. (BPC 4427.2(i) As a reminder, a self-assessment form is required for an exempt AUDS.

CORRECTIVE ACTION OR ACTION PLAN: _____

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25. Repackaging by the Pharmacy

Yes No N/A

☐☐☐ 25.1. 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)

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

☐☐☐ 25.3. 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.

☐☐☐ 25.4. 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: _____

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26. Refill Pharmacy

Yes No N/A

☐☐☐ 26.1. Pharmacy processes refills for another California licensed pharmacy (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 the three 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. Standards of Service for Providers of Blood Clotting Products for Home Use (HSC 125286.10)

Yes No N/A

☐☐☐ 27.1. The pharmacy is a provider of blood clotting products for home use in compliance with HC 125286.20 and 125286.25. (HSC 125286.20, 125286.25)

~~☐ 27.1.1. Health system pharmacy. (HSC 125286.20[j][1][B])~~

~~☐ 27.1.2. Pharmacy affiliated with hemophilia treatment centers. (HSC 125286.20[j][1][C])~~

~~☐ 27.1.3. Specialty home care pharmacy. (HSC 125286.20[j][1][D])~~

~~☐ 27.1.4. Retail pharmacy. (HSC 125286.20[j][1][E])~~

~~☐☐☐ 27.2. The pharmacy meets the following requirements:~~

~~☐ 27.2.1. Has sufficient knowledge and understanding of bleeding disorders to accurately follow the instructions of the prescribing physician and ensure high-quality service for the patient. (HSC 125286.25[a])~~

~~☐ 27.2.2. Has access to a provider with sufficient clinical experience that enables the provider to know when patients have an appropriate supply of clotting factor on hand and about proper storage and refrigeration of clotting factors. (HSC 125286.25[b])~~

~~☐ 27.2.3. Maintains 24-hour on-call service 7 days a week, screens telephone calls for emergencies, acknowledges all telephone calls within one hour or less, and has access to knowledgeable pharmacy staffing on call 24 hours a day. (HSC 125286.25[c])~~

~~☐ 27.2.4. Has the ability to obtain all brands of blood clotting products approved by the FDA in multiple assay ranges and vial sizes, including products manufactured from human plasma and those manufactured with recombinant biotechnology techniques, provided manufacturer supply exists and payer authorization is obtained. (HSC 125286.25[d])~~

~~☐ 27.2.5. Supplies all necessary ancillary infusion equipment and supplies with each prescription, as needed. (HSC 125286.25[e])~~

☐ ~~27.2.6. Stores and ships, or otherwise delivers, all blood clotting products in conformity with all state and federally mandated standards, including those set forth in the product's approved package insert. (HSC 125286.25[f])~~

☐ ~~27.2.7. Upon authorization for a nonemergency prescription, ships the prescribed blood clotting products and ancillary infusion equipment and supplies to the patient within two business days or less. (HSC 125286.25[g])~~

☐ ~~27.2.8. Upon approved authorization to dispense a prescription for an emergency situation, provided manufacturer supply exists, delivers prescribed blood products, ancillary infusion equipment and supplies, and medications to the patient within 12 hours for patients living within 100 miles of a major metropolitan airport, and within one day for patients living more than 100 miles from a major metropolitan airport. (HSC 125286.25[h])~~

☐ ~~27.2.9. Provides patients who have ordered their products with a designated contact telephone number for reporting problems with a delivery, and responds to calls within a reasonable time period. (HSC 125286.25[i])~~

☐ ~~27.2.10. Notifies patients of Class 1 and Class 2 recalls and withdrawals of blood clotting products and ancillary infusion equipment within 24 hours of receiving such notice, and participates in the National Patient Notification System for blood clotting recalls. (HSC 125286.25[j])~~

☐ ~~27.2.11. Provides language interpretive services over the telephone or in person, as needed by the patient. (HSC 125286.25[k])~~

☐ ~~27.2.12. Has a detailed plan for meeting the requirements of the Standards of Service for Providers of Blood Clotting Products for Home Use Act in the event of a natural or manmade disaster or other disruption of normal business operations. (HSC 125286.25[*l*])~~

28. Policies and Procedures

Yes No N/A

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

☐ 28.1.1. 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 their ability to practice the profession or occupation authorized by their license, including the reporting to the board within 14 days of receipt or development; (BPC 4104[a],[c])

☐ 28.1.2. 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])

☐ 28.1.3. 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[a], CCR 1707.2[b][2])

☐ 28.1.4. Operation of the pharmacy during the temporary absence of the pharmacist for breaks and meal periods including authorized duties of personnel, the

pharmacist's responsibilities for checking all work performed by ancillary staff, and the pharmacist's responsibility for maintaining the security of the pharmacy; (CCR 1714.1[f])

☐ 28.1.5. 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])

☐ 28.1.6. 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])

☐ 28.1.7. Compliance with Title VII of Public Law 109-177 – Combat Methamphetamine Epidemic Act of 2005;

☐ 28.1.8. A policy to establish how a patient will receive a medication when a pharmacist has a conscientious objection; (BPC 733[b][3])

☐ 28.1.9. 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; (BPC 733[b][1])

☐ 28.1.10. 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; and (CCR 1707.5[d])

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

Yes No N/A

☐☐☐ 28.2. Does your pharmacy employ the use of a common electronic file? (CCR 1717.1)

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

☐☐☐ 28.3. Does your pharmacy furnish emergency contraceptives pursuant to BPC 4052.3[b][1]? (BPC 4052, CCR 1746)

If yes, does the pharmacy:

☐ 28.3.1. 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[b])

☐ 28.3.2. Provide the patient with a copy of the current EC Fact Sheet approved by the Board of Pharmacy? (CCR 1746[b][4])

☐ 28.3.3. 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[b][8])

☐ 28.3.4. Prior to furnishing EC, the pharmacist has completed a minimum of one hour of continuing education specific to emergency contraception. (BPC 4052.3[b][2], CCR 1746[b][10])

☐ 28.3.5. 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? (BPC 773[b], CCR 1746[b][5])

☐ 28.3.6. 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])

☐ 28.3.7. If a pharmacist declines to dispense a prescription drug or device pursuant to an order or prescription, the pharmacist has previously notified their employer in writing? (BPC 733[b][3], 4052.3)

Yes No N/A

☐☐☐ 28.4. Furnishes ~~naloxone hydrochloride~~ federal FDA-approved opioid antagonists 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)

☐ 28.4.1. 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.

☐ 28.4.2. 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.

☐☐☐ 28.5. 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)

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

☐☐☐ 28.7. 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])

☐ 28.7.1. 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) completion of the CDC Yellow Fever Vaccine Course; and current basic life support certification. (CCR 1746.5[c])

☐ 28.7.2. Pharmacists 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])

☐ 28.7.3. 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])

☐ 28.7.4. 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 enters 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 their primary care provider, the pharmacist provides the patient with a written record of the drugs or devices furnished and advises the patient to consult a physician of the patient's choice. (CCR 1746.5[f])

☐ 28.7.5. 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's 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: _____

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29. Compounding

Yes No N/A

☐☐☐ 29.1. Prior to allowing any drug product to be compounded in a pharmacy, the pharmacist-in-charge must complete the "Compounding Self-Assessment" required by CCR 1735.2[k].

30. Nuclear Pharmacy

Yes No N/A

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

☐☐☐ 30.2. 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)

☐☐☐ 30.3. The pharmacy possesses a current Sterile Compounding Permit (BPC 4127) and is compliant with CCR 1751. (Must also complete Compounding Self-Assessment, required by CCR 1735.2[k].

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

31. Telepharmacy Systems and Remote Dispensing Site Pharmacies

Yes No N/A

☐☐☐ 31.1. Pharmacy provides telepharmacy services and has obtained a remote dispensing site pharmacy license from the board. (BPC 4130[e], 4044.6, 4044.3[a])

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

Name: _____ License No.: _____

List the names of all qualified remote dispensing site pharmacy technician:

TCH Name: _____ License No. _____

TCH Name: _____ License No. _____

TCH Name: _____ License No. _____

TCH Name: _____ License No. _____

TCH Name: _____ License No. _____

If the answer to the question above is “no” or “not applicable” go to section 32.

Yes No N/A

☐☐☐ 31.2. 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])

☐☐☐ 31.3. Both the supervising and remote dispensing site pharmacies operate in accordance with BPC 4130, 4131, 4132, 4133, 4134, 4135, 4044, 4044.3, 4044.6, 4044.7, 4059.5.

☐☐☐ 31.4. The remote dispensing site pharmacy will cease to be a remote dispensing site pharmacy and may 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])

~~31.2. 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 4130[a], BPC 4044.7)~~

~~☐☐☐ 31.3. The remote dispensing site pharmacy is located in a medically underserved area unless otherwise approved by the board. (BPC 4130[c])~~

~~☐☐☐ 31.4. The remote dispensing site pharmacy does not employ any unlicensed personnel. (BPC 4130[d])~~

~~☐☐☐ 31.5. The supervising pharmacy has only obtained one remote dispensing site pharmacy license. (BPC 4130[e])~~

☐☐☐ 31.6. 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])

☐☐☐ 31.7. The remote dispensing site pharmacy will cease to be a remote dispensing site pharmacy and may 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])

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

☐☐☐ 31.9. 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])

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

☐☐☐ 31.11. The remote dispensing site pharmacy is staffed by a pharmacist, or at least one registered pharmacy technician meeting the qualifications of BPC section 4132 (BPC 4130[d]).

☐☐☐ 31.12. 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])

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

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

☐☐☐ 31.15. 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 4130[f])

☐☐☐ 31.16. In addition to the requirements of BPC 4202, a pharmacy technician working at the remote dispensing site pharmacy has met the requirements required by BPC 4132. (BPC 4132[a])

- ☐ Possess a pharmacy technician license that is in good standing.
- ☐ Possess and maintain a certification issued by the board-approved pharmacy technician certification program.

PIC Initials

- ☐ Possess one of the following: a minimum of an associated degree in pharmacy technology, a minimum of a bachelor's degree in any subject, or a certification of completion from a course of training specified by regulations adopted by the board pursuant to BPC 4202.
- ☐ Complete a minimum of 2,000 hours of experience working as a pharmacy technician within the two years preceding first commencing work in the remote dispensing site pharmacy.

☐☐☐ 31.17. 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])

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

- ☐ 31.18.1. Receive a new prescription order orally from a prescriber or other person authorized to prescribe by law. (BPC 4132[c][1])
- ☐ 31.18.2. Consult with a patient or their 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])
- ☐ 31.18.3. Identify, evaluate, or interpret a prescription. (BPC 4132[c][3])
- ☐ 31.18.4. Interpret the clinical data in a patient medication record system or patient chart. (BPC 4132[c][4])
- ☐ 31.18.5. Consult with any prescriber, nurse, or other health care professional or authorized agent thereof. (BPC 4132[c][5])
- ☐ 31.18.6. Supervise the packaging of drugs and check the packaging procedures and product upon completion. (BPC 4132[c][6])
- ☐ 31.18.7. Perform any function that requires the professional judgment of a licensed pharmacist. (BPC 4132[c][7])
- ☐ 31.18.8. Compound drug preparations. (BPC 4132[c][8])

Yes No N/A

☐☐☐ 31.19. 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])

☐☐☐ 31.20. 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])

☐☐☐ 31.21. 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])

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

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

- ☐ 31.23.1. 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])
- ☐ 31.23.2. 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])
- ☐ 31.23.3. Require the pharmacy technician to use barcode technology to verify the accuracy of the drug to be dispensed. (BPC 4133[d][3])
- ☐ 31.23.4. 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])
- ☐ 31.23.5. 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

☐☐☐ 31.24. 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])

☐☐☐ 31.25. 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])

☐☐☐ 31.26. 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])

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

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

☐☐☐ 31.29. 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])

☐☐☐ 31.30. 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])

☐☐☐ 31.31. 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. (BPC 4134[f]) This compilation shall include the following:

- ☐ 31.31.1. 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])
- ☐ 31.31.2. A review of all acquisitions and dispositions of federal Schedule II controlled substances since the last inventory reconciliation report. (BPC 4134[f][2])
- ☐ 31.31.3. A comparison of the two above-mentioned items to determine if there are any variances. (BPC 4134[f][3])
- ☐ 31.31.4. 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. (BPC 4134[f][4])

☐☐☐ 31.32. The remote dispensing site pharmacy reports in writing, any identified losses of controlled substances and possible causes of losses to the board within 31 days of discovery unless the cause of the loss is theft, diversion, or self-use in which case the report is 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])

Yes No N/A

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

☐☐☐ 31.34. 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 is 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])

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

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

☐☐☐ 31.37. 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])

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

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

☐☐☐ ~~31.40. 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[g])~~

☐☐☐ ~~31.41. A controlled substance signed for by a pharmacy technician under BPC section 4059.5 is stored separately from existing inventory until the time the controlled substance is reviewed and countersigned by a pharmacist. (BPC 4059.5[g])~~

☐☐☐ ~~31.42. Any receipt and storage of a controlled substance by a pharmacy technician pursuant to BPC section 4059.5 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[g])~~

~~CORRECTIVE ACTION OR ACTION PLAN: _____~~

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32. Prescription Drug Take-Back Services

Yes No N/A

☐☐☐ 32.1. 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])

If the answer to the question above is “no” or “not applicable” go to section 33.

Yes No N/A

☐☐☐ 32.2. 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[f])

☐☐☐ 32.3. 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) are not collected as part of the pharmacy’s drug take-back service. (CCR 1776.1[f])

☐☐☐ 32.4. 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])

☐☐☐ 32.5. Quarantined, recalled or outdated prescription drugs from the pharmacy stock are not disposed of 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)

☐☐☐ 32.6. 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])

☐☐☐ 32.7. 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])

☐☐☐ 32.8. 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])

☐☐☐ 32.9. The preaddressed envelope and package contain 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])

☐☐☐ 32.10. 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: _____

Yes No N/A

☐☐☐ 32.11. 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][1])

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

Yes No N/A

☐☐☐ 32.12. 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, CCR 1776)

☐☐☐ 32.13. The pharmacy notified the board in writing within 30 days of establishing the collection program. (CCR 1776.1[i][1])

Date the board was notified: _____

☐☐☐ 32.14. 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])

☐☐☐ 32.15. 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: _____

☐☐☐ 32.16. 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.

☐☐☐ 32.17. 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])

☐☐☐ 32.18. 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[a])

☐☐☐ 32.19. 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])

☐☐☐ 32.20. 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])

☐☐☐ 32.21. 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

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

☐☐☐ 32.23. The inner liner used is made of material that is certified by the manufacturer to meet the ASTM D1709 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])

- ☐ 32.23.1 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. (CCR 1776.3[f][1], [2])
- ☐ 32.23.2. The liner is clearly marked to display the maximum contents (for example, in gallons). (CCR 1776.3[f][2]
- ☐ 32.23.3. 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])
- ☐ 32.23.4. The liner is removable as specified pursuant to CCR 1776.3.

☐☐☐ 32.24. 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[g])

☐☐☐ 32.25. 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 1776.3[h])

☐☐☐ 32.26. 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])

☐☐☐ 32.27. 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])

☐☐☐ 32.28. The pharmacy maintains records for collected unwanted drugs from consumers for three years, including the records for each liner identified in 1776(a). (CCR 1776.3[k], 1776.6[a])

☐☐☐ 32.29. 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 premises. (CCR 1776.3[l])

Yes No N/A

☐☐☐ 32.30. 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) are not to be deposited, and (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

☐☐☐ 32.31. 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])

☐☐☐ 32.32. If the pharmacy provides mail back envelopes or packages to skilled nursing facilities, the pharmacy requires 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])

☐☐☐ 32.33. 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:

_____

_____

_____

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

☐☐☐ 32.35. 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?

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

☐☐☐ 32.37. 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])

☐☐☐ 32.38. The collection receptacle is 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

☐☐☐ 32.39. 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])

☐☐☐ 32.40. 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])

☐☐☐ 32.41. 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])

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

☐☐☐ 32.43. 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])

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

☐☐☐ 32.45. 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])

☐☐☐ 32.46. Sealed inner liners placed in a container are 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])

☐☐☐ 32.47. Liners housed in a rigid container are 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

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

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

- ☐ 32.49.1. 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])
- ☐ 32.49.2. 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])
- ☐ 32.49.3. 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])
- ☐ 32.49.4. 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])

☐ 32.49.5. 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: _____

_____

~~**33. Pharmacies That Donate Drugs to a Voluntary County-Approved Drug Repository and Distribution Program**~~

~~Yes No N/A~~

~~☐☐☐ 33.1. The pharmacy donates medications to a county-approved drug repository and distribution program, and meets all requirements as specified in the laws.: (HSC 150202, 150202.5, 150204, BPC 4169.5)~~

~~☐ 33.1.1. The pharmacy is licensed by and is not on probation with the California State Board of Pharmacy, and (HSC 150202.5)~~

~~☐ 33.1.2. 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)~~

~~Yes No N/A~~

~~☐☐☐ 33.2. 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)~~

~~☐☐☐ 33.3. No controlled substances shall be donated. (HSC 150204[c][1])~~

~~☐☐☐ 33.4. Drugs that are donated are unused, unexpired and meet the following requirements: (HSC 150202.5, 150204[c])~~

~~☐ 33.4.1. Have not been adulterated, misbranded, or stored under conditions contrary to standards set by the USP or the product manufacturer. (HSC 150204[c][2])~~

~~☐ 33.4.2. Were received directly from a manufacturer or wholesaler. (HSC 150202.5[a])~~

~~☐ 33.4.3. 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. (HSC 150202.5[b], 150204[c][3])~~

☐ 33.4.4. Are in unopened, tamper-evident packaging or modified unit dose containers with lot numbers and expiration dates affixed. (HSC 105204[d])

☐ 33.4.5. 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])

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

Yes No N/A

☐☐☐ 34.1. The pharmacy conducts a county-approved drug repository and distribution program. (HSC 150201[b][1], 150204)

☐ 34.1.1. The pharmacy is licensed by and is not on probation with the California State Board of Pharmacy, **and:** (HSC 150201[b][1])

☐ 34.1.1.1. Is county owned (HSC 150201[b][1]) or

☐ 34.1.1.2. Contracts with the county to establish a voluntary drug repository and distribution program. (HSC 150201[b][1], 150200, 150204[b][1])

☐ 34.1.2. 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[b][2])

☐☐☐ 34.2. 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: _____

Yes No N/A

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

☐☐☐ 34.4. 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: _____

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

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

Yes No N/A

☐☐☐ 34.6. 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])

☐☐☐ 34.7. 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])

☐☐☐ 34.8. 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])

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

- ☐ 34.9.1. Are received from authorized sources. (HSC 150202, 150203)
- ☐ 34.9.2. No controlled substances are received. (HSC 150204[c][1])
- ☐ 34.9.3. Are not adulterated, misbranded, or stored under conditions contrary to USP standards or the product manufacturer. (HSC 150204[c][2])
- ☐ 34.9.4. 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])
- ☐ 34.9.5. Are received in unopened, tamper-evident packaging or modified unit dose containers with lot numbers and expiration dates affixed. (HSC 150204[d])
- ☐ 34.9.6. Are maintained in the donated packaging until dispensed to an eligible patient under the program, who presents a valid prescription. (HSC 150204[i])
- ☐ 34.9.7. For donated medication 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])

☐☐☐ 34.10. Donated medication received in open containers is not dispensed under the program or transferred to another participating entity; and once identified, is quarantined immediately and disposed of in accordance with the Medical Waste Management Act. (HSC 150204[d][1], 150204[h])

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~~

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

☐☐☐ 34.12. 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 medication are transferred:

_____
_____

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

☐☐☐ 34.14. When transferring donated medication, 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])

PIC Initials _____

☐☐☐ 34.15. 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

Yes No N/A

☐☐☐ 34.16. Donated medications that are dispensed to an eligible patient who presents a valid prescription are dispensed in a new and properly labeled container, specific to the eligible patient. (HSC 150204[i])

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

PHARMACIST-IN-CHARGE CERTIFICATION:

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

Signature _____ _____ Date
(Pharmacist-in-Charge)

ACKNOWLEDGEMENT BY PHARMACY OWNER OR HOSPITAL ADMINISTRATOR:

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

Signature _____ _____ Date
Pharmacy Owner or Hospital Administrator

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

Attachment 1B

HOSPITAL PHARMACY SELF-ASSESSMENT 17M-14 (Rev. 1/23)

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

WHOLESALER/THIRD-PARTY LOGISTICS PROVIDER SELF-ASSESSMENT

All legal references used throughout this self-assessment form are explained on page 21.

All references to "drugs" throughout this self-assessment form refer to dangerous drugs and dangerous devices as defined in Business & Professions Code (BPC) section 4022. (http://www.pharmacy.ca.gov/laws_regs/lawbook.pdf).

For purposes of completing this assessment, the following abbreviations refer to specified licensing categories:

- WLS = Wholesaler
- 3PL = Third-Party Logistics Provider
- DRIC = Designated Representative-in-Charge
- RM = Responsible Manager
- DR = Designated Representative, Designated Representative-3PL, and Designated Representative Reverse Distributor

Licensed Premises Name: _____

Address: _____

Phone: _____

Licensed Premises Email address: _____

Ownership: Please mark one

○ sole owner ○ partnership ○ corporation ○ LLC

○ non- licensed owner ○ Other (please specify) _____

License #_____ Expiration Date_____

Other License #_____ Expiration Date_____
(Use additional sheets if needed.)

DEA Registration #_____ Expiration Date_____

VAWD Accreditation # _____ Expiration Date_____

Date of most recent DEA Inventory _____

Hours: Weekdays _____Sat_____ Sun_____ 24 Hours ○

DRIC / RM _____

DR License # / RPH License #_____ Expiration Date_____

Website Address (optional): _____

Other Licensed Staff (DR, pharmacist (RPH)):

1. _____ DR#/RPH#_____ Exp. Date _____

2. _____ DR#/RPH#_____ Exp. Date _____

3. _____ DR#/RPH#_____ Exp. Date _____

4. _____ DR#/RPH#_____ Exp. Date _____

5. _____ DR#/RPH#_____ Exp. Date _____

6. _____ DR#/RPH#_____ Exp. Date _____

7. _____ DR#/RPH#_____ Exp. Date _____

8. _____ DR#/RPH#_____ Exp. Date _____

9. _____ DR#/RPH#_____ Exp. Date _____

10._____ DR#/RPH#_____ Exp. Date _____

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

1. Ownership/Location

Yes No N/A

☐ ☐ ☐ 1.1. Review the current WLS/3PL license for this business. Are the listed owners correct and is the listed address correct? If not, please indicate discrepancy. If either is incorrect, notify the board in writing immediately. (BPC 4160[a], [c], [f]) **Attach a copy of the notification letter to the board to this document.**

☐ ☐ ☐ 1.2. Have you established and do you maintain a list of officers, directors, managers and other persons in charge of drug distribution, handling and storage? The list must contain a summary of the duties and qualifications for each job listed. (CCR 1780[f][3], BPC 4082) **Please attach a copy of the list to this document.** (This list should be dated.)

Note: Upon request, the owner must provide the board with the names of the owners, managers and employees and a brief statement of the capacity in which they are employed. (BPC 4082)

☐ ☐ ☐ 1.3. Has there been a transfer of the management or control over the WLS/3PL to a person or entity who did not have management or control over the license at the time the original license was issued? Written notification to the board is required of within 30 days of the transfer (CCR 1709[b]) **Please attach a copy of the notification letter to the board to this document.**

☐ ☐ ☐ 1.4. Is there any beneficial interest of the WLS/3PL held in a trust? (CCR 1709[d]) **Please attach a copy of the trust document and any related amendments to this document.**

CORRECTIVE ACTION OR ACTION PLAN _____

_____

2. Facility

2.1. Premises, fixtures and equipment:

Yes No N/A

☐ ☐ ☐ 2.1.1. Are clean and orderly
☐ ☐ ☐ 2.1.2. Are well ventilated
☐ ☐ ☐ 2.1.3. Are free from rodents and insects
☐ ☐ ☐ 2.1.4. Are adequately lit
☐ ☐ ☐ 2.1.5. Have plumbing in good repair

Yes No N/A

☐ ☐ ☐ 2.1.6. Have temperature & humidity monitoring to assure compliance with USP Standards. (The standards for various drugs may differ, see the standards set forth in the latest edition of the USP) (CCR 1780[b])

☐ ☐ ☐ 2.2. Is there a quarantine area for outdated, damaged, deteriorated, adulterated or misbranded drugs, drugs with the outer or secondary seal broken, partially used containers, or any drug returned under conditions that cast doubt on the drugs' safety, identity, strength, quality or purity? (CCR 1780[e])

☐ ☐ ☐ 2.3. Are dangerous drugs and dangerous devices stored in a secured and locked area? (BPC 4167, CCR 1780[a])

☐ ☐ ☐ 2.4. Is access to areas where dangerous drugs or dangerous devices are stored limited to authorized personnel? (BPC 4116, 4167, CCR 1780[c])

List personnel with keys to the area(s) where dangerous drugs or dangerous devices are stored (list by name or job title):

_____

_____

_____

☐ ☐ ☐ 2.5. Does this business operate only when a DR or pharmacist is on the premises? (CCR 1781)

2.6. The licensed premises is equipped with the following specific security features:

☐ ☐ ☐ 2.6.1. There is an alarm to detect after-hours entry. (CCR 1780[c][1]).

☐ ☐ ☐ 2.6.2. The outside perimeter of the building is well lit (CCR 1780[c][3]).

☐ ☐ ☐ 2.6.3. The security system provides protection against theft and diversion including tampering with computers and or electronic records. (CCR 1780[c][2]).

Explain how your security system complies with these requirements.

_____

_____

☐ ☐ ☐ 2.7. Is this business a "reverse distributor", that is, does the business act as an agent for pharmacies, drug wholesalers, third-party logistics provider, manufacturers, or others, by receiving, inventorying, and managing the disposition of outdated or nonsaleable dangerous drugs or dangerous devices? (BPC 4040.5)

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Yes No N/A

☐ ☐ ☐ 2.8. The facility has obtained approval from the board if acting as a reverse distributor which acquires dangerous drugs or dangerous devices from an unlicensed source that was previously licensed with the board for the sole purpose of destruction of the dangerous drugs or dangerous devices. (BPC 4163[~~(~~c]~~)~~)

Date of approval from the board: _____

☐ ☐ ☐ 2.9. The facility is subscribed to the board's email notifications. (BPC 4013)

Date Last Notification Received: _____

Email address registered with the board: _____

CORRECTIVE ACTION OR ACTION PLAN _____

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☐ ☐ ☐ 2.10. The facility receives the board's email notifications through the owner's electronic notice system. (BPC 4013[c])

Date Last Notification Received: _____

Email address registered with the board: _____

CORRECTIVE ACTION OR ACTION PLAN _____

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Note: There are specific requirements for wholesaling, storage, distribution, and disposal of controlled substances – these additional requirements are in Section 11 of this document.

3. Designated Representative-in-Charge/ Responsible Manager / Designated Representative-Reverse Distributor / Owner Responsibilities

Yes No N/A

☐ ☐ ☐ 3.1. The owner and the DRIC/RM are both equally responsible for maintenance of the records and inventory of the facility. (BPC 4081[b])

☐ ☐ ☐ 3.2. Is the DRIC/RM at least 18 years of age and responsible for the compliance with all state and federal laws for the distribution of drugs? The DRIC may be a pharmacist. (BPC 4160[d], 4053.1[b], 4053.2)

☐ ☐ ☐ 3.3. The owner must notify the board within 30 days of termination of the DRIC/RM. (BPC 4305.5[a])

☐ ☐ ☐ 3.4. The owner must identify and notify the board of a proposed new DRIC/RM within 30 days of the termination of the former DRIC/RM. (BPC 4160[f], 4160[g], 4331[c]) The appropriate form for this notification is available on the board's website.

☐ ☐ ☐ 3.5. The DRIC/RM who ends their employment at a licensed premises, must notify the board within 30 days. (BPC 4305.5[c], 4101[b][c]). This notification is in addition to that required of the owner.

☐ ☐ ☐ 3.6. The DRIC/RM has provided an electronic mail address to the board and shall maintain a current electronic mail address, if any, with the board and must notify the board within 30 days of any change of electronic mail address, giving both the old and new electronic mail address. (CCR 1704[b])

CORRECTIVE ACTION OR ACTION PLAN _____

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4. Ordering Drugs by this Business for Future Sale/Transfer or Trade

Yes No N/A

☐ ☐ ☐ 4.1. Are drugs ordered only from a business licensed by this board or from a licensed manufacturer? (BPC 4163[b], 4169)

☐ ☐ ☐ 4.2. If drugs are returned to your premises by a business that originally purchased the drugs from you, do you document the return with an acquisition record for your business and a disposition record for the business returning the drugs? (BPC 4081, 4332)

☐ ☐ ☐ ~~4~~.3. For license verification, the licensed premises may use the licensing information displayed on the board's Internet web site. (BPC 4106)

CORRECTIVE ACTION OR ACTION PLAN _____

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Note: There are specific requirements for wholesaling, storage, distribution, and disposal of controlled substances – these additional requirements are in Section 11 of this document.

5. Receipt of Drugs by this Business

Yes No N/A

☐ ☐ ☐ 5.1. When drugs are received by your business, are they delivered to the licensed premises, and received by and signed for only by a DR or a pharmacist? (BPC 4059.5[a])

☐ ☐ ☐ 5.2. When drugs are received by your business, are the outside containers visibly inspected to identify the drugs and prevent acceptance of contaminated drugs by detecting container damage? (CCR 1780[d][1])

CORRECTIVE ACTION OR ACTION PLAN _____

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Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 11 of this document.

6. Drug Stock

Yes No N/A

☐ ☐ ☐ 6.1. Is all drug stock open for inspection during regular business hours? (BPC 4080)

☐ ☐ ☐ 6.2. Are all drugs you order maintained in a secure manner at your licensed premises? You cannot order, obtain or purchase drugs that you are not able to store on your licensed premises. (BPC 4167)

☐ ☐ ☐ 6.3. Do all drugs you sell conform to the standards and tests for quality and strength provided in the latest edition of United States Pharmacopoeia or Sherman Food Drug and Cosmetic Act? (BPC 4342[a])

☐ ☐ ☐ 6.4. Do all drug containers you store on your premises have a manufacturer's expiration date? Any drug without an expiration date is considered expired and may not be distributed. (CCR 1718.1)

☐ ☐ ☐ 6.5. Are outdated, damaged, deteriorated or misbranded drugs held in a quarantine area physically separated from other drugs until returned to the supplier or sent for destruction? (CCR 1780[e][1])

☐ ☐ ☐ 6.6. Are drugs with the outer or secondary seal broken, or partially used or returned drugs held in a quarantine area and physically separated from other drugs until returned to the supplier or sent for destruction? (CCR 1780[e][2])

☐ ☐ ☐ 6.7. When the conditions under which drugs were returned to your premises cast doubt on the drugs' safety, identity, strength, quality or purity, are the drugs quarantined and either returned to your supplier or destroyed? If testing or investigation proves the drugs meet USP standards, the drugs may be returned to normal stock. (CCR 1780[e][3])

CORRECTIVE ACTION OR ACTION PLAN _____

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Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 11 of this document.

7. Sale or Transfer of Drugs by this Business

Yes No N/A

☐ ☐ ☐ 7.1. Are drugs sold only to businesses or persons licensed by this board, licensed by a prescriber board, licensed as a manufacturer, or to a licensed health care entity authorized to receive drugs?

7.2. Describe how you verify a business or person is appropriately licensed. (BPC 4059.5[a], [b],[d],[g], BPC 4169)

_____

_____

7.3. List any businesses or individuals that order drugs from you that are not licensed according to the list above:

_____

_____

Yes No N/A

☐ ☐ ☐ 7.4. Are drugs only furnished by your business to an authorized person? (BPC 4163[a]) Note: An authorized person can be a business or natural person.

7.5. Does your business only receive drugs from a pharmacy if:

☐ ☐ ☐ 7.5.1. the pharmacy originally purchased the drugs from you?

☐ ☐ ☐ 7.5.2. your business is a "reverse distributor"?

☐ ☐ ☐ 7.5.3. the drugs are needed to alleviate a shortage? (and only a quantity sufficient to alleviate a specific shortage). (BPC 4126.5[a])

Yes No N/A

☐ ☐ ☐ 7.6 Are all drugs that are purchased from another business or that are sold, traded or transferred by your business:

☐ ☐ ☐ 7.6.1. transacted with a business licensed with this board as a WLS/3PL or pharmacy?

☐ ☐ ☐ 7.6.2. free of adulteration as defined by the CA Health & Safety Code section 111250?

☐ ☐ ☐ 7.6.3. free of misbranding as defined by CA Health & Safety Code section 111335?

☐ ☐ ☐ 7.6.4. **confirmed** to not be beyond their use date (expired drugs)? (BPC 4169)

7.7. List any incidents where adulterated, misbranded or expired drugs were purchased, sold, traded or transferred by this business in the past 2 years.

_____

_____

7.8. If your business sells, transfers, or delivers dangerous drugs or devices outside of California, either to another state within the United States or a foreign country, do you:

Yes No N/A

☐ ☐ ☐ 7.8.1. comply with all CA pharmacy laws related to the distribution of drugs?

☐ ☐ ☐ 7.8.2. comply with the pharmacy law of the receiving state within the United States?

☐ ☐ ☐ 7.8.3. comply with the statues and regulations of the Federal Food and Drug Administration and the Drug Enforcement Administration relating to the wholesale distribution of drugs?

☐ ☐ ☐ 7.8.4. comply with all laws of the receiving foreign country related to the wholesale distribution of drugs?

☐ ☐ ☐ 7.8.5. comply with all applicable federal regulations regarding the exportation of dangerous drugs?

7.9. Describe how you determine a business in a foreign country is authorized to receive dangerous drugs or dangerous devices. (BPC 4059.5[e])

_____

_____

Yes No N/A

☐ ☐ ☐ 7.10. For products included in the Drug Supply Chain Security Act, transaction histories, transaction information, and transaction statements are provided to authorized trading partners when the products are sold, traded, or transferred. (21 USC 360eee-1[c])

☐ ☐ ☐ 7.11. If preferentially priced drugs are sold by your business, that sale complies with CA Pharmacy Law. (BPC 4380)

Yes No N/A

☐ ☐ ☐ 7.12. Does your business' advertisements for dangerous drugs or devices contain false, fraudulent, misleading or deceptive claims? (BPC 4341, BPC 651, CCR 1766)

☐ ☐ ☐ 7.13. Do you offer or receive any rebates, refunds, commissions or preferences, discounts or other considerations for referring patients or customers? If your business has any of these arrangements, please list with whom. (BPC 650)

_____

_____

☐ ☐ ☐ 7.14. Does your business sell dangerous drugs or devices to the master or first officer of an ocean vessel, after your business has received a written prescription? If so, describe how you comply with the ordering, delivery and record keeping requirements for drugs including controlled substances, and the requirement to notify the board of these sales. (BPC 4066, CFR 1301.25)

_____

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CORRECTIVE ACTION OR ACTION PLAN _____

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Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 11 of this document.

8. Donations of Medication to Voluntary Drug Repository and Distribution Programs (HSC 150200, 150203, 150204)

Yes No N/A

☐☐☐ 8.1. The wholesaler donates medications to a county-approved drug repository and distribution program, provided the following requirements are met: (HSC 150203, 150204)

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

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

- ☐ 8.3.1. Have not been adulterated, misbranded, or stored under conditions contrary to standards set by the USP or the product manufacturer. (HSC 150204[c][2])
- ☐ 8.3.2. Have never been in the possession of a patient or individual member of the public. (HSC 150204[c][3])
- ☐ 8.3.3. Are in unopened, tamper-evident packaging or modified unit dose containers with lot numbers and expiration dates affixed. (HSC 105204[d])

☐ 8.3.4. For donated medications that require refrigeration, are medications that are stored, packaged and transported at appropriate temperatures and in accordance with USP standards and pharmacy law. (HSC 150204[m])

9. Outgoing Shipments of Drugs

Yes No N/A

☐ ☐ ☐ 9.1. Before you ship drugs to a purchaser, do you inspect the shipment to assure the drugs were not damaged while stored by your business? (CCR 1780[d][2])

☐ ☐ ☐ 9.2. Does your business use a common carrier (a shipping or delivery company — UPS, US Mail, FedEx, DHL) for delivery of drug orders to your customers? (BPC 4166[a])

9.3. List the common carriers (shipping or delivery companies) you use.

_____

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CORRECTIVE ACTION OR ACTION PLAN _____

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Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 11 of this document.

10. Delivery of Drugs

Yes No N/A

☐ ☐ ☐ 10.1. Are all drugs ordered by a pharmacy or another wholesaler are delivered to the address of the buyer's licensed premises and signed for and received by a pharmacist or designated representative where allowed? (BPC 4059.5[a])

☐ ☐ ☐ 10.2. Are all drugs ordered by a manufacturer or prescriber delivered to the manufacturer~~'~~s or prescriber's licensed business address and signed for by a person duly authorized by the manufacturer or prescriber? (BPC 4059.5[d])

☐ ☐ ☐ 10.3. All drugs delivered to a hospital are delivered either to the pharmacy premises or to a central receiving area within the hospital. (BPC 4059.5[c])

☐ ☐ ☐ 10.4. If drugs are delivered to a pharmacy when the pharmacy is closed and a pharmacist is not on duty, documents are left with the delivery in the secure storage facility, indicating the name and amount of each dangerous drug delivered. (BPC 4059.5[f])

CORRECTIVE ACTION OR ACTION PLAN _____

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11. **Controlled Substances**

Yes No N/A

☐ ☐ ☐ 11.1. Are there effective controls to prevent theft or diversion of controlled substances? (CFR 1301.71)

☐ ☐ ☐ 11.2. Are DEA requirements for storage of Schedule II controlled substances being met? (specific requirements are listed in CFR 1301.72[a])

☐ ☐ ☐ 11.3. Are DEA requirements for storage of Schedule III, IV and V controlled substances being met? (Specific requirements are listed in CFR 1301.72[b])

☐ ☐ ☐ 11.4. Is a DEA inventory completed by your business every two years for all schedules (II - V) of controlled substances? (CFR 1304.11[a],[c],[e])

☐ ☐ ☐ 11.5. Is the biennial record of the DEA inventory required for Schedule II – V controlled substances conducted every 2 years, retained for 3 years? (CFR 1304.11, CCR 1718, 1780(f)[2])

☐ ☐ ☐ 11.6. Does the biennial inventory record document that the inventory was taken at the "close of business" or "opening of business." (CFR 1304.11)

☐ ☐ ☐ 11.7. Has the person within your business who signed the original DEA registration, or the last DEA registration renewal, created a power of attorney for each person allowed to order Schedule II controlled substances for this business? (CFR 1305.05)

11.7.1. List the individuals at this location authorized by power of attorney to order controlled substances.

_____

_____

Yes No N/A

☐ ☐ ☐ 11.8. Does your business follow employee-screening procedures required by DEA to assure the security of controlled substances? (CFR 1301.90)

☐ ☐ ☐ 11.9. If any employee of this business possesses, sells, uses or diverts controlled substances, in addition to the criminal liability you must evaluate the circumstances of the illegal activity and determine what action you should take against the employee. (CFR 1301.92)

☐ ☐ ☐ 11.10. Are all controlled substances purchased, sold or transferred by your business, done so for legitimate medical purposes? (HSC 11153.5[a],[b],[c])

Yes No N/A

☐ ☐ ☐ 11.11. If your business distributes controlled substances through an agent (i.e. detail person), do you have adequate security measures in place to prevent theft or diversion of those controlled substances. (CFR 1301.74[f])

☐ ☐ ☐ 11.12. If a person attempts to purchase controlled substances from your business and the person is unknown to you, you make a good faith effort to determine the person (individual or business) is appropriately licensed to purchase controlled substances. (CFR 1301.74 [a])

11.13. Explain how your business determines an unknown business or individual is appropriately licensed to purchase controlled substances

_____

_____

Yes No N/A

☐ ☐ ☐ 11.14. If your business uses a common carrier to deliver controlled substances, your business determines the common carrier has adequate security to prevent the theft or diversion of controlled substances. (CFR 1301.74[f])

☐ ☐ ☐ 11.15. If your business uses a common carrier to deliver controlled substances, are the shipping containers free of any outward indication that there are controlled substances within, to guard against storage or in-transit theft? (CFR 1301.74[e])

☐ ☐ ☐ 11.16. Are all Schedule II controlled substances ordered from your business using a fully completed DEA 222 order form? (CFR 1305.03, 1305.06)

☐ ☐ ☐ 11.17. When your business fills orders for Schedule II controlled substances, is the date filled and the number of containers filled recorded on copies 1 and 2 of DEA 222 from? Is copy 1 retained and copy 2 sent to DEA at the close of the month the controlled substance order was filled? (CFR 1305.13 [b])

☐ ☐ ☐ 11.18. If a Schedule II controlled substance order cannot be filled, does your business return copy 1 and 2 of the DEA 222 order form to the buyer with a letter indicating why the order could not be filled? (CFR 1305.15)

☐ ☐ ☐ 11.19. When your business partially fills Schedule II controlled substances, is the balance provided within 60 days of the date of the order form? After the final partial filling, is copy 1 retained in your files and copy 2 of the completed DEA 222 order form sent to DEA by the close of that month? (CFR 1305.13[b])

Yes No N/A

☐ ☐ ☐ 11.20. For all Schedule II controlled substances received by your business, is copy 3 of the DEA 222 order form completed by writing in for each item received, the date received, and the number of containers received? (CFR 1305.13[e])

☐ ☐ ☐ 11.21. Does your business use the online CSOS secure transmission system offered by the Drug Enforcement Administration in place of a paper DEA 222 Form for Schedule II controlled substances? (CFR 1305.21, 1305.22)

☐ ☐ ☐ 11.22. Does your business follow the procedure outlined by DEA to obtain Schedule II controlled substances when the original DEA 222 order form is lost or stolen? (CFR 1305.16(a))

☐ ☐ ☐ 11.23. Are all records of purchase and sale for all schedules of controlled substances for your business kept on your licensed business premises for 3 years from the making? (BPC 4081, CCR 1718, CFR 1304.03, 1305.17[c], 1305.17[a], [b], and HSC 11252, 11253)

☐ ☐ ☐ 11.24. Are records of Schedule II controlled substances stored separate from all others? (CFR 1304.04 [f][1])

☐ ☐ ☐ 11.25. Are records for Schedule III-V controlled substances stored so that they are easily retrievable? (CFR 1304.04 [f][2])

☐ ☐ ☐ 11.26. Before your business distributes carfentanil etorphine HCL and or diprenorphine, do you contact the DEA to determine the person (individual or business) is authorized to receive these drugs? (CFR 1301.74[g])

☐ ☐ ☐ 11.27. Do you separate records for the sale of carfentanil etorphine hydrochloride and or diprenorphine from all other records? (CFR 1305.17[d])

☐ ☐ ☐ 11.28. Does the owner of your business notify the DEA, on a DEA 106 form, of any theft or significant loss of controlled substances upon discovery of the theft? (CFR 1301.74[c])

☐ ☐ ☐ 11.29. Does the owner of your business notify the board of any loss of controlled substances within 30 days of discovering the loss? (CCR 1715.6)

☐ ☐ ☐ 11.30. Do you report suspicious orders to the Suspicious Orders Report System (SORS)? Suspicious Orders may include, but is not limited to: an order of a controlled substance of unusual size; an order of a controlled substance deviating substantially from a normal pattern, and; orders of controlled substances of unusual frequency. (21 USC 832[a][3], 21 USC 802[57], 21 CFR 1301.74[b])

CORRECTIVE ACTION OR ACTION PLAN _____

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12. Policies and Procedures

12.1. Does this business maintain and adhere to policies and procedures for the following: (CCR 1780[f])

Yes No N/A

☐ ☐ ☐ 12.1.1. Receipt of drugs

☐ ☐ ☐ 12.1.2. Security of drugs

☐ ☐ ☐ 12.1.3. Storage of drugs (including maintaining records to document proper storage)

☐ ☐ ☐ 12.1.4. Inventory of drug (including correcting inaccuracies in inventories)

☐ ☐ ☐ 12.1.5. Distributing drugs

☐ ☐ ☐ 12.1.6. Identifying, recording and reporting theft or losses

☐ ☐ ☐ 12.1.7. Correcting errors and inaccuracies in inventories

Physically quarantining and separating:

☐ ☐ ☐ 12.1.8. returned, damaged, outdated, deteriorated, misbranded or adulterated drugs

☐ ☐ ☐ 12.1.9. drugs that have been partially used

☐ ☐ ☐ 12.1.10. drugs where the outer or secondary seals on the container have been broken

☐ ☐ ☐ 12.1.11. drugs returned to your business, when there is doubt about the safety, identity, strength, quality, or purity of the drug

Yes No N/A

☐ ☐ ☐ 12.1.12. drugs where the conditions of return cast doubt on safety, identity, strength, quality or purity (CCR 1780[e],[f])

CORRECTIVE ACTION OR ACTION PLAN _____

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13. Training

Yes No N/A

☐ ☐ ☐ 13.1 Are training and experience provided to all employees to assure all personnel comply with all licensing requirements? (CCR 1780[f][4])

List the types of training you have provided to staff in the last calendar year and the dates of that training.

_____

_____

CORRECTIVE ACTION OR ACTION PLAN _____

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14. Dialysis Drugs

Yes No N/A

☐ ☐ ☐ 14.1. Does your business provide dialysis drugs directly to patients, pursuant to a prescription? (BPC 4054, 4059[c]) If so, please complete the next 4 questions, if not proceed to Section 15.

☐ ☐ ☐ 14.2. Do home dialysis patients complete a training program provided by a dialysis center licensed by Department of Health Services? Prescriber must provide proof of completion of this training to your business. (BPC 4059[d])

☐ ☐ ☐ 14.3. Do you have written or oral orders for authorized dialysis drugs for each dialysis patient being serviced. Are such orders received by either a designated representative or a pharmacist? Note: refill orders cannot be authorized for more than 6 months from the date of the original order. (CCR 1787[a],[b],[c])

☐ ☐ ☐ 14.4. Does your business provide an "expanded invoice" for dialysis drugs dispensed directly to the patient including name of drug, manufacturer, quantities, lot number, date of shipment, and name of the designated representative or pharmacist responsible for distribution? A copy of the invoice must be sent to the prescriber, the patient and a copy retained by this business. Upon receipt of drugs, the patient or patient agent must sign for the receipt for the drugs with any irregularities noted on the receipt. (CCR 1790)

Yes No N/A

☐ ☐ ☐ 14.5. Is each case or full shelf package of the dialysis drugs dispensed labeled with the patient's name and the shipment? Note that additional information as required is provided with each shipment. (CCR 1791)

CORRECTIVE ACTION OR ACTION PLAN _____

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15. Record Keeping Requirements

Yes No N/A

☐ ☐ ☐ 15.1. Does your business' sales record for drugs include date of sale, your business name and address, the business name and address of the buyer, and the names and quantities of the drugs sold? (BPC 4059[b])

☐ ☐ ☐ 15.2. Does your business maintain transaction histories, transaction information, and transaction statements for products included in the Drug Supply Chain Security Act? (21 USC 360eee-1[c])

☐ ☐ ☐ 15.3. Are purchase and sales records for all transactions retained on your licensed premises for 3 years from the date of making? (BPC 4081~~[a]~~, 4105[c], 4332)

☐ ☐ ☐ 15.4. Are all purchase and sales records retained in a readily retrievable form? (BPC 4105[a])

☐ ☐ ☐ 15.5. Is a current accurate inventory maintained for all dangerous drugs? (BPC 4081, 4332, CCR 1718)

☐ ☐ ☐ 15.6. If you temporarily remove purchase or sales records from your business, does your business retain on your licensed premises at all times, a photocopy of each record temporarily removed? (BPC 4105[b])

☐ ☐ ☐ 15.7. Are required records stored off-site only if a board issued written waiver has been granted?

15.8. If your business has a written waiver, write the date the waiver was approved and the off-site address where the records are stored below. (CCR 1707[a])

Date _____ Address_____

☐ ☐ ☐ 15.9. Is an off-site written waiver in place and is the storage area secure from unauthorized access? (CCR 1707[b][1])

Yes No N/A

☐ ☐ ☐ 15.10. If an off-site written waiver is in place, are the records stored off-site retrievable within 2 business days? (CCR 1707[b][2])

☐ ☐ ☐ 15.11. Can the records that are retained electronically be produced immediately in hard copy form by any designated representative, if the designated representative-in-charge is not present? (BPC 4105[d][2])

☐ ☐ ☐ 15.12. Are records of training provided to employees to assure compliance with licensing requirements, retained for 3 years? (CCR 1780[f][4])

☐ ☐ ☐ 15.13. Has this licensed premises, or the designated representative-in-charge/responsible manager, been cited, fined or disciplined by this board or any other state or federal agency within the last 3 years? If so, list each incident with a brief explanation (BPC 4162[a][5]):

_____

_____

☐ ☐ ☐ 15.14. Has the licensed premises received any orders of correction from this board? A copy of the order and the corrective action plan must be on the licensed premises for 3 years. (BPC 4083)

☐ ☐ ☐ 15.15. Has this licensed premises received a letter of admonishment from this board? A copy must be retained on the premises for 3 years from the date of issue. (BPC 4315[f])

☐ ☐ ☐ 15.16. If this licensed premises dispenses dialysis drugs directly to patients, are the prescription records retained for 3 years, including refill authorizations and expanded invoices for dialysis patients? (CCR 1787[c], 1790)

CORRECTIVE ACTION OR ACTION PLAN _____

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Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 11 of this document.

16. Reporting Requirements to the Board

Yes No N/A

☐ ☐ ☐ 16.1. A designated representative-in-charge/responsible manager who terminates employment at this business, must notify the board within 30 days of the termination (BPC 4101[b], 4305.5[c].

☐ ☐ ☐ 16.2. The owner must report to the board within 30 days the termination of the designated representative-in-charge or responsible manager. (BPC 4305.5[a])

☐ ☐ ☐ 16.3. The owner must report to the board within 30 days of discovery, any loss of controlled substances, including amounts and strengths of the missing drugs. (CCR 1715.6)

☐ ☐ ☐ 16.4. The owner must notify the DEA, on a DEA form 106, any theft or significant loss of controlled substances upon discovery. (CFR 1301.74[c])

Yes No N/A

☐ ☐ ☐ 16.5. Do your employees know about their obligation to report any known diversion or loss of controlled substances to a responsible person within your business? (CFR 1301.91)

☐ ☐ ☐ 16.6. The owner must notify the board within 30 days of any change in the beneficial ownership of this business. (BPC 4201[j], CCR 1709[b])

- ☐ 16.6.1. identify any transfer, in a single transaction or in a serious of transaction, of 10 percent or more of the beneficial interest in a business entity licensed by the board to a person or entity who did not hold a beneficial interest at the time of the original license was issued
- ☐ 16.6.2. identify any transfer of the management or control over a business entity licensed by the board to a person or entity who did not have management or control over the license at the time the original license was issued
- ☐ 16.6.3. identify any new ownership and their application to the board of licensure in advance of the proposed transaction taking place

Yes No N/A

☐ ☐ ☐ 16.7. When called upon by the board, your business can report all sales of dangerous drugs or controlled substances subject to abuse. (BPC 4164[a])

☐ ☐ ☐ 16.8. The wholesaler maintains a tracking system for individual sales of dangerous drugs at preferential or contract prices to pharmacies that primarily or solely dispense prescription drugs to patients of long-term care facilities. Your system must:

- ☐ 16.8.1. identify pharmacies that primarily or solely dispense prescription drugs to patients of long-term care facilities
- ☐ 16.8.2. identify purchases of any dangerous drugs at preferential or contract prices
- ☐ 16.8.3. identify current purchases that exceed prior purchases by 20 percent over the previous 12 calendar months. (BPC 4164[b])

☐ ☐ ☐ 16.9. I understand that this license is not transferable to a new owner. A change of ownership must be reported to this board, as soon as the parties have agreed to the sale. Before the ownership actually changes, an additional application for a temporary permit must be submitted to the board if the new owner wants to conduct business while the board is processing the change of ownership application and until the new permanent permit is issued. A company cannot transfer the ownership of the business via a contract with another individual or business, without the board's approval (BPC 4201[g])

☐ ☐ ☐ 16.10. The owner of this business must immediately notify the board in writing if any assignment is made for the benefit of creditors, if the business enters into any credit compromise arrangement, files a petition in bankruptcy, has a receiver

appointed, or enters into liquidation or any other arrangement that might result in the sale or transfer of drugs. (CCR 1705)

☐ ☐ ☐ 16.11. If this business requires a temporary closure, the owner must notify the board of any temporary closure of a facility as soon as any closure exceeds three consecutive calendar days. (CCR 1708.1)

☐ ☐ ☐ 16.12. If this business is discontinued, the owner must notify the board in writing before the actual discontinuation of business. (CCR 1708.2). If the business holds a DEA registration, the owner must notify the DEA promptly of the discontinuation of business and all unused DEA 222 order forms must be returned to the DEA. (CFR 1301.52[a], 1305.14)

☐ ☐ ☐ 16.13. Upon discovery, the business notifies the board in writing of any suspicious orders of controlled substances placed by a California-licensed pharmacy or wholesaler as required by BPC 4169.1.

CORRECTIVE ACTION OR ACTION PLAN _____

_____

17. Additional Licenses/Permits Required

17.1. List all licenses and permits required to conduct this business, including local business licenses, licenses held in other states, permits or licenses required by foreign countries or other entities (BPC 4059.5[e], 4107, CFR 1305.11[a]) Use additional sheets if necessary.

_____

_____

DESIGNATED REPRESENTATIVE-IN-CHARGE / RESPONSIBLE MANAGER CERTIFICATION:

I, (please print) _____, hereby certify that I have completed the self-assessment of this licensed premises of which I am the designated representative-in-charge (DRIC) / responsible manager (RM). Any deficiency identified herein will be corrected by _____(Date). I understand that all responses are subject to verification by the Board of Pharmacy. I further state under penalty of perjury that the information contained in this self-assessment form is true and correct.

Signature _____ Date _____
Designated Representative-in-Charge (DRIC) / Responsible Manager (RM)

ACKNOWLEDGEMENT BY OWNER, PARTNER OR CORPORATE OFFICER:

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

Signature _____ Date _____

Legal References

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

Business and Professions Code (BPC), Division 2, Chapter 1 – General Provisions

BPC, Division 2, Chapter 9 – Pharmacy

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

Code of Federal Regulations (CFR), Title 21, Chapter 2 – 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 6 – Drugs and Devices

HSC, Division 116 – Surplus Medication Collection and Distribution

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

Attachment 1C

WHOLESALER/THIRD-PARTY LOGISTICS PROVIDER SELF-ASSESSMENT

17M-26 (Rev. 1/23)

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

WHOLESALER/THIRD-PARTY LOGISTICS PROVIDER SELF-ASSESSMENT

All legal references used throughout this self-assessment form are explained on page 21.

All references to "drugs" throughout this self-assessment form refer to dangerous drugs and dangerous devices as defined in Business & Professions Code (BPC) section 4022. (http://www.pharmacy.ca.gov/laws_regs/lawbook.pdf).

For purposes of completing this assessment, the following abbreviations refer to specified licensing categories:

- WLS = Wholesaler
- 3PL = Third-Party Logistics Provider
- DRIC = Designated Representative-in-Charge
- RM = Responsible Manager
- DR = Designated Representative, Designated Representative-3PL, and Designated Representative Reverse Distributor

Licensed Premises Name: _____

Address: _____

Phone: _____

Licensed Premises Email address: _____

Ownership: Please mark one

○ sole owner ○ partnership ○ corporation ○ LLC

○ non- licensed owner ○ Other (please specify) _____

License #_____ Expiration Date_____

Other License #_____ Expiration Date_____
(Use additional sheets if needed.)

DEA Registration #_____ Expiration Date_____

VAWD Accreditation # _____ Expiration Date_____

Date of most recent DEA Inventory _____

Hours: Weekdays _____Sat_____ Sun_____ 24 Hours ○

DRIC / RM _____

DR License # / RPH License #_____ Expiration Date_____

Website Address (optional): _____

Other Licensed Staff (DR, pharmacist (RPH)):

1. _____ DR#/RPH#_____ Exp. Date _____

2. _____ DR#/RPH#_____ Exp. Date _____

3. _____ DR#/RPH#_____ Exp. Date _____

4. _____ DR#/RPH#_____ Exp. Date _____

5. _____ DR#/RPH#_____ Exp. Date _____

6. _____ DR#/RPH#_____ Exp. Date _____

7. _____ DR#/RPH#_____ Exp. Date _____

8. _____ DR#/RPH#_____ Exp. Date _____

9. _____ DR#/RPH#_____ Exp. Date _____

10._____ DR#/RPH#_____ Exp. Date _____

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

1. Ownership/Location

Yes No N/A

☐ ☐ ☐ 1.1. Review the current WLS/3PL license for this business. Are the listed owners correct and is the listed address correct? If not, please indicate discrepancy. If either is incorrect, notify the board in writing immediately. (BPC 4160[a], [c], [f]) **Attach a copy of the notification letter to the board to this document.**

☐ ☐ ☐ 1.2. Have you established and do you maintain a list of officers, directors, managers and other persons in charge of drug distribution, handling and storage? The list must contain a summary of the duties and qualifications for each job listed. (CCR 1780[f][3], BPC 4082) **Please attach a copy of the list to this document.** (This list should be dated.)

Note: Upon request, the owner must provide the board with the names of the owners, managers and employees and a brief statement of the capacity in which they are employed. (BPC 4082)

☐ ☐ ☐ 1.3. Has there been a transfer of the management or control over the WLS/3PL to a person or entity who did not have management or control over the license at the time the original license was issued? Written notification to the board is required of within 30 days of the transfer (CCR 1709[b]) **Please attach a copy of the notification letter to the board to this document.**

☐ ☐ ☐ 1.4. Is there any beneficial interest of the WLS/3PL held in a trust? (CCR 1709[d]) **Please attach a copy of the trust document and any related amendments to this document.**

CORRECTIVE ACTION OR ACTION PLAN _____

_____

2. Facility

2.1. Premises, fixtures and equipment:

Yes No N/A

☐ ☐ ☐ 2.1.1. Are clean and orderly
☐ ☐ ☐ 2.1.2. Are well ventilated
☐ ☐ ☐ 2.1.3. Are free from rodents and insects
☐ ☐ ☐ 2.1.4. Are adequately lit
☐ ☐ ☐ 2.1.5. Have plumbing in good repair

Yes No N/A

☐ ☐ ☐ 2.1.6. Have temperature & humidity monitoring to assure compliance with USP Standards. (The standards for various drugs may differ, see the standards set forth in the latest edition of the USP) (CCR 1780[b])

☐ ☐ ☐ 2.2. Is there a quarantine area for outdated, damaged, deteriorated, adulterated or misbranded drugs, drugs with the outer or secondary seal broken, partially used containers, or any drug returned under conditions that cast doubt on the drugs' safety, identity, strength, quality or purity? (CCR 1780[e])

☐ ☐ ☐ 2.3. Are dangerous drugs and dangerous devices stored in a secured and locked area? (BPC 4167, CCR 1780[a])

☐ ☐ ☐ 2.4. Is access to areas where dangerous drugs or dangerous devices are stored limited to authorized personnel? (BPC 4116, 4167, CCR 1780[c])

List personnel with keys to the area(s) where dangerous drugs or dangerous devices are stored (list by name or job title):

_____

_____

_____

☐ ☐ ☐ 2.5. Does this business operate only when a DR or pharmacist is on the premises? (CCR 1781)

2.6. The licensed premises is equipped with the following specific security features:

☐ ☐ ☐ 2.6.1. There is an alarm to detect after-hours entry. (CCR 1780[c][1]).

☐ ☐ ☐ 2.6.2. The outside perimeter of the building is well lit (CCR 1780[c][3]).

☐ ☐ ☐ 2.6.3. The security system provides protection against theft and diversion including tampering with computers and or electronic records. (CCR 1780[c][2]).

Explain how your security system complies with these requirements.

_____

_____

☐ ☐ ☐ 2.7. Is this business a "reverse distributor", that is, does the business act as an agent for pharmacies, drug wholesalers, third-party logistics provider, manufacturers, or others, by receiving, inventorying, and managing the disposition of outdated or nonsaleable dangerous drugs or dangerous devices? (BPC 4040.5)

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Yes No N/A

☐ ☐ ☐ 2.8. The facility has obtained approval from the board if acting as a reverse distributor which acquires dangerous drugs or dangerous devices from an unlicensed source that was previously licensed with the board for the sole purpose of destruction of the dangerous drugs or dangerous devices. (BPC 4163[~~(~~c]~~)~~)

Date of approval from the board: _____

☐ ☐ ☐ 2.9. The facility is subscribed to the board's email notifications. (BPC 4013)

Date Last Notification Received: _____

Email address registered with the board: _____

CORRECTIVE ACTION OR ACTION PLAN _____

_____

☐ ☐ ☐ 2.10. The facility receives the board's email notifications through the owner's electronic notice system. (BPC 4013[c])

Date Last Notification Received: _____

Email address registered with the board: _____

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Note: There are specific requirements for wholesaling, storage, distribution, and disposal of controlled substances – these additional requirements are in Section 11 of this document.

3. Designated Representative-in-Charge/ Responsible Manager / Designated Representative-Reverse Distributor / Owner Responsibilities

Yes No N/A

☐ ☐ ☐ 3.1. The owner and the DRIC/RM are both equally responsible for maintenance of the records and inventory of the facility. (BPC 4081[b])

☐ ☐ ☐ 3.2. Is the DRIC/RM at least 18 years of age and responsible for the compliance with all state and federal laws for the distribution of drugs? The DRIC may be a pharmacist. (BPC 4160[d], 4053.1[b], 4053.2)

☐ ☐ ☐ 3.3. The owner must notify the board within 30 days of termination of the DRIC/RM. (BPC 4305.5[a])

☐ ☐ ☐ 3.4. The owner must identify and notify the board of a proposed new DRIC/RM within 30 days of the termination of the former DRIC/RM. (BPC 4160[f], 4160[g], 4331[c]) The appropriate form for this notification is available on the board's website.

☐ ☐ ☐ 3.5. The DRIC/RM who ends their employment at a licensed premises, must notify the board within 30 days. (BPC 4305.5[c], 4101[b][c]). This notification is in addition to that required of the owner.

☐ ☐ ☐ 3.6. The DRIC/RM has provided an electronic mail address to the board and shall maintain a current electronic mail address, if any, with the board and must notify the board within 30 days of any change of electronic mail address, giving both the old and new electronic mail address. (CCR 1704[b])

CORRECTIVE ACTION OR ACTION PLAN _____

_____

4. Ordering Drugs by this Business for Future Sale/Transfer or Trade

Yes No N/A

☐ ☐ ☐ 4.1. Are drugs ordered only from a business licensed by this board or from a licensed manufacturer? (BPC 4163[b], 4169)

☐ ☐ ☐ 4.2. If drugs are returned to your premises by a business that originally purchased the drugs from you, do you document the return with an acquisition record for your business and a disposition record for the business returning the drugs? (BPC 4081, 4332)

☐ ☐ ☐ ~~4~~.3. For license verification, the licensed premises may use the licensing information displayed on the board's Internet web site. (BPC 4106)

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Note: There are specific requirements for wholesaling, storage, distribution, and disposal of controlled substances – these additional requirements are in Section 11 of this document.

5. Receipt of Drugs by this Business

Yes No N/A

☐ ☐ ☐ 5.1. When drugs are received by your business, are they delivered to the licensed premises, and received by and signed for only by a DR or a pharmacist? (BPC 4059.5[a])

☐ ☐ ☐ 5.2. When drugs are received by your business, are the outside containers visibly inspected to identify the drugs and prevent acceptance of contaminated drugs by detecting container damage? (CCR 1780[d][1])

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 11 of this document.

6. Drug Stock

Yes No N/A

☐ ☐ ☐ 6.1. Is all drug stock open for inspection during regular business hours? (BPC 4080)

☐ ☐ ☐ 6.2. Are all drugs you order maintained in a secure manner at your licensed premises? You cannot order, obtain or purchase drugs that you are not able to store on your licensed premises. (BPC 4167)

☐ ☐ ☐ 6.3. Do all drugs you sell conform to the standards and tests for quality and strength provided in the latest edition of United States Pharmacopoeia or Sherman Food Drug and Cosmetic Act? (BPC 4342[a])

☐ ☐ ☐ 6.4. Do all drug containers you store on your premises have a manufacturer's expiration date? Any drug without an expiration date is considered expired and may not be distributed. (CCR 1718.1)

☐ ☐ ☐ 6.5. Are outdated, damaged, deteriorated or misbranded drugs held in a quarantine area physically separated from other drugs until returned to the supplier or sent for destruction? (CCR 1780[e][1])

☐ ☐ ☐ 6.6. Are drugs with the outer or secondary seal broken, or partially used or returned drugs held in a quarantine area and physically separated from other drugs until returned to the supplier or sent for destruction? (CCR 1780[e][2])

☐ ☐ ☐ 6.7. When the conditions under which drugs were returned to your premises cast doubt on the drugs' safety, identity, strength, quality or purity, are the drugs quarantined and either returned to your supplier or destroyed? If testing or investigation proves the drugs meet USP standards, the drugs may be returned to normal stock. (CCR 1780[e][3])

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 11 of this document.

7. Sale or Transfer of Drugs by this Business

Yes No N/A

☐ ☐ ☐ 7.1. Are drugs sold only to businesses or persons licensed by this board, licensed by a prescriber board, licensed as a manufacturer, or to a licensed health care entity authorized to receive drugs?

7.2. Describe how you verify a business or person is appropriately licensed. (BPC 4059.5[a], [b],[d],[g], BPC 4169)

_____

_____

7.3. List any businesses or individuals that order drugs from you that are not licensed according to the list above:

_____

_____

Yes No N/A

☐ ☐ ☐ 7.4. Are drugs only furnished by your business to an authorized person? (BPC 4163[a]) Note: An authorized person can be a business or natural person.

7.5. Does your business only receive drugs from a pharmacy if:

☐ ☐ ☐ 7.5.1. the pharmacy originally purchased the drugs from you?

☐ ☐ ☐ 7.5.2. your business is a "reverse distributor"?

☐ ☐ ☐ 7.5.3. the drugs are needed to alleviate a shortage? (and only a quantity sufficient to alleviate a specific shortage). (BPC 4126.5[a])

Yes No N/A

☐ ☐ ☐ 7.6 Are all drugs that are purchased from another business or that are sold, traded or transferred by your business:

☐ ☐ ☐ 7.6.1. transacted with a business licensed with this board as a WLS/3PL or pharmacy?

☐ ☐ ☐ 7.6.2. free of adulteration as defined by the CA Health & Safety Code section 111250?

☐ ☐ ☐ 7.6.3. free of misbranding as defined by CA Health & Safety Code section 111335?

☐ ☐ ☐ 7.6.4. **confirmed** to not be beyond their use date (expired drugs)? (BPC 4169)

7.7. List any incidents where adulterated, misbranded or expired drugs were purchased, sold, traded or transferred by this business in the past 2 years.

_____

_____

7.8. If your business sells, transfers, or delivers dangerous drugs or devices outside of California, either to another state within the United States or a foreign country, do you:

Yes No N/A

☐ ☐ ☐ 7.8.1. comply with all CA pharmacy laws related to the distribution of drugs?

☐ ☐ ☐ 7.8.2. comply with the pharmacy law of the receiving state within the United States?

☐ ☐ ☐ 7.8.3. comply with the statues and regulations of the Federal Food and Drug Administration and the Drug Enforcement Administration relating to the wholesale distribution of drugs?

☐ ☐ ☐ 7.8.4. comply with all laws of the receiving foreign country related to the wholesale distribution of drugs?

☐ ☐ ☐ 7.8.5. comply with all applicable federal regulations regarding the exportation of dangerous drugs?

7.9. Describe how you determine a business in a foreign country is authorized to receive dangerous drugs or dangerous devices. (BPC 4059.5[e])

_____

_____

Yes No N/A

☐ ☐ ☐ 7.10. For products included in the Drug Supply Chain Security Act, transaction histories, transaction information, and transaction statements are provided to authorized trading partners when the products are sold, traded, or transferred. (21 USC 360eee-1[c])

☐ ☐ ☐ 7.11. If preferentially priced drugs are sold by your business, that sale complies with CA Pharmacy Law. (BPC 4380)

Yes No N/A

☐ ☐ ☐ 7.12. Does your business' advertisements for dangerous drugs or devices contain false, fraudulent, misleading or deceptive claims? (BPC 4341, BPC 651, CCR 1766)

☐ ☐ ☐ 7.13. Do you offer or receive any rebates, refunds, commissions or preferences, discounts or other considerations for referring patients or customers? If your business has any of these arrangements, please list with whom. (BPC 650)

_____

_____

☐ ☐ ☐ 7.14. Does your business sell dangerous drugs or devices to the master or first officer of an ocean vessel, after your business has received a written prescription? If so, describe how you comply with the ordering, delivery and record keeping requirements for drugs including controlled substances, and the requirement to notify the board of these sales. (BPC 4066, CFR 1301.25)

_____

_____

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 11 of this document.

8. Donations of Medication to Voluntary Drug Repository and Distribution Programs (HSC 150200, 150203, 150204)

Yes No N/A

☐☐☐ 8.1. The wholesaler donates medications to a county-approved drug repository and distribution program, provided the following requirements are met: (HSC 150203, 150204)

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

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

- ☐ 8.3.1. Have not been adulterated, misbranded, or stored under conditions contrary to standards set by the USP or the product manufacturer. (HSC 150204[c][2])
- ☐ 8.3.2. Have never been in the possession of a patient or individual member of the public. (HSC 150204[c][3])
- ☐ 8.3.3. Are in unopened, tamper-evident packaging or modified unit dose containers with lot numbers and expiration dates affixed. (HSC 105204[d])

☐ 8.3.4. For donated medications that require refrigeration, are medications that are stored, packaged and transported at appropriate temperatures and in accordance with USP standards and pharmacy law. (HSC 150204[m])

9. Outgoing Shipments of Drugs

Yes No N/A

☐ ☐ ☐ 9.1. Before you ship drugs to a purchaser, do you inspect the shipment to assure the drugs were not damaged while stored by your business? (CCR 1780[d][2])

☐ ☐ ☐ 9.2. Does your business use a common carrier (a shipping or delivery company — UPS, US Mail, FedEx, DHL) for delivery of drug orders to your customers? (BPC 4166[a])

9.3. List the common carriers (shipping or delivery companies) you use.

_____

_____

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 11 of this document.

10. Delivery of Drugs

Yes No N/A

☐ ☐ ☐ 10.1. Are all drugs ordered by a pharmacy or another wholesaler are delivered to the address of the buyer's licensed premises and signed for and received by a pharmacist or designated representative where allowed? (BPC 4059.5[a])

☐ ☐ ☐ 10.2. Are all drugs ordered by a manufacturer or prescriber delivered to the manufacturer~~'~~s or prescriber's licensed business address and signed for by a person duly authorized by the manufacturer or prescriber? (BPC 4059.5[d])

☐ ☐ ☐ 10.3. All drugs delivered to a hospital are delivered either to the pharmacy premises or to a central receiving area within the hospital. (BPC 4059.5[c])

☐ ☐ ☐ 10.4. If drugs are delivered to a pharmacy when the pharmacy is closed and a pharmacist is not on duty, documents are left with the delivery in the secure storage facility, indicating the name and amount of each dangerous drug delivered. (BPC 4059.5[f])

CORRECTIVE ACTION OR ACTION PLAN _____

_____

11. **Controlled Substances**

Yes No N/A

☐ ☐ ☐ 11.1. Are there effective controls to prevent theft or diversion of controlled substances? (CFR 1301.71)

☐ ☐ ☐ 11.2. Are DEA requirements for storage of Schedule II controlled substances being met? (specific requirements are listed in CFR 1301.72[a])

☐ ☐ ☐ 11.3. Are DEA requirements for storage of Schedule III, IV and V controlled substances being met? (Specific requirements are listed in CFR 1301.72[b])

☐ ☐ ☐ 11.4. Is a DEA inventory completed by your business every two years for all schedules (II - V) of controlled substances? (CFR 1304.11[a],[c],[e])

☐ ☐ ☐ 11.5. Is the biennial record of the DEA inventory required for Schedule II – V controlled substances conducted every 2 years, retained for 3 years? (CFR 1304.11, CCR 1718, 1780(f)[2])

☐ ☐ ☐ 11.6. Does the biennial inventory record document that the inventory was taken at the "close of business" or "opening of business." (CFR 1304.11)

☐ ☐ ☐ 11.7. Has the person within your business who signed the original DEA registration, or the last DEA registration renewal, created a power of attorney for each person allowed to order Schedule II controlled substances for this business? (CFR 1305.05)

11.7.1. List the individuals at this location authorized by power of attorney to order controlled substances.

_____

_____

Yes No N/A

☐ ☐ ☐ 11.8. Does your business follow employee-screening procedures required by DEA to assure the security of controlled substances? (CFR 1301.90)

☐ ☐ ☐ 11.9. If any employee of this business possesses, sells, uses or diverts controlled substances, in addition to the criminal liability you must evaluate the circumstances of the illegal activity and determine what action you should take against the employee. (CFR 1301.92)

☐ ☐ ☐ 11.10. Are all controlled substances purchased, sold or transferred by your business, done so for legitimate medical purposes? (HSC 11153.5[a],[b],[c])

Yes No N/A

☐ ☐ ☐ 11.11. If your business distributes controlled substances through an agent (i.e. detail person), do you have adequate security measures in place to prevent theft or diversion of those controlled substances. (CFR 1301.74[f])

☐ ☐ ☐ 11.12. If a person attempts to purchase controlled substances from your business and the person is unknown to you, you make a good faith effort to determine the person (individual or business) is appropriately licensed to purchase controlled substances. (CFR 1301.74 [a])

11.13. Explain how your business determines an unknown business or individual is appropriately licensed to purchase controlled substances

_____

_____

Yes No N/A

☐ ☐ ☐ 11.14. If your business uses a common carrier to deliver controlled substances, your business determines the common carrier has adequate security to prevent the theft or diversion of controlled substances. (CFR 1301.74[f])

☐ ☐ ☐ 11.15. If your business uses a common carrier to deliver controlled substances, are the shipping containers free of any outward indication that there are controlled substances within, to guard against storage or in-transit theft? (CFR 1301.74[e])

☐ ☐ ☐ 11.16. Are all Schedule II controlled substances ordered from your business using a fully completed DEA 222 order form? (CFR 1305.03, 1305.06)

☐ ☐ ☐ 11.17. When your business fills orders for Schedule II controlled substances, is the date filled and the number of containers filled recorded on copies 1 and 2 of DEA 222 from? Is copy 1 retained and copy 2 sent to DEA at the close of the month the controlled substance order was filled? (CFR 1305.13 [b])

☐ ☐ ☐ 11.18. If a Schedule II controlled substance order cannot be filled, does your business return copy 1 and 2 of the DEA 222 order form to the buyer with a letter indicating why the order could not be filled? (CFR 1305.15)

☐ ☐ ☐ 11.19. When your business partially fills Schedule II controlled substances, is the balance provided within 60 days of the date of the order form? After the final partial filling, is copy 1 retained in your files and copy 2 of the completed DEA 222 order form sent to DEA by the close of that month? (CFR 1305.13[b])

Yes No N/A

☐ ☐ ☐ 11.20. For all Schedule II controlled substances received by your business, is copy 3 of the DEA 222 order form completed by writing in for each item received, the date received, and the number of containers received? (CFR 1305.13[e])

☐ ☐ ☐ 11.21. Does your business use the online CSOS secure transmission system offered by the Drug Enforcement Administration in place of a paper DEA 222 Form for Schedule II controlled substances? (CFR 1305.21, 1305.22)

☐ ☐ ☐ 11.22. Does your business follow the procedure outlined by DEA to obtain Schedule II controlled substances when the original DEA 222 order form is lost or stolen? (CFR 1305.16(a))

☐ ☐ ☐ 11.23. Are all records of purchase and sale for all schedules of controlled substances for your business kept on your licensed business premises for 3 years from the making? (BPC 4081, CCR 1718, CFR 1304.03, 1305.17[c], 1305.17[a], [b], and HSC 11252, 11253)

☐ ☐ ☐ 11.24. Are records of Schedule II controlled substances stored separate from all others? (CFR 1304.04 [f][1])

☐ ☐ ☐ 11.25. Are records for Schedule III-V controlled substances stored so that they are easily retrievable? (CFR 1304.04 [f][2])

☐ ☐ ☐ 11.26. Before your business distributes carfentanil etorphine HCL and or diprenorphine, do you contact the DEA to determine the person (individual or business) is authorized to receive these drugs? (CFR 1301.74[g])

☐ ☐ ☐ 11.27. Do you separate records for the sale of carfentanil etorphine hydrochloride and or diprenorphine from all other records? (CFR 1305.17[d])

☐ ☐ ☐ 11.28. Does the owner of your business notify the DEA, on a DEA 106 form, of any theft or significant loss of controlled substances upon discovery of the theft? (CFR 1301.74[c])

☐ ☐ ☐ 11.29. Does the owner of your business notify the board of any loss of controlled substances within 30 days of discovering the loss? (CCR 1715.6)

☐ ☐ ☐ 11.30. Do you report suspicious orders to the Suspicious Orders Report System (SORS)? Suspicious Orders may include, but is not limited to: an order of a controlled substance of unusual size; an order of a controlled substance deviating substantially from a normal pattern, and; orders of controlled substances of unusual frequency. (21 USC 832[a][3], 21 USC 802[57], 21 CFR 1301.74[b])

CORRECTIVE ACTION OR ACTION PLAN _____

_____

12. Policies and Procedures

12.1. Does this business maintain and adhere to policies and procedures for the following: (CCR 1780[f])

Yes No N/A

☐ ☐ ☐ 12.1.1. Receipt of drugs

☐ ☐ ☐ 12.1.2. Security of drugs

☐ ☐ ☐ 12.1.3. Storage of drugs (including maintaining records to document proper storage)

☐ ☐ ☐ 12.1.4. Inventory of drug (including correcting inaccuracies in inventories)

☐ ☐ ☐ 12.1.5. Distributing drugs

☐ ☐ ☐ 12.1.6. Identifying, recording and reporting theft or losses

☐ ☐ ☐ 12.1.7. Correcting errors and inaccuracies in inventories

Physically quarantining and separating:

☐ ☐ ☐ 12.1.8. returned, damaged, outdated, deteriorated, misbranded or adulterated drugs

☐ ☐ ☐ 12.1.9. drugs that have been partially used

☐ ☐ ☐ 12.1.10. drugs where the outer or secondary seals on the container have been broken

☐ ☐ ☐ 12.1.11. drugs returned to your business, when there is doubt about the safety, identity, strength, quality, or purity of the drug

Yes No N/A

☐ ☐ ☐ 12.1.12. drugs where the conditions of return cast doubt on safety, identity, strength, quality or purity (CCR 1780[e],[f])

CORRECTIVE ACTION OR ACTION PLAN _____

_____

13. Training

Yes No N/A

☐ ☐ ☐ 13.1 Are training and experience provided to all employees to assure all personnel comply with all licensing requirements? (CCR 1780[f][4])

List the types of training you have provided to staff in the last calendar year and the dates of that training.

_____

_____

CORRECTIVE ACTION OR ACTION PLAN _____

_____

14. Dialysis Drugs

Yes No N/A

☐ ☐ ☐ 14.1. Does your business provide dialysis drugs directly to patients, pursuant to a prescription? (BPC 4054, 4059[c]) If so, please complete the next 4 questions, if not proceed to Section 15.

☐ ☐ ☐ 14.2. Do home dialysis patients complete a training program provided by a dialysis center licensed by Department of Health Services? Prescriber must provide proof of completion of this training to your business. (BPC 4059[d])

☐ ☐ ☐ 14.3. Do you have written or oral orders for authorized dialysis drugs for each dialysis patient being serviced. Are such orders received by either a designated representative or a pharmacist? Note: refill orders cannot be authorized for more than 6 months from the date of the original order. (CCR 1787[a],[b],[c])

☐ ☐ ☐ 14.4. Does your business provide an "expanded invoice" for dialysis drugs dispensed directly to the patient including name of drug, manufacturer, quantities, lot number, date of shipment, and name of the designated representative or pharmacist responsible for distribution? A copy of the invoice must be sent to the prescriber, the patient and a copy retained by this business. Upon receipt of drugs, the patient or patient agent must sign for the receipt for the drugs with any irregularities noted on the receipt. (CCR 1790)

Yes No N/A

☐ ☐ ☐ 14.5. Is each case or full shelf package of the dialysis drugs dispensed labeled with the patient's name and the shipment? Note that additional information as required is provided with each shipment. (CCR 1791)

CORRECTIVE ACTION OR ACTION PLAN _____

_____

15. Record Keeping Requirements

Yes No N/A

☐ ☐ ☐ 15.1. Does your business' sales record for drugs include date of sale, your business name and address, the business name and address of the buyer, and the names and quantities of the drugs sold? (BPC 4059[b])

☐ ☐ ☐ 15.2. Does your business maintain transaction histories, transaction information, and transaction statements for products included in the Drug Supply Chain Security Act? (21 USC 360eee-1[c])

☐ ☐ ☐ 15.3. Are purchase and sales records for all transactions retained on your licensed premises for 3 years from the date of making? (BPC 4081~~[a]~~, 4105[c], 4332)

☐ ☐ ☐ 15.4. Are all purchase and sales records retained in a readily retrievable form? (BPC 4105[a])

☐ ☐ ☐ 15.5. Is a current accurate inventory maintained for all dangerous drugs? (BPC 4081, 4332, CCR 1718)

☐ ☐ ☐ 15.6. If you temporarily remove purchase or sales records from your business, does your business retain on your licensed premises at all times, a photocopy of each record temporarily removed? (BPC 4105[b])

☐ ☐ ☐ 15.7. Are required records stored off-site only if a board issued written waiver has been granted?

15.8. If your business has a written waiver, write the date the waiver was approved and the off-site address where the records are stored below. (CCR 1707[a])

Date _____ Address_____

☐ ☐ ☐ 15.9. Is an off-site written waiver in place and is the storage area secure from unauthorized access? (CCR 1707[b][1])

Yes No N/A

☐ ☐ ☐ 15.10. If an off-site written waiver is in place, are the records stored off-site retrievable within 2 business days? (CCR 1707[b][2])

☐ ☐ ☐ 15.11. Can the records that are retained electronically be produced immediately in hard copy form by any designated representative, if the designated representative-in-charge is not present? (BPC 4105[d][2])

☐ ☐ ☐ 15.12. Are records of training provided to employees to assure compliance with licensing requirements, retained for 3 years? (CCR 1780[f][4])

☐ ☐ ☐ 15.13. Has this licensed premises, or the designated representative-in-charge/responsible manager, been cited, fined or disciplined by this board or any other state or federal agency within the last 3 years? If so, list each incident with a brief explanation (BPC 4162[a][5]):

_____

_____

☐ ☐ ☐ 15.14. Has the licensed premises received any orders of correction from this board? A copy of the order and the corrective action plan must be on the licensed premises for 3 years. (BPC 4083)

☐ ☐ ☐ 15.15. Has this licensed premises received a letter of admonishment from this board? A copy must be retained on the premises for 3 years from the date of issue. (BPC 4315[f])

☐ ☐ ☐ 15.16. If this licensed premises dispenses dialysis drugs directly to patients, are the prescription records retained for 3 years, including refill authorizations and expanded invoices for dialysis patients? (CCR 1787[c], 1790)

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 11 of this document.

16. Reporting Requirements to the Board

Yes No N/A

☐ ☐ ☐ 16.1. A designated representative-in-charge/responsible manager who terminates employment at this business, must notify the board within 30 days of the termination (BPC 4101[b], 4305.5[c].

☐ ☐ ☐ 16.2. The owner must report to the board within 30 days the termination of the designated representative-in-charge or responsible manager. (BPC 4305.5[a])

☐ ☐ ☐ 16.3. The owner must report to the board within 30 days of discovery, any loss of controlled substances, including amounts and strengths of the missing drugs. (CCR 1715.6)

☐ ☐ ☐ 16.4. The owner must notify the DEA, on a DEA form 106, any theft or significant loss of controlled substances upon discovery. (CFR 1301.74[c])

Yes No N/A

☐ ☐ ☐ 16.5. Do your employees know about their obligation to report any known diversion or loss of controlled substances to a responsible person within your business? (CFR 1301.91)

☐ ☐ ☐ 16.6. The owner must notify the board within 30 days of any change in the beneficial ownership of this business. (BPC 4201[j], CCR 1709[b])

- ☐ 16.6.1. identify any transfer, in a single transaction or in a serious of transaction, of 10 percent or more of the beneficial interest in a business entity licensed by the board to a person or entity who did not hold a beneficial interest at the time of the original license was issued
- ☐ 16.6.2. identify any transfer of the management or control over a business entity licensed by the board to a person or entity who did not have management or control over the license at the time the original license was issued
- ☐ 16.6.3. identify any new ownership and their application to the board of licensure in advance of the proposed transaction taking place

Yes No N/A

☐ ☐ ☐ 16.7. When called upon by the board, your business can report all sales of dangerous drugs or controlled substances subject to abuse. (BPC 4164[a])

☐ ☐ ☐ 16.8. The wholesaler maintains a tracking system for individual sales of dangerous drugs at preferential or contract prices to pharmacies that primarily or solely dispense prescription drugs to patients of long-term care facilities. Your system must:

- ☐ 16.8.1. identify pharmacies that primarily or solely dispense prescription drugs to patients of long-term care facilities
- ☐ 16.8.2. identify purchases of any dangerous drugs at preferential or contract prices
- ☐ 16.8.3. identify current purchases that exceed prior purchases by 20 percent over the previous 12 calendar months. (BPC 4164[b])

☐ ☐ ☐ 16.9. I understand that this license is not transferable to a new owner. A change of ownership must be reported to this board, as soon as the parties have agreed to the sale. Before the ownership actually changes, an additional application for a temporary permit must be submitted to the board if the new owner wants to conduct business while the board is processing the change of ownership application and until the new permanent permit is issued. A company cannot transfer the ownership of the business via a contract with another individual or business, without the board's approval (BPC 4201[g])

☐ ☐ ☐ 16.10. The owner of this business must immediately notify the board in writing if any assignment is made for the benefit of creditors, if the business enters into any credit compromise arrangement, files a petition in bankruptcy, has a receiver

appointed, or enters into liquidation or any other arrangement that might result in the sale or transfer of drugs. (CCR 1705)

☐ ☐ ☐ 16.11. If this business requires a temporary closure, the owner must notify the board of any temporary closure of a facility as soon as any closure exceeds three consecutive calendar days. (CCR 1708.1)

☐ ☐ ☐ 16.12. If this business is discontinued, the owner must notify the board in writing before the actual discontinuation of business. (CCR 1708.2). If the business holds a DEA registration, the owner must notify the DEA promptly of the discontinuation of business and all unused DEA 222 order forms must be returned to the DEA. (CFR 1301.52[a], 1305.14)

☐ ☐ ☐ 16.13. Upon discovery, the business notifies the board in writing of any suspicious orders of controlled substances placed by a California-licensed pharmacy or wholesaler as required by BPC 4169.1.

CORRECTIVE ACTION OR ACTION PLAN _____

_____

17. Additional Licenses/Permits Required

17.1. List all licenses and permits required to conduct this business, including local business licenses, licenses held in other states, permits or licenses required by foreign countries or other entities (BPC 4059.5[e], 4107, CFR 1305.11[a]) Use additional sheets if necessary.

_____

_____

DESIGNATED REPRESENTATIVE-IN-CHARGE / RESPONSIBLE MANAGER CERTIFICATION:

I, (please print) _____, hereby certify that I have completed the self-assessment of this licensed premises of which I am the designated representative-in-charge (DRIC) / responsible manager (RM). Any deficiency identified herein will be corrected by _____(Date). I understand that all responses are subject to verification by the Board of Pharmacy. I further state under penalty of perjury that the information contained in this self-assessment form is true and correct.

Signature _____ Date _____
Designated Representative-in-Charge (DRIC) / Responsible Manager (RM)

ACKNOWLEDGEMENT BY OWNER, PARTNER OR CORPORATE OFFICER:

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

Signature _____ Date _____

Legal References

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

Business and Professions Code (BPC), Division 2, Chapter 1 – General Provisions

BPC, Division 2, Chapter 9 – Pharmacy

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

Code of Federal Regulations (CFR), Title 21, Chapter 2 – 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 6 – Drugs and Devices

HSC, Division 116 – Surplus Medication Collection and Distribution

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

Attachment 1D

AUTOMATED DRUG DELIVERY SYSTEM SELF-ASSESSMENT 17M-112 (Rev. 1/23)

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

LEGEND: Proposed changes made to the current regulation language are shown by ~~double strikethrough~~ for deleted language and double underline for added language.

2023 changes are shown by ~~*italicized double strikethrough*~~ **for deleted language and** *italicized wavy underline* **for added language.**

AUTOMATED DRUG DELIVERY SYSTEM SELF-ASSESSMENT

Business and Professions Code (BPC) section 4427.7(a) requires that the pharmacy holding an automated drug delivery system (ADDS) license complete ~~an annual~~ a self-assessment, performed pursuant to section 1715.1 of Title 16 of the California Code of Regulations, evaluating the pharmacy's compliance with pharmacy law relating to the use of the ADDS. The assessment shall be performed **before July 1 of every odd-numbered year** by the pharmacist-in-charge of each pharmacy under BPC sections 4029 (Hospital Pharmacy) or ~~section~~ 4037 (Pharmacy). The pharmacist-in-charge (PIC) must also complete a self-assessment within 30 days whenever; (1) a new automated drug delivery system permit has been issued, ~~or~~ (2) there is a change in the pharmacist-in-charge ~~and becomes the new pharmacist-in-charge of an automated drug delivery system~~, or (3) there is a change in the licensed location of an automated drug delivery system to a new address. The primary purpose of the self-assessment is to promote compliance through self-examination and education. All information regarding operation, maintenance, compliance, error, omissions, or complaints pertaining to the ADDS shall be included in this Self-Assessment.

All references to Business and Professions Code (BPC) are to Division 2, Chapter 9~~, Division 2~~; California Code of Regulations (CCR) are to Title 16; and Code of Federal Regulations (21 CFR) to Title 21 unless otherwise noted.

The self-assessment must be completed, and the signed original must be readily available and retained in the pharmacy for three (3) years after performed.

Note: For a hospital pharmacy operating an ADDS pursuant to BPC 4427.2(i) the exemption only applies to the licensure requirements for the ADDS. The hospital pharmacy is required to comply with all other requirements including completing the ADDS Self-Assessment pursuant to BPC 4427.7(a). The PIC may complete a single self-assessment if the mechanical devices used are the same and the same policies are procedures are used. (CCR 1715.1(g))

Please mark the appropriate box for each item. If "NO", enter an explanation and timeframe when the deficiency will be completed on the "CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE" lines at the end of the section. If more space is needed, you may add additional sheets.

Pharmacy Name: _____
Address: _____
City: _____ **Zip Code:** _____

Phone: _____ **Fax number:** _____
Website: _____
Pharmacy License #: _____ **Expiration Date:** _____
DEA Registration #: _____ **DEA Expiration Date:** _____
DEA Inventory Date: _____ **Last ~~C2~~ CS Inventory Reconciliation Date (CCR 1715.65(c)):** _____
Pharmacy Hours: M-F: _____ **Saturday**_____ **Sunday**_____
PIC: _____ **RPH#**_____
ADDS License #: _____ **ADDS Expiration Date:** _____
ADDS Address: _____
City: _____ **Zip Code:** _____
ADDS Hours: M-F: _____ **Saturday**_____ **Sunday**_____
Please explain if the ADDS hours are different than the pharmacy:
_____
_____

Reason for completing self-assessment:

☐ Performing self-assessment before July 1 of every odd-numbered year. [BPC 4427.7, CCR 1715.1(a)]
☐ Completing a self-assessment within 30 days when a new ADDS license was issued. [BPC 4427.7, CCR 1715.1(b)(1)]
☐ Completing a self-assessment within 30 days when there was a change in PIC. [BPC 4427.7, CCR 1715.1(b)(2)]
☐ Completing a self-assessment within 30 days when there was a change in the licensed location of an ADDS to a new address. [BPC 4427.7, CCR 1715.1(b)(3)]

FOR ALL TYPES OF ADDS: COMPLETE SECTIONS 1, 2 AND 3

SECTION 1: DEFINITIONS/TYPE OF ADDS DEVICE USED

An **ADDS – "Automated drug delivery system**," a mechanical system that performs operations or activities other than compounding or administration, relative to storage, dispensing, or distribution of drugs. An ADDS, shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability. [BPC 4119.11(b)(1), 4017.3(a)]

IDENTIFY THE TYPE OF ADDS DEVICE USED

Yes No N/A

☐☐☐ 1.1. The pharmacy uses an **APDS – "Automated PATIENT dispensing system**," an ADDS for storage and dispensing of prescribed drugs directly to the patients pursuant to prior authorization by a pharmacist. [BPC 4119.11(b)(2), 4017.3(c)]

☐☐☐ 1.2 The pharmacy uses an **AUDS – "Automated UNIT DOSE system**," an ADDS for the storage and retrieval of unit dose drugs for administration to patient by persons authorized to perform these functions. [BPC 4119.11(b)(3), 4017.3(b)]

☐☐☐ 1.3 The pharmacy uses an **AUDS – "Automated UNIT DOSE system**," an ADDS for the storage and retrieval of unit dose drugs for administration and dispensing to patients by a physician in a drug room or hospital emergency room when the pharmacy is closed. [BPC 4427.2(i), ~~BPC~~ 4056, ~~BPC~~4068]

SECTION 2: LOCATION OF DEVICES

Yes No N/A

☐☐☐ 2.1 Provides pharmacy services to the patient of **covered entities**, as defined that are eligible for discount drug programs under federal law as specified through the use of an APDS as defined. The APDS need not be at the same location as the underlying operating pharmacy if all the specific conditions are met. "Covered entity" as defined by section 256b of Title 42 of United Sates Code. [BPC 4119.11(a)~~ (a)(11)~~]

☐☐☐ 2.2 Provides pharmacy services through an ~~ADDS~~APDS **adjacent to the secured pharmacy area** of the pharmacy holding the ADDS license. [BPC 4427.3(b)(1)]

☐☐☐ 2.3 Provides pharmacy services through an ~~ADDS~~AUDS in **a health facility** licensed pursuant to section 1250 of the Health and Safety Code (HSC)~~(Long Term Care (LTC))~~ that complies with section 1261.6 of the Health and Safety Code. [BPC 4427.3(b)(2), HSC 1250, HSC 1261.6]

~~Yes No N/A~~

☐☐☐ 2.4 Provides pharmacy services through an AUDS in **a clinic** licensed pursuant to section 1204 or 1204.1 of the Health and Safety Code, or section 4180 or 4190 of Business and Professions Code. [BPC 4427.3(b)3)]

☐☐☐ 2.5 Provides pharmacy services through a **correctional clinic**. [BPC 4187.1, 4427.3(b)(4)]

☐☐☐ 2.6 Provides pharmacy services through a **medical office** or other location where patients are regularly seen for purposes of diagnosis and treatment, and the APDS is only used to dispense dangerous drugs and dangerous devices to patients of the practice. [BPC 4427.3(b)(5), 4427.6(j)]

☐☐☐ 2.7 **AUDS operated by a licensed hospital pharmacy**, as defined in section 4029 of the Business and Professions Code, and is used solely to provide doses administered to patients while in a licensed general acute care hospital facility or a licensed acute psychiatric hospital facility, as defined in subdivision (a) and (b) of section 1250 of the Health and Safety Code, shall be exempt from the requirement of obtaining an ADDS license, if the licensed hospital pharmacy owns or leases the AUDS and owns the dangerous drugs and dangerous devices in the AUDS. The AUDS shall comply with all other requirements for an ADDS in Article 25 of the Business and Professions Code. The licensed hospital pharmacy shall maintain a list of the locations of each AUDS it operates and shall make the list available to the board upon request. [BPC 4427.2(i)]

☐☐☐ 2.8 **AUDS operated by a licensed hospital that contains 100 beds or fewer (Drug Room)**, as defined in section 4056 of the Business and Professions Code, and is used to provide doses administered to patients while in a licensed general acute care hospital and to dispense drugs to outpatients if the physician determines that it is in the best interest of the patient that a particular drug regimen be immediately commenced or continued, and the physician reasonably believes that a pharmacy located outside the hospital is not available and accessible at the time of dispensation to the patient within 30 minutes of the hospital pharmaceutical services or within a 30-mile radius. The quantity dispensed is limited to an amount necessary to maintain uninterrupted therapy and does not exceed a 72-hour supply. [BPC 4056, 4427.2(i)]

Yes No N/A

☐☐☐ 2.9 **AUDS located in the emergency room operated by a licensed hospital pharmacy**, as defined in subdivisions (a) and (b) of section 4029 of the Business and Professions Code, and is used to provide **doses administered** to patients while in a licensed general acute care hospital facility or a licensed acute psychiatric hospital facility, as defined in subdivisions (a) and (b) of section 1250 of the Health and Safety Code**, and to dispense** to an emergency room patient if: [BPC 4068, 4427.2(i)]

- ☐ 2.9.1. The hospital pharmacy is closed and there is no pharmacist available in the hospital.
- ☐ 2.9.2. The drug is acquired by the hospital pharmacy.
- ☐ 2.9.3. The dispensing information is recorded and provided to the pharmacy when the pharmacy reopens.
- ☐ 2.9.4. The hospital pharmacy retains the dispensing information and controlled substances dispensing information is reported to the Department of Justice pursuant to section 11165 of the Health and Safety Code.
- ☐ 2.9.5. The prescriber determines it is in the best interest of the patient that a particular drug regimen be immediately commenced or continued and the prescriber reasonably believes a pharmacy located outside the hospital is not available and accessible at the time of dispensing to the patient.
- ☐ 2.9.6. The quantity is limited to an amount necessary to maintain uninterrupted therapy, but shall not exceed a 72-hour supply.

Note: Licensure of AUDS operated under these provisions is required.

☐☐☐ 2.10 **A facility licensed in CA with the statutory authority to provide pharmaceutical services**. [BPC 4427.65(a)(1)]

Type of Facility: _____

Statutory authority to provide pharmaceutical services (List code section): _____

☐☐☐ 2.11 **Jail, youth detention facility, or other correctional facility where drugs are administered within the facility under the authority of the medical director**. [BPC 4427.3(b)(6), BPC 4427.65(a)(2)]

Type of Facility: _____

Statutory authority for type of Facility (List code section): _____

Please Note: An ADDS license is not required for technology, installed **within the secured licensed premises area of a pharmacy,** used in the selecting, counting, packaging, and labeling of dangerous drugs and dangerous devices. [BPC 4427.2(j)]

SECTION 3: GENERAL REQUIREMENTS FOR ALL TYPES OF ADDS

(Answer N/A if licensure not required)

Yes No N/A

☐☐☐ 3.1 The ADDS is installed, leased, owned, or operated in California and is licensed by the board. [BPC 4427.2(a), 4427.4(a)]

Yes No N/A

☐☐☐ 3.2 The ADDS license was issued to a holder of a current, valid, and active pharmacy license of a pharmacy located and licensed in California. [BPC 4427.2(b)]

☐☐☐ 3.3 Each ADDS has a separate license. [BPC 4427.2(c)]

☐☐☐ 3.4 The licensed ADDS meets the following conditions: [BPC 4427.2(d)]

- ☐ 3.4.1 Use of the ADDS is consistent with legal requirements.
- ☐ 3.4.2 The proposed location for installation of the ADDS meets the requirements of section 4427.3 and the ADDS is secure from access and removal by unauthorized individuals.
- ☐ 3.4.3 The pharmacy's policies and procedures related to the ADDS include appropriate security measures and monitoring of the inventory to prevent theft and diversion.
- ☐ 3.4.4 The pharmacy's policy and procedures include provisions for reporting to the board drug losses from the ADDS inventory, as required by law.

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

☐☐☐ 3.5 A prelicensure inspection was conducted within 30 days of a completed application for the ADDS license at the proposed location(s). [BPC 4427.2(e)]
List date~~(s)~~ of pre-license inspection~~(s)~~:

_____

_____

_____

☐☐☐ 3.6 The pharmacy is aware a relocation of an ADDS shall require a new application for licensure. [BPC 4427.2(e)]

☐☐☐ 3.7. The pharmacy is aware a replacement of an ADDS shall require notification to the board within 30 days. [BPC 4427.2(e)]

☐☐☐ 3.8 The pharmacy is aware the ADDS license will be canceled by operation of law if the underlying pharmacy license is not current, valid, and active. Upon reissuance or reinstatement of the underlying pharmacy license, a new application for an ADDS license is submitted to the board. [BPC 4427.2(f)]

☐☐☐ 3.9 The pharmacy is aware the holder of an ADDS license will advise the board in writing within 30 days if use of an ADDS is discontinued. [BPC 4427.2(g)]

☐☐☐ 3.10 The ADDS license~~(s)~~ is~~/were~~ renewed annually, and the renewal date is the same as the underlying pharmacy license. [BPC 4427.2(h)]

☐☐☐ 3.11 The ADDS is placed and operated inside an enclosed building, with a premises address, at a location approved by the board. [BPC 4427.3(a)]

Yes No N/A

☐☐☐ 3.12 Prior to installation, the pharmacy holding the ADDS license and the location where the ADDS is placed pursuant to subdivision (b) of Business and Professions Code section 4427.3, jointly developed and implemented written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the ADDS, as well as quality, potency, and purity of the drugs and devices. The policies and procedures are maintained at the location of the ADDS and at the pharmacy holding the ADDS license. [BPC 4427.3(c)]

☐☐☐ 3.13 Each ADDS is operated under the supervision of the pharmacy holding the ADDS license. [BPC 4427.4(b)]

☐☐☐ 3.14 The ADDS is considered an extension and part of the pharmacy holding the ADDS license, regardless of the ADDS location, and is subject to inspection pursuant to BPC section 4008. [BPC 4427.4(c)]

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

☐☐☐ 3.15 Drugs and devices stored in an ADDS will be deemed part of the inventory and the responsibility of the pharmacy holding the ADDS license, and the drugs and devices dispensed from the ADDS shall be considered to have been dispensed by the pharmacy. [BPC 4427.4(d), 4119.11(a)(3)]

☐☐☐ 3.16 The stocking and restocking of an ADDS is performed by a pharmacist, or by a pharmacy technician or intern pharmacist under the supervision of a pharmacist, except for an ADDS located in a health facility pursuant to HSC 1250, where the stocking and restocking of the ADDS may be performed in compliance with HSC 1261.6. [BPC 4427.4(e)(1)]

☐☐☐ 3.17 Access to the ADDS is controlled and tracked using an identification or password system or biosensor. [BPC 4427.4(e)(2), 4427.65(c)(5)(D), HSC 1261.6(f)(4)]

☐☐☐ 3.18 The ADDS makes a complete and accurate record of all transactions including all users accessing the system and all drugs added to, or removed from, the system. [BPC 4427.4(e)(3), BPC 4427.65(c)(5)(D), BPC 4119.11(f), HSC 1261.6(f)(5)]

☐☐☐ 3.19 Are drugs or devices not immediately transferred into an ADDS upon arrival at the ADDS location~~,~~ stored for no longer than 48 hours in a secured room within the ADDS location

approved by the board under section 4427.3 of the Business and Professions Code, and, upon retrieval of the dangerous drugs and dangerous devices from the secured storage, is an inventory taken to detect any losses or overages? [BPC 4427.4(f)]

☐☐☐ 3.20 Prior to installation, and annually thereafter, the pharmacy holding the ADDS license provides training on the operation and use of the ADDS to the pharmacy personnel and to personnel using the ADDS at the location where the ADDS is placed pursuant to BPC 4427.3(b). [BPC 4427.5]

Yes No N/A

☐☐☐ 3.21 The pharmacy complies with all recordkeeping and quality assurance requirements established in pharmacy law and regulations, and maintains records within the licensed pharmacy holding the ADDS license and separate from other pharmacy records. [BPC 4427.7(b), BPC 4427.7(b), BPC 4119.11(j)]

☐☐☐ 3.22 The record of quality assurance review, as provided in California Code of Regulation section 1711(e), is immediately retrievable in the pharmacy for at least one year from the date the record was created. [CCR 1711(f)]

☐☐☐ 3.23 An investigation of each medication error shall commence as soon as is reasonably possible, but no later than 2 business days from the date the medication error is discovered. The pharmacy will submit to the board any quality assurance record related to the use of a licensed ADDS within 30 days of completion of the quality assurance review. Any facility with an unlicensed ADDS must report the quality assurance review to the board at the time of annual renewal of the pharmacy's license. [CCR 1711 (e), CCR 1711(f)]

~~☐☐☐ *3.24 The PIC of EACH ADDS completes a self-assessment of the pharmacy's compliance with federal and state pharmacy law and is performed [CCR 1715.1(a), (b)]:*~~

- ~~*Before July 1 of every odd-numbered year.*~~
- ~~*Within 30 days whenever a new ADDS licensed has been issued.*~~
- ~~*Within 30 days when there is a change in PIC.*~~
- ~~*When there is a change in the licensed location of an ADDS to a new address.*~~

~~☐☐☐ *3.25 The PIC of an ADDS assesses the system's compliance with current laws and regulations by using the components of Form 17M-112 (Rev 1/22) entitled "Automated Drug Delivery System Self-Assessment." [CCR 1715.1(c)]*~~

~~☐☐☐ *3.26 The PIC responds "yes", "no", or "not applicable" about whether the ADDS is, at the time of the self-assessment, in compliance with laws and regulations that apply to that pharmacy setting. [CCR 1715.1(c)(2)]*~~

~~☐☐☐ *3.27 For each "no" response, the PIC provides a written corrective action or action plan to come into compliance with the law. [CCR 1715.1(c)(3)]*~~

~~☐☐☐ 3.28 The PIC initialed each page of the self-assessment with original handwritten initials in ink or digitally signed in compliance with Civil Code Section 1633.2(h) of the self-assessment form. [CCR 1715.1(c)(4)]~~

~~☐☐☐ 3.29 The PIC has certified on the last page of the self-assessment that they are the PIC, has certified a timeframe within which any deficiency identified within the self-assessment will be corrected, and has acknowledged all responses are subject to verification by the Board of Pharmacy. The certification is made under penalty of perjury of the laws of the State of California and the information provided in the self-assessment form is true and correct with an original handwritten signature in ink or digitally signed in compliance with Civil Code Section 1633.2(h) on the self-assessment form. [CCR 1715.1(c)(5)]~~

~~Yes No N/A~~

~~☐☐☐ 3.30 The ADDS owner has certified the final page of the self-assessment that they have read and reviewed the completed self-assessment and acknowledges that failure to correct any deficiency identified in the self-assessment could result in the revocation of the ADDS license issued by the Board. The certification is made under penalty of perjury of the laws of the State of California with an original handwritten signature or digitally signed in compliance with Civil Code Section 1633.2(h) on the self-assessment form. [CCR 1715.1(c)(6)]~~

~~☐☐☐ 3.31 Each self-assessment is completed in its entirety and kept on file in the underlying pharmacy for three (3) years after it is performed. The completed, initialed, and signed original is readily available for review during any inspection by the Board. [CCR 1715.1(d)]~~

~~☐☐☐ 3.32 Any identified area of noncompliance shall be corrected as specified in the self-assessment. [CCR 1715.1(e)]~~

~~☐☐☐ 3.33 The PIC ensures the following: [CCR 1715.65(h)]~~

- ~~☐ 3.33.1 All controlled substances added to an ADDS are accounted for.~~
- ~~☐ 3.33.2 Access to the ADDS is limited to authorized facility personnel.~~
- ~~☐ 3.33.3 An ongoing evaluation of discrepancies or unusual access associated with controlled substances is performed.~~
- ~~☐ 3.33.4 Confirmed losses of controlled substance are reported to the board.~~

☐☐☐ *3.24 The pharmacy's inventory reconciliation report prepared at least once every three months for federal Schedule II controlled substances, includes the federal Schedule II controlled substances stocked in the ADDS. (CCR 1715.65[a][1])*

☐☐☐ *3.25 The pharmacy's inventory reconciliation report prepared at least once every 12 months for alprazolam 1mg/unit, alprazolam 2mg/unit, Tramadol 50mg/unit and promethazine/codeine 6.25mg/10mg/5ml, includes these controlled substances stocked in the ADDS. (CCR 1715.65([a][2])*

☐☐☐ *3.26 Inventory activities are performed at least once every two years from the performance of the last inventory activities for each controlled substance that is not listed as a federal Schedule II controlled substance, alprazolam 1mg/unit, alprazolam 2mg/unit, tramadol 50mg/unit and promethazine/codeine 6.25mg/10mg/5ml and includes the controlled substances stocked in the ADDS. (CCR 1715.65[a][3][B])*

☐☐☐ *3.27 For any controlled substance stocked in the ADDS that is not a federal Schedule II controlled substance, alprazolam 1mg/unit, alprazolam 2mg/unit, tramadol 50mg/unit and promethazine/codeine 6.25mg/10mg/5ml, the pharmacy prepares an inventory reconciliation report for the identified loss of that controlled substance in the ADDS no later than three months after the discovery of the reportable loss and is completed if the loss is discovered either by the inventory activities or any other manner. (CCR 1715.65[a][3][A])*

☐☐☐ *3.28 A physical count, not an estimate, of the federal controlled substances in the ADDS is taken for the inventory reconciliation reports, except for an inpatient hospital pharmacy or correctional pharmacy where the inventory in the ADDS may be accounted for using means other than a physical count. (CCR 1715.65[c][1], CCR 1715.65[h])*

☐☐☐ *3.29 The PIC or the consulting pharmacist for a clinic (BPC 4180 or 4190) reviews all inventory activities performed and inventory reconciliation reports prepared in accordance with CCR 1715.65 and has established and maintained secure methods to prevent losses of federal controlled substances. (CCR 1715.65[b])*

☐☐☐ *3.30 The pharmacy has written policies and procedures developed for performing the inventory activities and preparing the inventory reconciliation reports in accordance with CCR 1715.65 that includes the inventory of federal controlled substances stored in the ADDS. (CCR 1715.65)*

☐☐ 3.3~~4~~*1* The original board-issued ADDS permit and current renewal are posted at the ADDS premise, where they may be clearly read by the public. [BPC 4058]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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CHECK OFF THE TYPE OF ADDS USED BY THE PHARMACY AND COMPLETE THE FOLLOWING SECTION(S) AS IT APPLIES TO THE TYPE OF ADDS THE PHARMACY IS USING.

Please Note: The Pharmacist-in-Charge of the pharmacy and the pharmacy owner of the ADDS shall sign the Certification Acknowledgment on page ~~33~~ 48 after completing the assessment.

☐ SECTION 4: ~~–~~APDS used to provide pharmacy service to covered entities and medical professionals contracted with a covered entity.

☐ SECTION 5: ~~– ADDS~~

- APDS adjacent to the secured pharmacy area (or)
- APDS located in a Medical Office~~s~~ (or)
- APDS located where patients are regularly seen for purposes of diagnosis and treatment to only be used for patients of the practice (or)
- APDS located at a clinic pursuant to HSC 1204, HSC 1204.1, BPC 4180, or BPC 4190.

☐ SECTION 6: ~~–~~ADDS in a health facility pursuant to HSC 1250 that complies with HSC 1261.6.

~~☐ SECTION 7 – APDS through a clinic pursuant to HSC 1204 or 1204.1 or BPC 4180 or 4190.~~

☐ SECTION ~~8~~7:– ADDS operated by a correctional clinic pursuant to BPC 4187.1, 4427.3(b)(6), or 4427.65(a)(2).

☐ SECTION ~~9~~8:

- Hospital Pharmacy: AUDS used for dispensing pursuant to BPC 4068 ~~(~~when the hospital pharmacy is closed and no pharmacist is available~~)~~.
- Drug Room: AUDS used for dispensing pursuant to BPC 4056.

☐ SECTION 9:

- AUDS through a facility licensed in California with statutory authority to provide pharmaceutical services (or)
- AUDS through a jail, youth detention facility, or other correctional facility where drugs are administered within the facility under the authority of the medical director pursuant to BPC 4187.1, 4427.3(b)(6), or 4427.65(a)(2).

SECTION 4: APDS USED TO PROVIDE PHARMACY SERVICES TO COVERED ENTITIES AND MEDICAL PROFESSIONALS CONTRACTED WITH A COVERED ENTITY

A. GENERAL REQUIREMENTS

Yes No N/A

☐☐☐ 4.1 A Covered Entity May Contract with Pharmacy to Provide Services. The operating pharmacy providing pharmacy services to the patients of the covered entity, including, unless prohibited by any other law, patients enrolled in the Medi-Cal program, shall be under contract with the covered entity as described in BPC section 4126 to provide those pharmacy services through the use of the APDS. [BPC 4119.11(a)(2)]

☐☐☐ 4.2 Contracts between the covered entities and the pharmacy shall comply with the guidelines published by the Health Resources and Services Administration and are available for inspection by Board during normal business hours. [BPC 4126(a)]

☐☐☐ 4.3 Drugs purchased and received pursuant to section 256b of Title 42 of the United States Code (USC) shall be segregated from the pharmacy's other drug stock by physical or electronic means. [BPC 4126(b)]

Yes No N/A

☐☐☐ 4.4 All records of acquisition and disposition of these drugs shall be readily retrievable in a form separate from the pharmacy's other records. [BPC 4126(b)]

☐☐☐ 4.5 The drugs shall be returned to the distributor from which the drugs were obtained if drugs to be dispensed to patient of a covered entity pursuant to section 256b of Title 42 USC cannot be distributed because of a change in circumstances of the covered entity or the pharmacy. [BPC 4126(c)]

☐☐☐ 4.6 A licensee that participates in a contract to dispense preferentially priced drugs pursuant to this section shall not have both a pharmacy and a wholesaler license. [BPC 4126(d)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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B. UNDERLYING OPERATING PHARMACY

Yes No N/A

☐☐☐ 4.7 The operating pharmacy has obtained a license from the Board to operate the APDS which includes the address of the APDS location and the identity of the covered entity or affiliated site. [BPC 4119.11(a)(1)]

☐☐☐ 4.8 A separate license was obtained for each APDS location and has been renewed annually concurrent with the pharmacy license. (Note: The Board may issue a license for operation of an APDS at an address for which the Board has issued another site license.) [BPC 4119.11(a)(1), 4119.11(a)(8), 4107]

☐☐☐ 4.9 A prelicensure inspection of the proposed APDS location was conducted by the Board within 30 days after Board receipt of the APDS application before Board approval. [BPC 4119.11(a)(9)]

Date of Inspection: _____

☐☐☐ 4.10 The pharmacy will submit a new APDS licensure application for Board approval if the current APDS is relocated. [BPC 4119.11(a)(9)]

☐☐☐ 4.11 The pharmacy will notify the Board within 30 days of replacement of an APDS or discontinuing an APDS. [BPC 4119.11(a)(9), 4119.11(a)(11)]

☐☐☐ 4.12 A new APDS licensure application will be submitted if original APDS is cancelled due to the underlying operating pharmacy's permit being cancelled, not current, not valid, or inactive. (Once cancelled, a new APDS license can only be issued if the underlying pharmacy's permit is reissued or reinstated.) [BPC 4119.11(a)(10)]

Yes No N/A

☐☐☐ 4.13 The pharmacy does not have more than 15 APDS licenses for one underlying operating pharmacy under this section. [BPC 4119.11(d)(10), 4427.6(k)] List of current APDS licenses:

1._____ 2. _____

3._____ 4. _____

5._____6. _____

7._____8. _____

9._____10._____

11. _____ 12._____

13._____14. _____

15. _____

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

☐☐☐ 4.14 The operating pharmacy will maintain the written APDS policies and procedures for 3 years after the last date of use for that APDS. [BPC 4119.11(d)(11), CCR 1713(f)]

☐☐☐ 4.15 The operating pharmacy of an APDS has completed a~~n annual~~ biennial Self-Assessment pursuant to CCR 1715.1 or BPC 4427.7(a) evaluating the pharmacy's compliance with pharmacy law relating to the use of the APDS. [BPC 4119.11(i)]

Date of Last Self-Assessment: _____
Reason: ☐ Biennial; ☐ New ADDS; ☐ Change in PIC; ☐ Change in location of ADDS

~~☐☐☐ 4.16 The operating pharmacy has complied with all recordkeeping and quality assurance requirements pursuant to BPC 4119.11 and those records will be maintain within the pharmacy holding the APDS and separately from the other pharmacy records. [BPC 4119.11(j)]~~

~~☐☐☐ 4.17 The pharmacy is aware that the drugs stored in an APDS are a part of the operating pharmacy's drug inventory and the drugs dispensed by the APDS shall be considered to have been dispensed by that pharmacy. [BPC 4119.11(a)(3)]~~

☐☐☐ 4.1~~8~~6 The underlying operating pharmacy is solely responsible for: [BPC 4119.11(a)(5), (6)]

- ☐ 4.16.1 The security of the APDS. [BPC 4119.11(a)(5)]
- ☐ 4.16.2 The operation of the APDS. [BPC 4119.11(a)(5)]
- ☐ 4.16.3 The maintenance of the APDS. [BPC 4119.11(a)(5)]
- ☐ 4.16.4 The training regarding the operation and use of the APDS for both the pharmacy and covered entity personnel using system. [BPC 4119.11(a)(6)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE: _____
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C. PHARMACIST RESPONSIBILITIES

Yes No N/A

☐☐☐ 4.1~~9~~7 The operation of the APDS is under the supervision of a licensed pharmacist acting on behalf of the operating pharmacy. [BPC 4119.11(a)(7)]. Note: The pharmacist need not be physically present at the site of the APDS and may supervise the system electronically.

☐☐☐ 4.~~20~~18 The pharmacist performs the stocking of the APDS or if the APDS utilizes removable pockets, cards, drawers, similar technology, or unit of use or single dose containers are used, the stocking of the APDS may be done outside of the facility if the following conditions are met: [BPC 4119.11(g)]

- ☐ 4.~~20~~18.1 A pharmacist, intern pharmacist or pharmacy technician working under the supervision of the pharmacist may place drugs into the removeable pockets, cards, drawers, similar technology, or unit of use or single dose containers. [BPC 4119.11(g)(1)]
- ☐ 4.~~20~~18.2 Transportation of removeable pockets, cards, drawers or similar technology o~~O~~r unit of use or single dose container between the pharmacy and the facility are in a tamper-evident container. [BPC 4119.11(g)(2]
- ☐ 4.~~20~~18.3 There are policies and procedures to ensure the removeable pockets, cards, drawers, similar technology, or unit of use or single dose containers are properly placed into the APDS. [BPC 4119.11(g)(3)]

☐☐☐ 4.~~21~~19 ~~The~~ A pharmacist conducts a monthly review of the APDS including a physical inspection of the drugs contained within, operation, maintenance, and cleanliness of the APDS, and a review of all transaction records in order to verify the security and accountability of the APDS. [BPC 4119.11(h)]

Date of Last Review: _____

☐☐☐ 4.~~22~~20 The Pharmacist-in-charge of the offsite ADDS/APDS has ensured the following: [CCR 1715.65(h)]

☐ 4.20.1 All controlled substances added to the ADDS/APDS are accounted for;
☐ 4.20.2 Access to ADDS/APDS is limited to authorized facility personnel;
☐ 4.20.3 An ongoing evaluation of discrepancies or unusual access associated with controlled substance is performed; and
☐ 4.20.4 Confirmed losses of controlled substances are reported to the Board.

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE:

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D. DEVICE REQUIREMENTS

Yes No N/A

☐☐☐ 4.2~~3~~1 Access to the APDS is controlled and tracked using an identification or password system or biosensor. Systems tracked via password shall include a camera that records a picture of the individual accessing the APDS and the picture must be maintained for a minimum of 180 days. [BPC 4119.11(e)]

~~☐☐☐ 4.24 The APDS makes complete and accurate records of all transactions including users accessing system and drugs added and removed from the APDS. [BPC 4119.11(f)]~~

☐☐☐ 4.2~~5~~2 The APDS will collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of APDS. [BPC 4119.11(c)(1)]

☐☐☐ 4.2~~6~~3 The APDS will maintain transaction information in a readily available in downloadable format for review and inspection by authorized individuals for a minimum of 3 years. [BPC 4119.11(c)(2)]

☐☐☐ 4.2~~7~~4The APDS may dispense medications **DIRECTLY** to the patient if **all** the following are met: [BPC 4119.11(d)]

☐ 4.2~~7~~4.1 The pharmacy has developed, ~~and~~ implemented, and maintained~~s~~ written policies and procedures with respect to all the following and the policies are reviewed annually: [BPC 4119.11(d)(1)~~(d)(1)(F)~~, CCR 1713(e)]

☐ 4.24.1.1 Maintaining the security of the APDS and dangerous drug and devices within the APDS.

☐ 4.24.1.2 Determining ~~e~~ and applying inclusion criteria regarding which drugs~~,~~ and devices are appropriate for placement in the APDS and for which patients, including when consultation is needed.

☐ 4.24.1.3 Ensuring patients are aware that consultation with a pharmacist is available for any prescription medication, including those delivered via APDS.

☐ 4.24.1.4 Describing assignment of responsibilities and training of pharmacy personnel, and other personnel using the APDS at that location, regarding maintenance and filling procedures for the APDS.

☐ 4.24.1.5 Orienting patients on the use of APDS and notifying patients when expected medications are not available in the APDS. The pharmacy must ensure the use of the APDS does not interfere with the delivery of drugs and devices.

☐ 4.24.1.6 Ensuring the delivery of drugs and devices to patients expecting medications from the APDS in the event that the APDS is disabled or malfunctions.

Date of Last Policy Review: _____

☐ 4.2~~7~~4.2 The APDS may only be used for patients who have signed a written consent demonstrating their informed consent to receive prescribed drugs and devices from the APDS. Attach a copy of the consent form to the back of the self-assessment. [BPC 4119.11(d)(2), CCR 1713(d)(1)]

~~Yes No N/A~~

☐ 4.2~~7~~4.3 The ~~device~~ APDS shall have a means to identify each patient and only release the identified patient's drugs and devices to the patient or the patient's agent. [BPC 4119.11(d)(3), CCR 1713(d)(3)]

☐ 4.2~~7~~4.4 The pharmacist has performed all clinical services as part of the dispensing process, including, but not limited to, drug utilization review and consultation. [BPC 4119.11(d)(4)]

☐ 4.2~~7~~4.5 Drugs are dispensed from the APDS only upon authorization from the pharmacist after the pharmacist has reviewed the prescription and the patient's profile for potential~~s~~ contraindications and adverse drug reactions. [BPC 4119.11(d)(5)]

☐ 4.2~~7~~4.6 The pharmacist shall consult patients for the first time on all prescribed drugs and devices dispensed from the APDS. The consultation shall be provided by a Board-licensed pharmacist via telecommunication link that has two-way audio and video capabilities. [BPC 4119.11(d)(6)]

☐ 4.2~~7~~4.7 The APDS shall prominently post a notice that provides the name, address and telephone number of the pharmacy [BPC 4119.11(d)(7)]

☐ 4.2~~7~~4.8 The prescription labels on all drugs dispensed via APDS shall comply with BPC 4076 and CCR 1707.5. [BPC 4119.11(d)(8)]

~~☐☐☐ 4.27.9 Any complaint, error or omission involving the APDS shall be reviewed as a part of the pharmacy's quality assurance program pursuant to BPC 4125. [BPC 4119.11(d)(9)]~~

☐☐☐ 4.2~~8~~5 The federal warning label prohibiting transfer of controlled substances is on the prescription container. [21 CFR 290.5]

Yes No N/A

☐☐☐ 4.2~~9~~6 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]

☐☐☐ 4.~~30~~27 Patient package inserts are dispensed with all estrogen medications. [21 CFR 310.515]

☐☐☐ 4.~~31~~28 The pharmacy provides patients with Black Box Warning Information in conformance with 21 CFR 201.57(c).

☐☐☐ 4.~~32~~29Medication guides are provided on required medications. [~~(~~21 CFR 208.1]~~)~~

☐☐☐ 4.30 The pharmacy uses the APDS to deliver prescription medications to patients as provided: [CCR 1713(d)]

- ☐ 4.30.1 The pharmacist has determined that each patient using the APDS met the inclusion criteria for use of the APDS established by the pharmacy prior to the delivery of the prescription medication to the patient.
- ☐ 4.30.2 The APDS has a means to identify each patient and only release the patient's prescription medications to the patient or patient's agent.
- ☐ 4.30.3 The pharmacy provides an immediate consultation with a pharmacist, either in-person or via telephone, upon the request of a patient.
- ☐ 4.30.4 Any incident involving the APDS where a complaint, deliver error, or omission has occurred shall be reviewed as part of the pharmacy's quality assurance program mandated by Business and Professions Code section 4125.

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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E. RECORD KEEPING REQUIREMENTS

Yes No N/A

~~☐☐☐ 4.33 The operating pharmacy has complied with all recordkeeping and quality assurance requirements pursuant to BPC 4119.11 and those records shall be maintain within the pharmacy holding the APDS and separately from the other pharmacy records. [BPC 4119.11(j)]~~

~~☐☐☐ 4.34 The operating pharmacy will maintain records of acquisition and disposition of dangerous drugs stored in the APDS separate from other pharmacy records. [BPC 4119.11(a)(4)]~~

☐☐☐ 4.3~~5~~1 Any records maintained electronically must be maintained so that the pharmacist-in-charge, or the pharmacist on duty if the pharmacist-in-charge is not on duty, must, at all times during which the licensed premises are open for business, be able to produce a hardcopy and electronic copy of all records of acquisition and disposition or other drug or dispensing-related records maintained electronically. [BPC 4105(d)(1)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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F. POLICIES AND PROCEDURES

Yes No N/A

☐☐☐ 4.3~~6~~2 The pharmacy has developed and implemented written policies and procedures with respect to all the following and the policies are reviewed annually [BPC 4119.11(d)(1), CCR 1713(e)]:

- ☐ 4.32.1 Maintaining the security of the APDS and dangerous drugs and devices within the APDS.
- ☐ 4.32.2 Determine and apply inclusion criteria regarding which drugs, devices are appropriate for placement in the APDS and for which patients, including when consultation is needed.
- ☐ 4.32.3 Ensuring patients are aware that consultation with a pharmacist is available for any prescription medication including those delivered via APDS.
- ☐ 4.32.4 Describing assignment of responsibilities and training of pharmacy personnel and other personnel using the APDS at that location regarding maintenance and filling procedures for the APDS.
- ☐ 4.32.5 Orienting patients on use of the APDS and notifying patients when expected medications are not available in the APDS. The pharmacy must ensure the use of the APDS does not interfere with the delivery of drugs and devices.
- ☐ 4.32.6 Ensuring the delivery of drugs and devices to patients expecting medications from the APDS ~~in the event~~ if the APDS is disabled or malfunctions.

Date of Last Policy Review: _____

☐☐☐ 4.3~~7~~3 The pharmacy has policies and procedures for security measures and monitoring of the inventory to prevent theft and diversion. [BPC 4427.2(d)(3)~~4105.5(c)(2)~~]

☐☐☐ 4.3~~8~~4 The pharmacy reports drug losses as required by law. [BPC 4104, 4427.2(d)(4)~~4105.5(c)~~, CCR 1715.6, 21 CFR 1301.76]

Last Reported Drug Loss: _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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SECTION 5: ~~ADDS~~

- ☐ **APDS ADJACENT TO THE SECURED PHARMACY AREA ~~OR~~**
- ☐ **APDS LOCATED IN MEDICAL OFFICES ~~(OR)~~**
- ☐ **APDS A LOCATION WHERE PATIENTS ARE REGULARLY SEEN FOR PURPOSES OF DIAGNOSIS AND TREATMENT TO ONLY BE USED FOR PATIENTS OF THE PRACTICE~~(OR).~~**
- ☐ **APDS THROUGH A CLINIC PURSUANT TO HSC 1204 OR 1204.1 OR BPC 4180 OR 4190.**

A. GENERAL REQUIREMENTS

Yes No N/A

☐☐☐ 5.1 The pharmacy maintains the APDS policies and procedures for 3 years after the last date of use for that APDS. [BPC 4427.6(l), CCR 1713(f)]

~~☐☐☐ 5.2 The pharmacy developed and implemented, and reviewed annually the APDS policy and procedures pertaining to the APDS, including: [BPC 4427.6(a)]~~

- ~~Maintaining the security of the APDS and the dangerous drugs and devices within the APDS.~~
- ~~Determining and applying inclusion criteria regarding which drugs and devices are appropriate for placement in the APDS and for which patients.~~
- ~~Ensuring patients are aware consultation with a pharmacist is available for any prescription medications, including those delivered via the APDS.~~
- ~~Describing assignment of responsibilities to, and training of, pharmacy personnel and other personnel using the APDS at the location where the APDS is placed, regarding maintenance and filing procedures for the APDS.~~
- ~~Orienting participating patients on the use of the APDS, notifying patients when expected prescription medications are not available in the APDS, and ensuring patient use of the APDS does not interfere with delivery of drugs and devices.~~
- ~~Ensuring delivery of drugs and devices to patients expecting to receive them from the APDS in the event the APDS is disabled or malfunctions.~~

☐☐☐ 5.2 The pharmacy uses the APDS to deliver prescription medications to patients provided: [CCR 1713(d)]

☐ 5.2.1 A pharmacist has determined that each patient using the APDS meets inclusion

criteria for use of the APDS established by the pharmacy prior to deliver of prescription medication to the patient.

☐ 5.2.2 The APDS has a means of identifying each patient and only release that patient's prescription medication to the patient or patient's agent.

☐ 5.2.3 The pharmacy provides an immediate consultation with a pharmacist, either in-person or via telephone, upon the request of a patient.

☐ 5.2.4 Any incident involving the APDS where a complaint, delivery error, or omission has occurred shall be reviewed as part of the pharmacy's quality assurance program mandated by Business and Professions Code section 4125.

Yes No N/A

☐☐☐ 5.3 The pharmacy does not have more than 15 APDS licenses for one underlying operating pharmacy under this section. [BPC 4427.6(k)] List of current APDS licenses:

1._____ 2. _____

3._____ 4. _____

5._____ 6. _____

7._____ 8. _____

9._____ 10._____

11. _____ 12._____

13._____ 14. _____

15. _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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B. PHARMACIST RESPONSIBILITIES:

Yes No N/A

☐☐☐ 5.4 A pharmacist licensed by the board performs all clinical services conducted as part of the dispensing process, including, but not limited to, drug utilization review and consultation. [BPC 4427.6(d)]

☐☐☐ 5.5 Drugs are dispensed from the APDS only upon authorization from the pharmacist after the pharmacist has reviewed the prescription and the patient's profile for potential contraindications and adverse drug reactions. [BPC 4427.6(e)]

Yes No N/A

☐☐☐ 5.6 ~~The pharmacist shall consult patients for the first time on all prescribed drugs and devices dispensed from the APDS.~~ All prescribed drugs and devices dispensed to the patient from the APDS for the first time are accompanied by a consultation conducted by a California licensed pharmacist. The consultation shall be provided by a Board licensed pharmacist via telecommunication link that has two-way audio and video capabilities. [BPC 4427.6(f)]

~~Yes No N/A~~

☐☐☐ 5.7 The ~~P~~pharmacist-in-charge of the offsite ADDS/APDS has ensured the following: [CCR 1715.65(h)]

- ☐ 5.7.1 All controlled substances added to the ADDS/APDS are accounted for;
- ☐ 5.7.2 Access to ADDS/APDS is limited to authorized facility personnel;
- ☐ 5.7.3 An ongoing evaluation of discrepancies or unusual access associated with controlled substance is performed; and
- ☐ 5.7.4 Confirmed losses of controlled substances are reported to the Board.

~~☐☐☐ 5.8. The pharmacy operating the APDS has completed an annual Self-Assessment pursuant to CCR 1715 evaluating the pharmacy's compliance with pharmacy law relating to the use of the APDS. [BPC 4427.7(a)]~~

~~Date of Last Self-Assessment: _____~~

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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C. DEVICE REQUIREMENTS:

~~Yes No N/A~~

~~☐☐☐ 5.9 The stocking of the APDS is performed by a pharmacist, or by a pharmacy technician or intern pharmacist under the supervision of a pharmacist, except for an APDS located in a health facility pursuant to HSC 1250, where the stocking and restocking of the APDS may be performed in compliance with HSC 1261.6. [BPC 4427.4(e)(1)]~~

~~☐☐☐ 5.10 Access to the APDS is controlled and tracked using an identification or password system or biosensor. [BPC 4427.4(e)(2)]~~

~~☐☐☐ 5.11 The ADDS makes a complete and accurate record of all transactions including all users accessing the system and all drugs added to, or removed from, the system. [BPC 4427.4(e)(3)]~~

~~☐☐☐ 5.12 Drugs and devices not immediately transferred into an APDS upon arrival at the APDS location are stored for no longer than 48 hours in a secured room within the APDS location. Upon retrieval of these drugs and devices from secured storage, an inventory is taken to detect any losses or overages. [BPC 4427.4(f)]~~

~~☐☐☐ 5.13 Drugs stored in the APDS are part of the inventory of the operating pharmacy and drugs dispensed by the APDS shall be considered to have been dispensed by the pharmacy. [BPC 4427.4(d)]~~

Yes No N/A

☐☐☐ 5.~~14~~8 The APDS may only be used for patients who have signed a written consent demonstrating their informed consent to receive prescribed drug and devices from the APDS. Attach a copy of the consent form to the back of the self-assessment. [BPC 4427.6(b)]

☐☐☐ 5.~~15~~9 The APDS has a means to identify each patient and only release the identified patient's drugs and devices to the patient or the patient's agent. [BPC 4427.6(c)]

☐☐☐ 5.~~16~~10 The APDS has a notice, prominently posted on the APDS, which provides the name, address, and phone number of the pharmacy. [BPC 4427.6(g)]

☐☐☐ 5.~~17~~11 Any incident involving the APDS where a complaint, error, or omission occurred is reviewed as part of the pharmacy's quality assurance program pursuant to BPC 4125. [BPC 4427.6(i)]

☐☐☐ 5.~~18~~12 If the APDS is located and operated in a medical office or other location where patients are regularly seen for purposes of diagnosis and treatment, the APDS is only used to dispense dangerous drugs and dangerous devices to patients of the practice. [BPC 4427.6(j)]

☐☐☐ 5.~~19~~13 The labels on all drugs and devices dispensed by the APDS comply with section 4076 and with section 1707.5 of Title 16 of the California Code of Regulations. [BPC 4427.6(h)]

☐☐☐ 5.~~20~~14 The federal warning label prohibiting transfer of controlled substances is on the prescription container. [21 CFR 290.5]

☐☐☐ 5.~~21~~15 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]

☐☐☐ 5.~~22~~16 Patient package inserts are dispensed with all estrogen medications. [21 CFR 310.515]

☐☐☐ 5.~~23~~17 The pharmacy provides patients with Black Box Warning Information in conformance with 21 CFR 201.57(c).

☐☐☐ 5.~~24~~18 Medication guides are provided on required medications. [21 CFR 208.1]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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D. RECORD KEEPING REQUIREMENTS

Yes No N/A

~~☐☐☐ 5.25 The operating pharmacy has complied with all recordkeeping and quality assurance requirements pursuant to BPC 4427.6 and those records shall be maintain within the pharmacy holding the APDS and separately from the other pharmacy records. [BPC 4427.7(b)]~~

☐☐☐ 5.~~26~~19 The operating pharmacy will maintain records of acquisition and disposition of dangerous drugs stored in the APDS separate from other pharmacy records. [BPC 4119.11(a)(4)]

☐☐☐ 5.~~27~~20 Any records maintained electronically must be maintained so that the pharmacist-in-charge, or the pharmacist on duty if the pharmacist-in-charge is not on duty, must, at all times during which the licensed premises are open for business, be able to produce a hardcopy and electronic copy of all records of acquisition and disposition or other drug or dispensing-related records maintained electronically. [BPC 4105(d)(1)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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E. POLICIES AND PROCEDURES

Yes No N/A

☐☐☐ 5.~~28~~21 The pharmacy has developed and implemented written policies and procedures with respect to all the following and the policies are maintained and reviewed annually: [BPC 4427.6(a)~~, 4427.6(a)(6)~~, CCR 1713(e)]

- ☐ 5.21.1 Maintaining the security of the APDS and dangerous drug and devices within the APDS.
- ☐ 5.21.2 Determining~~e~~ and applying inclusion criteria regarding which drugs and~~,~~ devices are appropriate for placement in the APDS and for which patients.
- ☐ 5.21.3 Ensuring patients are aware that consultation with a pharmacist is available for any prescription medication including those delivered via APDS.
- ☐ 5.21.4 Describing assignment of responsibilities and training of pharmacy personnel

and other personnel using the APDS at that location regarding maintenance and filling procedures for the APDS.

☐ 5.21.5 Orienting patients on use of APDS and notifying patients when expected medications are not available in the APDS. The pharmacy must ensure the use of the APDS does not interfere with the delivery of drugs and devices.

☐ 5.21.6 Ensuring the delivery of drugs and devices to patients expecting medications from the APDS in the event the APDS is disabled or malfunctions.

Date of Last Policy Review: _____

Yes No N/A

☐☐☐ 5.~~29~~22 The pharmacy reports drug losses as required by law. [BPC 4104, 4427.2(d)(4)~~4105.5(c)~~, CCR 1715.6, 21 CFR 1301.76]

Last Reported Drug Loss: _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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SECTION 6: ADDS IN A HEALTH FACILITY PURSUANT TO HSC 1250 ~~– LONG TERM CARE FACILITIES~~ THAT COMPLIES WITH HSC 1261.6

A. GENERAL REQUIREMENTS

For purposes of this section, "FACILITY" means any health facility licensed pursuant to ~~subdivision (c), (d), or (k) of~~ section 1250 of the Health and Safety Code that has an ADDS provided by a pharmacy. [HSC ~~1261.6(a)(2)~~ 1250]

For purposes of this section, "PHARMACY SERVICES" means the provision of both routine and emergency drugs and biologicals to meet the needs of the patient, as prescribed by a physician. [HSC 1261.6(a)(3)]

Yes No N/A

~~☐☐☐ 6.1 The facility and the pharmacy has developed and implemented written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the ADDS as well as quality, potency, and purity of the stored drugs and devices. [BPC 4427.3(c), HSC 1261.6 (d)(1)]~~

☐☐☐ 6.~~2~~1The ADDS policies and procedures define access to the ADDS and limits to access to equipment and drugs. [HSC 1261.6(d)(1)]

~~☐☐☐ 6.3 All ADDS policies and procedures are maintained at the pharmacy and the location where the ADDS is being used. [HSC 1261.6(d)(2), BPC 4427.3(c)]~~

☐☐☐ 6.~~4~~2 The pharmacy is responsible for review of drugs contained within the ADDS and the operation and maintenance of the ADDS. [HSC 1261.6(h)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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B. PHARMACIST RESPONSIBILITIES:

Yes No N/A

☐☐☐ 6.~~5~~3 The stocking of the ADDS is performed by a pharmacist, or, if the ADDS utilizes removable pockets, cards, drawers, similar technology, or unit of use or single dose containers ~~are used~~, the stocking system may be done outside the facility and be delivered to the facility if the following conditions are met: [HSC 1261.6(g)]

- ☐ 6.~~5~~3.1 The task of placing drugs into the removeable pockets, cards, drawers, or unit or use or single dose containers is performed by a pharmacist, or by an intern pharmacist or a pharmacy technician under the direct supervision of a pharmacist. [HSC 1261.6(g)(1)]
- ☐ 6.~~5~~3.2 The removable pockets, cards, drawers, or unit of use or single dose containers are transported between the pharmacy and the facility in a secure tamper-evident container. [HSC 1261.6(g)(2)]
- ☐ 6.~~5~~3.3 The facility, in conjunction with the pharmacy, has developed policies and procedures to ensure that the removable pockets, cards, drawers, or unit of use or single dose containers are properly placed into the ADDS. [HSC 1261.6(g)(3)]

Yes No N/A

☐☐☐ 6.~~6~~4 Individualized and specific access to the ADDS is limited to facility and contract personnel authorized by law to administer drugs. [HSC 1261.6(c)]

☐☐☐ 6.~~7~~5 A pharmacist reviews and approves all orders prior to a drug being removed from the ADDS for administration to a patient. The pharmacist reviews the prescriber's orders and the patient's profile for potential contraindications and adverse drug reactions. [HSC 1261.6(f)(2)]

☐☐☐ 6.6 A Schedule II controlled substance for a patient in a licensed skilled nursing facility or licensed intermediate care facility is dispensed only after the pharmacist has received:

- ☐ 6.6.1 An **orally transmitted** prescription for a Schedule II controlled substance from the prescriber and only after the pharmacist reduced the prescription to writing in ink in the handwriting of the pharmacist on a form developed by the pharmacy. The prescription must contain: [HSC 11167.5(a)]
  - ☐ 6.6.1.1 The date the prescription was orally transmitted by the prescriber.
  - ☐ 6.6.1.2 The name of the person for whom the prescription was authorized.

☐ 6.6.1.3 The name and address of the licensed skilled nursing facility or licensed intermediate care facility in which the person is the patient.

☐ 6.6.1.4 The name and quantity of the controlled substance prescribed.

☐ 6.6.1.5 The directions for use, and the name, address, category of the professional licensure, license number, and federal controlled substance registration number of the prescriber.

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

☐ 6.6.2 Prior to filling a prescription for a Schedule II controlled substance that has been **electronically transmitted,** the pharmacist has produced, signed, and dated a hard copy prescription. The prescription must contain: [HSC 11167.5(a)]

☐ 6.6.2.1 The date the prescription was electronically transmitted by the prescriber;

☐ 6.6.2.2 The name of the person for whom the prescription was authorized;

☐ 6.6.2.3 The name and address of the licensed skilled nursing facility or licensed intermediate care facility in which the person is the patient;

☐ 6.6.2.4 The name and quantity of the controlled substance prescribed;

☐ 6.6.2.5 The directions for use, and the name, address, category of the professional licensure, license number, and federal controlled substance registration number of the prescriber.

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

☐ 6.6.2.7 The prescription contains the signature of the person who received the controlled substance for the licensed skilled nursing facility or licensed intermediate care facility.

☐ 6.6.3 An original Schedule II prescription is written on a form that complies with Health and Safety Code section 11162.1. [HSC 11164(a)]

☐ 6.6.4 An original Schedule II prescription is written with the "11159.2 exemption" for the terminally ill. [HSC 11159.2]

☐ 6.6.5 In an emergency where failure to issue the prescription may result in loss of life or intense suffering, a Schedule II controlled substance may be dispensed from a prescription transmitted orally or electronically by a prescriber or written on a form not as specified in HSC 11162.1, subject to the following: [HSC 11167(a)-(c)]

☐ 6.6.5.1 The order contains all information required by subdivision (a) of Section 11164.

☐ 6.6.5.2 If the order is written by the prescriber, the prescription is in ink, signed, and dated by the prescriber.

☐ 6.6.5.3 If the prescription is orally or electronically transmitted, it must be reduced to hard copy.

☐ 6.6.5.4 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.

☐ 6.6.6 An electronic prescription (e-script) for controlled substances that is received from the prescriber and meets federal requirements. [21 CFR 1306.08, 21 CFR 1311]

Yes No N/A

☐☐☐ 6.~~8~~7 The review of the drugs contained within the ADDS and the operation and maintenance of the ADDS is conducted, on a monthly basis, by a pharmacist. The review includes a physical inspection of the ADDS for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system. [HSC 1261.6(h)]

Date of Last Review: _____

☐☐☐ 6.~~9~~8 The p~~P~~harmacist-in-charge of the offsite ADDS has ensured the following: [CCR 1715.65(h)]

- ☐ 6.8.1 All controlled substances added to the ADDS are accounted for;
- ☐ 6.8.2 Access to ADDS is limited to authorized facility personnel;
- ☐ 6.8.3 An ongoing evaluation of discrepancies or unusual access associated with controlled substance is performed; and
- ☐ 6.8.4 Confirmed losses of controlled substances are reported to the Board.

☐☐☐ 6.~~10~~9 The pharmacy operating the ADDS has completed a~~n~~ biennial Self-Assessment pursuant to BPC 4427.7(a) evaluating the pharmacy's compliance with pharmacy law relating to the use of the APDS. ~~(~~[BPC 4427.7(a)]~~)~~

Date of Last Self-Assessment: _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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C. DEVICE REQUIREMENTS:

Yes No N/A

☐☐☐ 6.~~11~~10 The stocking and restocking of the ADDS is performed in compliance with section 1261.6 of the Health and Safety Code. [BPC 4427.4(e)(1), HSC 1261(c), (g)]

~~☐☐☐ 6.12 Drugs and devices not immediately transferred into an ADDS upon arrival at the ADDS location are stored for no longer than 48 hours in a secured room within the ADDS location. Upon retrieval of these drugs and devices from secured storage, an inventory is taken to detect any losses or overages. [BPC 4427.4(f)]~~

~~Yes No N/A~~

☐☐☐ 6.~~13~~11 Transaction information from the ADDS will be made readily available in a written format for review and inspection by individuals authorized by law and maintained in the facility for a minimum of three years. [HSC 1261.6(b)]

☐☐☐ 6.~~14~~12 The information required by BPC section 4076 and HSC 111480 is readily available at the time of drug administration if unit dose packaging or unit of use packaging is used. Unit dose packaging, for purposes of this section, includes blister pack cards. [HSC 1261.6(i)]

When the ADDS is used as an emergency pharmaceutical supplies container, drugs removed from the ADDS are limited to the following [HSC 1261.6(e)]:

~~Yes No N/A~~

☐☐☐ 6.~~15~~13 A new drug order given by a prescriber for a patient of the facility for administration prior to the next scheduled delivery from the pharmacy, or 72 hours, whichever is less. The drug is retrieved only upon the authorization of a pharmacist and after the pharmacist has reviewed the prescriber's order and the patient's profile for potential contraindications and adverse drug reactions. [HSC 1261.6(e)(1)]

☐☐☐ 6.~~16~~14 Drugs that a prescriber has ordered for a patient on an as-needed basis, if the utilization and retrieval of those drugs are subject to ongoing review by a pharmacist. [HSC 1261.6(e)(2)]

☐☐☐ 6.~~17~~15 Drugs designed by the patient care policy committee or pharmaceutical service committee of the facility as emergency drugs or acute onset drugs. These drugs are retrieved from the ADDS pursuant to the order of a prescriber for emergency or immediate administration to a patient of the facility and reviewed by a pharmacist within 48 hours. [HSC 1261.6(e)(3)]

When the ADDS is used to provide pharmacy services pursuant to BPC 4017.3, the ADDS is subject to the following requirements [HSC 1261.6(f)]:

~~Yes No N/A~~

☐☐☐ 6.~~18~~16 Drugs removed from the ADDS for administration to a patient are in properly labeled units of administration containers or packages. [HSC 1261.6(f)(1)]

☐☐☐ 6.~~19~~17 A pharmacist reviews and approves all orders prior to a drug being removed from the ADDS for administration to a patient. The pharmacist reviews the prescriber's orders and the patient's profile for potential contraindications and adverse drug reactions. [HSC 1261.6(f)(2)]

☐☐☐ 6.~~20~~18 The pharmacy controls access to the drugs stored in the ADDS. [HSC 1261.6(f)(3)]

~~☐☐☐ 6.21 Access to the ADDS is controlled and tracked using an identification or password system or biosensor. [BPC 4427.4(e)(2), HSC 1261.6(f)(4)]~~

~~☐☐☐ 6.22 The ADDS makes a complete and accurate record of all transactions that includes all users accessing the system and all drugs added to, or removed from, the system. [BPC 4427.4(e)(3), HSC 1261.6(f)(5)]~~

Yes No N/A

☐☐☐ 6.~~23~~19 After the pharmacist reviews the prescriber's order, access by licensed personnel to the ADDS is limited only to drugs ordered by the prescriber and reviewed by the pharmacist and that are specific to the patient. [HSC 1261.6(f)(6)]

☐☐☐ 6.~~24~~20 When the prescriber's order requires a dosage variation of the same drug, licensed personnel only have access to the drug ordered for that scheduled time of administration. [HSC 1261.6 (f)(6)]

☐☐☐ 6.~~25~~21 If the ADDS allows licensed personnel to have access to multiple drugs and ~~are~~ is not patient specific in its~~their~~ design, the ADDS has electronic and mechanical safeguards in place to ensure that the drugs delivered to the patient are specific to that patient. ~~(~~[HSC 1261.6(f)(7)]~~)~~.

Please Note: A skilled nursing facility or intermediate care facility using an ADDS that allows licensed personnel to have access to multiple drugs is required to contact the California Department of Public Health, Licensing, and Certification in writing prior to utilizing this type of ADDS. [HSC 1261.6(f)(7)(A)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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D. RECORD KEEPING REQUIREMENTS

~~Yes No N/A~~

~~☐☐☐ 6.26 The pharmacy complies with all recordkeeping and quality assurance requirements, established in pharmacy law and regulation, and maintains those records within the licensed pharmacy holding the ADDS license and separate from the other pharmacy records. [BPC 4427.7(b)]~~

Yes No N/A

☐☐☐ 6.~~27~~22 Transaction information from the ADDS will be made readily available in a written format for review and inspection by individuals authorized by law and maintained in the facility for a minimum of three years. [HSC 1261.6(b)]

☐☐☐ 6.23 Records of inspections completed by the pharmacist are kept for at least three years. [HSC 1261.6(b), 22 CCR 70263(f)(3)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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E. POLICIES AND PROCEDURES

Yes No N/A

☐☐☐ 6.~~28~~24 The facility and the pharmacy has developed and implemented written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the ADDS as well as quality, potency, and purity of the stored drugs and devices. [BPC 4427.3(c), HSC 1261.6(d)(1)]

☐☐☐ 6.~~29~~25 The ADDS policies and procedures define access to the ADDS and limits to access to equipment and drugs. [HSC 1261.6(d)(1)]

☐☐☐ 6.~~30~~26 All ADDS policies and procedures are maintained at the pharmacy and the location where the ADDS is being used. [HSC 1261.6(d)(2), BPC 4427.3(c)]

☐☐☐ 6.~~31~~27 The facility, in conjunction with the pharmacy, has developed policies and procedures to ensure that the removable pockets, cards, drawers, or unit of use or single dose containers are properly placed into the ADDS. [HSC 1261.6(g)(3)]

~~☐☐☐ 6.32 The pharmacy has policies and procedures that include appropriate security measures and monitoring of the inventory to prevent theft and diversion. [BPC 4427.2(d)(3)]~~

☐☐☐ 6.~~33~~28 The pharmacy's policies and procedures include provisions for reporting to the board drug losses from the ADDS inventory, as required by law. [BPC 4104, 4427.2(d)(4), CCR 1715.6, 21 CFR 1301.76]

Last Reported Drug Loss: _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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~~**SECTION 7: APDS THROUGH A CLINIC PURSUANT TO HSC 1204 OR 1204.1 OR BPC 4180 OR 4190**~~

A. GENERAL REQUIREMENTS

Yes No N/A

☐☐☐ 7.1 The ADDS is located inside an enclosed building with a premises address, at a location approved by the Board [BPC 4427.3 (a)]. The clinic has a current Board of Pharmacy Clinic license pursuant to BPC 4180 or BPC 4190? or the clinic is licensed pursuant to HSC 1204 or 1204.1. [BPC 4427.3(b)(3)]

License number: _____ Expiration Date: _____

☐☐☐ 7.2 The clinic has developed and implemented written policies and procedures that ensure the safety, accuracy, accountability, security and patient confidentiality. Additionally, the policies and procedures shall ensure the maintenance of the quality, potency and purity of the drugs. **The policies and procedures shall be maintained at the location where the ADDS is being used.** [BPC 4186(a)]

☐☐☐ 7.3 Drugs removed from the ADDS shall be provided to the patient by a health professional licensed pursuant to BPC 4186(b).

☐☐☐ 7.4 The clinic is responsible for the review of the drugs contained within, and the operation and maintenance of, the ADDS. [BPC 4186(d)]

☐☐☐ 7.5 Drugs dispensed from the clinic ADDS shall comply with labeling requirements in BPC 4076 with CCR 1707.5. [BPC 4186(g), 4426.7(h)]

☐☐☐ 7.6 The clinic shall keep records of the kind and amounts of drugs purchased, administered, and dispensed and the records shall be available and maintained for a minimum of three years for inspection by all authorized personnel. [BPC 4180(a)(2)]

☐☐☐ 7.7 The proposed ADDS installation location meets the requirement of BPC 4427.3 and the ADDS is secure from access and removal by unauthorized individuals. [BPC 4427.2(d)(2)]

☐☐☐ 7.8 The clinics licensed under BPC 4180 or BPC 4190 perform periodic inventory and inventory reconciliation functions to detect and prevent the loss of controlled substances. [CCR 1715.65(a)]

☐☐☐ 7.9 The clinic shall compile an inventory reconciliation report of all **federal Schedule II controlled substance** at least every three months. [CCR 1715.65(c)] The compilation requires:

- A physical count (not estimate) of all quantities of all **federal Schedule II controlled substances.**
- A review of all acquisition and disposition records of **federal Schedule II controlled substances** since that last inventory reconciliation report.

Date of last inventory_____

- A comparison of (1) and (2) to determine if there are any variances.
- All records used to compile each inventory reconciliation report shall be maintained at clinic for 3 years in a readily retrievable form.
- Possible causes of overages shall be identified in writing and incorporated into the inventory reconciliation report.

Yes No N/A

☐☐☐ 7.10 The clinic shall report in writing identified drug losses and known cause to the Board within 30 days of discovery. Cases of the loss is due to theft, diversion or self-use shall be reported to the Board within 14 days of discovery. If the clinic is unable to identify the cause of loss, further investigation shall be undertaken to identify the cause and actions necessary to prevent additional losses of controlled substances. [CCR 1715.65(d)]

☐☐☐ 7.11 The individuals performing the inventory AND the clinic professional director shall date and sign the inventory reconciliation reports. The reports shall be readily retrievable at the clinic for 3 years. [CCR 1715.65(e)]

☐☐☐ 7.12 Any incident involving the APDS where a complaint, error, or omission has occurred is reviewed as part of the pharmacy's quality assurance program pursuant to BPC 4125. [BPC 4427.6(i)]

☐☐☐ 7.13 The federal warning label prohibiting transfer of controlled substances is on the prescription container. [21 CFR 290.5]

☐☐☐ 7.14 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]

☐☐☐ 7.15 Patient package inserts are dispensed with all estrogen medications. [21 CFR 310.515]

☐☐☐ 7.16 The pharmacy provides patients with Black Box Warning Information in conformance with 21 CFR 201.57(c).

☐☐☐ 7.17 Medication guides are provided on required medications. [21 CFR 208.1]

☐☐☐ 7.18 Is the APDS located and operated only used to dispense dangerous drugs and dangerous devices to patients of the clinic? [BPC 4427.6j)]

☐☐☐ 7.19 Does the pharmacy have no more than 15 ADDS licensed as APDS units? [BPC 4427.6(k)]
List of current APDS licenses:

1. _____ 2. _____

3._____ 4._____

5._____ 6._____

7._____ 8._____

9._____ 10._____

11._____ 12._____

13._____ 14._____

15._____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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B. PHARMACIST RESPONSIBILITY

Yes No N/A

☐☐☐ 7.20 The pharmacist performs the stocking of the ADDS. [BPC 4186(c)]

☐☐☐ 7.21 Drugs are removed from the ADDS system only upon the authorization of the pharmacist after the pharmacist has reviewed the prescription and patient profile for potential contraindications and adverse drug reactions. [BPC 4186(b)]

☐☐☐ 7.22 The pharmacist shall conduct a review on a monthly basis including a physical inspection of the drugs in the ADDS for cleanliness and a review of all transaction records in order to verify the security and accountability of the ADDS. [BPC 4186(d)]

Date of Last Review: _____

☐☐☐ 7.23 The pharmacist licensed by the board performs all clinical services conducted as part of the dispensing process, including, but not limited to, drug utilization review and consultation. [BPC 4427.6(d)]

Yes No N/A

☐☐☐ 7.24 Drugs are dispensed from the APDS after the pharmacist has reviewed the prescription and the patient's profile for potential contraindications and adverse drug reactions. [BPC 4427.6(e)]

☐☐☐ 7.25 All prescribed drugs and devices dispensed to the patient from an APDS for the first time shall be accompanied by a consultation conducted by a pharmacist licensed by the board via telecommunication link with a two-way audio and video. [BPC 4427.6(f)]

☐☐☐ 7.26 The APDS has a notice, prominently posted on the APDS, with the name, address, and phone number of the pharmacy holding the ADDS license for the APDS. [BPC 4427.6(g)]

☐☐☐ 7.27 The pharmacist shall provide patient consultation pursuant to CCR 1707.2 via a two-way audio and video telecommunication link for drugs dispensed by the clinic ADDS. [BPC 4186(e)]

☐☐☐ 7.28 The pharmacist operating the ADDS shall be located in California. [BPC 4186(f)]

☐☐☐ 7.29 The clinic consultant pharmacist shall review all inventory and inventory reconciliation reports taken and establish and maintain secure methods to prevent losses of controlled substances. The clinic shall develop written policies and procedures for performing the inventory reconciliation reports. (CCR 1715.65(b))

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

C. POLICIES AND PROCEDURES

Yes No N/A

☐☐☐ 7.32 The pharmacy has developed and implemented, and reviewed annually, written policies and procedures pertaining to the APDS, including all the following: [BPC 4427.6(a)]

- Maintaining the security of the APDS and dangerous drugs and dangerous devices within the APDS.
- Determining and applying inclusion criteria regarding which drugs and devices are appropriate for placement in the APDS and for which patients.
- Ensuring patients are aware consultation with a pharmacist is available for any prescription medication, including those delivered via the APDS.
- Describing assignments of responsibilities to, and training of, pharmacy personnel, and other personnel using the APDS at the location where the APDS is placed pursuant to subdivision (b) of section 4427.3, regarding maintenance and filing procedures for the APDS.
- Orienting participating patients on the use of the APDS, notifying patient when expected prescription medications are not available in the APDS, and ensuring the patient use of the APDS does not interfere with delivery of drugs and devices.
- Ensuring delivery of drugs and devices to patients expecting to receive them from the APDS in the event the APDS is disabled or malfunctions.

Date of Last Policy Review: _____

Yes No N/A

☐☐☐ ~~7.33 Is the APDS only used for patients who have signed a written consent form demonstrating their informed consent to receive prescribed drugs and devices from an APDS, and whose use of the APDS meets inclusion criteria established by policies and procedures. [BPC 4427.6(b)]~~

☐☐☐ ~~7.34 The APDS shall have a means of identifying each patient and only release the identified patient's drugs and devices to the patient or patient's agent. [BPC 4427.6(c)]~~

☐☐☐ ~~7.35 The pharmacy holding the ADDS license for an APDS maintains its policies and procedures for three (3) years after the last date of use of an APDS. [BPC 4427.6(l)]~~

☐☐☐ ~~7.36 Does the pharmacy maintain all recordkeeping and quality assurance requirements established in pharmacy law and regulations, and maintain these records within the licensed pharmacy holding the ADDS license and separate from other pharmacy records. [BPC 4427.7(b)]~~

SECTION ~~8~~7: ADDS OPERATED BY A CORRECTIONAL CLINIC

A. GENERAL REQUIREMENTS

Yes No N/A

☐☐☐ 7~~8~~.1 The pharmacy uses an "automated drug delivery system" used in a correctional clinic, meaning a mechanical system controlled remotely by a pharmacist that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of prepackaged dangerous drugs or dangerous devices. An automated drug delivery system shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability. [BPC 4187.5(h)]

☐☐☐ 7~~8~~.2 The ADDS is located in a "correctional clinic," a primary care clinic, as referred to in subdivision (b) of section 1206 of the Health and Safety Co~~n~~de, conducted, maintained, or operated by the state to provide health care eligible patients of the Department of Corrections and Rehabilitation. ~~(~~[BPC 4187(a)].

~~Yes No N/A~~

☐☐☐ 7~~8~~.3 The correctional clinic licensed by the board obtains the drugs from a licensed correctional pharmacy, the Department of Correction and Rehabilitation's Central Fill Pharmacy, or from another correctional clinic licensed by the board within the same institution for the administration or dispensing of drugs or devices to patients eligible for care at the correctional facility if under either: [BPC 4187.1(a), 4187.2]

- The direction~~s~~ of a physician and surgeon, dentist, or other person lawfully authorized to prescribe.
- An approved protocol as identified within the ~~statewide Inmate Medical Services Policies and Procedures.~~ California Correctional Health Care Services Health Care Department Operations Manual. [BPC 4187.2]

☐☐☐ 7~~8~~.4 The dispensing or administering of drugs in the correctional clinic is performed pursuant to a chart order, as defined in section 4019, a valid prescription consistent with chapter 9 division 2 of the Business and Professions Code, or pursuant to an approved protocol as identified within the ~~statewide Inmate Medical Services Policies and Procedures.~~ California Correctional Health Care Services Health Care Department Operations Manual. [BPC 4187.1(b), 4187.2]

Yes No N/A

☐☐☐ 7~~8~~.5 Medications dispensed to patients that are kept on the patient's person for use shall meet the labeling requirements of section 4076 and all record~~-~~keeping requirements of chapter 9 division 2 of the Business and Professions Code. [BPC 4187.1(b)]

☐☐☐ 7~~8~~.6 The correctional clinic keeps records of the kind and amounts of drugs acquired, administered, transferred, and dispensed. The records must be readily available and maintained for a minimum of three years for inspection by all properly authorized personnel. [BPC 4187.1(c)]

☐☐☐ 7~~8~~.7 The correctional clinic has obtained a license from the board. [BPC 4187.1(d)(1)]

☐☐☐ 7~~8~~.8 A separate license was obtained for each correctional clinic location where an APDS is located and is not to be transferrable. [BPC 4187.1(d)(2)]

☐☐☐ 7~~8~~.9 The correctional clinic's location and address is identified by the correctional institution and building within the correctional institution. [BPC 4187.1(d)(3)]

☐☐☐ 7~~8~~.10 The correctional clinic will notify the board in advance of any change in the clinic's address on a form furnished by the board. [BPC 4187.1(d)(4)]

~~☐☐☐ 8.11 The ADDS is secured from access and removal by unauthorized individuals. [BPC 4427.2(d)(2)]~~

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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B. POLICIES AND PROCEDURES

Yes No N/A

☐☐☐ 7~~8~~.1~~2~~1 The policies and procedures to implement the laws and regulations of this article within the correctional clinic was developed and approved by the statewide Correctional Pharmacy and Therapeutics Committee referenced in section 5024.2 of the Penal Code. [BPC 4187.2(a)]

☐☐☐ 7~~8~~.1~~3~~2 Prior to the issuance of the correctional clinic license by the board, an acknowledgment of the policies and procedures was signed by the correctional facility pharmacist-in-charge

servicing the institution, the pharmacist-in-charge for the California Department of Correction and Rehabilitation's Central Fill Pharmacy, and the correctional clinic's chief medical executive, supervising dentist, chief nurse executive, and chief executive officer. [BPC 4187.2(a)]

Yes No N/A

☐☐☐ 7~~8~~.1~~4~~3 The chief executive officer is responsible for the safe, orderly and lawful provision of pharmacy services. [BPC 4187.2(b)(1)]

☐☐☐ 7~~8~~.1~~5~~4 The pharmacist-in-charge of the correctional facility shall implement the policies and procedures developed and approved by the statewide Correctional Pharmacy and Therapeutics Committee referenced in section 5042.2 of the Penal Code and the ~~statewide Inmate Medical Services~~ California Correctional Health Care Services ~~Policies and Procedures~~ Health Care Department Operations Manual in conjunction with the chief executive officer, the chief medical executive, the supervising dentist, and the chief nurse executive. [BPC 4187.2(b)(1)]

☐☐☐ 7~~8~~.1~~6~~5 The licensed correctional clinic will notify the board within 30 days of any change in the chief executive officer on a form furnished by the board. [BPC 4187.2(b)(2)]

☐☐☐ 7~~8~~.1~~7~~6 Schedule II, III, IV or V controlled substances may be administered by health care staff of the licensed correctional clinic lawfully authorized to administer pursuant to a chart order, as defined in section 4019, a valid prescription consistent with chapter 9 division 2 of the Business and Professions Code, or pursuant to an approved protocol as identified within the ~~statewide Inmate Medical Services Policies and Procedures~~ California Correctional Health Care Services Health Care Department Operations Manual. [BPC 4187.2, 4187.3]

☐☐☐ 7~~8~~.1~~8~~7 The ADDS located in a licensed correctional clinic has implemented the statewide Correctional Pharmacy and Therapeutics Committee's policies and procedures and the ~~statewide Inmate Medical Services~~ California Correctional Health Care Services Health Care Department Operations Manual ~~Policies and Procedures~~ to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the quality, potency, and purity of drugs. [BPC 4187.5(a)]

☐☐☐ 7~~8~~.1~~9~~8 All policies and procedures are maintained either in an electronic form or paper form at the location where the ~~automated drug system~~ ADDS is being used. [BPC 4187.5(a)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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C. PHARMACIST RESPONSIBILITIES

Yes No N/A

☐☐☐ 7~~8~~.~~20~~19 A correctional facility pharmacist inspects the clinic at least quarterly. [BPC 4187.2(c)]

☐☐☐ 7~~8~~.~~21~~20 Drugs removed from the ~~automated drug system.~~ADDS ~~is~~ are removed upon authorization by a pharmacist after the pharmacist has reviewed the prescription and the patient profile for potential contraindications and adverse drug reactions. ~~If the correctional pharmacy is closed,~~ Where administration of the drug is necessary before a pharmacist has reviewed the prescription and if, in the prescriber's professional judgment, a delay in therapy may cause patient harm, the medication may be removed from the ~~automated drug delivery system.~~ADDS and administered or furnished to the patient under the direction of the prescriber. Where the drug is otherwise unavailable, a medication may be removed and administered or furnished to the patient pursuant to an approved protocol as identified within the ~~statewide Inmate Medical Services Policies and Procedures.~~California Correctional Health Care Services Health Care Department Operations Manual. Any removal of the medication from an ~~automated drug delivery~~ ADDS ~~system~~ is documented and provided to the correctional pharmacy when it reopens. [BPC 4187.5(b)]

Yes No N/A

☐☐☐ 7~~8~~.~~22~~21 The review is conducted on a monthly basis by a pharmacist and shall include a physical inspection of the drugs in the ~~automated drug delivery system.~~ADDS, an inspection of the ~~automated drug delivery system.~~ADDS machine for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system. [BPC 4187.5(e)]

Date of Last Review: _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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D. DEVICE REQUIREMENT

Yes No N/A

☐☐☐ 7~~8~~.~~23~~22 Drugs removed from the ADDS ~~is~~ are provided to the patient by a health professional licensed pursuant to division 2 of the Business and Professions Code who is lawfully authorized to perform the task. [BPC 4187.5(c)]

☐☐☐ 7~~8~~.~~24~~23 The review of the drugs contained within, and the operation and maintenance of, the ADDS shall be the responsibility of the correctional clinic. [BPC 4187.5(e)]

☐☐☐ 7~~8~~.~~25~~24 The ADDS is operated by a licensed correctional pharmacy. Any drugs within the ADDS are considered owned by the licensed correctional pharmacy until they are dispensed from the ADDS. [BPC 4187.5(f)]

☐☐☐ 7~~8~~.~~26~~25 Drugs from the ADDS in the correctional clinic are removed by a person authorized to stock the ADDS, or by a person lawfully authorized to administer or dispense the drugs. [BPC 4187.5(g)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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E. RECORD KEEPING REQUIREMENTS

Yes No N/A

☐☐☐ 7~~8~~.~~27~~26 All records of manufacture and of sale, acquisition, receipt, shipment, or disposition of dangerous drugs or dangerous devices, at all times during business hours, are open for inspection by authorized officer of the law and ~~is~~are preserved for at least three years from the date of making. A current inventory is kept by the licensed correctional clinic. [BPC 4081(a)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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SECTION ~~9~~8:

- ☐ **DRUG ROOM: AUDS ~~used for dispensing pursuant to BPC 4056 (Drug Room) or BPC 4068 (Hospital Pharmacy is closed and no pharmacist is available)~~ USED FOR DISPENSING PURSUANT TO BPC 4056 (DRUG ROOM) OR**
- ☐ **HOSPITAL PHARMACY: AUDS USED FOR DISPENSING PURSUANT TO BPC 4068**

Please Note: Hospital pharmacies and drug rooms must also complete Section 6 for ADDS used for administration. This section addresses additional requirements for hospital pharmacies and drug rooms operating an ADDS uses for dispensing.

A. GENERAL REQUIREMENTS

Yes No N/A

☐☐☐ 8~~9~~.1 The licensed drug room does not employ a full-time pharmacist and the AUDS is used for administration and dispensation by a physician to persons registered as inpatients of the hospital, to emergency cases under treatment in the hospital, or to outpatients if the physician determines that it is in the best interest of the patient that a particular drug regimen be immediately commenced or continued, and the physician reasonably believes that a pharmacy located outside the hospital is not available and accessible at the time of dispensation to the patient within 30 minutes of the hospital pharmaceutical services or within a 30-mile radius by means of the method of transportation the patient states they ~~he/she~~ intend to use. The quantity dispensed is limited to the amount necessary to maintain uninterrupted therapy, but shall not exceed a 72-hour supply. [BPC 4056(a), (f)]

☐☐☐ 8~~9~~.2 ~~The~~ Where the prescriber in a hospital emergency room dispenses a dangerous drug, including a controlled substance, from the AUDS to an emergency room patient, the following conditions apply [BPC 4068(a)]:

- ☐ 8.2.1 ~~when t~~ The hospital pharmacy is closed and there is no pharmacist available in the hospital.
- ☐ 8.2.2 The drugs ~~is~~ are acquired by the hospital pharmacy.
- ☐ 8.2.3 The dispensing information is recorded and provided to the pharmacy when the pharmacy reopens.
- ☐ 8.2.4 The hospital pharmacy retains the dispensing information and, if the drug is a schedule II, schedule III, or schedule IV controlled substance, reports the dispensing information to the Department of Justice pursuant to Section 11165 of the Health and Safety Code.
- ☐ 8.2.5 The prescriber determines it is in the best interest of the patient that a particular drug regimen be immediately commenced or continued, and the prescriber reasonable believes that a pharmacy located outside the hospital is not available and accessible at the time of dispensing to the patients.
- ☐ 8.2.6 The quantity dispensed is limited to the amount necessary to maintain uninterrupted therapy when pharmacy services outside the hospital are not readily available or accessible, and shall not exceed a 72-hour supply. ~~[BPC 4068(a)(1-6)]~~
- ☐ 8.2.7 The prescriber ensures that the label on the drug contains all the information required by BPC section 4076.

Yes No N/A

☐☐☐ 8.3 The operating pharmacy has obtained a license from the Board to operate the AUDS that is used for administration and dispensing which includes the address of the AUDS location. [BPC 4427.2(i)]

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

☐☐☐ ~~9.3~~8.4 The prescriber ensures the label on the drug contains all the information required by BPC 4076 and~~,~~ CCR 1707.5.

☐☐☐ ~~9.4~~8.5 The federal warning label~~s~~ prohibiting transfer of controlled substances is on the prescription container. [21 CFR 290.5]

☐☐☐ ~~9.5~~8.6 The prescription drug is 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 request of the prescriber or patient. [15 USC 1473(b), 16 CFR 1700.15, CCR 1717]

☐☐☐ ~~9.6~~8.7 The hospital pharmacy or drug room reports the dispensing information of a Schedule II, III or IV controlled substance to the Dept of Justice pursuant to HSC 11165 as soon as

reasonably possible, but not more than seven days after the date a controlled substance is dispensed. [BPC 4068(a)(4), HSC 11165(d)]

☐☐☐ ~~9.7~~8.8 Patient package inserts are dispensed with all estrogen medications. [21 CFR 310.515]

Yes No N/A

☐☐☐ ~~9.8~~8.9 The hospital has written policies and procedures to ensure each patient receives information regarding each drug given at the time of discharge or dispensed from a prescriber from a drug room, including the use and storage of each drug, the precautions and relevant warnings, and the importance of compliance with directions. [BPC 4074(e)]

~~☐☐☐ 9.9 The operating pharmacy has obtained a license from the Board to operate the AUDS that is used for administration and dispensing which includes the address of the AUDS location. [BPC 4427.2(i)]~~

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

☐☐☐ 8.10 Medication guides are provided on required medications. [21 CFR 208.1]

☐☐☐ 8.11 Black box warning information is in conformance with 21 CFR 201.57(c).

☐☐☐ 8.12 Whenever an opioid prescription drug is dispensed to a patient for outpatient use, the pharmacy or practitioner dispensing the drug prominently displays on the label or container, by means of a flag or other notification mechanism attached to the container, a notice that states, "Caution: Opioid. Risk of overdose and addiction." [BPC 4076.7]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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SECTION 9 – AUDS THROUGH A FACILITY LICENSED IN CALIFORNIA WITH STATUTORY AUTHORITY TO PROVIDE PHARMACEUTICAL SERVICES (OR) AUDS THROUGH A JAIL, YOUTH DETENTION FACILITY, OR OTHER CORRECTIONAL FACILITY WHERE DRUGS ARE ADMINISTERED WITH THE FACILITY UNDER THE AUTHORITY OF THE MEDICAL DIRECTOR.

A. GENERAL REQUIREMENTS

Yes No N/A

☐☐☐ 9.1 Review of the drugs contained within, and the operation and maintenance of, the ADDS is done in accordance with law and is the responsibility of the pharmacy. A pharmacist conducts the review on a monthly basis, which includes a physical inspection of the drugs in the ADDS, an inspection of the ADDS for cleanliness, and a review of all transaction records in order to verify the security and accountability of the ADDS. [BPC 4427.65(c)(7)]

Date of Last Review: _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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B. PHARMACIST RESPONSIBILITIES:

Yes No N/A

☐☐☐ 9.2 The stocking of an ADDS is performed by a pharmacist. If the ADDS utilizes removable pockets, cards, drawers, similar technology, or unit of use or single dose containers, as defined by the United States Pharmacopoeia, the stocking system may be done outside of the facility and be delivered to the facility, if all the following conditions are met: [BPC 4427.65(c)(6)]

☐ 9.2.1 The task of placing drugs into the removable pockets, cards, drawers, or unit of use or single dose containers is performed by a pharmacist, or by an intern pharmacist or a pharmacy technician working under the direct supervision of a pharmacist.

☐ 9.2.2 The removable pockets, cards, drawers, or unit of use or single dose containers are transported between the pharmacy and the facility in a secure tamper-evident container.

☐ 9.2.3 The facility, in conjunction with the pharmacy, has developed policies and procedures to ensure that the removable pockets, cards, drawers, or unit of use or single dose containers are properly placed into the ADDS.

☐☐☐ 9.3 The pharmacist-in-charge of a pharmacy servicing an onsite or offsite ADDS ensures the following: [CCR 1715.65(h)]

☐ 9.3.1 All controlled substances added to an ADDS are accounted for.

☐ 9.3.2 Access to the ADDS is limited to authorized facility personnel.

☐ 9.3.3 An ongoing evaluation of discrepancies or unusual access associated with controlled substances is performed.

☐ 9.3.4 Confirmed losses of controlled substances are reported to the board.

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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C. DEVICE REQUIREMENTS:

Yes No N/A

☐☐☐ 9.4 Individualized and specific access to the ADDS is limited to facility and contract personnel authorized by law to administer drugs. [BPC 4427.65(c)(2)]

When the ADDS is used as an emergency pharmaceutical supplies container, drugs removed from the ADDS are limited to the following [BPC 4427.65(c)(4)]:

Yes No N/A

☐☐☐ 9.5 A new drug order given by a prescriber for a patient of the facility for administration prior to the next scheduled delivery from the pharmacy, or 72 hours, whichever is less. The drugs are retrieved only upon authorization by a pharmacist and after the pharmacist has reviewed the prescriber's order and the patient's profile for potential contraindications and adverse drug reactions. [BPC 4427.65(c)(4)(A)]

☐☐☐ 9.6 Drugs that a prescriber has ordered for the patient on an as-needed basis, if the utilization and retrieval of the drugs are subject to ongoing review by the pharmacist. [BPC 4427.65(c)(4)(B)]

☐☐☐ 9.7 Drugs designed by the patient care policy committee or pharmaceutical service committee of the facility as emergency drugs or acute onset drugs. These drugs may be retrieved from the ADDS pursuant to the order of the prescriber for emergency or immediate administration to the patient of the facility. Within 48 hours after retrieval, the case is reviewed by the pharmacist. [BPC 4427.65(c)(4)(C)]

When the ADDS is used to provide pharmacy services pursuant to BPC 4017.3, the ADDS is subject to the following requirements [BPC 4427.65(c)(5)]:

☐☐☐ 9.8 The drugs removed from the ADDS for administration to a patient are in properly labeled units of administration containers or packages. [BPC 4427.65(c)(5)(A)]

☐☐☐ 9.9 The pharmacist reviewed and approved all orders prior to a drug being removed from the ADDS for administration to the patient. The pharmacist reviewed the prescriber's order and the patient's profile for potential contraindications and adverse drug reactions. [BPC 4427.65(c)(5)(B)]

☐☐☐ 9.10 The pharmacy providing services to the facility controls the access to the drugs stored in the ADDS. [BPC 4427.65(c)(5)(C)]

☐☐☐ 9.11 After the pharmacist reviews the prescriber's order, access by licensed personnel to the ADDS is limited only to drugs ordered by the prescriber and reviewed by the pharmacist and that are specific to the patient. When the prescriber's order requires a dosage variation of the same drug, licensed personnel has access to the drug ordered for that scheduled time of administration. [BPC 4427.65(c)(5)(F)]

☐☐☐ 9.12 ADDS that allow licensed personnel to have access to multiple drugs and are not patient specific in their design, shall be allowed if the ADDS has electronic and mechanical safeguards in place to ensure the drugs delivered to the patient are specific to the patient. [BPC 4427.65(c)(5)(G)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

D. RECORD KEEPING REQUIREMENTS

Yes No N/A

☐☐☐ 9.13 Transaction information shall be made readily available in a written format for review and inspection by individuals authorized by law and are maintained in the facility for a minimum of three years. [BPC 4427.65(c)(1)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

E. POLICIES AND PROCEDURES

Yes No N/A

☐☐☐ 9.14 The pharmacy operating the AUDS shall develop and implement, and review annually, the written policies and procedures pertaining to the ADDS. [BPC 4427.65(b)]

☐☐☐ 9.15 The facility and the pharmacy has developed and implemented written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the quality, potency, and purity of stored drugs. The policies and procedures define access to the ADDS and limits to access to equipment and drugs. [BPC 4427.5(c)(3)(A)

☐☐☐ 9.16 All policies and procedures are maintained at the pharmacy operating the ADDS and the location where the ADDS is being used. [BPC 4427.5(c)(3)(B)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

CERTIFICATION ACKNOWLEDGMENT

PHARMACIST-IN-CHARGE CERTIFICATION:

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

Signature _____ Date _____
(Pharmacist-in-Charge)

ACKNOWLEDGMENT BY OWNER OF ADDS:

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

Signature _____Date _____

CERTIFICATION OF COMPLETED ACTION PLAN

PHARMACIST-IN-CHARGE CERTIFICATION:

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

Signature _____Date _____
(Pharmacist-in-Charge)

ACKNOWLEDGMENT BY OWNER OF ADDS:

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

Signature _____Date _____

Attachment 2

Federal Requirements for Compounding

Eileen Smiley, Board Counsel

Overview of Federal Requirements for Compounding

- Similar to other areas of pharmacy law, there is a federal overlay to compounding by state-licensed pharmacists.
- Violation of federal law could subject licensees to potential enforcement by FDA or federal Department of Justice and discipline of their state-issued licenses or permits.
- This presentation contains just a summary of some of the federal law and guidance governing compounding. Compounding pharmacists should consult their own attorney or other resources to ensure that they are aware of, and in compliance, with current federal law on compounding.
- FDA also has section on its website related to human drug compounding. Human Drug Compounding | FDA

Need for an Exemption for Compounding

- Generally compounding a substance would result in a new drug that would require FDA approval and could result in violations of federal provisions, including new drug approval process, without an exemption.
- 503A Exemption provides exemption from certain provisions under the federal Food, Drug and Cosmetic (FDCA) Act, including Section 505, Section 502(f), and 501(a)(2)(B).
- Non-compliance with ALL of the requirements of the 503A exemption could result in violations of one or all of these three statutory provisions or other provisions of the FDCA.
- Section 503A exemption does not provide an exemption from other provisions of the FDCA.

What is the 503A Exemption

Section 503A generally provides an exemption from the following provisions of the FDCA for drug products compounded by a state-licensed pharmacist or state-licensed physician:

1) Section 501(a)(2)(B) (concerning requirement to comply with current good manufacturing practices);
2) Section 502(f)(1) (concerning the labeling of drugs with adequate directions for use)
3) Section 505 (concerning the approval of drugs under new drug applications (NDAs) or abbreviated new drug applications (ANDAs)).

Section 503A exemption does not provide relief from any other provision of the FDCA.

Summary of the 503A Exemption

- Section 503A(b)(1) contains the specific substantive requirements for a state-licensed pharmacist and pharmacy to qualify for the exemption. There are detailed requirements set out in this section. The FDA has put out written guidance discussing the specific requirements. Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act Guidance (fda.gov) (Pharmacy Compounding Guidance). FDA has other guidance documents applicable to compounding. Regulatory Policy Information | FDA.
- Section III.A of the Pharmacy Compounding Guidance, pages 2-5 detail the conditions of the exemption.
- Other guidance documents also apply and clarify some definitions. *See e.g.*, Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act Guidance for Industry (fda.gov) (pages 2-3 makes clear an applicable USP or NF monograph means a drug monograph.

Summary of 503A Exemption

- Finally, when the FDA publishes guidance documents and proposed and final rules, they issue proposing and adopting releases that accompany those documents. You should read both releases as the FDA addresses substantive comments raised by commenters.
- Under legal decisions, positions taken in notices subject to notice and comment may constitute interpretations of the agency that are accorded deference if deemed to be a reasonable interpretation.
- Accordingly, it is important that you raise comments to proposed FDA rules and guidance as part of the federal notice and comment process. Making such comments to this Board does not make it part of the FDA record.
- Given the end of COVID emergency, as FDA gets more time, we anticipate further guidance and rules to implement the 2012 amendments.
- Compounding pharmacists and pharmacies are responsible for knowing and complying with federal law and should keep abreast of changes in this area by following the FDA.

State Requirements also Apply

- California law, including pharmacy and health and safety code provisions, also establish requirements for human drug compounding.
- This Committee will be considering changes to California law in response to the USP changes that go into effect in November 2023.
- The Committee does not intend to summarize operative federal law in its regulations as federal law could and will change or evolve over time. The requirement to comply with existing federal law is independent of state law.
- If you have questions regarding operative federal law, you should consult an attorney or other resources, including contacting the FDA.

Attachment 3

UNITED STATES PHARMACOPEIA (USP)

GENERAL CHAPTER <825>

RADIOPHARMACEUTICALS—PREPARATION, COMPOUNDING, DISPENSING, AND REPACKAGING

OFFICIAL ON 12/1/20
COMPENDIAL ON 11/1/23

PRESENTATION ADAPTED WITH PERMISSION FROM PAUL B. MAHAN, RPH., BCNP
HTTPS://PHARMACY.CA.GOV/MEETINGS/MINUTES/2019/19_JUN_CMPD_MIN.PDF

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GLOSSARY

- **Compounding:** combining, mixing, pooling, or otherwise altering (excluding preparation with minor deviations) of a conventionally manufactured radiopharmaceutical or synthesizing/formulating a radiopharmaceutical from bulk drug substances and radionuclides.
- **Dispensing:** manipulation or labeling of a radiopharmaceutical to render it in its final form for administration
- **Preparation:** combining a conventionally manufactured kit with a conventionally manufactured radionuclide following manufacturer's recommended instructions. Mixing, reconstituting, combining, diluting, or repackaging of a radiopharmaceutical, or other such acts, performed in accordance with directions contained in the FDA-approved labeling.

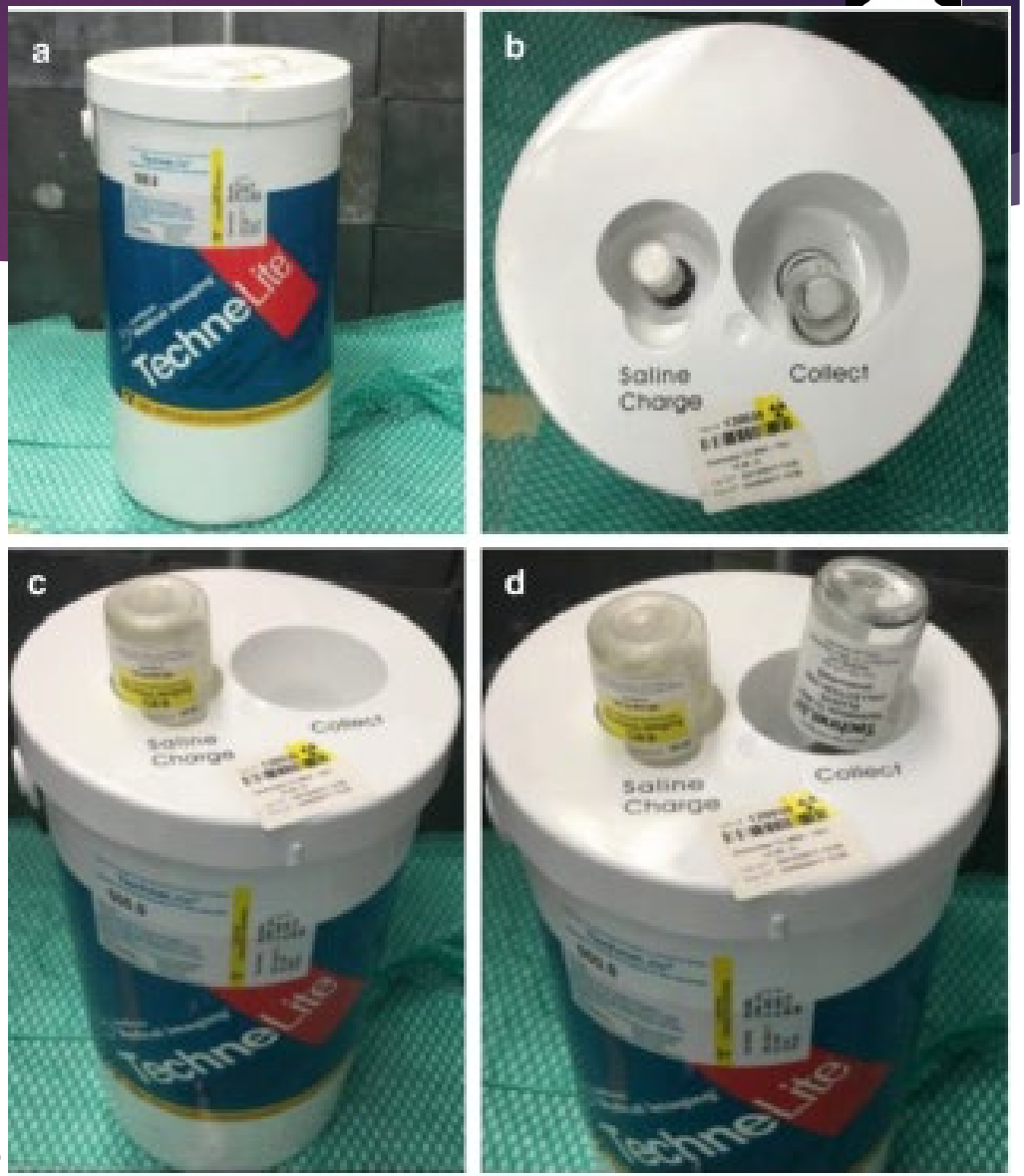
GLOSSARY

- **Preparing with minor deviations:** preparing a conventionally manufactured kit with a conventionally manufactured radionuclide with volume, and/or radioactivity, and/or step-by-step deviations from the manufacturers recommended labeling while ensuring that the final preparation maintains appropriate radiochemical and radionuclidic purity for the entirety of the BUD.
- **Radiopharmaceutical** (radiopharmaceutical preparation/ radioactive drug)**:** Finished dosage that contains a radioactive substance in association with one or more other ingredients and that is intended to diagnose, stage a disease, monitor treatment, or provide therapy.

GLOSSARY

- **Repackaging:** removing a conventionally manufactured radiopharmaceutical from the container in which it was distributed by the original manufacturer and placing it into a different container without further manipulation of the product. Repackaging also includes the act of placing the contents of multiple containers (e.g., vials) of the same finished drug product into one container, as long as the container does not include other ingredients
- **Segregated radiopharmaceutical processing area (SRPA): A** designated, unclassified space, area, or room with a defined (by facility procedures) perimeter that contains a PEC. An SRPA is only suitable for radiopharmaceutical preparation (with and without minor deviations), dispensing, and repackaging. If the SRPA is used to elute radionuclide generators it must have ISO Class 8 particle count non-viable particle count air quality.

Generator



https://nuclear.pharmacy.purdue.edu/what.php
https://med.uth.edu/radiology/wp-content/uploads/sites/9/2017/09/Nuclear-Lab-2-Generator.pdf

Generator

Figure 1

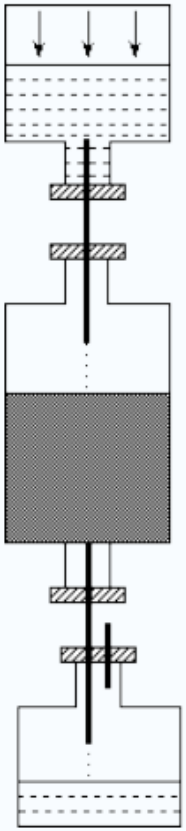


Figure 2

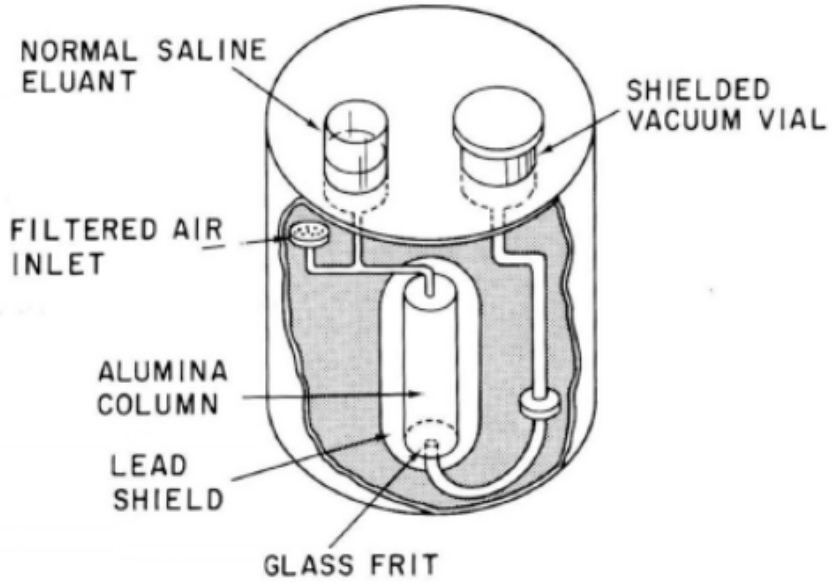
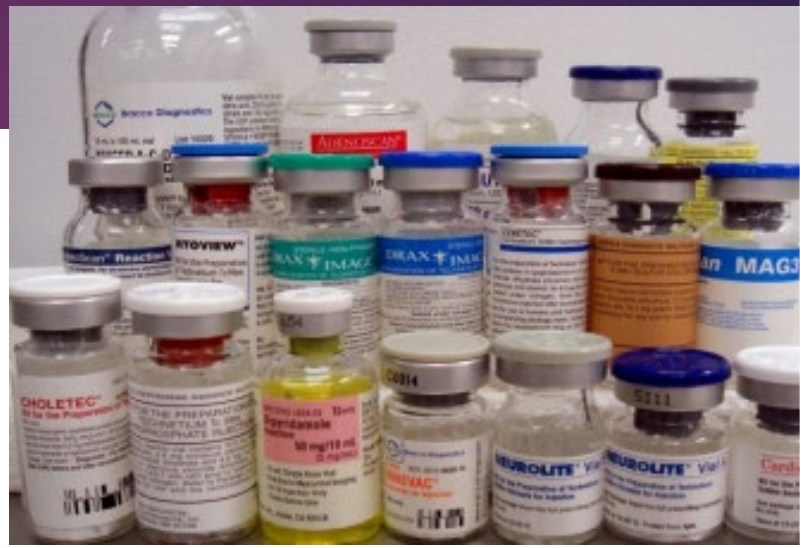


Fig. 7-5. Cross-sectional drawing of a ^{99}Mo-^{99m}Tc generator. (Courtesy of the Society of Nuclear Medicine and Thomas R. Gnau.)

https://nuclear.pharmacy.purdue.edu/what.php
https://med.uth.edu/radiology/wp-content/uploads/sites/9/2017/09/Nuclear-Lab-2-Generator.pdf

PEC

Conventionally Manufactured Kits



https://nuclear.pharmacy.purdue.edu/what.php
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Preparation

https://nuclear.pharmacy.purdue.edu/what.php
https://med.uth.edu/radiology/wp-content/uploads/sites/9/2017/09/Nuclear-Lab-2-Generator.pdf

Dispensing

https://nuclear.pharmacy.purdue.edu/what.php
https://med.uth.edu/radiology/wp-content/uploads/sites/9/2017/09/Nuclear-Lab-2-Generator.pdf

1. INTRODUCTION

- Intended to provide uniform **minimum** standards for the preparation, compounding, dispensing, and repackaging of radiopharmaceuticals for humans and animals that occur as part of state-licensed activities
- Radiopharmaceuticals are:
  - Radioactive materials (RAMs) falling under the control of the US Nuclear Regulatory Commission (NRC) or NRC-contracted agreement state agency.
  - Prescription drugs falling under the control of the US FDA for manufacturing and marketing.
  - Regulated by other federal authorities (e.g., Department of Transportation)

1.1 NONSTERILE RADIOPHARMACEUTICALS
1.2 STERILE RADIOPHARMACEUTICALS

- Nonsterile prepared or compounded preparations, must comply with applicable identity, quality, and purity standards, as described in manufacturer labeling, *USP* monographs, or other appropriate sources
- Sterile prepared or compounded preparations, must comply with applicable identity, quality, and purity standards.

2. RADIATION SAFETY CONSIDERATIONS

- Must handle meeting the radiation regulatory agency requirements for worker safety.
- Involves licensing commitments to keep all exposure levels for the workers involved as low as reasonably achievable (ALARA) practices. **Principles of radiation safety involve time, distance, shielding, and contamination control.**
- Radiation exposure:
  - **Time**: increase exposure time = increased risk, move quickly
  - **Distance**: increased distance = decreased risk, special tools
  - **Shielding:** increased shielding = decreased risk, special tools and equipment
- Radiation detection and measuring devices are necessary

2. RADIATION SAFETY CONSIDERATIONS

https://nuclear.pharmacy.purdue.edu/what.php
https://med.uth.edu/radiology/wp-content/uploads/sites/9/2017/09/Nuclear-Lab-2-Generator.pdf

2.4 RADIATION CONTAMINATION CONTROL

- Radiation contamination (e.g., spills, drips, sprays, volatility) is an important concern for radiation protection.
  - Disposable absorbent pads
    - In an ISO Class 5 PEC, must be clean and low-lint.
  - Vertical air flow, not horizontal, in a PEC is used to control contamination.
- Require measurement with a suitable radiation measuring device (e.g., dose calibrator).
- Individuals must wear body and extremity dosimeters (e.g., a ring worn on a finger) for long-term monitoring of personnel radiation exposure.
  - Body dosimeter should be worn underneath the gown.
  - Extremity dosimeter must be worn underneath gloves and must not interfere with proper fit of gloves.

MeasuRing Dosimeter

- Individually calibrated
- Available in four sizes

Ultra Rings

- Strong hard plastic construction
- Available in three sizes

Flex Rings

- Soft plastic construction with velcro closure straps

Fingertip Dosimeter

- Comfortable design
- Individually calibrated

4. PERSONNEL QUALIFICATIONS, TRAINING AND HYGIENE

- Personnel
  - must be trained to work with radiopharmaceuticals per the policies and standard operating procedures (SOPs) authorized by an ANP or AU physician.
  - must follow these policies and SOPs
- As appropriate, this should include bloodborne pathogens training.

Authorized nuclear pharmacists (ANPs) and authorized user (AU) physicians

4.1 ASEPTIC QUALIFICATIONS

- Qualifications may be conducted at a different site if all SOPs are identical for the applicable job function.
- **Gloved Fingertip And Thumb Sampling**
  - Garbing competency required for personnel that enter and perform tasks in the ISO-5 PEC
  - Successful completion:
    - initial zero cfu
    - after media-fill testing is defined as ≤3 cfu
- **Media-Fill Testing**
  - all personnel who prepare, compound, dispense, and repackage sterile radiopharmaceuticals.
  - reflective of the actual manipulations to be carried out
  - must simulate the most challenging and stressful conditions to be encountered

4.2 RE-EVALUATION, RETRAINING AND REQUALIFICATION

- **Visual observation:** initially, and every 12 months
- **Gloved fingertip and thumb sampling**: 3 times initially, and then every 12 months (with media-fill testing)
- **Media-fill testing:** After initial qualification, conduct a media-fill test of all personnel engaged in sterile radiopharmaceutical processing at least every 12 months
- **Cleaning and disinfecting**: every 12 months or with change(s) in cleaning and disinfecting SOPs
- **>6month pause in sterile processing**: requalified in all core competencies before resuming duties
- **Sterile compounding using a nonsterile drug substance or components:** requalified in all core competencies every 6 months.

4.5 Hand Hygiene and Garbing for Buffer Areas and Segregated Radiopharmaceutical Processing Area

- Do not bring electronic devices that are not necessary for compounding
- Before entering:
  - Remove outer garments, all cosmetics; all hand, wrist, and other exposed jewelry
  - Remove visible debris from underneath fingernails under warm running water
  - Wash hands and arms up the elbows with soap and water for at least 30 s and then dry hands using low-lint towels.
  - Don garb: shoe covers, head/hair/facial hair covers, face mask
- While inside:
  - Periodically apply sterile 70% IPA to gloves
  - Routinely inspect gloves for holes, punctures, contamination, or tears.
  - Avoid touch contamination
- When leaving:
  - Gowns may be used for the shift if maintained in the classified area or the SRPA

5.1 FACILITY DESIGN AND ENVIRONMENTAL CONTROLS

- Classified areas and SRPA maintained at a temperature of 25° or cooler
- Temperature and humidity must be monitored in the classified areas each day that it is used, either manually or by a continuous recording device
- Free-standing humidifiers/ dehumidifiers and air conditioners must not be used within the classified area or SRPA.
- Temperature and humidity devices must be verified for accuracy at least every 12 months or as required by the manufacturer
- PEC must be located in secondary engineering control (SEC),
  - ISO-classified buffer room with ante-room
  - Segregated radiopharmaceutical processing area (SRPA):

5.1 FACILITY DESIGN AND ENVIRONMENTAL CONTROLS

- ISO-classified buffer room with ante-room:
  - separated from surrounding unclassified areas with fixed walls and doors
  - Air supplied introduced through HEPA filters in the ceiling
  - Returns low on the wall unless a visual smoke study demonstrates an absence of stagnant airflow where particulate will accumulate.
  - Smoke study of the PEC must be repeated whenever a change to the placement of the PEC within the area is made.
  - Equipped with a pressure-differential monitoring system.
  - Ante-room must have a line of demarcation to separate the clean side from the less clean side.
    - Entered through the less clean side, and the clean side is the area closest to the buffer area.
    - Garb must be worn prior to crossing the line of demarcation.

5.1 FACILITY DESIGN AND ENVIRONMENTAL CONTROLS

- Segregated radiopharmaceutical processing area (SRPA):
  - Unclassified area
    - may be perform only sterile radiopharmaceutical preparation, preparation with minor deviations, dispensing, and repackaging
  - If ISO Class 8; storage and elution of non-direct infusion radionuclide generators (e.g., Tc-99m).
  - Located away from unsealed windows, doors that connect to the outdoors, and traffic flow which may adversely affect the air quality in the PEC.
  - Visible perimeter must establish the boundaries of the SRPA.
  - Access restricted to authorized personnel and required materials.
  - not located adjacent to environmental control challenges

5.1 FACILITY DESIGN AND ENVIRONMENTAL CONTROLS

- PEC:
  - certified to meet ISO Class 5 or better conditions
  - designed to minimize microbial contamination
  - located out of traffic patterns and away from area air currents that could disrupt the intended airflow patterns inside the PEC.
  - to prepare, prepare with minor deviations, dispense, or repackage sterile radiopharmaceuticals the ISO Class 5 PEC may be placed in an unclassified SRPA.
  - to compound sterile radiopharmaceuticals, must be located within an ISO Class 7 or better buffer area with an ISO Class 8 or better ante-room.
  - Dynamic airflow smoke pattern test: initially, and at least every 6 months

5.2 Creating Areas to Achieve Easily Cleanable Conditions

- Classified areas:
  - Surfaces of ceilings, walls, floors, doors, door frames, fixtures, shelving, work surfaces, counters, and cabinets in the classified area must be smooth, impervious, free from cracks and crevices, and non-shedding
  - Junctures must be sealed to eliminate cracks and crevices.
  - Walls must be constructed of/or covered with a durable material and the integrity of the surface must be maintained.
  - Floors must include coving to the sidewall or the juncture between the floor and wall must be caulked.
  - Exterior lens surface of ceiling light fixtures must be smooth, mounted flush, and sealed.
  - Penetrations through the ceiling or walls must be sealed

5.3 Water Sources

- Buffer area must not contain plumbed water sources [e.g., sink(s), eyewash(es), shower(s), or floor drain(s)].
- Ante-room must not contain floor drain(s).
- SRPA, the sink must be accessible but located at least 1 m from the PEC and generators, if present.
  - sink must not be located inside the perimeter of the SRPA

5.7 Environmental Controls

- Must comply with conditions specified in RAM license and regulations, RAM license conditions may supersede the following requirements for environmental controls described in this section
- May be both positive and negative air pressure within the facility;
  - positive pressure to minimize the potential of microbial contamination in sterile drug preparation areas, ≥ 0.02-inch water column
  - negative pressure to minimize potential radioactive contamination from volatile or airborne radiopharmaceuticals., RAM license will define
- In classified area:
  - Pressure monitoring device must be used to continuously monitor the pressure differential
  - Results from the pressure monitoring system must be reviewed and documented at least daily on days the area is used.
  - Devices must be tested for accuracy and required performance at least every 6 months.

6. MICROBIOLOGICAL AIR AND SURFACE MONITORING
6.1 General Monitoring Requirements

- Air and surface monitoring:
  - All classified spaces
  - During actual or simulated dynamic operating conditions
  - Results and the corrective actions must be documented, and records must be readily retrievable as required by jurisdictional laws and regulations
  - Performed with:
    - Certification of new facilities and equipment
    - After any modification of facilities or equipment
    - In response to identified problems
    - In response to identified trends
    - In response to changes that could impact the controlled area environments

6.2 Monitoring Air Quality for Viable Airborne Particulates

- **Viable air sampling**:
  - Volumetric impaction device sampling
  - Classified areas during dynamic operating or simulated
  - Initially and least every 6 months
- Exceed Action Levels:
  - must be investigated
  - corrective action must be taken
  - attempt must be made to identify any microorganism

ISO Class	Air Sampling Action Levels [cfu/m^3 (1000 L) of air per plate]
5	>1
7	>10
8	>100

6.3 Monitoring Surfaces for Viable Particles

- **Surface sampling**
  - all classified areas
  - at least monthly
- Exceed the Action Levels:
  - must be investigated
  - corrective action must be taken.
  - an attempt must be made to identify any microorganism

ISO Class	Surface Sampling Action Levels (cfu/device or swab)
5	>3
7	>5
8	>50

7. Cleaning and Disinfecting

Site	Cleaning	Disinfecting	Sporicidal
PEC / equipment in PEC	Prior to daily sterile processing	Following cleaning	Monthly
Surfaces of sink(s)	Daily	Daily	Monthly
Hot-Cell interior	Daily	Daily	Monthly
Hot-Cell PEC and equip. in PEC	Prior to daily sterile processing	Following cleaning	Monthly
Work surfaces outside PEC	Daily	Daily	Monthly
Ceilings	Monthly	Monthly	Monthly
Walls/doors & fixtures	Monthly	Monthly	Monthly
Floor(s)	Daily	Daily	Monthly
Storage shelving and bins	Monthly	Monthly	Monthly

8. Assigning BUD
Sterility BUD

Table 7.Preparation Conditions for Sterile Radiopharmaceuticals

Manipulation	PEC	SEC	BUD (h)
Dispensing, repackaging, preparation with and without minor deviations	ISO Class 5	SRPA	12
Radionuclide generator storage/elution (e.g. Tc-99m)	-	SRPA with ISO Class 8 total airborne particle count	12
Radionuclide generator storage/elution (e.g. Tc 99m)	-	ISO Class 8 or better buffer area with ISO Class 8 or better ante-room	24
Dispensing, repackaging, preparation with and without minor deviations	ISO Class 5	ISO Class 8 or better buffer area with ISO Class 8 or better ante-room	24
Dispensing, repackaging, preparation with and without minor deviations and compounding using sterile components	ISO Class 5	ISO Class 7 or better buffer area with ISO Class 8 or better ante-room	96
Dispensing, repackaging, preparation with and without minor deviations and compounding using a nonsterile component and performing sterilization procedure (w/o sterility testing)	ISO Class 5	ISO Class 7 or better buffer area with ISO Class 8 or better ante-room	24
Radiolabeled blood components (e.g. radiolabeled leukocytes)	ISO Class 5 BSC	ISO Class 7 or better buffer area with ISO Class 8 or better ante-room	6 h after the blood sample is obtained

9. Documentation

- Applicable records (hard-copy or electronic), must be maintained for all activities involved in repackaging, preparing, preparing with minor deviations, compounding, and dispensing radiopharmaceuticals.
- Master Formulation Record (MFR)
  - Required only for a preparation with minor deviations or compounding

10.2 Preparation with Minor Deviations

- **Examples:**
  - Altering the quantity of radioactivity or volume added to the vial
  - Changes in step-by-step operations (e.g., dilute Tc-99m sodium pertechnetate after rather than before addition to the vial)
  - Using alternative devices or equipment (e.g., a heating block rather than a hot water bath, using a different sized needle, different shielding materials)
  - Using QC test methods other than those described in the product labeling (e.g., radiochemical purity)
  - Filtering Tc-99m sulfur colloid

10.3 Preparation of Radiolabeled Blood Components

- Must be administered as soon as possible **but no later than 6 hours after blood sample is obtained from the patient or blood bank.**
- Blood sample may present a risk to the individual performing the preparation as well as cross-contamination to other blood samples or other non-blood related radiopharmaceuticals.

11.1 Compounding Nonsterile Radiopharmaceuticals

- **Compounding** combining, mixing, diluting, pooling, reconstituting or otherwise altering a drug or bulk drug substance other than as provided by the manufacturer's package insert to create a nonsterile radiopharmaceutical.
- Areas designated for nonsterile compounding must be cleaned and uncluttered and separated from areas designated for sterile radiopharmaceuticals.
- The placement of equipment and materials must take into account a design that prevents cross-contamination.
- BUD:
  - must be validated, taking into account the stability of the ingredients, any intermediate containers, the final container, and the storage conditions.
  - cannot be extended past the labeled expiration date of any component in the compound.

11.2 Sterile Compounding

- Must be performed using aseptic technique
- Must be performed in an ISO 5 PEC.
- Must not be performed for any radiopharmaceutical(s) that has been withdrawn from the market
- Must not be essentially copies of marketed FDA-approved radiopharmaceuticals.
- Personnel must consider all possible interactions between the components.
- In some cases, this may require systematic quality control testing over time to validate the appropriateness of a particular BUD.
- "Kit-splitting" or "fractionation" is splitting of kits is compounding

12.1 Dispensing and Radioassay

- Dispensing can take place from single-dose or multi-dose containers of prepared, prepared with minor deviations, compounded, or manufactured radiopharmaceuticals.
- Dispensing may involve needle changes, affixing a sterile cap, or dilution (e.g., adding 0.9% sodium chloride injection) in the final container.
- Except for an unopened manufacturer container, the final dose or ordered amount must be radio assayed (i.e., in a dose calibrator).
  - The measured activity should be mathematically corrected for radioactive decay to the time of scheduled administration (calibration time)

12.2 Labeling

- The labeling falls under the jurisdiction of numerous regulatory agencies
- The **inner** container must be labeled with the following:
  - Standard radiation symbol
  - The words "Caution—Radioactive Material"
  - For all therapeutic and blood-products, the patient name/identifier
  - Radionuclide and chemical form (generic name)
  - Radioactivity at the date and time of calibration
- The **outer** shielding must be labeled with the following:
  - Standard radiation symbol
  - The words "Caution—Radioactive Material"
  - For all therapeutic and blood-products, the patient name/identifier
  - Radionuclide and chemical form (generic name)
  - Radioactivity at the date and time of calibration
  - Volume or number of units dispensed (e.g., 2 capsules), as applicable
  - Product expiration or BUD (see Table 7), as applicable, and any special storage and handling instructions for non-immediate use (e.g., refrigeration, resuspension)
  - Route of administration

13. Repackaging

- **Repackaging**
  - removing a conventionally manufactured radiopharmaceutical(s) from the container in which it was distributed by the original manufacturer and placing it into a different container without further manipulation of the product.
  - act of placing the contents of multiple containers of the same finished drug product into one container, as long as the container does not include other ingredients.
- must be radio assayed (i.e., in a dose calibrator).
- The inner container should be labeled with the following:
  - Standard radiation symbol
  - The words "Caution—Radioactive Material"
  - The radionuclide and chemical form (generic name)
  - Radioactivity with units at time of calibration and the calibration time
- The outer shielding should be labeled with the following:
  - Standard radiation symbol
  - The words "Caution—Radioactive Material"
  - The radionuclide and chemical form (generic name)
  - Radioactivity with units at time of calibration and the calibration time
  - Volume, or number of units (e.g., capsules), as applicable
  - Product expiration or BUD (see Table 7), as applicable
  - Special storage and handling instructions

14. Quality Assurance and Quality Control

- **Quality assurance (QA):** system of procedures, activities, and oversight that ensures that radiopharmaceutical processing consistently meets quality standards
- **Quality control (QC):** sampling, testing, and documentation of results that, taken together, ensure that specifications have been met before release of the radiopharmaceutical(s)
- A facility's QA and QC programs must be formally established and documented in SOPs that ensure all aspects of the handling of radiopharmaceuticals are conducted in accordance with this chapter and applicable federal, state, and local laws and regulations.

Questions??

Attachment 4

Repeal:

~~**1708.3. Radioactive Drugs.**~~

~~A radioactive drug is any substance defined as a drug in Section 201(g)(1) of the Federal Food, Drug and Cosmetic Act or a radioactive biological product as defined in 21 CFR 600.3(ee) which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any such drug or biological product which is intended to be made radioactive. This definition includes non-radioactive reagent kits and nuclide generators which are intended to be used in the preparation of any such substance but does not include drugs such as carbon-containing compounds, potassium-containing compounds or potassium-containing salts which contain trace quantities of naturally occurring radionuclides.~~

~~Authority cited: Section 4005, Business and Professions Code. Reference: Section 4025, Business and Professions Code.~~

~~**1708.4. Pharmacist Handling Radioactive Drugs.**~~

~~A pharmacist handling radioactive drugs must be competent in the preparation, handling, storage, receiving, dispensing, disposition and pharmacology of radioactive drugs. He must have completed a nuclear pharmacy course and/or acquired experience in programs approved by the Board. Education and experience in non-approved programs may be granted partial or equivalent credit, if, in the opinion of the Board, such programs provide the level of competence as approved programs or the Nuclear Pharmacy Competency Statement adopted by the Board.~~

~~Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4021, 4022, 4025, 4036 and 4037, Business and Professions Code.~~

~~**1708.5. Pharmacy Furnishing Radioactive Drugs.**~~

~~A pharmacy furnishing radioactive drugs is any area, place or premises described in a permit issued by the board where radioactive drugs are stored, processed, compounded, repackaged, or dispensed. A pharmacy exclusively furnishing radioactive drugs shall be exempt from the patient consultation area requirements of Title 16 Cal. Code of Regulations Section 1714(a) unless the Board finds that the public health and safety require their application.~~

~~A pharmacist qualified under Section 1708.4 to furnish radioactive drugs shall be in the pharmacy whenever the furnishing of radioactive drugs occurs. All personnel involved in the furnishing of radioactive drugs shall be under the immediate and direct supervision of such a qualified pharmacist.~~

~~Authority cited: Sections 4005, 4008 and 4008.2, Business and Professions Code. Reference: Sections 4005, 4008 and 4008.2, Business and Professions Code.~~

Proposal to Add Article XX as proposed with the following:

Article XX Radiopharmaceutical- Preparation, Compounding, Dispensing, and Repackaging

1738. Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging

This article applies to radiopharmaceuticals as defined in USP Chapter 825. In addition to the requirements provided in this Article, the processing of radiopharmaceuticals shall comply with the standards established by United States Pharmacopeia General Chapter 825, titled *Radiopharmaceuticals –Preparation, Compounding, Dispensing, and Repackaging* ("USP Chapter 825" for the purposes of this Article).

Necessity: Clarity to the regulated public about the requirements to comply with the Section consistent with authority established in the law and the requirements of the Chapter.

Authority cited: Sections 4005, 4008 and 4008.2, Business and Professions Code. Reference: Sections 4005, 4126.8, 4301, 4306.5, and 4342, Business and Professions Code.

1738.1 INTRODUCTION SCOPE AND COMPOUNDING DEFINITIONS

In addition to the definitions contained in USP Chapter 825, the following definitions apply to this Article and supplement the standards established in USP Chapter 825 when not otherwise provided in USP Chapter 825.

(a) "Added substances" means ingredients that are necessary to compound a preparation but are not intended or expected to cause a pharmacologic response if administered alone in the amount or concentration contained in a single dose of the compounded preparation. The term is used synonymously with the terms inactive ingredients, excipients, and pharmaceutical ingredients.

(b) "Designated person" means a pharmacist identified as assigned, responsible, and accountable for the performance and operation of the radiopharmaceutical processing facility and for personnel who prepare, compound, dispense, and repackage radiopharmaceuticals.

(b) "Component" means any ingredient used in the compounding of a preparation, including any active ingredient, added substance, or conventionally manufactured product.

(c) "Diluent" means a liquid with no pharmacological activity used in reconstitution, such as sterile water for injection.

(d) "Processing," "processed" or "processing activity" means the preparation, compounding, repackaging, or dispensing of a radiopharmaceutical.

(e) The use of technologies, techniques, material, and procedures not described in USP 825 shall be based upon published peer-reviewed literature or documents meeting FDA approved labeling requirements in accordance with sections 201.56 and 201.57 of title 21, Code of Federal Regulations, showing the technologies, techniques, material, and procedures to be equivalent or superior to those described in USP Chapter 825.

(f) Processing with human whole blood or human whole blood derivatives shall be done in compliance with Health and Safety Code section 1602.5.

Authority cited: Sections 4005, 4008 and 4008.2, Business and Professions Code. Reference: Sections 4005, 4126.8, 4301, 4306.5, and 4342, Business and Professions Code.

1738.2 RADIATION SAFETY CONSIDERATIONS

In addition to the standards in the USP Chapter 825, the processing of radiopharmaceuticals shall meet the following radiation safety requirements of this section.

(a) Radiation detectors and measuring devices, and other necessary equipment may be placed inside an ISO Class 5 PEC but must be placed in a manner that minimizes disruptions of airflow.

Necessity: To provide clarity and ensure the appropriate type and material is used. The language establishes a requirement about what actions must be done versus should be done.

(b) Disposable absorbent pads shall be changed after each type of radiopharmaceutical processing.

Necessity: To provide clarity as the Chapter does not specify that pads must be changed. Changing pads is necessary to avoid cross contamination.

(c) Any deviation made to lower radiation exposure to workers shall be evaluated and documented in an SOP by the designated person prior to the deviation occurring. Exceptions to the environmental controls requirements must be documented in the specific radioactive materials license conditions issued by the California Department of Public Health pursuant to section 30190 of Title 17 of the California Code of Regulations, or a specific radioactive materials license issued by another state or the United States Nuclear Regulatory Commission pursuant to pursuant to section 32.72 of title 10 of the Code of Federal Regulations.

Necessity: Provides clarity to ensure that SOPs document the need for deviations.

Authority cited: Sections 4005, 4008 and 4008.2, Business and Professions Code. Reference: Sections 4005, 4126.8, 4301, 4306.5, and 4342, Business and Professions Code.

1738.3. IMMEDIATE USE OF STERILE RADIOPHARMACEUTICALS

The processing of radiopharmaceuticals for immediate use may only be done in a patient care setting meeting the applicable requirements in this Article. The patient care facility shall maintain all records required in Section 9 of USP Chapter 825 in accordance with Business and Professions Code section 4081.

1738.4 PERSONNEL QUALIFICATIONS, TRAINING, AND HYGIENE

In addition to the requirements in the USP Chapter 825, the processing of radiopharmaceuticals shall comply with all of the requirements of this section.

(a) Processing personnel experiencing any of the following: rashes, recent tattoos or oozing sores, conjunctivitis, active respiratory infection or and other conditions which could contaminate a sterile radiopharmaceutical, or the environment shall not be allowed to enter the compounding area unless approved by the designated person.

(b) The pharmacist with direct oversight over personnel performing radiopharmaceutical processing shall demonstrate proficiency in skills necessary to ensure the integrity, potency, quality, and labeled strength of radiopharmaceuticals as defined in the facilities SOPs.

(c) Aseptic qualifications from one premises may be used for another premises if the SOPs and, facilities are identical..

(d) SOPs must clearly define the acceptable use and cleaning for reusable gowns that prevent possible contamination of the CSP and designated compounding area. However, laundered garb must not be reused beyond one day unless garb is laundered with a validated cycle. The facility's SOPs must describe the process that must be followed should the facility allow for the reuse of garb.

(e) Eyeglasses shall be cleaned as part of hand hygiene and garbing, consistent with the standards specified in the SOPs.

(f) Garb shall be donned and removed in an ante-area or immediately outside the SPRA. Donning and doffing garb shall not occur in the ante-room or the SPRA at the same time unless the SOPs define specific processes which must be followed to prevent contamination.

Authority cited: Sections 4005, 4008 and 4008.2, Business and Professions Code. Reference: Sections 4005, 4126.8, 4301, 4306.5, and 4342, Business and Professions Code.

1738.5. FACILITIES AND ENGINEERING CONTROLS

In addition to the requirements in the USP Chapter 825, the processing of radiopharmaceuticals shall comply with all of the requirements of this section.

(a) A sink used for compounding or hand hygiene shall not be part of a restroom or water closet.

(b) The temperature shall be monitored in SRPAs segregated radiopharmaceutical processing area and classified areas each day that processing is performed, either manually or by a continuous recording device.

(c) Storage and elution of non-direct infusion radionuclide generators shall take place in an ISO Class 8 or better area.

(d) If an SRPA is used:

(1) Except for walls, the SRPA's visible perimeter shall be at least 1 meter from all sides of the PEC or in a separate room.

(2) Surfaces within the SRPA shall be smooth, impervious, free from cracks and crevices, and non-shedding so they can be easily cleaned and disinfected and to minimize spaces in which microorganisms and other contaminants can accumulate.

(3) Compounding shall not take place in the SRPA.

(e)(1) Testing and certification of all classified areas shall be completed by a competent individual. A competent individual is a technician who possesses a current accreditation issued by The Controlled Environment Testing Association (CETA), or under the direct supervision of an individual who possesses a current accreditation issued by CETA Certification shall be completed consistent with the provisions established in the USP Chapter 797, titled "Pharmaceutical Compounding—Sterile Preparations" (USP Chapter 797). The facility shall review and maintain a copy of the accreditation documentation in accordance with requirements in section 1738.9.

(2) CETA standard(s) used to perform certification testing in all classified areas shall be recorded on the certification report as required and specified in USP Chapter 797.

(f) SOPs shall specify steps to be taken if a classified area(s) fails to meet the specified ISO classification including the investigative and corrective actions, allowable activities, and retesting procedures.

(g) All classified spaces and equipment must be recertified when there is any change in the Primary Engineering Control (PEC), or the compounding environment. For purposes of this subsection, a change includeswhen the PEC is moved, repaired or replaced, when the facility is modified in a manner that affects airflow or traffic patterns, or when improper aseptic techniques are observed. Further, SOPs must address the conditions under which recertification must also be completed when relocating a PEC.

(h) Activities and tasks carried out within the SRPA and classified areas shall be limited to only those necessary for processing a radiopharmaceutical.

(i) Food, drinks, and materials exposed in patient care and treatment areas must not enter SRPA or classified areas.

(j) A dynamic airflow smoke pattern test must be performed initially and at least every 6 months for all classified spaces and equipment. All dynamic airflow smoke pattern tests shall be immediately retrievable during inspection. A copy of the test shall be provided to the Board's inspector if requested in accordance with the timeframes set forth in Section 4105 of the Business and Professions Code.

Authority cited: Sections 4005, 4008 and 4008.2, Business and Professions Code. Reference: Sections 4005, 4081, 4105 4126.8, 4301, 4306.5, and 4342, Business and Professions Code.

1738.6. MICROBIOLOGICAL AIR AND SURFACE MONITORING

In addition to the requirements in the USP Chapter 825, the processing of radiopharmaceuticals shall comply with all of the requirements of this section.

(a) SOPs shall specify steps to be taken for processing radiopharmaceuticals when the microbiological air and surface monitoring action levels are exceeded, including the investigative and corrective actions, allowable activities, and resampling procedures.

(b) At a minimum, to trend for growth of microorganisms, during biannual (every 6 months) recertification, any microorganism recovered (growth) shall be identified at least to the genus species, regardless of the CFU count. Professional judgement shall be used to determine the appropriate action necessary to remedy identified trends regardless on the action level. Investigation of a microorganism growth must be consistent with the deviation identified and must include evaluation of trends.

(c) The designated person shall review the sampling results and identify data trends at least every time sample results are received. The designated person shall evaluate trends to determine if corrective action is needed. The results of the review shall be documented in the facility's SOPs and readily retrievable during inspection in accordance with the requirements in section 1738.9.

(d) Incubators must be calibrated and operated in accordance with the manufacturer's specifications and temperatures must be monitored during incubation, either manually or by a continuous recording device, and the results must be reviewed and documented as described in the facility's SOPs.

Authority cited: Sections 4005, 4008 and 4008.2, Business and Professions Code. Reference: Sections 4005, 4081, 4126.8, 4301, 4306.5, and 4342, Business and Professions Code.

1738.7. CLEANING AND DISINFECTING

In addition to the requirements in the USP Chapter 825, the processing of radiopharmaceuticals shall comply with all of the requirements of this section.

(a) Cleaning, disinfection, and sporicidal agents shall be used in accordance with manufacturers' specifications and shall occur at the minimum frequencies listed in Table 5 of USP Chapter 825. Incubators must be cleaned at least monthly.

(b) Reusable cleaning supplies shall not be stored within 1 meter of the PEC.

Authority cited: Sections 4005, 4008 and 4008.2, Business and Professions Code. Reference: Sections 4005, 4126.8, 4301, 4306.5, and 4342, Business and Professions Code.

1738.8. ASSIGNING BUD

In addition to the requirements in the USP Chapter 825, the processing of radiopharmaceuticals shall comply with all of the requirements of this section.

(a)A radiopharmaceutical CSP's beyond-use date (BUD) shall not exceed the shortest BUD of any of its components.

(b) No radiopharmaceutical CSP shall be administered after the labeled BUD. A dose shall not be sent for a scheduled administration that would occur after the labeled BUD.

(c) Extension of a conventionally manufactured kit with a suggested use-by time shall not exceed the BUDs in Table 7 of USP Chapter 825, for the sterility of the preparation or product.
Prior to the extension of a suggested use-by time for a conventionally manufactured kit, the SOPs must document at a minimum the following:
(1) Factors which necessitate its extension, which shall include a full assessment of patient needs for the extension.
(2) Evidence which supports that the extension maintains the appropriate quality and purity (radiochemical purity and radionuclidic purity) as specified in individual monographs, and other applicable parameters as clinically appropriate.

For the purposes of this section, the facility shall have SOPs that cover and are specific to each facility's location and kit.

Authority cited: Sections 4005, 4008 and 4008.2, Business and Professions Code. Reference: Sections 4005, 4126.8, 4301, 4306.5, and 4342, Business and Professions Code.

1738.9. DOCUMENTATION

In addition to the requirements in the USP Chapter 825, the processing of radiopharmaceuticals shall comply with all of the requirements of this section.

(a) A record of a preparation must include a compounding record compliant with section 9.2 of USP Chapter 825.

(b) Records of preparation with minor deviations or compounding shall be a single document. The document shall satisfy the requirements of USP Chapter 825, as well as the following:

(1) The assigned internal identification number shall be unique for each preparation.
(2) The manufacturer, lot number, and expiration date shall be recorded for each component for CSPs. Documenting solely the National Drug Code (NDC) does not meet this requirement.
(3) The total quantity compounded shall include the number of units made and either the volume or the weight of each unit.
(4) The identity of each person performing the compounding and pharmacist verifying the final drug preparation
(5) When applicable, endotoxin level calculations and readings.

(c) Records required by USP Chapter 825 or this Article, shall be maintained in a readily retrievable form, for at least three years from the date the record was created or relied upon. If only recorded and stored electronically, on magnetic media, or in any other computerized form, the records shall be maintained as specified by Business and Professions Code section

4081 and 4105.

(d) Records created shall be created and maintained in a manner to provide an audit trail for revisions and updates of each record document as described in this subsection. Prior versions of each record must be maintained in a readily retrievable format (easily readable or easily rendered into an electronic or paper format that a person can read) and include the changes to the document, identification of individual who made the change, and the date of each change.

Authority cited: Sections 4005, 4008 and 4008.2, Business and Professions Code. Reference: Sections 4005, 4081, 4105, 4126.8, 4301, 4306.5, and 4342, Business and Professions Code.

1738.10. PREPARATION

In addition to the requirements in the USP Chapter 825, the processing of radiopharmaceuticals shall comply with all of the requirements of this section.

(a) Processing nonsterile radiopharmaceutical shall:

(1) Follow manufacturer preparation instructions, unless minor deviations are made pursuant to subsection (c).

(2) Only use an area which is suitably cleaned and is uncluttered.

(3) Have documented processes in its SOPs for activities (e.g., cleaning) between the preparation cycles of different nonsterile products.

(b) Processing sterile radiopharmaceutical (including intravascular devices) shall:

(1) Follow manufacturer preparation instructions, unless minor deviations are made pursuant to subsection (c).

(2) Use at least the minimum environmental standards from section 7 of USP Chapter 825.

(c) When preparing radiopharmaceuticals with minor deviations ("preparation with minor deviations" as defined in the USP Chapter 825) an SOP shall at least define the circumstances which necessitated the deviation and all quality control testing requirements and limits. Such circumstances shall, at a minimum, include patient need or facts that support the deviation that maintains the appropriate quality and purity (radiochemical purity and radionuclidic purity) as specified in individual monographs, and other applicable parameters as clinically appropriate in the professional judgment of the pharmacist.

For the purposes of this section, the facility shall have SOPs that cover and are specific to each location and manufacturer. Preparations with minor deviations shall maintain the same ingredients but may differ in their proportions. A deviation from the ingredients or proportions thereof exceeds the provisions allowed under a minor deviation and is not allowed under this Article.

(d) Equipment and supplies initially used for processing of blood components (included Red Blood Cells) shall be solely dedicated for processing of blood components. Equipment and supplies shall be thoroughly cleaned and disinfected, in accordance with section 1738.7, prior to initiation of the next patient's prescription.

(e) When processing blood components all garb must be removed and replaced for each patient.

Authority cited: Sections 4005, 4008 and 4008.2, Business and Professions Code. Reference: Sections 4005, 4126.8, 4301, 4306.5, and 4342, Business and Professions Code.

1738.11. COMPOUNDING

In addition to the requirements in the USP Chapter 825, the processing of radiopharmaceuticals shall comply with all of the requirements of this section.

(a) All compounding of radiopharmaceuticals shall comply with all radioactive materials licensing requirements for appropriate radiation safety considerations issued by the California Department of Public Health pursuant to section 30190 of Title 17 of the California Code of Regulations, another state licensing agency that issues specific radioactive materials licenses, or the United States Nuclear Regulatory Commission pursuant to pursuant to section 32.72 of title 10 of the Code of Federal Regulations, and utilize applicable environmental controls.

(b) Any active pharmaceutical ingredient (API) or added component used to compound a radiopharmaceutical shall be obtained from an FDA-registered facility and shall be accompanied by a valid certificate of analysis (COA). This COA shall be, at minimum, in English.

(c) Except for sterile radiopharmaceuticals made for inhalation or ophthalmic administration, prior to releasing a sterile radiopharmaceutical made from one or more nonsterile component(s) results of bacterial endotoxin testing shall be reviewed and recorded. Results shall be documented in the compounding record specified in Section 9.2 of the USP Chapter 825.

Authority cited: Sections 4005, 4008 and 4008.2, Business and Professions Code. Reference: Sections 4005, 4126.8, 4301, 4306.5, and 4342, Business and Professions Code.

1738.12. DISPENSING

In addition to the requirements in the USP Chapter 825, the processing of radiopharmaceuticals shall comply with all of the requirements of this section.

(a) All dispensed radiopharmaceutical doses shall be labeled with the information required by Business and Professions Code section 4076 and section 1707.5. Outer shielding labels shall contain the name and contact information of the dispensing pharmacy.

Authority cited: Sections 4005, 4008 and 4008.2, Business and Professions Code. Reference: Sections 4005, 4126.8, 4301, 4306.5, and 4342, Business and Professions Code.

1738.13. REPACKAGING

In addition to the requirements in the USP Chapter 825, the processing of radiopharmaceuticals shall comply with all of the requirements of this section.

(a) The inner container of a repackaged radiopharmaceutical shall be labeled with the following:
(1) Standard radiation symbol
(2) The words "Caution—Radioactive Material"
(3) The radionuclide and chemical form (generic name)
(4) Radioactivity with units at time of calibration and the calibration time

(b)The outer shielding of a repackaged radiopharmaceutical shall be labeled with the following:
(1) Standard radiation symbol
(2) The words "Caution—Radioactive Material"
(3) The radionuclide and chemical form (generic name)
(4) Radioactivity with units at time of calibration and the calibration time
(5) Volume, or number of units (e.g., capsules), as applicable
(6) Product expiration or BUD (consistent with Table 7 of USP Chapter 825), as applicable
(7) Special storage and handling instructions

Authority cited: Sections 4005, 4008 and 4008.2, Business and Professions Code. Reference: Sections 4005, 4126.8, 4301, 4306.5, and 4342, Business and Professions Code.

1738.14. QUALITY ASSURANCE AND QUALITY CONTROL

In addition to the requirements in the USP Chapter 825, the processing of radiopharmaceuticals shall comply with all of the requirements of this section.

(a) The quality assurance program shall comply with section 1711 and the standards contained in USP Chapter 1163, titled "Quality Assurance in Pharmaceutical Compounding". In addition, the program shall include a written procedure for any scheduled action, such as a recall, in the event that radiopharmaceutical processing is discovered to be outside the expected quality and purity of the radiopharmaceutical.

(b)The Board shall be notified in writing within 72 hours of a complaint or adverse drug event involving a radiopharmaceutical.

(c) All complaints related to a potential quality problem with a radiopharmaceutical and all adverse events shall be reviewed by the pharmacist-in-charge within 72 hours of receipt of the complaint or occurrence of the adverse event. Such review shall be documented and dated as defined in the SOPs.

(d) Failure to follow written SOPs shall constitute a basis for enforcement action.

Authority cited: Sections 4005, 4008 and 4008.2, Business and Professions Code. Reference: Sections 125.9, 4005, 4126.8, 4301, 4306.5, and 4342, Business and Professions Code.

Attachment 5

Board of Pharmacy

Enforcement Workload Statistics FY 2022/23

Complaint Investigations	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Received	912	873	0	0	1,785
Closed	637	822	0	0	1,459
Pending	1,875	1,999	0	0	1,999
Average Days for Investigation	173	166	0	0	166

Cases Under Investigation (By Team)	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Quarter Ending
Compliance / Routine	716	732	0	0	732
Drug Diversion / Fraud	251	269	0	0	269
Prescription Drug Abuse	273	319	0	0	319
Compounding	62	48	0	0	48
Outsourcing	20	18	0	0	18
Probation / PRP	87	81	0	0	81
Enforcement	14	10	0	0	10
Criminal Conviction	452	522	0	0	522

Application Investigations	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Received	60	43	0	0	103
Closed					
Approved	30	25	0	0	55
Denied	20	16	0	0	36
Total Closed (includes withdrawn)	***50***	***46***	***0***	***0***	***96***
Pending	100	97	0	0	97

Complaint Closure Outcomes Not Resulting in Further Action	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Insufficient Evidence	135	189	0	0	324
Non-Jurisdictional	135	169	0	0	304
No Violation	67	84	0	0	151
No Further Action	27	112	0	0	139
Other - Non-Substantiated	33	52	0	0	85
Subject Educated	20	36	0	0	56

Letter of Admonishment / Citations	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
LOA Issued	44	48	0	0	92
Citations Issued	281	218	0	0	499
Proof of Abatement Requested	68	55	0	0	123
Appeals Referred to AG's Office	6	20	0	0	26
Dismissed	1	3	0	0	4
Total Fines Collected	***$448,797***	***$643,100***	***$0***	***$0***	***$1,091,897***

Administrative Cases	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Referred to the AG's Office	51	53	0	0	104
Pleadings Filed	34	34	0	0	68
Pending					Quarter Ending
Pre-Accusation	94	105	0	0	105
Post-Accusation	140	138	0	0	138
Total Pending	**234**	**215**	**0**	**0**	**215**
Total Closed	46	46	0	0	92

Administrative Case Outcome	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Revocation					
Pharmacist	1	3	0	0	4
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	7	7	0	0	14
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Pharmacy	2	2	0	0	4
Sterile Compounding	0	1	0	0	1
Outsourcing	0	0	0	0	0
Total	***10***	***13***	***0***	***0***	***23***

Administrative Case Outcomes	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Revocation; stayed suspension/probation					
Pharmacist	1	1	0	0	2
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	0	0	0	0	0
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Pharmacy	0	0	0	0	0
Sterile Compounding	0	0	0	0	0
Outsourcing	0	0	0	0	0
Total	***1***	***1***	***0***	***0***	***2***

Administrative Case Outcome	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Revocation; stayed; probation					
Pharmacist	11	5	0	0	16
Intern Pharmacist	1	0	0	0	1
Pharmacy Technician	1	2	0	0	3
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Pharmacy	4	5	0	0	9
Sterile Compounding	0	1	0	0	1
Outsourcing	0	0	0	0	0
Total	***17***	***13***	***0***	***0***	***30***

Administrative Case Outcome	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Surrender / Voluntary Surrender					
Pharmacist	5	4	0	0	9
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	3	1	0	0	4
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Pharmacy	7	6	0	0	13
Sterile Compounding	0	0	0	0	0
Outsourcing	0	0	0	0	0
Total	***15***	***11***	***0***	***0***	***26***

Administrative Case Outcome	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Public Reproval / Reprimand					
Pharmacist	4	2	0	0	6
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	0	0	0	0	0
Designated Representative	0	0	0	0	0
Wholesaler	0	1	0	0	1
Pharmacy	1	1	0	0	2
Sterile Compounding	0	0	0	0	0
Outsourcing	0	0	0	0	0
Total	***5***	***4***	***0***	***0***	***9***

Administrative Case Outcome	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Licenses Granted					
Pharmacist	0	2	0	0	2
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	0	1	0	0	1
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Pharmacy	1	0	0	0	1
Sterile Compounding	0	0	0	0	0
Outsourcing	0	0	0	0	0
Total	***1***	***3***	***0***	***0***	***4***

Administrative Case Outcome	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Licenses Denied					
Pharmacist	0	0	0	0	0
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	0	0	0	0	0
Designated Representative	0	0	0	0	0
Wholesaler	1	0	0	0	1
Pharmacy	2	0	0	0	2
Sterile Compounding	0	0	0	0	0
Outsourcing	0	0	0	0	0
Total	***3***	***0***	***0***	***0***	***3***

Administrative Case Cost Recovery Efforts	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Cost Recovery Requested	***$340,239***	***$476,654***	***$0***	***$0***	***$816,893***
Cost Recovery Collected	***$154,930***	***$484,154***	***$0***	***$0***	***$639,084***

Immediate Public Protection Sanctions	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Interim Suspension Orders	2	1	0	0	3
Automatic Suspension Orders	2	0	0	0	2
Penal Code 23 Restrictions	2	2	0	0	4
Cease and Desist - Outsourcing	0	0	0	0	0
Cease and Desist - Unlicensed Activity	0	0	0	0	0
Cease and Desist - Sterile Compounding	0	0	0	0	0

Probation Statistics	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Quarter Ending
Licenses on Probation					
Pharmacist	208	190	0	0	190
Intern Pharmacist	1	1	0	0	1
Pharmacy Technician	17	16	0	0	16
Designated Representative	2	1	0	0	1
Wholesaler / 3PL	3	3	0	0	3
Pharmacy	57	54	0	0	54
Sterile Compounding	8	8	0	0	8
Outsourcing	1	1	0	0	1
Total	***297***	***274***	***0***	***0***	***274***

Probation Statistics	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Probation Office Conferences	16	10	0	0	26
Probation Interviews / Site Inspections	97	56	0	0	153
Probation Terminated / Completed	35	37	0	0	72
Referred to AG for Non-Compliance	2	2	0	0	4

As of 12/31/2022

Board of Pharmacy

Citation and Fine Statistics FY 2022/23

Citation Outcomes	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Pharmacist with Fine	41	24	0	0	65
Pharmacist-in-Charge with Fine*	30	67	0	0	97
Pharmacist no Fine	67	69	0	0	136
Pharmacist-in-Charge no Fine*	44	19	0	0	63
Pharmacy with Fine	110	18	0	0	128
Pharmacy no Fine	30	32	0	0	62
Pharmacy Technician with Fine	5	5	0	0	10
Pharmacy Technician no Fine	1	7	0	0	8
Wholesalers	5	3	0	0	8
Designated Representative	0	1	0	0	1
Clinics	0	0	0	0	0
Drug Room	0	0	0	0	0
Exempt Hospital	1	0	0	0	1
Hospital Pharmacy	6	5	0	0	11
Miscellaneous**	16	19	0	0	35
Unlicensed Premises	1	0	0	0	1
Unlicensed Person	1	1	0	0	2

*These numbers are also represented in the RPH columns, but reflect how many RPHs were cited as PICs

**Intern Pharmacist, Licensed Correctional Facilities, Exempt Pharmacies, Non-Resident Pharmacies, and Vet Retailers

Pharmacists	%	Pharmacies	%	Pharmacists In Charge	%
1716 - Variation from prescription	24%	1716 - Variation from prescription	39%	1716 - Variation from prescription	21%
1735.3(a)(2)(b) - For each compounded drug product, the pharmacy records shall include (2)A compounding log consisting of a single document containing all of the following…(B)The date the drug preparation	16%	4113(d) - Every pharmacy shall notify the board in writing within 30 days of the date of a change in pharmacist-in-charge	14%	1715(a) - Self-assessment form of a pharmacy by the pharmacist-in-charge; shall complete a self-assessment of pharmacy compliance with federal and state pharmacy law	17%
1735.3(a)(2)(J) - For each compounded drug preparation, pharmacy records shall include a compounding log consisting of a single document containing documentation of quality reviews and required post-c	16%	4305(b) - Operation of a pharmacy for more than 30 days without supervision or management by a pharmacist-in-charge shall constitute grounds for disciplinary action	11%	4301(g) - Unprofessional Conduct - Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts	14%
1751.8(e) - Beyond Use Dating for Sterile Compounded Drug Preparations	16%	733(a) - Dispensing prescription drugs and devices- No licentiate shall obstruct a patient in obtaining a prescription	8%	1707.2(a)(3) - A pharmacist shall provide oral consultation to his or her patient or the patient's agent in all care settings whenever the prescription drug has not previously been dispensed to a patient	7%
4301(g) - Unprofessional Conduct - Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts	9%	1715(a) - Self-assessment form of a pharmacy by the pharmacist-in-charge; shall complete a self-assessment of pharmacy compliance with federal and state pharmacy law	8%	1735.2(b) - Compounding Limitations and Requirements	7%
1715(b)(2) - Self-Assessment of a pharmacy by the pharmacist-in-charge; shall complete a self-assessment within 30 days whenever: there is a change in pharmacist-in-charge	3%	1764/56.10(a) - Unauthorized disclosure of prescription and medical information	6%	1711(d) - Quality assurance program finding shall be used to develop systems to prevent medication errors…	7%
1732.5(a) - Renewal requirements for pharmacist - 30 hours of continuing education	3%	4301(O) - Unprofessional conduct; assist in violation	5%	1715(b)(2) - Self-Assessment of a pharmacy by the pharmacist-in-charge; shall complete a self-assessment within 30 days whenever: there is a change in pharmacist-in-charge	7%
4115(e) - No person shall act as a pharmacy technician without first being licensed by the board as a pharmacy technician	3%	1715(b)(2) - Self-Assessment of a pharmacy by the pharmacist-in-charge; shall complete a self-assessment within 30 days whenever: there is a change in pharmacist-in-charge	5%	4301(f) - Unprofessional Conduct - Acts of moral turpitude, dishonesty, fraud, deceit or corruption	7%
4081(a)/1718 - Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory/Current Inventory Defined	3%	4081(a)/1718 - Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory/Current Inventory Defined	3%	4115(f)(1) - A pharmacy with only one pharmacist shall have no more than one pharmacy technician performing tasks... The ratio of pharmacy technicians performing the tasks to any additional pharmacist	7%
1715(a) - Self-assessment form of a pharmacy by the pharmacist-in-charge; shall complete a self-assessment of pharmacy compliance with federal and state pharmacy law	3%	4301(f) - Unprofessional Conduct - Acts of moral turpitude, dishonesty, fraud, deceit or corruption	3%	4081(a)/1718 - Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory/Current Inventory Defined	7%

California State Board of Pharmacy
SB 1441 Uniform Standards

The data includes licensees participating in the Pharmacist Recovery Program (PRP) and licensees on probation with substance use disorders. This data includes July 2022 through December 2022.

Board of Pharmacy	July Sep	Oct Dec	Jan-Mar	Apr-Jun	22/23
PRP Intakes					
PRP Self-Referrals					
PRP Probation Referrals					
PRP Under Investigation	3				3
PRP In Lieu Of (investigation conducted)					
Total Number of PRP Intakes	3				3
New Probationers					
Pharmacists	2	1			3
Intern Pharmacists					
Pharmacy Technicians		1			1
Total New Probationers	2	2			4
PRP Participants and Recovery Agreements					
Total PRP Participants	39	34			39
Recovery Agreements Reviewed	26	34			60
Probationers and Inspections					
Total Probationers	48	5			48
Inspections Completed	31	33			64
Referrals to Treatment					
Referrals to Treatment (PRP and Probationers)	2				2
Drug Tests					
Drug Test Ordered (PRP and Probationers)	435	511			946
Drug Tests Conducted (PRP and Probationers)	431	489			920
Relapses (Break in Sobriety)					
Relapsed (PRP and Probationers)		1			1
Major Violation Actions					
Cease Practice/Suspension (PRP and Probationers)	3	3			6
Termination from PRP					
Probationers Referred for Discipline					
Closure					
Successful Completion (PRP and Probationers)	12	5			17
Termination (Probation)	1				1
Voluntary Surrender (Probation)					
Surrender as a result of PTR (Probation)					
Closed Public Risk (PRP)					
Non-compliance (PRP and Probationers)	46	49			95
Other (PRP)	1	2			3
Patients Harmed					
Number of Patients Harmed (PRP and Probationers)					Zero

Drug of Choice at PRP Intake or Probation

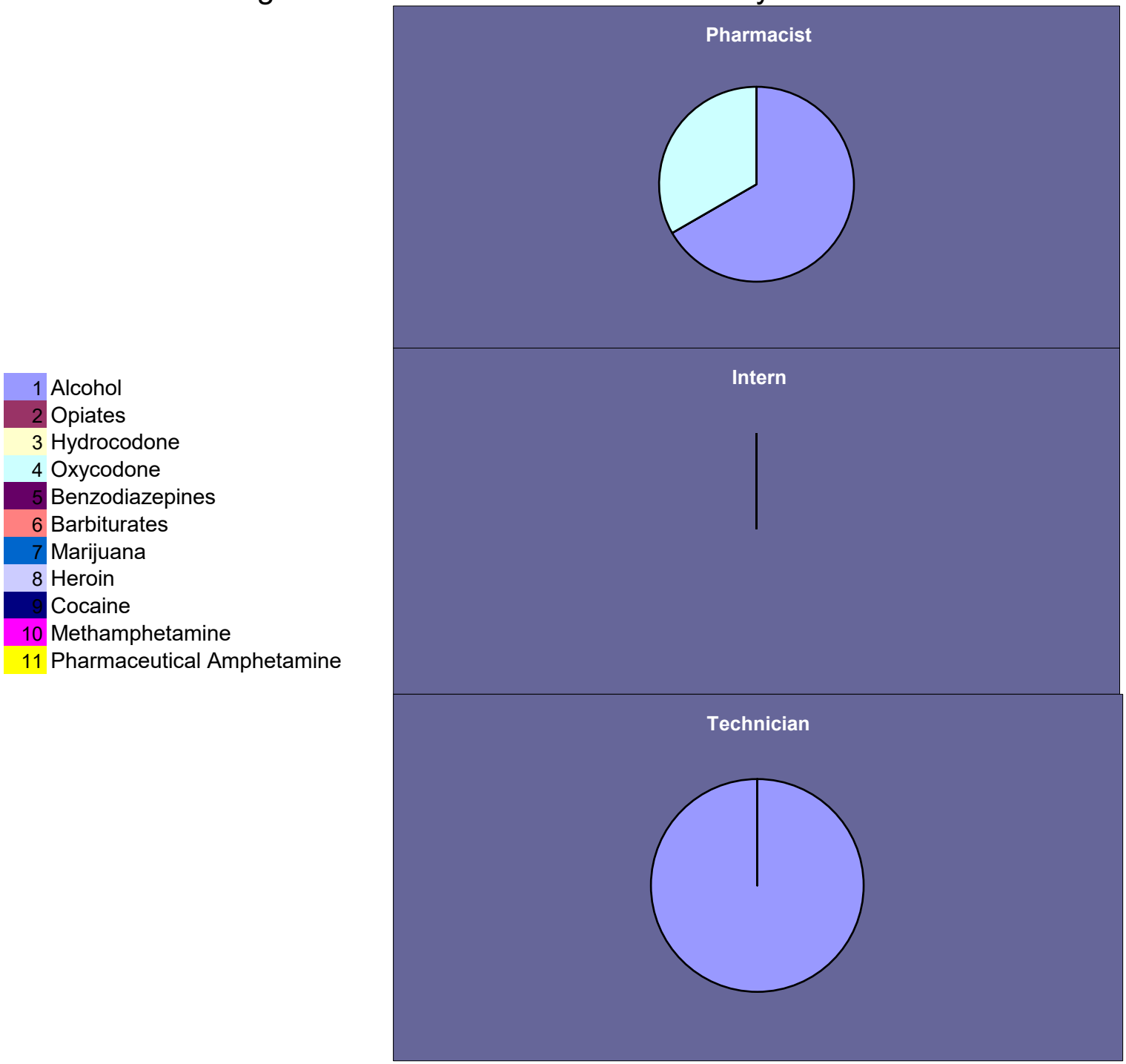
Pharmacists	July-Sep	Oct-Dec	Jan-Mar	Apr-Jun	Total 22/23
Alcohol	2				2
Ambien					
Opiates					
Hydrocodone	1				1
Oxycodone					
Morphine					
Benzodiazepines					
Barbiturates					
Marijuana					
Heroin					
Cocaine					
Methamphetamine					
Pharmaceutical Amphetamine					

SB 1441 Uniform Standards

The data includes licensees participating in the Pharmacist Recovery Program (PRP) and licensees on probation with substance use disorders. This data includes July 2022 through December 2022.

Board of Pharmacy	July Sep	Oct Dec	Jan-Mar	Apr-Jun	22/23
Phentermine					
Methadone					
Zolpidem Tartrate					
Hydromorphone					
Clonazepam					
Tramadol					
Carisprodol					
Phendimetrazine					
Promethazine w/Codeine					
Intern Pharmacists	**July-Sep**	**Oct-Dec**	**Jan-Mar**	**Apr-Jun**	**Total 22/23**
Alcohol					
Opiates					
Hydrocodone					
Oxycodone					
Benzodiazepines					
Barbiturates					
Marijuana					
Heroin					
Cocaine					
Methamphetamine					
Pharmaceutical Amphetamine					
Phentermine					
Methadone					
Zolpidem Tartrate					
Hydromorphone					
Clonazepam					
Tramadol					
Carisprodol					
Phendimetrazine					
Promethazine w/Codeine					
Pharmacy Technicians	**July-Sep**	**Oct-Dec**	**Jan-Mar**	**Apr-Jun**	**Total 22/23**
Alcohol		1			1
Opiates					
Hydrocodone					
Oxycodone					
Benzodiazepines					
Barbiturates					
Marijuana					
Heroin					
Cocaine					
Methamphetamine					
Pharmaceutical Amphetamine					
Phentermine					
Methadone					
Zolpidem Tartrate					
Hydromorphone					
Clonazepam					
Tramadol					
Carisprodol					
Phendimetrazine					
Promethazine w/Codeine					

Drug Of Choice - Data entered from July 2022 to December 2022



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