California State Board of Pharmacy
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www.pharmacy.ca.gov

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

Enforcement and Compounding Committee Report
March 27, 2025

Maria Serpa, Licensee Member, Chair
Renee Barker, Licensee Member, Vice-Chair
Jeff Hughes, Public Member
Seung Oh, Licensee Member, President
Ricardo Sanchez, Public Member
Nicole Thibeau, Licensee Member

I. Call to Order, Establishment of Quorum, and General Announcements

II. Public Comments on Items Not on the Agenda/Agenda Items for Future Meetings

Note: The Committee may not discuss or take action on any matter raised during this public comment section that is not included on this agenda, except to decide whether to place the matter on the agenda of a future meeting. [Government Code sections 11125, 11125.7(a)]

III. Approval of Draft Minutes from the October 16, 2024 Enforcement and Compounding Committee Meeting

Attachment 1 includes a copy of the draft minutes.

IV. Discussion and Consideration of Implementation of Assembly Bill 1902 (Alanis, Chapter 330, Statutes of 2024) Prescription Drug Labels: Accessibility

Background

Assembly Bill 1902 establishes requirements for a pharmacy to provide an accessible prescription label affixed to the container to a patient that is blind, has low-vision, or is otherwise print disabled, under specified conditions. This law further provides that if the accessible prescription label cannot be affixed to the container, the dispenser must provide the patient or their authorized representative with a supplemental document that meets the requirements of this section. (Note: Exempt from these requirements are drugs dispensed and administered by an institutional pharmacy (unless the medication is provided upon release from the health care facility), correctional institution, or licensed correctional pharmacy.)

For Committee Consideration and Discussion

During the meeting, it is recommended that members consider the measure and seek

input from interested stakeholders on proposed regulations to assist consumers and licensees with an understanding of the requirements of the legislation. To help guide the discussion, it may be appropriate for the Committee to consider the following questions.

1. The law specifies that the accessible prescription label be made available in a timely manner comparable to other patient wait times and lasting for at least the duration of the prescription.

   Should the Board further define through regulation the phrase, "in a timely manner comparable to other patient wait times?" Staff note that depending on the type of pharmacy, e.g. mail order, community pharmacy, closed door pharmacy, etc., the parameters for "timely manner" could require different provisions.

2. The law specifies that the accessible prescription label must be appropriate to the disability and language of the person making the request through the use of audible, large print, Braille, or translated directions.

   a. Should the Board further define through regulation how a pharmacy will determine what is appropriate to the disability?
   b. Should the Board establish a minimum font size to define "large print?"
   c. Should the Board specify that the accessible prescription label needs to be in the patient centered format?
   d. Staff note that it may be appropriate to establish requirements for pharmacies to develop policies and procedures to provide guidance to pharmacists on how to identify the appropriate accessible prescription label.

3. The law requires that accessible prescription labels must conform to the format-specific best practices established by the United State Access Board and the National Standards for Culturally and Linguistically Appropriate Services (CLAS) in Health and Health Care (also referred to as the National CLAS Standards).

   Should the Board further define through regulation how a pharmacy will educate pharmacists about these standards? Staff note that it may be appropriate to establish requirements for pharmacies to develop policies and procedures to provide guidance to pharmacists on how to evaluate for compliance with these standards.

Following the Committee and subsequent Board discussion, staff will develop proposed regulation text for consideration at a future meeting.

V. Discussion, Consideration and Possible Action on Updates to Self-Assessment Forms Incorporated by Reference

a. Community Pharmacy/Hospital Outpatient Pharmacy Self-Assessment Form 17M-13, California Code of Regulations (CCR), Title 16, Section 1715(c)
b. Hospital Pharmacy Self-Assessment Form 17M-14, CCR, Title 16, Section 1715(c)
c. Wholesaler/Third-Party Logistics Provider Self-Assessment Form 17M-26, CCR, Title 16,

Section 1784(c)

d. Automated Drug Delivery System Self-Assessment Form 17M-112, CCR, Title 16, Section 1715.1
e. Surgical Clinic Self-Assessment Form 17M-118, Business and Professions Code Section 4192

Relevant Law

California Code of Regulations, title 16, section 1715(c) establishes the self-assessment requirements for the pharmacist-in-charge of a community pharmacy to complete a "Community Pharmacy Self-Assessment/Hospital Outpatient Pharmacy Self-Assessment." Section 1715 (c) further establishes a similar requirement for the pharmacist-in-charge of a hospital pharmacy serving inpatient consumers to complete a "Hospital Pharmacy Self-Assessment." Both forms are incorporated by reference in this section of the regulation.

California Code of Regulations, title 16, section 1784(c) establishes the self-assessment requirements for a wholesaler or third-party logistics provider (3PL), through its designated representative-in-charge or responsible manager, to complete a "Wholesaler/Third Party Logistics Provider Self-Assessment." The form is incorporated by reference in the regulation.

California Code of Regulations, title 16, section 1715.1(c) establishes the self-assessment requirements for the pharmacist-in-charge of an automated drug delivery system (ADDS) to complete an "Automated Drug Delivery System Self-Assessment." The form is incorporated by reference in this section of the regulation.

Business and Professions Code section 4192 establishes a self-assessment requirement for the consulting pharmacist of a surgical clinic to complete a Surgical Clinic Self-Assessment Form.

Background

As pharmacy law is very dynamic, on an annual basis, the self-assessment forms must be updated to reflect the most current law. During discussions on the proposed updates to the self-assessment forms in February 2023, given that the forms restate law and do not create requirements not already established in statute and regulation, the Board determined updates to the forms could best be facilitated through a streamlined Section 100 regulation process. Regrettably, staff was advised by the Office of Administrative Law (OAL) that updates to these forms cannot be made via this streamlined process.

Since that time, Board staff have completed the initial rulemaking package to amend sections 1715 and 1784 and self-assessment forms 17M-13, 17M-14, and 17M-26 (community pharmacy, hospital pharmacy, and wholesaler/3PL), incorporated by reference, to update the forms to include statutory and regulatory changes, which became effective on January 1, 2024 (as approved by the Board in February 2024). The amendments were noticed for a 45-day public comment period on January 10, 2025.

The Board will be considering comments during the comment period at the April 9-10, 2025 Board Meeting.

Additionally, Board staff is working with the Department of Consumer Affairs on the amendment to section 1715.1 and ADDS self-assessment form 17M-112, incorporated by reference, as approved by the Board in April 2024.

For Committee Consideration and Discussion
During the meeting, members will have the opportunity to review the proposed updates to the self-assessment forms. The forms incorporate the changes considered by the Committee last year and now also reflect additional changes to incorporate more recent changes in pharmacy law.

Given the various stages of promulgation for the respective forms, it is recommended that during the meeting members provide staff with feedback to finalize the draft forms. Once approved by the Board, staff will update the drafts available on the Board's website and will work with counsel on the appropriate manner to update the self-assessment forms currently undergoing the formal rulemaking process.

Attachment 2 includes copies of the updated self-assessment forms. Proposed changes to the forms are reflected in yellow highlight.

VI. Discussion and Consideration of Petition Request Forms used for Petitions for Reinstatement of a License, Petitions for Modification of Penalty, and Petitions for Early Termination of Probation

Relevant Law
Business and Professions Code section 4309 permits a person whose license has been revoked or suspended or who has been placed on probation to petition the Board for reinstatement or modification of penalty, including modification or termination of probation, after not less than the following minimum periods have elapsed from the effective date of the decision ordering disciplinary action:

(1) At least three years for reinstatement of a revoked license.
(2) At least two years for early termination of probation of three years or more.
(3) At least one year for modification of a condition, or reinstatement of a license revoked for mental or physical illness, or termination of probation of less than three years.

Background
Petitioners are required to answer several questions on the application, including but not limited to, questions related to personal history and current and/or prior discipline whether it occurred in California or out of state.

The Board uses different forms to reflect the different types of petitions that may be considered by the Board. Board staff recently revised the petition forms as they had not been revised since 1999.

Recently staff revised the various applications, as detailed below:

1. The petition for reinstatement application form was updated to align the personal history questions with those used on initial applications for licensure. In addition, the application was converted to a fillable pdf to improve accessibility and ease of use.
2. The petition for early termination of probation and the petition for reduction (modification) of penalty application forms were also converted to a fillable pdf to improve accessibility and ease of use. In addition, the forms were updated to remove questions related to disclosure of arrests or disciplinary information. These questions were removed for streamlining purposes, as this information is reported as part of the renewal application process and as part of standard terms and conditions of probation.

These changes were made in consultation with prior Board counsel but were not reviewed by the Committee or the Board.

More recently, the Licensing Committee considered changes to the proposed individual applications for licensure to update questions related to impairment so that the applications are free of intrusive mental health questions and stigmatizing language.

In advance of the Committee meeting, staff consulted with the Committee chair to review the revised applications and is now proposing a new consolidated application form to be used for all types of petitions.

For Committee Consideration and Discussion

During the meeting, members will have the opportunity to review updates to the petition forms and provide feedback to staff on the use of the consolidated application. In addition, members might consider delegating to staff to make changes to the application instructions and guidelines in coordination with the Committee chair.

Attachment 3 includes the following:

- Attachment 3a: Proposed New Form
- Attachment 3b: Current Forms (recently updated)
- Attachment 3c: Prior Forms

VII. Discussion and Consideration of Enforcement Statistics

During the first eight months of the new fiscal year, July 2024-February 2025, the Board initiated 2,099 complaints and closed 1,971 investigations. The Board has issued 117 letters of admonishment and 470 citations and referred 100 cases to the Office of the Attorney General. The Board has revoked 63 licenses, accepted the disciplinary surrender of 25 licenses, formally denied five applications, and imposed other levels of discipline against 79 licensees and/or applicants.

As of March 1, 2025, the Board had 1,495 field investigations pending. Following is a breakdown providing more detail in the various investigation processes:

	Mar. 1, 2024		July 1, 2024		Oct. 1, 2024		Jan. 1, 2025		Mar. 1, 2025	
	Vol.	Avg. Days	Vol.	Avg. Days	Vol.	Avg. Days	Vol.	Avg. Days	Vol.	Avg. Days
Awaiting Assignment	107	7	44	6	63	14	31	10	35	8
Cases Under Investigation	1,061	134	1,005	136	908	146	978	141	1,032	136
Pending Supervisor Review	355	85	223	74	147	74	173	62	276	65
Pending Second Level Review	115	26	99	22	229	26	116	64	111	55
Awaiting Final Closure	24	3	56	8	34	14	49	34	41	30

Attachment 4 includes the enforcement statistics. Updated statistics that include the data for March 2025 will be provided during the April 9-10, 2025, Board meeting.

VIII. Future Committee Meeting Dates

- June 11, 2025
- October 16, 2025

IX. Adjournment

Attachment 1

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California State Board of Pharmacy
Department of Consumer Affairs
DRAFT Enforcement and Compounding Committee Meeting Minutes

Date: October 16, 2024

Location: OBSERVATION AND PUBLIC COMMENT IN PERSON:
California State Board of Pharmacy
2720 Gateway Oaks Drive, First Floor Hearing Room
Sacramento, CA 95833

Board of Pharmacy staff members were present at the observation and public comment location.

PUBLIC PARTICIPATION AND COMMENT FROM REMOTE LOCATIONS VIA WEBEX

Board Members Present:
Maria Serpa, PharmD, Licensee Member, Chair
Renee Barker, PharmD, Licensee Member, Vice Chair
Jeff Hughes, Public Member
Seung Oh, PharmD, Licensee Member
Nicole Thibeau, PharmD, Licensee Member

Board Members Not Present: Indira Cameron-Banks, Public Member

Staff Present:
Anne Sodergren, Executive Officer
Julie Ansel, Deputy Executive Officer
Corinne Gartner, DCA Counsel
Debbie Damoth, Executive Specialist Manager

I. Call to Order, Establishment of Quorum, and General Announcements

Chairperson Serpa called the meeting to order at approximately 9:01 a.m. As part of the opening announcements, Chairperson Serpa reminded everyone that the Board is a consumer protection agency charged with administering and enforcing Pharmacy Law. Department of Consumer Affairs' staff provided instructions for participating in the meeting.

Roll call was taken. The following members were present via WebEx: Renee Barker, Licensee Member; Jeff Hughes, Public Member; Seung Oh, Licensee

Member; Nicole Thibeau, Licensee Member; and Maria Serpa, Licensee Member. A quorum was established.

Dr. Serpa reminded Committee members to remain visible with cameras on throughout the open session of the meeting. Dr. Serpa advised if members needed to temporarily turn off their camera due to challenges with internet connectivity, they must announce the reason for their non-appearance when the camera was turned off.

II. Public Comments on Items Not on the Agenda/Agenda Items for Future Meetings

Members of the public in Sacramento and via WebEx were provided the opportunity to comment; however, no comments were made.

III. Approval of Draft Minutes from the July 17, 2024 Enforcement and Compounding Committee Meeting

The draft minutes of the July 17, 2024 Enforcement and Compounding Committee meeting were presented for review and approval.

Motion: Approve July 17, 2024 Enforcement and Compounding Committee meeting minutes as presented

M/S: Oh/Barker

Members of the public were provided the opportunity to comment in Sacramento and via WebEx; however, no comments were made.

Support: 5 Oppose: 0 Abstain: 0 Not Present: 1

Board Member	Vote
Barker	Support
Cameron-Banks	Not Present
Hughes	Support
Oh	Support
Serpa	Support
Thibeau	Support

IV. Presentation on Distribution of Controlled Substances, Wholesalers Perspective, Provided by Leah Lindahl, Vice President, State Government

Affairs, Healthcare Distribution Alliance and Sara Watson, CPhT, Manager, State Regulatory Outreach, Cardinal Health

Chairperson Serpa referenced meeting materials containing background information. Dr. Serpa recalled the Board receives public comments from patients and chronic pain advocates about impacts to patients who are facing challenges receiving their controlled substances. She noted the Committee also received information on actions taken by the DEA to change allocation quotas for stimulant medications. Dr. Serpa welcomed Leah Lindahl, Vice President, State Government Affairs with the Healthcare Distribution Alliance (HDA), and Sara Watson, State Regulatory Outreach Manager with Cardinal Health, to provide a presentation on the issue from the wholesalers' perspective as part of the Committee's ongoing education.

Ms. Lindahl provided an overview of HDA, which is a national association that represents wholesaler distributors, and discussed the importance of communication with wholesaler distributors.

Ms. Watson reviewed Cardinal Health's Controlled Substance Monitoring Program (CSMP) and the enhancements to the CSMP that Cardinal Health has put into place as a result of the National Opioid Settlement. She highlighted areas of the CSMP including onboarding, thresholds, and reporting, and also discussed resources available.

Members were provided the opportunity to comment.

Members were surprised to hear that wholesalers can't proactively reach out to their pharmacy customers to inform them how to increase their threshold. A member suggested having the wholesalers continue to reach out to their pharmacy customers periodically, in addition to onboarding processes, to provide them with education and remind them of the tools available to them.

Members asked if there were ways for the wholesalers to dynamically look at store closures to anticipate the shifting in prescription volume and adjust thresholds accordingly. Ms. Watson indicated the pharmacy customers would be more aware of these changes and it would a difficult IT solution for the wholesaler to manage on its own. She continued to explain that under the injunctive relief provisions of the National Opioid Settlement wholesalers are prohibited from disclosing anything about thresholds or how they are set. Additionally, if an order hits the threshold, the order would be held and

cancelled, and the Board of Pharmacy would be notified. Ms. Lindahl indicated the DEA was made aware of shortages, but the DEA controls quotas. The presenters were asked if there was a way a wholesaler can supply data going back over time to identify trends in volumes of drugs sold to pharmacies. They were aware of a report but would have to look into seeing if it was available.

Members discussed what could be done through the Board and/or the distributors to change the injunctive relief provisions, as the perception is that the provisions are not helping address the opioid crisis. A member provided an example based on personal experience and expressed concern that patients were suffering when algorithms control over the context and clinical considerations behind specific orders. Ms. Lindahl suggested informing congressional members, and the DEA directly, about these concerns, as well as notifying the wholesaler when shortages are identified so they are aware of changing purchasing patterns. Ms. Lindahl pointed out the injunctive relief terms were dictated to the wholesalers by the Attorneys General and there's likely not an opportunity to change them.

Members also expressed concerns about nomenclature, noting that the term "suspicious order" is scary for the pharmacy making the order, and unintended consequences when thresholds are exceeded and this results in a report to the Board. Ms. Watson advised "suspicious order" was a federal definition from the controlled substance act. She continued education and communication was important. Ms. Watson also advised it does help the wholesaler identify and terminate players with nefarious intentions. Members continued to discuss the impact on patients of a 5-7 day threshold change evaluation and inquired if this timeframe could be adjusted based on patient-specific circumstances. Members were advised the 5-7 day threshold evaluation time is an average turnaround and would be faster if information requested by wholesalers was provided immediately. The timeframe of the injunctive relief was identified as at least 10 years.

Members of the public in Sacramento were provided the opportunity to comment; however, no comments were made.

Members of the public were provided the opportunity to comment via WebEx.

Public comment was received from members of the public including a patient pain advocate, a pharmacist, a pharmacist representative of Kaiser,

and a physician. Public comments expressed concerns including the negative impact to patients of the injunctive relief; impact on non-opioid drugs; lack of consideration of unique patient needs and changes in clinical practice; threshold adjustments not being made fast enough; and appearance that injunctive relief was mysterious and harmful to patients. Comment also requested clarification on the threshold process, application of the injunction relief, and primary/secondary wholesaler contracts.

Ms. Watson provided clarification on the threshold process, indicated three wholesalers were impacted by the injunctive relief, and explained that questions are asked about primary and secondary wholesalers to obtain a full picture of controlled substances purchased.

Public comment also suggested the Board of Pharmacy and the Medical Board of California should work together to try to address these concerning issues.

Members were provided the opportunity to comment after having received public comment.

Dr. Serpa recommended the Board of Pharmacy provide educational materials to licensees, such as a subscriber alert and/or article in *The Script*, to help inform them about their options for adjusting their thresholds. Members and staff were in favor of Dr. Serpa's recommendation. The Committee also discussed having a collaborative discussion with the Medical Board of California as well as the Director of Department of Consumer Affairs (DCA) to engage additional DCA Boards and Bureaus (*e.g.*, Nursing Board, Physician Assistant Board, *etc.*); issuing a policy statement; and continuing to discuss this issue at future meetings.

The Committee took a break from 10:40 a.m. to 10:55 a.m. Roll call was taken. The following members were present via WebEx: Renee Barker, Licensee Member; Jeff Hughes, Public Member; Seung Oh, Licensee Member; Nicole Thibeau, Licensee Member; and Maria Serpa, Licensee Member. A quorum was established.

V. Discussion and Consideration of Draft Report to the Legislature on Automated Drug Delivery Systems as Required in Business and Professions Code (BPC) Section 4427.8

Dr. Serpa advised as included in the meeting materials, the Board was required to submit a report to the Legislature on the use and oversight of

automated drug delivery systems (ADDS) as part of the upcoming sunset evaluation process. During the July 2023 Committee meeting, members received the first presentation related to the findings of quality assurance (QA) reports received, which revealed in part what appeared to be a lack of compliance with reporting requirements. Subsequently, staff undertook education of licensees on the reporting requirements. At the July 2024 Committee meeting, a presentation with updated data was provided.

Dr. Serpa referenced the draft report included in the meeting materials and noted that having reviewed the report, she believed the information was appropriate. She also agreed with the conclusions drawn from the information the Board has received.

Members were provided the opportunity to comment; however, no comments were made.

Motion: Recommend to the Board approval of the draft legislative report as presented.

M/S: Oh/Thibeau

Members of the public in Sacramento were provided the opportunity to comment; however, no comments were made.

Members of the public were provided the opportunity to comment via WebEx.

A pharmacist representative from Kaiser noted the report didn't address the continued need for the licensure of ADDS and recommended removing the ADDS error reporting requirement.

Members were provided the opportunity to comment after having received public comment. Dr. Serpa advised as part of the report, the Board found there were concerns with ADDS in skilled nursing facilities and jails.

Support: 5 Oppose: 0 Abstain: 0 Not Present: 1

Board Member	Vote
Barker	Support
Cameron-Banks	Not Present
Hughes	Support
Oh	Support
Serpa	Support
Thibeau	Support

VI. Discussion and Consideration of Enrolled or Recently Signed Legislation Impacting the Practice of Pharmacy

Chairperson Serpa referenced meeting materials discussing enrolled legislation that was either signed or vetoed by the governor and including recommendations of Board staff on implementation activities.

a. Assembly Bill 1842 (Reyes, Chapter 633, Statutes 2024) Health Care Coverage: Medication-Assisted Treatment

Dr. Serpa agreed the implementation activities identified by staff were appropriate.

Members were provided the opportunity to comment; however, no comments were made.

Members of the public in Sacramento and participating via WebEx were provided the opportunity to comment; however, no comments were made.

b. Assembly Bill 1902 (Alanis, Chapter 330, Statutes of 2024) Prescription Drug Labels: Accessibility

Dr. Serpa requested members comment on some of the issues raised in the meeting materials, including if the Committee believed development of regulations appeared appropriate.

Some members believed regulations were not needed while other members believed further clarification of the statute's provisions would be helpful. Members discussed having resources available to the regulated public, such as an article in the newsletter and updates to

the self-assessment form, as well as asking staff to consider if regulations might be required.

Members of the public in Sacramento were provided the opportunity to comment; however, no comments were made.

Members of the public were provided the opportunity to comment via WebEx.

A pharmacist representative from Kaiser believed the statute provided sufficient detail and a regulation was not required. The pharmacist encouraged the Board to exercise reasonableness for enforcing "timely manner" as identified in the statute.

Members were provided the opportunity to comment. Dr. Serpa requested staff develop possible regulation text as a way of continuing the discussion.

c. Assembly Bill 2115 (Haney, Chapter 634, Statutes of 2024) Controlled Substances

Dr. Serpa agreed that the implementation activities recommended by staff were appropriate regarding AB 2115, which authorizes specified entities to dispense a 72-hour supply of a schedule II controlled substance for purposes of relieving acute withdrawal symptoms while arrangements are being made for referral for treatment.

Members were provided the opportunity to comment; however, no comments were made.

Members of the public in Sacramento were provided the opportunity to comment; however, no comments were made.

Members of the public were provided the opportunity to comment via WebEx.

A pharmacist commented that this lifesaving rule deserved a lot of attention for patients addicted to opioids and transitioning to a treatment program.

d. Assembly Bill 3063 (McKinnor, 2024) Pharmacies: Compounding

Dr. Serpa advised AB 3063, relating to adding a flavoring agent to a prescription medication, had been vetoed, noting this was the second year the governor has vetoed this measure. The Board had opposed the measure, as it conflicted with USP standards. Dr. Serpa noted the meeting materials included the amendment the Board had requested of the author to address the Board's concerns. Regrettably, the amendment was not accepted. Dr. Serpa appreciated the question posed in the meeting materials and was interested in member's thoughts on the suggestion that the Board sponsor legislation in line with the amendment offered to the author's office, with the ultimate goal of assisting pharmacies with implementation challenges they may face in complying with national standards. The proposed legislation would not change USP requirements but would allow pharmacies to make flavoring additions without obtaining the prescribers' authorization each time.

Members were provided the opportunity to comment. Members discussed the proposed statutory language.

Members of the public in Sacramento were provided the opportunity to comment; however, no comments were made.

Members of the public were provided the opportunity to comment via WebEx.

Public comment was received from a pharmacist and representatives of Kaiser and FlavorRx. Comments indicated the proposed language would not make it easier to offer flavoring.

Members were provided the opportunity to comment after receiving public comment. Members were interested in working with stakeholders to make a path forward while following UPS Chapters and noted the Board was not trying to ban or take away flavoring. The FDA, and FAQs from USP, make it clear that adding flavoring is generally considered compounding. Members agreed the current statutory proposal was at least a starting point for future discussion.

Motion: Recommend that the chairperson and staff work

together to develop potential statutory language in line with the Board's prior requested amendment related to flavoring agents and prescription requirements.

A flavoring agent may be added to a prescribed FDA approved drug in an oral liquid dosage form at the request of a patient or patient's agent without consultation with the prescriber or their authorized agent. A pharmacist performing such action must provide documentation on the prescription record.

M/S: Oh/Barker

Members of the public in Sacramento were provided the opportunity to comment; however, no comments were made.

Members of the public were provided the opportunity to comment via WebEx.

A representative from FlavoRx disagreed with the Board's understanding that the FDA generally considered flavoring to be compounding.

Members were provided the opportunity to comment after having received public comment; however, no comments were made.

Support: 5 Oppose: 0 Abstain: 0 Not Present: 1

Board Member	Vote
Barker	Support
Cameron-Banks	Not Present
Hughes	Support
Oh	Support
Serpa	Support
Thibeau	Support

e. Senate Bill 164 (Committee on Budgets, Chapter 41, Statutes of 2024) State Government

Dr. Serpa advised implementation of SB 164, which increases the CURES fee from $9 annually to $15 annually, would be facilitated by the Department of Justice.

Members were provided the opportunity to comment; however, no comments were made.

Members of the public in Sacramento and participating via WebEx were provided the opportunity to comment; however, no comments were made.

f. Senate Bill 954 (Menjiva, 2024) Sexual Health

Dr. Serpa advised this measure would have included provisions prohibiting a retail establishment from refusing to furnish nonprescription contraception to a person based solely on age and was vetoed by the governor. Dr. Serpa didn't believe the measure required discussion by the Committee.

Members were provided the opportunity to comment. A member asked if there was space for education on current law regarding access to contraception. DCA Counsel would have to research the question and report back.

Members of the public in Sacramento were provided the opportunity to comment; however, no comments were made.

Members of the public were provided the opportunity to comment via WebEx. A pharmacist supported the idea of educating the public on current law in this area.

g. Senate Bill 966 (Wiener, 2024) Pharmacy Benefits

Dr. Serpa noted Senate Bill 966 was vetoed by the governor and would have established the regulation of Pharmacy Benefit Managers within the California Department of Insurance. She noted that as included in meeting materials, the Board has identified payor practices that negatively impact patients as a possible sunset issue and that this will be discussed at the October 2024 Licensing Committee meeting.

Members were provided the opportunity to comment; however, no comments were made.

Members of the public in Sacramento and participating via WebEx were provided the opportunity to comment; however, no comments were made.

h. Senate Bill 1067 (Smallwood-Cuevas, 2024) Healing Arts: Expedited Licensure Process: Medically Underserved Area or Population

Dr. Serpa noted the governor vetoed this measure, which would have required the Board, and other DCA healing arts boards, to develop a process to expedite the licensure process by giving priority review to applications for which the applicant demonstrates that they intend to practice in a medically underserved area or serve a medically underserved population.

Members were provided the opportunity to comment; however, no comments were made.

Members of the public in Sacramento and participating via WebEx were provided the opportunity to comment; however, no comments were made.

i. Senate Bill 1089 (Smallwood-Cuevas, Chapter 625, Statutes of 2024) Addressing Food Injustice: Notice of Grocery and Pharmacy Closures

Dr. Serpa advised Senate Bill 1089 will require a covered establishment, which includes a pharmacy, to provide 45 days' advance notice of any closure to the Board. She added the Board has a pending regulation to amend California Code of Regulations (CCR), title 16, section 1708.2 related to Discontinuance of Business to require at least 30 days' notice of any closure to the Board. Dr. Serpa believed it was appropriate to update the Board's proposed regulation language to align with the timeframes included in the measure.

Members were provided the opportunity to comment; however, no comments were made.

Members of the public in Sacramento and participating via WebEx were provided the opportunity to comment; however, no comments were made.

Executive Officer Sodergren advised to update the regulation text to align with the Committee's intent, it would be helpful for staff to work with counsel on the best way to effectuate the change. Members agreed and discussed having strong education on the topic for the regulated public.

j. Senate Bill 1468 (Ochoa Bogh and Roth, Chapter 488, Statutes of 2024) Department of Consumer Affairs

Dr. Serpa advised Senate Bill 1468 requires the Board, as well as other DCA healing arts boards that license prescribers, to develop and biannually disseminate educational materials about the federal "Three Day Rule" mentioned in AB 2115, which authorized dispensing of not more than a 3-day supply of narcotic drugs for the purpose of initiating maintenance treatment or detoxification treatment while arrangements were being made for referral for treatment. Dr. Serpa believed it would be appropriate to request that the Communication and Public Education Committee oversee the development of the educational materials if the Department of Consumer Affairs does not coordinate such development.

Members were provided the opportunity to comment; however, no comments were made.

Members of the public in Sacramento and participating via WebEx were provided the opportunity to comment; however, no comments were made.

VII. Discussion and Consideration of FDA Actions Related to Implementation of the Drug Supply Chain Security Act

Chairperson Serpa referenced meeting materials including background information on the Drug Supply Chain Security Act (DSCSA). The Board has received presentations on implementation activities, including a presentation by Josh Bolin with the National Association of Boards of Pharmacy. Dr. Serpa further reminded those present that the DSCSA included milestones for implementation. Most recently, by November 27, 2023, the law required all

prescription drug packages to be serialized with a unique identifier. Dr. Serpa continued that the FDA has released a number of guidance documents on the DSCSA and recently released information that they are issuing exemptions to small dispensers under specified conditions.

Dr. Serpa confirmed that no action on this item was required by the Committee or Board. Rather, this information was included as a means to ensure licensees and other interested stakeholders remain apprised of activities undertaken by the FDA to implement the DSCSA. She noted that the provisions of the DSCSA related to track and trace requirements were very complex and believed it is extremely important for licensees to remain educated on the implementation milestones and the FDA's activities.

Members were provided the opportunity to comment; however, no comments were made.

Members of the public in Sacramento and participating via WebEx were provided the opportunity to comment; however, no comments were made.

VIII. Discussion and Consideration of Enforcement Statistics

Dr. Serpa advised the meeting materials included a summary of enforcement statistics for the first three months of fiscal year 2024/25. The Board has initiated 706 complaints and closed 764 investigations. As of October 1, 2024, the Board has 1,918 field investigations pending. The materials provide a breakdown of the average timeframe for the various stages of the field investigation process.

Members were provided the opportunity to comment; however, no comments were provided.

Members of the public were provided the opportunity to comment in Sacramento and via WebEx; however, no comments were made.

IX. Future meeting dates and adjournment

Chairperson Serpa thanked everyone for their time and participation, noting the next meeting was currently scheduled for January 8, 2025.

X. Adjournment

The meeting adjourned at 11:57 a.m.

Attachment 2

Attachment 2

a. Community Pharmacy/Hospital Outpatient Pharmacy Self-Assessment Form 17M-13, California Code of Regulations (CCR), Title 16, Section 1715(c)

California State Board of Pharmacy
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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 ~~strikethrough~~ for deleted language and dashed underline for added language.

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

Yes No N/A

☐☐☐ 1.12. The pharmacy has procedures in place to take action to protect the public when a licensed individual employed by or with the pharmacy is discovered or known to be chemically, mentally, or physically impaired to the extent it affects 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 email notifications. (BPC 4013)

Date Last Notification Received: _____

Email address registered with the board: _____

☐☐☐ 1.16. In addition to the email notification above, the pharmacy has provided to the Board its electronic mail address, if any, shall maintain a current electronic mail address with the Board, and shall notify the Board within 30 days of any change of electronic mail address. (CCR 1704)

☐☐☐ 1.~~16~~17. 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: _____

Email address registered with the board: _____

☐☐☐ 1.~~17~~18. 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])

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

- ☐ 1.20.1. The pharmacy's staff 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])
- ☐ 1.20.2. The pharmacy's staff is aware they are not required to verify that a prescription falls under one of the exceptions within BPC 688(e) and that they may continue to dispense medication from a legally valid written, oral, or fax prescription pursuant to BPC 688. (BPC 688[i])
- ☐ 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 National Council for Prescription Drug Programs (NCPDP)

SCRIPT standard, as amended from time to time. (BPC 688[g]~~)~~, 21 CFR 1300, 1304, 1306, 1311) ~~Unfulfilled controlled substance prescriptions are transferred or forwarded in compliance with Federal Law~~.

☐ 1.20.~~3~~5. If ~~the~~ pharmacy~~, 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. As a condition of renewal, the pharmacy must report to the Board any disciplinary action taken by any government agency since the issuance or last renewal of the license. (CCR 1702.5)

☐☐☐ 1.23. Except for Correctional Pharmacies, when the pharmacy temporarily closes, the pharmacy must notify the board of any temporary closure of the facility as soon as the 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)

☐☐☐ 1.24. If the pharmacy qualifies as a chain store as defined in BPC 4001, the chain community pharmacy does not establish a quota related to the duties for which a pharmacist or pharmacy technician license is required. (BPC 4113.7, BPC 4317)

☐☐☐ 1.25. A chain community pharmacy shall be staffed at all times with at least one clerk or pharmacy technician fully dedicated to performing pharmacy related services, unless the pharmacist on duty waives the requirement in writing during specified hours based on workload need; the pharmacy is open beyond normal business hours, which is

before 8:00am and after 7:00pm; or the pharmacy's average prescription volume per day is less than 75 prescriptions a day for the past calendar year and the pharmacist is not expected to provide any ancillary services provided by law. (BPC 4113.6[a][1],[2],[3])

Yes No N/A

☐☐☐ 1.26. Within a chain community pharmacy, where staffing of pharmacist hours does not overlap sufficiently, scheduled closures for lunch time for all pharmacy staff shall be established and publicly posted and included on the outgoing telephone message. (BPC 4113.6[b])

☐☐☐ 1.27. A pharmacy shall, no later than 45 days before a closure of the covered establishment takes effect, perform all the acts in compliance with all the requirements of HSC 22949.92.1. (HSC 22949.92.1)

☐☐☐ 1.27. A community pharmacy shall, no later than 45 days before a closure of the pharmacy takes effect, perform all of the following acts: (BPC 22949.92.1[a])

☐☐☐ 1.27.1 Provide written notice of the closure to all the following persons or entities (BPC 22949.92.1 [a][1][A]): See exceptions under (BPC 22949.92.1[b])

☐☐☐ 1.27.1.1 If the pharmacy employs more than five employees, no later than 45 days before a closure, provide written notice of closure to the employees of the pharmacy affected by the closure and their authorized representatives; (BPC 22949.92.1 [a][1][A][i][I])

☐☐☐ 1.27.1.2 If the pharmacy employs five or fewer employees, no later than 30 days, before a closure, provide written notice of the closure to the employees of the pharmacy affected by the closure and their authorized representatives; (BPC 22949.92.1 [a][1][A][i][II])

☐☐☐ 1.27.1.3 The Employment Development Department; (BPC 22949.92.1 [a][1][a][ii]). See exceptions and specific requirements under BPC 22949.92.1 [a][1][B] and [a][1][C] and [a][1][D]

☐☐☐ 1.27.1.4 The State Department of Social Services; (BPC 22949.92.1 [a][1][a][iii]). See exceptions and specific requirements under BPC 22949.92.1 [a][1][B] and [a][1][C] and [a][1][D]

☐☐☐ 1.27.1.5 The local workforce development board of any city and county government within which the closure occurs; (BPC 22949.92.1 [a][1][A][iv]). See exceptions and specific requirements under BPC 22949.92.1 [a][1][B] and [a][1][C] and [a][1][D]

☐☐☐ 1.27.1.6 The chief elected official of each city and county government within which the closure occurs; (BPC 22949.92.1 [a][1][A][v]). See exceptions and specific requirements under BPC 22949.92.1 [a][1][B] and [a][1][C] and [a][1][D]

☐☐☐ 1.27.1.7 Provide written notice of closure to the California State Board of Pharmacy. (BPC 22949.92.1 [a][1][A][vi])

☐☐☐ 1.27.2 Post a written notice of the closure in a conspicuous location at the entrance to the pharmacy premise that includes the planned closure date of the pharmacy, the name, address, and contact information of the pharmacy where any prescriptions will be transferred, the phone number, email address, or internet website where patients may obtain information regarding the process of transferring the prescription to a pharmacy of the patient's choosing. (BPC 22949.92.1 [a][2][A][B][i][ii])

☐☐☐ 1.27.3 Take reasonable steps to provide a written notice of the closure in at least one form other than the forms described in BPC 22949.92[a][1][A] and [a][2][A] in which the pharmacy regularly communicates or advertises to its patients. (BPC 22949.92[a][3])

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])

☐☐☐ 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: _____

_____

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.

☐☐☐ 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: _____

_____

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.)~~

☐ 4.1.1. 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: _____

_____

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, 4113.6, 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[e~~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)

☐☐☐ 5.8. The PIC or pharmacist on duty, if the PIC is not available, may make staffing decisions to ensure sufficient personnel are present in the pharmacy to prevent fatigue, distraction, or other conditions that may interfere with a pharmacist's ability to practice competently and safely. This paragraph does not apply to facilities of the Department of Corrections and Rehabilitation. (BPC 4113[c][2])

☐☐☐ 5.9. The PIC or pharmacist on duty shall immediately notify the store management of any conditions that present an immediate risk of death, illness, or irreparable harm to patients, personnel, or pharmacy staff. If the conditions are not resolved within 24 hours, the PIC or pharmacist on duty shall ensure the board is timely notified. (BPC 4113[d][1]

PIC Initials _____

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

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 1206.6, 4052.4, 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. A prescriber, a prescriber's authorized agent, or 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. (BPC 4071.1)

☐☐☐ 6.12. A pharmacist located and licensed in the state may, on behalf of a health care facility licensed pursuant to Chapter 2 (commencing with Section 1250) of Division 2 of the Health and Safety Code, from a location outside the facility, verify medication chart orders for appropriateness before administration consistent with federal requirements, as established in the health care facility's policies and procedures. The health care facility shall maintain a record of the pharmacist's verification of the medication chart order that meets the requirements of Sections 4081 and 4105. (BPC 4071.1[d][1], 4071.1[d][2])

☐☐☐ *6.13. A pharmacist may furnish COVID-19 oral therapeutics following a positive test for SARS-CoV-2, the virus that cause COVID-19, until January 1, 2026, under specified conditions (BPC 4052.04)*

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 in to 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 performing packaging, manipulative, repetitive, or other nondiscretionary tasks. If a pharmacy technician, under the direct supervision and control of the pharmacist, prepares and administers influenza and COVID-19 vaccines via injection or intranasally, prepares and administers epinephrine, performs specimen collection for tests that are classified as waived under CLIA, receives prescription transfers, and accepts clarification on prescriptions, a second pharmacy technician shall be assisting a pharmacist with performing the tasks as defined in BPC 4115(a). For each additional pharmacist present, the ratio may not exceed 2 technicians for each additional pharmacist. (BPC 4038, 4115[a], [g~~f~~][1], CCR 1793.7[f])

Yes No N/A

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

Yes No N/A

☐☐☐ 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 pharmacy technician certification only is not equivalent to being licensed by the Board as a pharmacy technician. (BPC 4115[f])

☐☐☐ 9.8. A pharmacy technician may, under the direct supervision and control of a pharmacist, prepare and administer influenza and COVID-19 vaccines via injection or intranasally, prepare and administer epinephrine, perform specimen collection for tests that are classified as waived under CLIA, receive prescription transfers, and accept clarification on prescriptions under the following conditions: (BPC 4115[b][1])

- ☐ 9.8.1. The pharmacy has scheduled another pharmacy technician to assist the pharmacist by performing the tasks as defined in BPC 4115(a), under the direct supervision of the pharmacist; (BPC 4115[b][1][A])
- ☐ 9.8.2. The pharmacy technician is certified and maintains the certification, by a pharmacy technician certifying organization offering a pharmacy technician certification program accredited by the National Commission for Certifying Agencies that is approved by the board; (BPC 4115[b][1][B], BPC 4202[a][4])
- ☐ 9.8.3. The pharmacy technician has completed at least six hours of practical training approved by the Accreditation Council for Pharmacy Education and includes hands-on injection technique, the recognition and treatment of emergency reactions to vaccines, and an assessment of the pharmacy technician's injection technique; (BPC 4115[b][1][C]; and
- ☐ 9.8.4. The pharmacy technician is certified in basic life support. (BPC 4115[b][1][D])

CORRECTIVE ACTION OR ACTION PLAN: _____

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PIC Initials

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.

~~Yes No N/A~~

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

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

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

☐☐☐ 11.5. Appropriate drug warnings are provided orally or in writing. (BPC 4074, CCR 1744)

☐☐☐ 11.6. If prescription medication is mailed or delivered, written notice about the availability of consultation is provided. (CCR 1707.2[b][2])

☐☐☐ 11.7. Drugs dispensed pursuant to a veterinary prescription shall include, as part of the consultation, the option for a representative of an animal patient to also receive drug documentation specifically designed for veterinary drugs. (BPC 4069)

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])

☐☐☐ 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 (Skilled Nursing Facilities), ICF (Intermediate Care Facilities), 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 date~~s~~ 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.

Yes No N/A

☐☐☐ 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])

Yes No N/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])

Yes No N/A

☐☐☐ 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 in the languages the board has made available, 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])

☐☐☐ 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 of any vaccine administered to the patient, 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 of the administration of any vaccine. (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.

Yes No N/A

☐☐☐ 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]).

☐☐☐ 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]).

☐☐☐ 13.31. If the person identifies as a person who is blind, has low-vision, or is otherwise print disabled, the dispenser shall provide, at no additional cost, an accessible prescription label affixed to the container or as a supplemental document, if it does not fit the container, which meets the following: (BPC 4076.8)

- ☐ 13.31.1 Is available to the person in a timely manner and lasting for at least the duration of the prescription; (BPC 4076.8[a][1])
- ☐ 13.31.2 Is appropriate to the disability and language of the person making the request through use of audible, large print, Braille, or translated directions; (BPC 4076.8[a][2])
- ☐ 13.31.3 Conforms to the format-specific best practice established by the United States Access Board and the National Standards for Culturally and Linguistically Appropriate Services (CLAS) in Health and Health Care; (BPC 4076.8[a][3])

☐☐☐ 13.32. If a prescription reader is provided, the prescription label is compatible with the prescription reader. (BPC 4076.8[b])

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])

Yes No N/A

☐☐☐ 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])

☐☐☐ 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)

☐☐☐ 16.9. The community pharmacy shall report, either directly or through a designated third party, including a component patient safety organization as defined in Section 3.20 of

Title 42 of the Code of Federal Regulations, all medication errors to an entity approved by the board. The report shall be submitted no later than 14 days following the date of discovery of the error. (BPC 4113.1)

☐☐☐ 16.10 An outpatient hospital pharmacy is not required to report a medication error that meets the requirements of an adverse event, and that has been reported to the State Department of Public Health pursuant to Section 1279.1 of the Health and Safety Code. (BPC 4113.1[e])

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

~~Yes No N/A~~

☐☐☐ 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])

Yes No N/A

☐☐☐ 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])

☐☐☐ 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: _____

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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 4052.04, 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)

☐ 20.2.11. Records documenting kind and amounts of COVID-19 oral therapeutics furnished following a positive test for SARS-CoV-2, as well as information regarding any testing services provided, in the patient's record in the record system maintained by the pharmacy (BPC 4052.04[d])

☐ 20.2.12. Records demonstrating compliance with medication error reporting requirements. (BPC 4113.1[a])

Yes No N/A

☐☐☐ 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])

☐☐☐ 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.

Yes No N/A

☐☐☐ 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: _____

Yes No N/A

☐☐☐ 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: _____

_____

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])

Yes No N/A

☐☐☐ 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])

~~Yes No N/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)

☐☐☐ 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.

Yes No N/A

☐☐☐ 21.14. ~~Any c~~ Controlled substances drug loss is reported within one business day of discovery to the DEA and within 30 days after the date of discovery to the Board of Pharmacy 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: (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 in 21.14.1, two or more multi-dose vials, infusion bags or other containers.

~~Yes No N/A~~

☐☐☐ 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 ~~I~~V 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])

~~Yes No N/A~~

☐☐☐ 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 individual who performs the inventory shall sign and date the inventory

or report. If not personally completed by the pharmacist-in-charge or professional director, the report must also be signed by the pharmacist-in-charge or professional director. (CCR 1715.65[e], [e][1])

Yes No N/A

☐☐☐ 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~~5~~. 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)

Yes No N/A

☐☐☐ 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)

~~Yes No N/A~~

☐☐☐ 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])

Yes No N/A

☐☐☐ 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.

~~Yes No N/A~~

☐☐☐ 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: _____

_____

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])

Yes No N/A

☐☐☐ 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: _____

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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.

~~Yes No N/A~~

☐☐☐ 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: _____

_____

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. _____

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])

~~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.
- ☐ 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])

☐☐☐ 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])

☐☐☐ 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])

☐☐☐ 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: _____

_____

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.~~

☐☐☐ 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)

Yes No N/A

☐☐☐ 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])

~~Yes No N/A~~

☐☐☐ 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: _____

☐☐☐ 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: _____

Yes No N/A

☐☐☐ 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])

~~Yes No N/A~~

☐☐☐ 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])

☐☐☐ 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.

Yes No N/A

☐☐☐ 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])

~~Yes No N/A~~

☐☐☐ 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])

☐☐☐ 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:

_____

_____

Yes No N/A

☐☐☐ 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?

~~Yes No N/A~~

☐☐☐ 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])

☐☐☐ 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])

Yes No N/A

☐☐☐ 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])

~~Yes No N/A~~

☐☐☐ 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 the following requirements: (HSC 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)~~

~~☐☐☐ 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])

Yes No N/A

☐☐☐ 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: _____

☐☐☐ 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])

Yes No N/A

☐☐☐ 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])

☐☐☐ 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

PIC Initials

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

- Business and Professions Code (BPC), Division 1, Chapter 1 – General Provisions
- BPC, Division 2, Chapter 1 – General Provisions
- BPC, Division 2, Chapter 3 – Clinical Laboratory Technology
- BPC, Division 2, Chapter 9 – Pharmacy
- California Code of Regulation (CCR), Title 16, Division 17 – California State Board of Pharmacy
- Civil Code, Division 1, Part 2.6, Chapter 2 – Disclosure of Medical Information by Providers
- Code of Federal Regulations (CFR), Title 16, Chapter II, Subchapter E, Part 1700 – Poison Prevention Packaging
- CFR, Title 21, Chapter I, Subchapter C, Part 201, Subpart B – Labeling Requirements for Prescription Drugs and/or Insulin
- CFR, Title 21, Chapter I, Subchapter C, Part 208 – Medication Guides for Prescription Drug Products
- CFR, Title 21, Chapter I, Subchapter C, Part 210 – Current Good Manufacturing Practice in Manufacturing, Processing, Packaging, or Holding of Drugs; General
- CFR, Title 21, Chapter I, Subchapter C, Part 211 – Current Good Manufacturing Practice for Finished Pharmaceuticals
- CFR, Title 21, Chapter I, Subchapter D, Part 310, Subpart E – Requirements for Specific New Drugs and Devices
- CFR, Title 21, Chapter II - Drug Enforcement Administration, Department of Justice Combat Methamphetamine Epidemic Act of 2005. Pub. L. 109-177. 120 Stat. 256.9 Mar. 2006
- Health and Safety Code (HSC), Division 2, Chapter 1 – Licensing Provisions
- HSC, Division 10 – Uniform Controlled Substances Act
- HSC, Division 104, Part 5 (Sherman Food, Drug, and Cosmetics Law), Chapter 2 – Administration
- HSC, Division 106, Part 5, Chapter 2 – Genetic Disease Services
- HSC, Division 116 – Surplus Medication Collection and Distribution
- United States Code (USC), Title 15, Chapter 39A – Special Packaging of Household Substances for Protection of Children
- USC, Title 21, Chapter 9, Subchapter V, Part H – Pharmaceutical Distribution Supply Chain (Drug Supply Chain Security Act)
- USC, Title 21, Chapter 13 – Drug Abuse Prevention and Control

Attachment 2

b. Hospital Pharmacy Self-Assessment Form 17M-14, CCR, Title 16, Section 1715(c)

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 ~~strikethrough~~ for deleted language and dashed underline for added language.

HOSPITAL PHARMACY SELF-ASSESSMENT

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

The self-assessment must be completed in its entirety. It may be completed online, printed, 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 dispensing prescriptions for outpatient use, a Community Pharmacy Self-Assessment/Hospital Outpatient Pharmacy Self-Assessment (17M-13, pursuant to 16 CCR 1715) must be completed also. A hospital 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 License #: _____ Exp. Date: _____

Licensed Sterile Compounding License #_____ Expiration: _____

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

Centralized Hospital Packaging #: _____ Exp. Date: _____

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

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

PIC: _____ RPH # _____ Exp. Date: _____

_____
PIC
Initials

Pharmacy staff (pharmacists, interns, technicians):
APH= Advanced Practice Pharmacist, DEA = Drug Enforcement Administration.

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

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

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

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

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

6. _____ INT # _____ Exp. Date: _____

7. _____ INT # _____ Exp. Date: _____

8. _____ INT # _____ Exp. Date: _____

9. _____ INT # _____ Exp. Date: _____

10. _____ TCH # _____ Exp. Date: _____

11. _____ TCH # _____ Exp. Date: _____

12. _____ TCH # _____ Exp. Date: _____

13. _____ TCH # _____ Exp. Date: _____

PIC Initials

HOSPITAL PHARMACY SELF-ASSESSMENT

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

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

1. Pharmacy

Yes No N/A

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

☐☐☐ 1.2. The pharmacy has procedures in place to take action to protect the public when a licensed individual employed by or with the pharmacy is discovered or known to be chemically, mentally, or physically impaired to the extent it affects 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])

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

☐☐☐ 1.4. The pharmacy reports to the board within 14 days of the receipt or development of the following information with regard to any licensed individual employed by or with the pharmacy: (1) any admission by a licensed individual of chemical, mental, or physical impairment affecting 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])

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

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

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

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

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

☐☐☐ 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)

PIC Initials

Yes No N/A

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

☐☐☐ 1.12. Does the pharmacy compound sterile drugs?

(If yes, complete the Compounding Self-Assessment required by CCR 1735.2[k])

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

Date Last Notification Received: _____

Email address registered with the board: _____

☐☐☐ 1.14. For a pharmacy whose owner owns two or more pharmacies, the pharmacy 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: _____

☐☐☐ 1.15. All medicinal cannabis is stored in a locked container in the patient's room, other designated areas, or with the patient's primary caregiver and is retrieved, administered, handled, removed and disposed in accordance with HSC 1649.1, 1649.2, 1649.3, 1649.4.

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

2. Nursing Stations

Yes No N/A

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

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

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

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

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

PIC Initials

3. Delivery of Drugs

Yes No N/A

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

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

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

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

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

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

PIC Initials

Yes No N/A

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

☐☐☐ 3.7. ~~The pharmacy is aware, effective November 27, 2020, pharmacies are required by the Drug Quality and Security Act (DQSA), to have pharmacy lot-level traceability and by November 27, 2023 unit-level traceability~~. The pharmacy has lot-level and unit-level traceability in accordance with the Drug Quality and Security Act (DQSA). (21 USC 360eee-1[d][2] and 582[g][1])

CORRECTIVE ACTION OR ACTION PLAN: _____

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4. Drug Stock

Yes No N/A

☐☐☐ 4.1. The drug stock is clean, orderly, properly stored, properly labeled and in-date. (21 USC sections 331, 351, 352, BPC 4169[a][2]-[4], 4342, HSC 111255, 111335, CCR 1714 ~~([~~[b]~~)~~, 22 CCR 70263[q])

☐☐☐ 4.2. All ward/floor drug stock and drug supplies that are maintained for access when the pharmacist is not available are properly labeled and stored. Records of drugs taken from the drug stock or drug supplies must be maintained and the pharmacist must be notified. (22 CCR 70263[n])

☐☐☐ 4.3. Preferentially priced drugs are furnished solely or predominately to inpatients in accordance with provisions of the Nonprofit Institutions Act (15 USC 13c). Such drugs also may be dispensed pursuant to prescriptions for inpatients at the time of discharge, for employees of the hospital, or on an emergency basis for a walk-in customer (provided that sales to walk-ins do not exceed one percent of the pharmacy's total prescription sales) or to any person in the occasional emergency situation where no other sources are readily available in the community to meet the emergency need. (BPC 4380, CCR 1710[a])

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

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

☐☐☐ 4.6. Dangerous drugs or dangerous devices are purchased, traded, sold or transferred with an entity licensed with the board as a wholesaler, third-party logistics provider, pharmacy or a manufacturer, and provided the dangerous drugs and devices: (BPC 4059.5, 4169, CCR 1718.1)

☐ 4.6.1. Are not known or reasonably should not be known to the pharmacy as being adulterated.

PIC Initials

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

Yes No N/A

☐☐☐ 4.7. 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)

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

☐☐☐ 4.9. An automated unit dose system (AUDS) operated by a licensed hospital pharmacy as defined by BPC 4029, and used solely to provide doses administered to patients while in a licensed general acute care hospital facility shall be exempted from the requirement of obtaining an ADDS license if the hospital pharmacy owns or leases the AUDS and owns the dangerous drugs or devices in the AUDS. The AUDS shall comply with all other requirements for an ADDS (i.e. Security, Record keeping, Self-Assessment, Quality Assurance, etc.) and maintain a list of the location of each AUDS it operates. (BPC 4119.11[b][3], 4427.2, 4427.65)

CORRECTIVE ACTION OR ACTION PLAN: _____

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

Yes No N/A

☐☐☐ 5.1. 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.)~~

- ☐ 5.1.1. 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)

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

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

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

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

~~☐ 5.3.1. Have not been adulterated, misbranded, or stored under conditions contrary to standards set by the USP or the product manufacturer. (HSC 150204[c][2])~~

~~☐ 5.3.2. Were received directly from a manufacturer or wholesaler. (HSC 150202.5[a])~~

~~☐ 5.3.3. Were centrally stored and under the control of a health facility staff member, and were never in the possession of a patient or individual member of the public. (HSC 150202.5[b], 150204[c][3])~~

~~☐ 5.3.4. Are in unopened, tamper-evident packaging or modified unit dose containers with lot numbers and expiration dates affixed. (HSC 105204[d])~~

~~☐ 5.3.5. For donated medications that require refrigeration, are medications that are stored, packaged and transported at appropriate temperatures and in accordance with USP standards and pharmacy law. (HSC 150204[m])~~

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

CORRECTIVE ACTION OR ACTION PLAN: _____

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6. Pharmacist-in-Charge (PIC)

Yes No N/A

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

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

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

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

If yes, name of other pharmacy _____

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

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

☐☐☐ 6.6. The PIC or pharmacist, if the PIC is not available, may make staffing decisions to ensure sufficient personnel are present in the pharmacy to prevent fatigue, distraction, or other conditions that may interfere with a pharmacist's ability to practice competently and safely. This paragraph does not apply to facilities of the Department of Corrections and Rehabilitation. (BPC 4113[c][2])

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PIC Initials

☐☐☐ 6.7. The PIC or pharmacist on duty shall immediately notify the store management of any conditions that present an immediate risk of death, illness, or irreparable harm to patients, personnel, or pharmacy staff. If the conditions are not resolved within 24 hours, the PIC or pharmacist on duty shall ensure the board is timely notified. (BPC 4113[d][1]

CORRECTIVE ACTION OR ACTION PLAN: _____

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7. Duties of a Pharmacist

Yes No N/A

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

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

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

- ☐ 7.2.1. Ordering or performing routine drug therapy-related patient assessment procedures; (BPC 4052.1[a][1]; 4052.2[a][1])
- ☐ 7.2.2. Ordering drug therapy-related laboratory tests; administering drugs or biologicals by injection; (BPC 4052.1[a][2],-[3]; 4052.2[a][2],-[3])
- ☐ 7.2.3. Initiating or adjusting the drug regimen of a patient; (BPC 4052.1[a][4], BPC 4052.2[a][4])

- ☐ 7.2.4. Performing moderate or waived laboratory tests. Prior to performing any of these functions, the pharmacist must have either (1) successfully completed clinical residency training, or (2) demonstrated clinical experience in direct patient care delivery as specified in BPC section 4052.2[d]. (BPC 4052.4)
- ☐ 7.2.5. A pharmacist may perform any aspect of any FDA-approved or authorized test that is classified as waived pursuant to the federal Clinical Laboratory Improvement Amendments of 1988 (42 USC Sec 263a) and the pharmacist completes the testing in a pharmacy laboratory that is licensed in California as a laboratory pursuant to BPC section 1265 unless otherwise authorized in law. The pharmacist has completed necessary training as specified in the pharmacy's policies and procedure maintained in subsection be of BPC section 4119.10 and that allows the pharmacist to demonstrate sufficient knowledge of the illness, condition or disease being tested as applicable. (BPC 4052.4)

Yes No N/A

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

☐☐☐ 7.4. All pharmacists have submitted an application to the Department of Justice to obtain approval to access information online regarding the controlled substance history of a patient. Upon approval, the DOJ shall release to the pharmacist or their delegate the CURES information for an individual under the pharmacist's care. (HSC 11165.1)

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

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

☐☐☐ 7.7. The pharmacist may initiate, adjust or discontinue drug therapy for a patient under a collaborative practice agreement with any health care provider with prescriptive authority. The collaborative practice agreement may be between a single or multiple pharmacists and a single or multiple health care providers with prescriptive authority. (BPC 4052[a][13], [14])

☐☐☐ 7.8. Only a prescriber, a prescriber's authorized agent, or 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. (BPC 4071.1)

☐☐☐ 7.9. A pharmacist located and licensed in the state may, on behalf of a health care facility licensed pursuant to Chapter 2 (commencing with Section 1250) of Division 2 of the Health and Safety Code, from a location outside the facility, verify medication chart orders for appropriateness before administration consistent with federal requirements, as established in the health care facility's policies and procedures. The health care facility shall maintain a record of the pharmacist's verification of the medication chart order that meets the same requirements as those described in Sections 4081 and 4105. (BPC 4071.1[d][1], 4071.1[d][2])

PIC Initials

CORRECTIVE ACTION OR ACTION PLAN: _____

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8. Duties of an Advanced Practice Pharmacist

Yes No N/A

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

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

CORRECTIVE ACTION OR ACTION PLAN: _____

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9. Duties of an Intern Pharmacist

Yes No N/A

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

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

PIC Initials

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

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

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

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

CORRECTIVE ACTION OR ACTION PLAN: _____

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10. Duties of a Pharmacy Technician

Yes No N/A

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

☐☐☐ 10.2. The ratio is not less than one pharmacist on duty for two technicians when filling prescriptions for an inpatient of a licensed health facility. (BPC 4115[g~~f~~], CCR 1793.7[f])

☐☐☐ 10.3. When prescriptions are dispensed to discharge patients with only one pharmacist, there is no more than one technician performing packaging, manipulative, repetitive, or other nondiscretionary tasks. If a pharmacy technician, under the direct supervision and control of the pharmacist, prepares and administers influenza and COVID-19 vaccines via injection or intranasally, prepares and administers epinephrine, performs specimen collection for tests that are classified as waived under CLIA, receives prescription transfers, and accepts clarification on prescriptions, a second pharmacy technician shall be assisting a pharmacist with performing the tasks as defined in BPC 4115(a). The ratio of pharmacy technicians performing those tasks for additional pharmacists does not exceed 2:1. (BPC 4038, 4115[g~~f~~][1], CCR 1793.7[f])

Yes No N/A

☐☐☐ 10.4. Any function performed by a technician in connection with the dispensing of a prescription or chart order, including repackaging from bulk and storage of pharmaceuticals is verified and documented in writing by a pharmacist or documented by a pharmacist using secure computer entry. (CCR 1712, 1793.7)

☐☐☐ 10.5. 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, BPC 4115.5[e], CCR 1793.7[d])

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

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

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

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

~~Yes No N/A~~
☐☐☐ 10.9. Pharmacy technician duties include the following:

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

Yes No N/A
☐☐☐ 10.10. All pharmacy technicians have joined the board's email notification list. (BPC 4013)

Yes No N/A
☐☐☐ 10.11. A person shall not act as a pharmacy technician without first being licensed by the board as a pharmacy technician. A pharmacy technician certification only is not equivalent to being licensed by the Board as a pharmacy technician. (BPC 4115[f])

☐☐☐ 10.12. A pharmacy technician may, under the direct supervision and control of a pharmacist, prepare and administer influenza and COVID-19 vaccines via injection or intranasally, prepare and administer epinephrine, perform specimen collection for tests that are classified as waived under CLIA, receive prescription transfers, and accept clarification on prescriptions under the following conditions: (BPC 4115[b][1])

PIC Initials

☐ 10.12.1. The pharmacy has scheduled another pharmacy technician to assist the pharmacist by performing the tasks as defined in BPC 4115(a), under the direct supervision of the pharmacist; (BPC 4115[b][1][A])

☐ 10.12.2. The pharmacy technician is certified and maintains the certification, by a pharmacy technician certifying organization offering a pharmacy technician certification program accredited by the National Commission for Certifying Agencies that is approved by the board; (BPC 4115[b][1][B], BPC 4202[a][4])

☐ 10.12.3. The pharmacy technician has completed at least six hours of practical training approved by the Accreditation Council for Pharmacy Education and includes hands-on injection technique, the recognition and treatment of emergency reactions to vaccines, and an assessment of the pharmacy technician's injection technique; (BPC 4115[b][1][C]; and

☐ 10.12.4. The pharmacy technician is certified in basic life support. (BPC 4115[b][1][D])

CORRECTIVE ACTION OR ACTION PLAN: _____

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11. Duties of Non-Licensed Personnel

Yes No N/A

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

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

CORRECTIVE ACTION OR ACTION PLAN: _____

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PHARMACY PRACTICE

12. Pharmaceutical Service Requirements

Yes No N/A

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

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

~~Yes No N/A~~

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

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

CORRECTIVE ACTION OR ACTION PLAN: _____

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13. Medication/Chart Order

Yes No N/A

☐☐☐ 13.1. The pharmacy receives the original, the electronic transmission, or a copy of the medication order. Faxed copies, tele-autograph copies, or transmissions between computers are permissible. (BPC 688, 4019, 4040, CCR 1717.4)

☐☐☐ 13.2. The chart or medical record of the patient contains all of the information required by BPC 4040 and the chart order is signed by the practitioner authorized by law to prescribe drugs if present or, if not present, within a specified time frame not exceeding 48 hours. (BPC 688, 4019, 4040, 22 CCR 70263[g])

☐☐☐ 13.3. A copy of the chart order is maintained on the premises for three years. An order for controlled substance for use by a patient in a county or licensed hospital shall be in the patient's records and the record of such orders shall be maintained as a hospital record for a minimum of seven years. (HSC 11159, BPC 4081, 4105, 4333)

Yes No N/A

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

CORRECTIVE ACTION OR ACTION PLAN: _____

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14. Labeling and Distribution

Yes No N/A

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

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

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

CORRECTIVE ACTION OR ACTION PLAN: _____

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15. Duration of Drug Therapy

Yes No N/A

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

CORRECTIVE ACTION OR ACTION PLAN: _____

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

Yes No N/A

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

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

Yes No N/A

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

☐☐☐ 16.4. The pharmacy ensures electronically transmitted prescriptions (chart orders, discharge patient or employee prescriptions) are received, maintained and transmitted in a secure and confidential manner. (BPC 688, CCR 1717.4)

☐☐☐ 16.5. Records regarding dangerous drugs and dangerous devices stored off-site (only for pharmacies who have obtained a waiver from the Board of Pharmacy to store records off-site) are secure and retrievable within two business days. (BPC 4105, CCR 1707)

Date Waiver Approved _____ Waiver Number _____

Address of offsite storage location: _____

Yes No N/A

☐☐☐ 16.6. Records for non-controlled substances are maintained on the licensed premises for at least one year from the date of dispensing. Records for controlled substances are maintained on the licensed premises for at least two years from the date of dispensing. (BPC 4105, CCR 1707)

CORRECTIVE ACTION OR ACTION PLAN: _____

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17. Quality Assurance and Medication Errors

Yes No N/A

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

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

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

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

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

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

- ☐ 17.6.1. Date, location, and participants in the quality assurance review;
- ☐ 17.6.2. Pertinent data and other information related to the medication error(s) reviewed;
- ☐ 17.6.3. Findings and determinations;

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

Yes No N/A

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

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

☐☐☐ 17.9. The PIC is reporting the quality assurance review reports for medication errors for all unlicensed ADDS to the Board at the time of annual renewal of the hospital pharmacy license. (CCR 1711[f])

CORRECTIVE ACTION OR ACTION PLAN: _____

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18. Record Keeping Requirements

Yes No N/A

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

☐☐☐ 18.2. All drug acquisition and disposition records (complete accountability) are maintained for at least three years. Any record maintained electronically, the pharmacist-in-charge or pharmacist on duty is able to produce a hardcopy and electronic copy of all records of acquisition and disposition or other drug or dispensing-related records maintained electronically. These records include:

- ☐ 18.2.1. Prescription records (BPC 4081[a])
- ☐ 18.2.2. Purchase Invoices and sales records for all prescription drugs (BPC 4081)
- ☐ 18.2.3. Biennial controlled substances inventory (21 CFR 1304.11)
- ☐ 18.2.4. U.S. Official Order Forms (DEA Form-222) (21 CFR 1305.13, 21 CFR 1305.22)
- ☐ 18.2.5. Power of Attorney for completion of DEA 222 forms (21 CFR 1305.05)
- ☐ 18.2.6. Theft and Loss Reports (DEA Form 106) (21 CFR 1301.74[c])
- ☐ 18.2.7. Record documenting return of drugs to wholesaler or manufacturer (BPC 4081)
- ☐ 18.2.8. Record documenting transfers or sales to other pharmacies, ~~and~~ prescribers, and reverse distributors. (BPC 4059, 4081, 4105, 4332, CCR 1718)
- ☐ 18.2.9. Centrally stored unused medications donated to a drug repository and distribution program. (HSC 150200, 150202[a][1], 150204[k], BPC 4105[c]).
- ☐ 18.2.10. Records documenting, to the extent possible, the kind and amounts of COVID-19 oral therapeutics furnished following a positive test for SARS-CoV-2, as

well as information regarding any testing services provided, in the patient's record in the record system maintained by the pharmacy. (BPC 4052.04[d])

Yes No N/A

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

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

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

Date completed: _____ (21 CFR 1304.11)

Yes No N/A

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

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

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

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

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

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

☐ 18.11.1. Tablets, capsules, or other oral medication, 99 dosage units

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

☐ 18.11.3. Injectable multi-dose medications, medications administered by continuous infusion, or any other multi-dose unit not described in 18.11.1, two or more multi-dose vials, infusion bags or other containers.

Yes No N/A

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

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

☐☐☐ 18.13. Do pharmacy staff hand initial prescription records and prescription labels, OR does the pharmacy comply with the requirement for a pharmacist to initial or sign a prescription record or prescription label by recording the identity of the reviewing pharmacist in a computer system by a secure means. This computer does not permit the record to be altered after made and the record of the pharmacist's identity made in the computer system is immediately retrievable in the pharmacy. (CCR 1712, 1717)

CORRECTIVE ACTION OR ACTION PLAN: _____

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19. Inventory Reconciliation Report of Controlled Substances

Yes No N/A

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

~~Yes No N/A~~

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

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

- ☐ 19.3.1. A physical count, not an estimate, of all quantities of federal Schedule II controlled substances. The biennial inventory of controlled substances required by federal law may serve as one of the mandated inventories under this section in the year where the federal biennial inventory is performed, provided the biennial inventory was taken no more than three months from the last inventory required by this section; (CCR 1715.65[c][1])
- ☐ 19.3.2. A review of all acquisitions and dispositions of federal Schedule II controlled substances since the last inventory reconciliation report; (CCR 1715.65[c][2])
- ☐ 19.3.3. A comparison of the two above-mentioned items to determine if there are any variances; (CCR 1715.65[c][3])
- ☐ 19.3.4. All records used to compile each inventory reconciliation report shall be maintained in the pharmacy or clinic for at least three years in a readily retrievable form; and (CCR 1715.65[c][4])
- ☐ 19.3.5. Possible causes of overages shall be identified in writing and incorporated into the inventory reconciliation report. (CCR 1715.65[c][5])
- ☐ 19.3.6. In addition to Schedule II controlled substance, the pharmacy is performing an inventory reconciliation of alprazolam 1mg/unit, alprazolam 2mg/unit, tramadol 50mg/unit, and promethazine with codeine 6.25mg promethazine/10mg codeine per 5ml of product at least every 12 months. (CCR 1715.65[a][2])

☐ 19.3.7. 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)

☐ 19.3.8. 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])

☐ 19.3.9. 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])

☐ 19.3.10. Inpatient hospital pharmacy, the inventory reconciliation for all federal Schedule II-controlled substances, and alprazolam 1mg/unit, alprazolam 2mg/unit, tramadol 50mg/unit, and promethazine with codeine (6.25mg promethazine/10mg codeine/5ml) must be performed on a quarterly basis. The report or reports shall include controlled substances stored within the pharmacy, within each pharmacy satellite location, and within each drug storage area in the hospital under the pharmacy's control. (CCR 1715.65[g])

Yes No N/A

☐☐☐ 19.4 The pharmacy reports in writing identified losses and known causes to the board within 30 days of discovery unless the cause of the loss is theft, diversion, or self-use in which case the report shall be made within 14 days of discovery. If the pharmacy is unable to identify the cause of the loss, further investigation is undertaken to identify the cause and actions necessary to prevent additional losses of controlled substances. (BPC 4104, CCR 1715.65[d], CCR 1715.6)

~~Yes No N/A~~

~~☐☐☐ 19.5 The inventory reconciliation report is dated and signed by the individual(s) performing the inventory, and countersigned by the pharmacist-in-charge and be readily retrievable in the pharmacy for three years. A countersignature is not required if the pharmacist-in-charge personally completed the inventory reconciliation report. (CCR 1715.65 [e])~~

☐☐☐ 19.~~6~~5 A new pharmacist-in-charge of the pharmacy completes an inventory reconciliation report as identified in CCR 1715.65 (c) within 30 days of becoming pharmacist-in-charge. When possible, the outgoing pharmacist-in-charge also completes an inventory reconciliation report as required in CCR 1715.65 (c). (CCR 1715.65 [f])

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

~~☐☐☐ 19.8 The pharmacist-in-charge of an inpatient hospital pharmacy or of a pharmacy servicing onsite or offsite automated drug delivery systems shall ensure that: (CCR 1715.65[h])~~

~~☐ 19.8.1 All controlled substances added to an automated drug delivery system are accounted for; (CCR 1715.65[h][1])~~

~~☐ 19.8.2 Access to automated drug delivery systems is limited to authorized facility personnel; (CCR 1715.65[h][2])~~

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~~☐ 19.8.3 An ongoing evaluation of discrepancies or unusual access associated with controlled substances is performed; and (CCR 1715.65[h][3])~~

~~☐ 19.8.4 Confirmed losses of controlled substances are reported to the board. (CCR 1715.65[h][4])~~

Yes No N/A

☐☐☐ 19.8. If the inpatient hospital pharmacy uses an ADDS, inventory in the ADDS may be accounted for under CCR section 1715.65(c)(1) using means other than a physical count. (CCR 1715.65[h])

CORRECTIVE ACTION OR ACTION PLAN: _____

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20. After-Hours Supply of Medication

Yes No N/A

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

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

CORRECTIVE ACTION OR ACTION PLAN: _____

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21. Drug Supplies for Use in Medical Emergencies

Yes No N/A

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

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

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

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

CORRECTIVE ACTION OR ACTION PLAN: _____

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

Yes No N/A

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

CORRECTIVE ACTION OR ACTION PLAN: _____

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23. Emergency Room Dispensing

Yes No N/A

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

- ☐ 23.1.1. The hospital pharmacy is closed and there is no pharmacist available in the hospital;
- ☐ 23.1.2. The dangerous drug is acquired by the hospital pharmacy;
- ☐ 23.1.3. The dispensing information is recorded and provided to the pharmacy when the pharmacy reopens;
- ☐ 23.1.4. The hospital pharmacy retains the dispensing information and, if the drug is a schedule II, III, IV or ~~I~~V controlled substance, transmits the dispensing data to the Department of Justice within one working day from the date the controlled substance is released to the patient. (HSC 11165[d])
- ☐ 23.1.5. The prescriber determines that it is in the best interest of the patient that a particular drug regimen be immediately commenced or continued, and the prescriber reasonably believes that a pharmacy located outside the hospital is not available and accessible at the time of dispensing to the patient; and
- ☐ 23.1.6. The quantity of drugs dispensed to any patient pursuant to this section are limited to that amount necessary to maintain uninterrupted therapy during the period when pharmacy services outside the hospital are not readily available or accessible, but shall not exceed a 72-hour supply;
- ☐ 23.17. If an ADDS is located in the emergency room and is used for dispensing to patients upon discharge, the ADDS is licensed with the Board. (BPC 4427.2[i]).

Yes No N/A

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

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

PIC Initials

Yes No N/A

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

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

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

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

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

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

☐☐☐ 23.10. Whenever an opioid prescription drug is dispensed to a 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).

☐☐☐ 23.11. A pharmacist may dispense a drug prescribed pursuant to HSC Section 120582 and label the drug without the name of an individual for whom the drug is intended if the prescription includes the words “expedited partner therapy” or the letters “EPT” and shall provide written notification that describes the right of an individual who received EPT to consult with a pharmacist about the medication dispensed and possible drug interactions. (BPC 4076[f], [h])

☐☐☐ 23.12. If emergency department patient dispensing is done via AUDS, the AUDS is licensed by the Board. (BPC 4427.2[i])

☐☐☐ 23.13. A practitioner specified in Section 11150 may dispense a controlled substance classified in Schedule II, which may be from a hospital pharmacy inventory, directly to an ultimate user in either of the following circumstances: (HSC 11158)

☐☐☐ 23.13.1 In an amount not to exceed a 72-hour supply for the patient in accordance with directions for use given by the dispensing practitioner only when the patient is not expected to require any additional amount of the controlled substance beyond the 72 hours; (HSC 11158[b][1])

☐☐☐ 23.13.2 For the purpose of initiating maintenance treatment or detoxification treatment, or both, for a person with an opioid use disorder. Not more than a three-day supply of such medication may be dispensed to the person at one time while arrangements are being made for referral for treatment. Such emergency treatment may not be renewed or extended. (HSC 11158[b][2])

CORRECTIVE ACTION OR ACTION PLAN: _____

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PIC Initials

24. Discharge Medication/Consultation Services

Yes No N/A

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

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

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

Yes No N/A

☐☐☐ 24.4. The pharmacist includes a written label on the drug container indicating that the drug may impair a person's ability to operate a vehicle or vessel. The label may be printed on an auxiliary label affixed to the prescription container. (BPC 4074 [a], [b], CCR 1744[a][1]-[7])

☐☐☐ 24.5 The pharmacist includes a written label on the drug container to alert the patient about possible potentiating effects when taken in combination with alcohol. The label may be printed on an auxiliary label affixed to the prescription container (BPC 4074[a], CCR 1744[b][1]-[6]).

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

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

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

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

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

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

~~Yes No N/A~~

PIC Initials

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

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

☐☐☐ 24.14. 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).

☐☐☐ 24.15. ~~Effective January 1, 2022, t~~ The pharmacy has the capability to receive electronic data transmission prescriptions on behalf of patients. (BPC 688)

☐☐☐ 24.16. The hospital pharmacy retains the dispensing information and, if the drug is a schedule II, III, IV or V controlled substance, transmits the dispensing data to the Department of Justice within one working day after the date the controlled substance is released to the patient or patients representative. (HSC 11165[d])

☐☐☐ 24.17. Drugs dispensed pursuant to a veterinary prescription shall include, as part of the consultation, the option for a representative of an animal patient to also receive drug documentation specifically designed for veterinary drugs. (BPC 4069)

CORRECTIVE ACTION OR ACTION PLAN: _____

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25. Central Filling of Patient Cassettes For Other Hospital Pharmacies

Yes No N/A

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

If the answer is “yes,” name of hospital: _____

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

If the answer is “yes,” name of supplying pharmacy:

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

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

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

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

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

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

26. Centralized Hospital Packaging Pharmacy

Yes No N/A

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

License Number: _____

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

Hospitals to which central packaged unit dose medications are provided:

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

Yes No N/A

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

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

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

☐☐☐ 26.5~~4~~. Any label for each unit dose medication produced by a centralized hospital packaging pharmacy displays a human-readable label that contains the following: (BPC 4128.5[a])

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

~~Yes No N/A~~

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

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

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

CORRECTIVE ACTION OR ACTION PLAN: _____

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27. Policies and Procedures

Yes No N/A

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

- ☐ 27.1.1. Oral consultation for discharge medication to an inpatient of a health care facility licensed pursuant to HSC 1250. The assurance that each patient received information regarding each medication given at the time of discharge. (BPC 4074[e], CCR 1707.2[b][2])
- ☐ 27.1.2. Action to be taken to protect the public when a licensed individual employed by or with the pharmacy is known to be chemically, mentally, or physically impaired to the extent that it effects their ability to practice the profession or occupation authorized by their license. (BPC 4104[a])
- ☐ 27.1.3. Action to be taken to protect the public when a licensed individual employed by or with the pharmacy is known to have engaged in the theft or diversion or self-use of prescription drugs belonging to the pharmacy. (BPC 4104[b])
- ☐ 27.1.4. Addressing chemical, mental, or physical impairment, as well as, theft, diversion, or self-use of dangerous drugs, among licensed individual employees by or with the pharmacy. (BPC 4104[b])

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☐ 27.1.5. Reporting to the board within 14 days of the receipt or development of information as specified in BPC 4104[c][1]-[6].

☐ 27.1.6. Operation of the pharmacy during the temporary absence of the pharmacist for breaks and meal periods including authorized duties of personnel, pharmacist's responsibilities for checking all work performed by ancillary staff, and pharmacist's responsibility for maintaining the security of the pharmacy. (CCR 1714.1[f])

☐ 27.1.7. Assuring confidentiality of medical information if your pharmacy maintains the required dispensing information for prescriptions, other than controlled substances, in a shared common electronic file. (CCR 1717.1[e])

☐ 27.1.8. Helping patients with limited or no English proficiency understand the information on the prescription container label in the patient's language, including the selected means to identify the patient's language and providing interpretive services in the patient's language. (CCR 1707.5)

☐ 27.1.9. Inventory reconciliation reporting requirements. (CCR 1715.65)

☐ 27.1.10. Pharmacy technician performing monthly checks of the drug supplies stored throughout the health care facility and reporting irregularities within 24 hours to the pharmacist-in-charge and the director or chief executive officer of the health care facility. (BPC 4115[~~j~~i][3])

☐ 27.1.11. Intern pharmacist, under the direct supervision and control of a pharmacist, may inspect the drugs maintained in the health care facility at least once per month. (BPC 4119.7[c])

☐ 27.1.12. Furnishing dangerous drug or dangerous device pursuant to preprinted or electronic standing orders, order sets, and protocol, if the order is dated, timed, and authenticated in the medical record of the patient to whom the dangerous drug or dangerous device is provided. (BPC 4119.7[a])

☐ 27.1.13. Storing and maintaining drugs in accordance with national standards regarding storage areas, refrigerator or freezer temperature, and otherwise pursuant to the manufacturer's guidelines. (BPC 4119.7[b], 22 CCR 70263 [c][1], [q][6])

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

☐ 27.1.15. If applicable, dispensing, storage and records of use if bedside medications are allowed. No controlled substances shall be left at bedside. (22 CCR 70263[*l*])

☐ 27.1.16. The use of investigational drugs. Basic information concerning the dosage form, route of administration, strength, actions, uses, side effects, adverse effects, interaction and symptoms of toxicity shall be available in the pharmacy and the nursing station. The pharmacist is responsible for the proper labeling, storage and distribution of such drug pursuant to the investigator's written orders. (22 CCR 70263[o]).

CORRECTIVE ACTION OR ACTION PLAN: _____

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28. Compounding

Yes No N/A

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

29. Automated Drug Delivery Systems

Yes No N/A

☐☐☐ 29.1. The hospital pharmacy operates automated drug delivery systems that are automated unit dose systems (AUDS) for doses administered at the facility and approved services listed on the hospital's license and the ADDS is/are exempt from licensure with the board. The AUDS must comply with all other requirements for an ADDS in Article 25. (BPC 4427.2[i])

☐☐☐ 29.2. The hospital pharmacy operates automated drug delivery systems that are automated patient delivery dispensing systems (APDS) for doses dispensed to patients at the facility and approved services listed on the hospital's license and the ADDS is/are licensed with the board. (BPC 4427.2[a])

☐☐☐ 29.3. If the pharmacy operates an automated drug delivery system, the pharmacist-in-charge has completed the self-assessment for automated drug delivery systems pursuant to CCR 1715. The pharmacy shall comply with all recording keeping and quality assurance requirements and maintain those records within the licensed pharmacy holding the ADDS license and separate from other pharmacy records. (BPC 4427.7)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

30. Prescription Drug Take-Back Services

Yes No N/A

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

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

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

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

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

~~Yes No N/A~~

PIC Initials

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

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

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

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

Yes No N/A

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

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

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

Yes No N/A

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

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

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

DEA Collector Registration Number: _____

Expiration Date: _____

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

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

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

Yes No N/A

PIC Initials

☐☐☐ 30.12. The pharmacy is registered with DEA as a collector for purposes of maintaining a prescription drug take-back collection receptacle. (21 CFR 1317.30, 1317.40, CCR 1776)

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

Date the board was notified: _____

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

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

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

Date reported: _____

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

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

Yes No N/A

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

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

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

☐☐☐ 30.20. The receptacle is visible to the pharmacy and DEA registrant employees, but not located in or near emergency areas, nor behind the pharmacy's counter or is located in an area that is regularly monitored by pharmacy or DEA registrant employees and not in the proximity of any emergency or urgent care areas. When no pharmacy or DEA registrant employees are present, the collection receptacle is locked so that drugs are not deposited into the collection receptacle. (CCR 1776.3[b], [c])

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

~~Yes No N/A~~

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

☐☐☐ 30.23. The inner liner used is made of material that is certified by the manufacturer to meet the ASTM D179 standard test for impact resistance of 165 grams (drop dart test) and the ASTM D1922standards for tear resistance of 480 grams in both parallel and perpendicular planes. (CCR1776.3[f])

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

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

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

☐☐☐ 30.25. If the liner is not already itself rigid or already inside of a rigid container when it is removed from the collection receptacle, the liner is immediately, without interruption, placed in a rigid container for storage, handling and transport. (CCR 1776.3[h])

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

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

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

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

~~Yes No N/A~~

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

CORRECTIVE ACTION OR ACTION PLAN: _____

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Onsite Pharmacies with Drug Take-Back Services in Skilled Nursing Facilities

Yes No N/A

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

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

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

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

If yes, continue answering the questions in this section.

List the location(s) of the collection receptacle:

_____

_____

Yes No N/A

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

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

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

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

☐☐☐ 30.37. The skilled nursing facility places a 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])

~~Yes No N/A~~

☐☐☐ 30.38. 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, has a small opening that allows deposit of drugs into the inside of the collection receptacle and directly into the inner liner, but does not allow for an individual to reach into the receptacle's contents, securely locked and substantially

constructed with a permanent outer container and a removable inner liner. (CCR 1776.4[e][f][g])

☐☐☐ 30.39. The liner is 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) and the ASTM D1922standards for tear resistance of 480 grams in both parallel and perpendicular planes, is waterproof, tamper evident, tear resistant, and opaque to prevent viewing and discourage removal of any contents once the liner is removed from the collection receptacle, marked to display the maximum contents, and bear a permanent, unique identification number. (CCR 1776.4[h])

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

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

~~Yes~~ No N/A

☐☐☐ 30.42. The rigid container is either 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])

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

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

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

☐☐☐ 30.46. Sealed inner liners placed in a container 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])

~~Yes No N/A~~

☐☐☐ 30.47. 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])

CORRECTIVE ACTION OR ACTION PLAN: _____

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Record Keeping Requirements for Board Licensees Providing Drug Take Back Services

Yes No N/A

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

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

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

CORRECTIVE ACTION OR ACTION PLAN: _____

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PIC Initials

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 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

(Hospital Administrator)

PIC Initials

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

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

Attachment 2

c. Wholesaler/Third-Party Logistics Provider Self-Assessment Form 17M-26, CCR, Title 16, Section 1784(c)

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 ~~strikethrough~~ for deleted language and dashed underline for added language.

WHOLESALER/THIRD-PARTY LOGISTICS PROVIDER SELF-ASSESSMENT

All legal references used throughout this self-assessment form are explained on page ~~21~~20.

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

Title 16 of the California Code of Regulations section 1784 requires each wholesaler and third-party logistics provider, as defined under section 4160 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 designated representative-in-charge or responsible manager must also complete a self-assessment within 30 days whenever: (1) a new license has been issued; (2) there is a change in the designated representative-in-charge or responsible manager; or (3) there is a change in the licensed location of the wholesaler or third-party logistics provider. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

Each self-assessment must be kept on file by the wholesaler and third-party logistics provider for three years after it is completed.

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 _____ DRIC/RM Email address:_____

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 _____

WHOLESALER/THIRD-PARTY LOGISTICS PROVIDER

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 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 the transfer~~ 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])
If yes, please have a copy of the trust readily available for inspection.

CORRECTIVE ACTION OR ACTION PLAN _____

_____

2. Facility

2.1. Premises, fixtures and equipment:

Yes No N/A

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

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

Yes No N/A

☐ ☐ ☐ 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 _____

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☐ ☐ ☐ 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: _____

Yes No N/A

☐ ☐ ☐ 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 of 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])

☐ ☐ ☐ 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])

☐ ☐ ☐ 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])

CORRECTIVE ACTION OR ACTION PLAN _____

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Note: There are specific requirements for wholesaling of 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 your business only furnishes ~~O~~only a quantity sufficient to alleviate a specific shortage). (BPC 4126.5[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)

☐ ☐ ☐ 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 of 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 _____

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Note: There are specific requirements for wholesaling of 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])

☐ ☐ ☐ 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])

☐ ☐ ☐ 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))

Yes No N/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 of the following:~~?~~

☐ Any loss of a controlled substance, 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:

☐ (A) For tablets, capsules, or other oral medication, 99 dosage units.

☐ (B) For single-dose injectable medications, lozenges, film, such as oral, buccal and sublingual, suppositories, or patches, 10 dosage units.

☐ (C) For injectable multi-dose medications, medications administered by continuous infusion, or any other multi-dose unit not described in subparagraph (A), two or more multi-dose vials, infusion bags, or other containers. (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:

Yes No N/A

☐ ☐ ☐ 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

☐ ☐ ☐ 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, 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)

Yes No N/A

☐ ☐ ☐ 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])

☐ ☐ ☐ 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])

~~Yes No N/A~~

☐ ☐ ☐ 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 of 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])

☐ ☐ ☐ 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])

☐ ☐ ☐ 16.7. 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 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)

☐ ☐ ☐ 16.12. 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.

☐ ☐ ☐ 16.13. The wholesaler/third-party logistics provider shall notify the board of any temporary closure of a facility as soon as any closure exceeds three consecutive calendar days. Closure dates will be public information. A temporary closure shall 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 _____

_____

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 2

d. Automated Drug Delivery System Self-Assessment Form 17M-112, CCR, Title 16, Section 1715.1

Title 16. Board of Pharmacy
Proposed Text

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

Proposal to amend §1715.1 of Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1715.1. Self-Assessment of an Automated Drug Delivery System by the Pharmacist-in-Charge.

(a) The pharmacist-in-charge of each automated drug delivery system as defined under section 4119.11, 4187.5 or section 4427.3 of the Business and Professions Code (BPC) shall complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. The assessment shall be performed ~~annually~~ before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

(b) In addition to the self-assessment required in subdivision (a) of this section, the pharmacist-in-charge shall complete a self-assessment within 30 days whenever:
  (1) A new automated drug delivery system license has been issued.
  (2) There is a change in the pharmacist-in-charge~~, and he or she becomes the new pharmacist-in-charge of an automated drug delivery system~~.
  (3) There is a change in the licensed location of an automated drug delivery system to a new address.

(c) A pharmacist-in-charge of an automated drug delivery system shall assess the system's compliance with current laws and regulations by using the components of Form 17M-112 (Rev 12/~~18~~24) entitled “Automated Drug Delivery System Self-Assessment”. Form 17M-112 shall be used for all automated drug delivery systems and is hereby incorporated by reference.
  (1) The pharmacist-in-charge shall provide identifying information about the underlying operating pharmacy including:
    (A) Name and any license number(s) of the underlying pharmacy and their expiration date(s);
    (B) Address, phone number, and website address, if applicable, of the underlying pharmacy;
    (C) DEA registration number, expiration date, and date of most recent DEA inventory;
    (D) Hours of operation of the pharmacy; and
    (E) ADDS license number, address, and hours of operation.
  (2) The pharmacist-in-charge shall respond “yes”, “no”, or “not applicable” (N/A) about whether the automated drug delivery system is, at the time of the self-assessment, in compliance with laws and regulations that apply to that pharmacy setting.
  (3) For each “no” response, the pharmacist-in-charge shall provide a written corrective action or action plan to come into compliance with the law.

(4) The pharmacist-in-charge shall initial each page of the self-assessment with original handwritten initials in ink or digitally signed in compliance with Civil Code Section 1633.2(h) on the self-assessment form.

(5) The pharmacist-in-charge shall certify on the last page of the self-assessment that ~~he or she has~~ they have completed the self-assessment of the automated drug delivery system of which ~~he or she is~~ they are the pharmacist-in-charge. The pharmacist-in-charge shall also certify a timeframe within which any deficiency identified within the self-assessment will be corrected and acknowledge that all responses are subject to verification by the Board of Pharmacy. The certification shall be made under penalty of perjury of the laws of the State of California that the information provided in the self-assessment form is true and correct with an original handwritten signature in ink or digitally signed in compliance with Civil Code Section 1633.2(h) on the self-assessment form.

(6) The automated drug delivery system owner shall certify on the final page of the self-assessment that ~~he or she~~ they have ~~has~~ 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 automated ~~dispensing~~ drug delivery system's license issued by the board. This certification shall be made under penalty of perjury of the laws of the State of California with an original handwritten signature in ink or digitally signed in compliance Civil Code Section 1633.2(h) on the self-assessment form.

(d) Each self-assessment shall be completed in its entirety and kept on file in the underlying pharmacy for three years after it is performed. The completed, initialed, and signed original must be readily available for review during any inspection by the board.

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

(f) The pharmacist-in-charge of a hospital using more than one unlicensed automated drug delivery system as authorized in BPC section 4427.2(i) may complete a single self-assessment of the hospital's compliance with federal and state pharmacy law for all automated drug delivery systems under the following conditions:

(1) The mechanical devices used as part of the automated drug delivery system to store, dispense, or distribute dangerous drugs are of the same manufacturer and controlled by the same software system on a single server;

(2) The same policies and procedures required by Section 4427.2 of the BPC are used; and

(3) All mechanical devices for which the single consolidated self-assessment applies shall be listed with license number and expiration date as part of the self-assessment.

(g) The pharmacist-in-charge of a licensed correctional pharmacy using more than one licensed automated drug delivery system at a single institution in compliancewith federal and state pharmacy law may complete a single consolidated self-assessment for all automated drug delivery systems licensed to the correctional pharmacy under the following conditions:

(1) The mechanical devices used as part of the automated drug delivery system to store, dispense, or distribute dangerous drugs are of the same manufacturer and

controlled by the same software system on a single server;

(2) The same policies and procedures required by Section 4427.2 of the BPC are used; and

(3) All mechanical devices for which the single consolidated self-assessment applies shall be listed with license number and expiration date as part of the self-assessment.

Note: Authority cited: Sections 4119.11 and 4427.7, Business and Professions Code. Reference: Sections 4001.1, 4008, 4017.3, 4021, 4022, 4036, 4037, 4038, 4040, 4050, 4051, 4052, 4059, 4070, 4076, 4081, 4101, 4105, 4107, 4113, 4117.3, 4119.1, 4119.11, 4125, 4126, 4180, 4186, 4305, 4330, 4332, 4333, 4400, 4427, 4427.1, 4427.2, 4427.3, 4427.4, ~~and~~ 4427.5, 4427.6, and 4427.7, Business and Professions Code; and Section 16.5, Government Code.

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

Legend:
2024 Changes (Approved by the Board in April 2024) – Proposed changes made to the current regulation language are shown by ~~double strikethrough~~ for deleted language and double underline for added language.

2025 Changes – Proposed changes are shown by ~~yellow highlight double strikethrough~~ for deleted language and yellow highlight 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 section 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~~ AUDS 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). Attach a list of all unlicensed ~~ADDS~~ AUDS, their locations and hours of operation. [CCR 1715.1(f)]

Note: **For a correctional pharmacy** operating more than one licensed automated drug delivery system at a single institution, the PIC may complete a single consolidated self-assessment for all licensed ADDS, if the mechanical devices used are the same manufacturer, are controlled by the same software system on a single server and use the same policies and procedures. Attach a list of all licensed ADDS and include the ADDS license number, manufacturer and model number. [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~~ Controlled Substance (CS) Inventory Reconciliation Date (CCR 1715.65(c)): _____
Pharmacy Hours: M-F: _____ **Saturday**_____ **Sunday**_____
PIC: _____ **RPH#**_____
PIC Email: _____
ADDS License #: _____ **ADDS Expiration Date:** _____
(Attach additional sheets if necessary)
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), 4427.65, ~~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: [BPC 4056, 4427.2(i)]

- ☐ 2.8.1. Only 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~~
- ☐ 2.8.2. 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 from the hospital pharmaceutical services by means of the method of transportation the patient states that they intend to use, and
- ☐ 2.8.3. The quantity dispensed to any outpatient is limited to an amount necessary to maintain uninterrupted therapy during the period when the pharmaceutical services outside the hospital are not readily available or accessible and does not exceed a 72-hour supply.

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 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 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, if the drug is a schedule II, schedule III, or schedule IV controlled substance, 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 of drugs dispensed to any patient pursuant to this section is limited to an amount necessary to maintain uninterrupted therapy during the period when pharmacy services outside the hospital are not readily available or accessible, but shall not exceed a 72-hour supply.

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

☐☐☐ 2.10. **An AUDS located and operated in a ~~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. **An AUDS located and operated in a j~~J~~ail, 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
(For 3.1 through 3.12, a~~A~~nswer 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)]

☐☐☐ 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), BPC 4119.11(a)(9)]

☐☐☐ 3.7. The pharmacy is aware a replacement of an ADDS shall require notification to the board within 30 days. [BPC 4427.2(e), BPC 4119.11(a)(9)]

☐☐☐ 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), BPC 4119.11(a)(10)]

☐☐☐ 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), BPC 4119.11(a)(11)]

☐☐☐ 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)]

☐☐☐ 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)(E~~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]

☐☐☐ 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 (d), 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], BPC 4427.4(c),(d))

☐☐☐ 3.25 The pharmacy's inventory reconciliation report is 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.~~ This report 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.~~ These inventory activities include 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 as identified in Section 3.26 above 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 licensed 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 licensed clinic (as included/defined in 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. These should include the inventory of federal controlled substances stored in the ADDS. ~~that includes the inventory of federal controlled substances stored in the ADDS.~~ [~~(~~CCR 1715.65(b)]~~)~~

☐☐☐ 3.31 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 or hospital administrator of the ADDS shall sign the Certification Acknowledgment on page ~~33~~ ~~48~~ 47 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**: ~~—~~AUDS~~-DDS~~ 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**:– AUDS~~-DDS~~ 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.

(Please note: Hospital pharmacies and drug rooms must also complete Section 6 for AUDS used for administration. Section 8 addresses additional requirements for hospital pharmacies and drug rooms operating an AUDS used for dispensing.

☐ **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)]

☐☐☐ 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 my 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~~8 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)]

☐☐☐ 4.13~~9~~ 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~~

☐☐☐ 4.1~~0~~ 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)]

☐☐☐ 4.1~~5~~ 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~~16 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~~17 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.~~22~~20.1 All controlled substances added to the ADDS/APDS are accounted for;
- ☐ 4.~~22~~20.2 Access to ADDS/APDS is limited to authorized facility personnel;
- ☐ 4.~~22~~20.3 An ongoing evaluation of discrepancies or unusual access associated with controlled substance is performed; and
- ☐ 4.~~22~~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

☐☐☐ 4.21~~3~~ 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)]~~

☐☐☐ 4.22~~5~~ 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)]

☐☐☐ 4.23~~6~~ 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)~~]

- ☐ 4.2~~7~~4.1.1 Maintaining the security of the APDS and dangerous drug and devices within the APDS.
- ☐ 4.2~~7~~4.1.2 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.
- ☐ 4.2~~7~~4.1.3 Ensuring patients are aware that consultation with a pharmacist is available for any prescription medication, including those delivered via APDS.
- ☐ 4.2~~7~~4.1.4 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.
- ☐ 4.2~~7~~4.1.5 Orienting patients on the use of APDS and notifying patients when expected prescription 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.
- ☐ 4.2~~7~~4.1.6 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~~70~~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~~70~~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~~29 Medication 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, 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.

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.~~35~~31 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.~~36~~32 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.~~37~~33 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~~ (Check the appropriate box)

☐ **APDS ADJACENT TO THE SECURED PHARMACY AREA ~~OR~~**

☐ **APDS LOCATED IN A MEDICAL OFFICE~~S~~ ~~(OR)~~**

☐ **APDS ~~A~~LOCATED~~ION~~ WHERE PATIENTS ARE REGULARLY SEEN FOR PURPOSES OF DIAGNOSIS AND TREATMENT TO ONLY BE USED FOR PATIENTS OF THE PRACTICE~~(OR).~~**

☐ **APDS LOCATED AT ~~THROUGH~~ A CLINIC PURSUANT TO HSC 1204, ~~OR~~ HSC 1204.1, ~~OR~~ BPC 4180, OR BPC 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 delivery 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)]

☐☐☐ 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)]

☐☐☐ 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: AUDDDS 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~~1 The 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~~ The stocking and restocking of an ADDS shall be 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 licensed pursuant to Section 1250 of the Health and Safety Code, where the stocking and restocking of the ADDS may be performed in compliance with Section 1261.6 of the Health and Safety Code: [*BPC 4427.4(e)(1),* ~~HSC 1261.6(g)~~]

☐ ~~6.53.1 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. [*BPC 4427.4(c)(1), HSC 1261.6(g)(1)*]~~

~~☐ 6.52.2 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)]~~

~~☐ 6.52.3 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)]~~

For pharmacies operating ADDS in Skilled Nursing Facilities, Intermediate Care Facilities and Nursing Facilities.

Yes No N/A

☐☐☐ 6.4 The stocking of the ADDS shall be performed by a pharmacist. If the ADDS utilizes removable pockets, cards, drawers, similar technology, or unit of us or single dose containers as defined by the United States Pharmacopeia, the stocking system may be done outside of the facility and be delivered to the facility if all conditions listed in HSC 1261.6(g) are met. [HSC 1261.6(g)].

☐☐☐ 6.~~6~~5 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~~6 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~~7 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~~7.1 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~~7.1.1 The date the prescription was orally transmitted by the prescriber.
  - ☐ 6.~~6~~7.1.2 The name of the person for whom the prescription was authorized.
  - ☐ 6.~~6~~7.1.3 The name and address of the licensed skilled nursing facility or licensed intermediate care facility in which the person is the patient.
  - ☐ 6.~~6~~7.1.4 The name and quantity of the controlled substance prescribed.
  - ☐ 6.~~6~~7.1.5 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~~7.1.6 The prescription is endorsed by the pharmacist with the pharmacy's name, license number, and address.

☐ 6.~~6~~7.2 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~~7.2.1 The date the prescription was electronically transmitted by the prescriber;
- ☐ 6.~~6~~7.2.2 The name of the person for whom the prescription was authorized;
- ☐ 6.~~6~~7.2.3 The name and address of the licensed skilled nursing facility or licensed intermediate care facility in which the person is the patient;
- ☐ 6.~~6~~7.2.4 The name and quantity of the controlled substance prescribed;
- ☐ 6.~~6~~7.2.5 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~~7.2.6 The prescription is endorsed by the pharmacist with the pharmacy's name, license number, and address.
- ☐ 6.~~6~~7.2.7 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~~7.3 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~~7.4 An original Schedule II prescription is written with the "11159.2 exemption" for the terminally ill. [HSC 11159.2]

☐ 6.~~6~~7.5 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~~7.5.1 The order contains all information required by subdivision (a) of Section 11164.
- ☐ 6.~~6~~7.5.2 ~~If the order is written by the prescriber, the prescription is in ink, signed, and dated by the prescriber.~~ The written order is signed and dated by the prescriber in ink, and the pharmacy reduces any oral or electronic data transmission order to hard copy form prior to dispensing the controlled substance.
- ~~☐ 6.6.5.3 If the prescription is orally or electronically transmitted, it must be reduced to hard copy.~~
- ☐ 6.~~6~~7.5.~~4~~3 The prescriber provides a written prescription on a controlled substance prescription form that meets the requirements of HSC 11162.1 by the seventh day following the transmission of the initial order.

☐ 6.~~6~~7.6 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~~8~~8 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: _____

~~☐☐☐ 6.98 The pPharmacist-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 AU~~T~~DS. ~~(~~[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 1261.6~~(e)~~(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 and are not patient specific in their design, 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.~~ Transaction information shall be made readily available in a written format for review and inspection by individuals authorized by law. These records shall be maintained in the facility for a minimum of 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.~~32~~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: AUD~~DD~~S OPERATED BY A CORRECTIONAL CLINIC PURSUANT TO BPC 4187.1, 4427.3(b)(6), or 4427.65(a)(2)

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)]

☐☐☐ 78.154 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 5024.2 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)]

☐☐☐ 78.165 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)]

☐☐☐ 78.176 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]

☐☐☐ 78.187 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)]

☐☐☐ 78.198 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

☐☐☐ 78.2019 A correctional facility pharmacist inspects the clinic at least quarterly. [BPC 4187.2(c)]

☐☐☐ 78.2120 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 of drugs contained within, and the operation and maintenance of the ADDS, 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: (Check the appropriate box)

☐ **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 (Drug Room) or BPC 4068 (Hospital Pharmacy is closed and no pharmacist is available)~~ USED FOR DISPENSING PURSUANT TO BPC 4056 ~~(DRUG ROOM) OR~~**

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~~AUDS 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]

☐☐☐ ~~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~~208.24(e)]

☐☐☐ 8.11 Boxed warning ("Black ~~b~~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 PURSUANT TO BPC 4187.1, 4427.3(b)(6), or 4427.65(a)(2).

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.

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE

~~☐☐☐ 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~~

C. DEVICE REQUIREMENTS:

Yes No N/A

☐☐☐ 9.3~~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)]:~~
For Sections 9.5-9.7: 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~~4 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)]

☐☐☐ 9.5~~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)]

☐☐☐ 9.6~~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)]:~~
For Sections 9.8-9.12: When the ADDS is used to provide pharmacy services pursuant to BPC 4017.3 and Article 25 in Chapter 9, Division 2 of the BPC, the ADDS is subject to the following requirements [BPC 4427.65(c)(5)]:

☐☐☐ 9.7~~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)]

☐☐☐ 9.8~~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)]

☐☐☐ 9.9~~10~~ The pharmacy providing services to the facility, pursuant to Article 25 in Chapter 9, Division 2 of the BPC, controls the access to the drugs stored in the ADDS. [BPC 4427.65(c)(5)(C)]

☐☐☐ 9.10~~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)]

☐☐☐ 9.1112 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_____

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D. RECORD KEEPING REQUIREMENTS

Yes No N/A

☐☐☐ 9.1213 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_____

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E. POLICIES AND PROCEDURES

Yes No N/A

☐☐☐ 9.1413 The pharmacy operating the AUDS shall develop and implement, and review annually, the written policies and procedures pertaining to the ADDSAUDS. [BPC 4427.65(b)]

☐☐☐ 9.1415 The facility and the pharmacy have 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)

☐☐☐ 9.1516 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_____

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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 THE~~ PHARMACY OWNER OR HOSPITAL ADMINISTRATOR OPERATING THE ~~OF~~ ADDS:

I, ~~*(please print)*~~ _____ [print ~~insert~~ name and title], hereby certify under penalty of perjury *under* ~~*of*~~ the laws of the State of California that I have full authority, without any limitations to provide this certification, that I am the Owner of the Pharmacy or the Hospital Administrator Operating the ADDS and that I have reviewed this form, and acknowledge that all facts and information stated herein are true, correct, and complete. ~~*read and reviewed this completed self-assessment.*~~ Further, 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 _____
(Pharmacy Owner or Hospital Administrator)

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 ~~OF THE~~ PHARMACY OWNER OR HOSPITAL ADMINISTRATOR OPERATING THE ~~OF~~ ADDS:

I, ~~*(please print)*~~ _____[print ~~insert~~ name and title], hereby certify under penalty of perjury *under* ~~*of*~~ the laws of the State of California that I have full authority, without any limitations to provide this certification, that I am the Owner of the Pharmacy or the Hospital Administrator Operating the ADDS and that I have reviewed this form, and acknowledge that all facts and information stated herein are true, correct, and complete. ~~*read and reviewed this completed self-assessment.*~~ Further, 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_____
(Pharmacy Owner or Hospital Administrator)

Attachment 2

e. Surgical Clinic Self-Assessment Form 17M-118, Business and Professions Code Section 4192

SURGICAL CLINIC SELF-ASSESSMENT FORM

Section 4192 of the Business and Professions Code requires the **consulting pharmacist** of a surgical clinic licensed under section 4190 of the Business and Professions Code to complete a self-assessment of the surgical clinic's compliance with federal and state laws.

The self-assessment must be completed before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education, and must assess the clinic's compliance with current laws and regulations, including information on compounding practices as specified on the most recent version of the surgical clinic Self-Assessment Form approved by the board and posted on its internet website.

The self-assessment must be completed in its entirety. It may be completed online, printed, initialed, signed, and readily available at the surgical clinic. Signatures and initials shall be an original handwritten signature or initial on the self-assessment form. Do not copy a previous assessment. Note: In addition to this form, the consulting pharmacist must certify in writing quarterly that the clinic is, or is not, operating in compliance with the requirements of this article.

All references to the board are to the California Board of Pharmacy. All references to the California Code of Regulations (CCR) are to the board's regulations contained in Title 16 unless otherwise noted. Additionally, Business and Professions Code (BPC) are to Division 2 Healing Arts. Health and Safety Code (HSC) citations are contained in Division 10 Uniformed Controlled Substance Act. The Code of Federal Regulations (CFR) citations are to Title 21 Food and Drugs. United States Code (USC) citations are to Title 21 Food and Drugs.

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

Surgical Clinic Name: _____

Address: _____ Phone: _____

Fax: _____ Email: _____ Website: _____

Ownership: ☐ Sole Owner; ☐ Partnership; ☐ Corporation; ☐ LLC; ☐ Trust;

☐ Non-Licensed Owner; ☐ Other (please specify) _____

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

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

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

Professional Director: _____ License #:_____ Exp. Date: _____

Consulting Pharmacist: _____ RPH # _____ Exp. Date: _____

Check the type of Clinic, pursuant to BPC 4190:

- ☐ Licensed pursuant to paragraph (1) of subdivision (b) of Section 1204 of the Health and Safety Code.
- ☐ An outpatient setting accredited by an accreditation agency, as defined in Section 1248 of the Health and Safety Code.
- ☐ An ambulatory surgical center certified to participate in the Medicare Program under Title XVIII of the federal Social Security Act (41 U.S.C. Section 1395 et seq.).

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. General Requirements

Yes	No	N/A	
☐	☐	☐	1.1 The clinic purchases or purchased drugs at wholesale for administration or dispensing, under the direction of a physician and surgeon, to patients registered for care at the clinic. (BPC 4190[b].)
☐	☐	☐	1.2 A separate license has been and will be issued for each clinic location. (BPC 4190[b].)
☐	☐	☐	1.3 The clinic did or will notify the board of any change in the clinic's address on a form furnished by the board. (BPC 4190[b].)
☐	☐	☐	1.4 The clinic keeps records of the kind and amounts of drugs purchased, administered, and dispensed, and the records are available and maintained for a minimum of three years for inspection by authorized officers of the law or representatives of the board. (BPC 4190[b], 4081, 4105.)
☐	☐	☐	1.5 The drug distribution service of the clinic is limited to the use of drugs for administration to the patients of the clinic and to the dispensing of drugs for the control of pain and nausea for patients of the clinic. (BPC 4190[c])
☐	☐	☐	1.6 Drugs are not dispensed in an amount greater than that required to meet the patient's needs for 72 hours. (BPC 4190[c].)
☐	☐	☐	1.7 Drugs for administration are those drugs directly applied, whether by injection, inhalation, ingestion, or any other means, to the body of the patient for their immediate needs. (BPC 4190[c].)
☐	☐	☐	1.8 Any proposed change in ownership or beneficial interest in the licensee will be reported to the board, on a form to be furnished by the board, at least 30 days prior to the execution of any agreement to purchase, sell, exchange, gift or otherwise transfer any ownership or beneficial interest or prior to any transfer of ownership or beneficial interest, whichever occurs earlier. (BPC 4190[e].)

Yes No N/A

☐☐☐ 1.9 The clinic complies with all applicable laws and regulations of the State Department of Public Health and the board related to drug distribution to ensure that inventories, security procedures, training, protocol development, recordkeeping, packaging, labeling, dispensing, and patient consultation are carried out in a manner that is consistent with the promotion and protection of the health and safety of the public. (BPC 4191[a].)

☐☐☐ 1.10 The clinic will or did notify the board within 30 days of any change in professional director on a form furnished by the board. (BPC4192[d].)

☐☐☐ 1.11 If the clinic has or had a temporary closure, the clinic will or did notify the board of any temporary closure as soon as any closure exceeds or exceeded three consecutive calendar days.. (CCR 1708.1.)

Note: A temporary closure does not include a routine closure (including weekends or state and federal holidays), unless the closure exceeds four consecutive calendar days. (CCR 1708.1.)

☐☐☐ 1.12 The clinic joined the board's email notification list within 60 days of obtaining its license or at time of license renewal. (BPC 4013[a].)

☐☐☐ 1.13 The clinic updated its email address with the board's email notification list within 30 days of a change, if any, in the clinic's email address. (BPC 4013[b].)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

2. Duties of the Professional Director

Yes No N/A

☐☐☐ 2.1 The professional director is a physician and surgeon acting in their capacity as medical director or a dentist or podiatrist acting in their capacity as a director in a clinic where only dental or podiatric services are provided. (BPC 4192[c].)

☐☐☐ 2.2 There is a professional director that is responsible for the safe, orderly, and lawful provision of pharmacy services. (BPC 4192[a].)

☐☐☐ 2.3 In carrying out the professional director's responsibilities, a consulting pharmacist has been retained to approve the policies and procedures in conjunction with the professional director and administrator. (BPC 4192[a].)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

3. Duties of the Consulting Pharmacist

Yes No N/A

☐☐☐ 3.1 The consulting pharmacist visits the clinic regularly and at least quarterly. Nothing prohibits the consulting pharmacist from visiting more than quarterly to

review the application of policies and procedures based on the agreement of all the parties approving the policies and procedures. (BPC 4192[a].)

Yes No N/A

☐☐☐ 3.2 The consulting pharmacist certifies in writing quarterly that the clinic is, or is not, operating in compliance with the requirements of Article 14 for clinics. (BPC 4192[b].)

☐☐☐ 3.3 Each written certification by the consulting pharmacist is kept on file in the clinic for three years and includes recommended corrective actions, if appropriate. (BPC 4192[b].)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

4. Dangerous Drugs and Dangerous Device Inventory

Yes No N/A

☐☐☐ 4.1 Dangerous drugs and dangerous devices transferred, sold, or delivered to the clinic are transferred, sold, or delivered only to the clinic. (BPC 4059.5[b].)

☐☐☐ 4.2 The clinic receiving the delivery of dangerous drugs and dangerous devices signs for the receipt of the dangerous drugs and dangerous devices. (BPC 4059.5[d].)

☐☐☐ 4.3 All stock of any dangerous drugs or dangerous devices is, at all times during business hours, open for inspection by authorized officers of the law. (BPC 4080.)

☐☐☐ 4.4 The clinic keeps a current inventory as defined by Section 1718 of the board's regulations. (BPC 4081[a], CCR 1718.)

☐☐☐ 4.5 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 clinic is provided transaction history, transaction information, and a transaction statement. (21 USC 360eee-1[d][1][A][i].)

☐☐☐ 4.6 The clinic 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].)

☐☐☐ 4.7 The clinic is aware of the requirements of the Drug Quality and Security Act (DQSA), to have lot level traceability and , unit-level traceability. (21 USC 360eee-1[d][2], [g][1]f)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

5. Controlled Substances

Yes No N/A

☐☐☐ 5.1 The clinic has obtained a registration from DEA to engage in the distribution and dispensing of controlled substances. (21 CFR 1301.11.)

☐☐☐ 5.2 No Schedule II controlled substances are dispensed in the clinic. (BPC 4194.)

☐☐☐ 5.3 Controlled substance inventories required by Title 21, Code of Federal Regulations Section 1304.04 are available for inspection upon request for at least three (3) years after the date of the inventory. (CCR 1718, 21 CFR 1304.11[c].)
Date completed:_____

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

☐☐☐ 5.5 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[h][3].)

☐☐☐ 5.6 U.S. Official Order Form (DEA Form 222) or its electronic equivalent (CSOS) is utilized when ordering all Schedule II controlled substances. When Schedule II controlled substance orders are received by the clinic, for each item received, the date and quantity received is recorded.. (21 CFR 1305.03, 1305.12, 1305.13, 1305.21, 1305.22[g].)

☐☐☐ 5.7 For each prescription for a federally Schedule II, III, IV or V controlled substance, the clinic reports the specified information to the Department of Justice or contracted prescription data processing vendor as soon as reasonably possible, but not more than one working day after the date a controlled substance is released to the patient or patient's representative, in a format specified by the Department of Justice. (HSC 11165[d].)

☐☐☐ 5.8 The clinic or affected prescriberreports the theft or loss of prescription forms immediately to the CURES Prescription Drug Monitoring Program, but no later than three days after the discovery of the theft or loss. (HSC 11165.3.)

☐☐☐ 5.9 The clinic's prescribers authorized to prescribe, order, administer, or furnish a controlled substance consult the patient activity report or information from the patient activity report obtained from the CURES database to review a patient's controlled substance history for the past 12 months before prescribing a Schedule II, Schedule III or Schedule IV controlled substance to the patient for the first time and at least once every six months thereafter if the prescriber renews the prescription and the substance remains part of the treatment of the patient. (HSC 11165.4[a][1][A][i]).

☐☐☐ 5.10 The clinic took an initial inventory of all stocks of controlled substance on hand on the date the clinic first engaged in the distribution or dispensing of controlled substances. (21 CFR 1304.11[b]).

☐☐☐ 5.11 The clinic takes a new inventory of all stocks of controlled substances on hand at least every two years. The biennial inventory can be taken on any date that is within two years of the previous biennial inventory date. (21 CFR 1304.11[c].)

☐☐☐ 5.12 The controlled substance inventory is taken either as of opening of business or as of the close of business on the inventory date and is indicated on the inventory. (21 CFR 1304.11[a].)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

6. Inventory Reconciliation

Yes No N/A

☐☐☐ 6.1 The clinic performs periodic inventory activities and prepares inventory reconciliation reports to detect and prevent the loss of federal controlled substances. (CCR 1715.65[a].)

☐☐☐ 6.2 Inventory reconciliation reports are prepared on an ongoing basis for federal Schedule II controlled substances, at least once every three months. (CCR 1715.65[a][1].)

☐☐☐ 6.3 Inventory reconciliation reports are prepared on an ongoing basis for the following strengths per tablet, capsule, other unit, or specified volume, at least once every 12 months for the following: (CCR 1715.65[a][2])

- ☐ 6.3.1 Alprazolam, 1 milligram/unit
- ☐ 6.3.2 Alprazolam, 2 milligram/unit
- ☐ 6.3.3 Tramadol, 50 milligram/unit
- ☐ 6.3.4 Promethazine/codeine, 6.25 milligrams of promethazine and 10 milligrams of codeine per 5 milliliters of product.

☐☐☐ 6.4 Inventory reconciliation reports are prepared on an ongoing basis for any controlled substance not covered in 6.2 and 6.3. (CCR 1715.65[a][3][A])

☐☐☐ 6.4.1 The inventory reconciliation report is prepared for identified controlled substances lost no later than three months after discovery of the reportable loss of that controlled substance.

☐☐☐ 6.4.2 The report is completed if the loss is discovered either by the inventory activities required by 6.2 and 6.3, or in any other manner.

☐☐☐ 6.4.3 The report covers the period from the last physical count of that controlled substance before the loss was discovered through the date of discovery.

☐☐☐ 6.4.3 At a minimum, the reportable loss or any pattern(s) of loss(es) identified by the consulting pharmacist or professional director, as defined by the clinic's policies and procedures.

☐☐☐ 6.4.4 There is an inventory reconciliation report for each pattern of loss identified.

☐☐☐ 6.5 Inventory activities for each controlled substance not covered in 6.2 and 6.3 are performed at least once every two years from the performance of the last inventory activities. (CCR 1715.65[a][3][B].)

Note: Inventory activities means inventory and all other functions sufficient to identify loss of controlled substance. The functions sufficient to identify loss outside of the inventory reconciliation process must be identified with the pharmacy's policies and procedures. (CCR 1715.65[a][3][B].)

☐☐☐ 6.6 The consulting pharmacist reviews all the inventory activities performed and inventory reconciliation reports prepared, and establishes and maintains secured methods to prevent losses of federal controlled substances. (CCR 1715.65[b].)

☐☐☐ 6.7 The prepared inventory reconciliation report includes all of the following:

☐☐☐ 6.7.1 A physical count, not an estimate, of all quantities of each federal controlled substance covered by the report that the clinic has an inventory. The biennial inventory of controlled substances required by federal law may serve as one of the mandated inventories 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. (CCR 1715.65[c][1].)

☐☐☐ 6.7.2 The signature of the individual who performs the required inventory and date of the inventory or the report. (CCR 1715.65[c][1].)

☐☐☐ 6.7.3 A review of all acquisitions and dispositions of each federal controlled substance covered by the report since the last inventory reconciliation report covering the controlled substance. (CCR 1715.65[c][2].)

☐☐☐ 6.7.4 A comparison of 6.7.1 and 6.7.3 to determine if there are any variances. (CCR 1715.65[c][3].)

☐☐☐ 6.7.5 Identification of all records used to compile the report, which, along with the records themselves, are maintained in the clinic and are readily retrievable in the clinic for three years. (CCR 1715.65[c][4], 1715.65[e][2].)

☐☐☐ 6.8 The clinic submits to the board a report containing the identity, amount, and strength of each controlled substance lost, and the date of discovery of the loss, for all losses that have made the report necessary, no later than thirty days after the date of discovery. (CCR 1715.6[a], [b])

☐☐☐ 6.9 The clinic submits to the board a report for the discovery of the following controlled substance losses: (CCR 1715.6[a], [b])

☐☐☐ 6.9.1 Any loss of a controlled substance in one of the following categories that causes the aggregated amount of unreported losses discovered in that category, on or after the same day of the previous year, to equal or exceed: (CCR 1715.6[a][1][A]-[C])

☐ 6.9.1.1 For tablets, capsules or other oral medication, 99 dosage units.

☐ 6.9.1.2 For single-dose injectable medication, lozenges, film, such as oral, buccal and sublingual suppositories or patches, 10 dosage units.

☐ 6.9.1.3 For Injectable multi-dose unit, two or more multi-dose vials, infusion bags, or other containers.

☐☐☐ 6.9.2 Any loss of controlled substances, regardless of the amount, attributed to employee theft. (CCR 1715.6[a][2].)

☐☐☐ 6.10 The clinic notifies the DEA in their area, in writing, of any theft or significant loss of any controlled substances within one business day of discovery of the theft or loss. (21 CFR 1301.74[c].)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

_____

7. Drug Dispensing

Yes No N/A

☐☐☐ 7.1 The dispensing of drugs in the clinic is performed only by a physician, a pharmacist, or other person lawfully authorized to dispense drugs, and only in compliance with all applicable laws and regulations. (BPC 4191[b].)

☐☐☐ 7.2 The clinic is aware that is it not eligible for any professional dispensing fee that is authorized under the Medi-Cal program (Chapter 7, commencing with Section 14000, of Part 3 of Division 9 of the Welfare and Institution Code). (BPC 4193)

☐☐☐ 7.3 The clinic does not offer drugs for sale or charge or bill for professional services for the dispensing or administering of drugs. (BPC 4193.)

☐☐☐ 7.4 Does the clinic have a licensed automated drug dispensing system (ADDS) placed and operated inside an enclosed building, with a premise address, at a location approved by the board that is owned/leased and operated by a pharmacy? If yes, (BPC 4427.1, 4427.3[b][3])

Name of Pharmacy: _____

ADDS license number:_____

☐☐☐ 7.5 Does the clinic have an unlicensed ADDS pursuant to Business and Professions Code section 4427.2(i) that is owned/leased and operated by a hospital pharmacy? If yes, (BPC 4427.1, 4427.2[i], 4427.3[b][3])

Name of Hospital Pharmacy:_____

Hospital Pharmacy license number: _____

☐☐☐ 7.6 The prescription labels contain all the required information. (BPC 4076.)

☐☐☐ 7.7 The prescription label is formatted in accordance with patient centered labeling requirements. (BPC 4076.5, CCR 1707.5.)

☐☐☐ 7.8 Whenever requested by a patient or patient's 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 appear on the prescription container or label, the English-language version of the directions for use also appear 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].)

☐☐☐ 7.9 The clinic provides translated directions for use in the language the board has made available, but is not required to provide translated directions for use beyond wht languages the board has made available or beyond the directions that the board has made available in translated form. (BPC 4076.6[c].)

☐☐☐ 7.10 The clinic provide their own translated directions for use to comply with the requirements. (BPC 4076.6[d].)

☐☐☐ 7.11 The clinic is aware they are responsible for the accuracy of the English-language directions for use provided to the patient. (BPC 4076.6[e].)

☐☐☐ 7.~~9~~12 The clinic provides patients with Black Box Warning Information in conformance with 21 CFR 201.57[c].

☐☐☐ 7.~~10~~13 Whenever an opioid prescription is dispensed to patient for outpatient use, the clinic 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.)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

_____

8. Drug Compounding

Yes No N/A

☐☐☐ 8.1 Does a pharmacy deliver compounded preparation to the clinic at which a patient receives health care services? (CCR 1713[b].) If yes:

Name of Pharmacy: _____

Pharmacy license number: _____

Sterile compounding license number: _____

Attach additional sheet if necessary.

☐☐☐ 8.2 Does the clinic purchase compounded drugs from a facility registered as an outsourcing facility with the federal Food and Drug Administration and concurrently licensed with the board as an outsourcing facility if it compounds sterile medication or nonsterile medication for nonpatient-specific distribution? (BPC 4129.) If yes:

Name of outsourcing facility: _____

Outsourcing Facility license #: _____

Attach additional sheet if necessary.

☐☐☐ 8.3 The clinic compounds for immediate use in compliance with the current United States Pharmacopeia Chapter 797 (USP 797). (USC 503A(b)(A)(i)(I))

☐☐☐ 8.4 The clinic compounds for future use in compliance with the current USP 797. (USC 503A(b)(A)(i)(I))

☐☐☐ 8.5 The clinic handles hazardous drugs in compliance with the current United State Pharmacopeia Chapter 800 (USP 800). (, USP 800)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

_____

9. Policies and Procedures

Yes No N/A

☐☐☐ 9.1 The clinic has developed and approved policies and procedures to implement the laws and regulations by the consulting pharmacist, professional director, and the clinic administrator. (BPC 4191[a].)

☐☐☐ 9.2 The clinic has policies and procedures that were developed and approved by the consulting pharmacist, the professional director, and the clinic administrator to implement the laws and regulations: (BPC 4191[a])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

_____

10. Record Keeping Requirements

Yes No N/A

☐☐☐ 10.1 Inventory reports and all records used to compile the report are readily retrievable in the clinic for three years. (CCR 1715.65[e][2].)

☐☐☐ 10.2 All records of manufacture and of sales, acquisition, receipt, shipment, or disposition of dangerous drugs and dangerous devices, at all times, during business hours are open for inspection by authorized officers of the law, and are preserved for at least three years from the date of making. This also includes the kind and amounts of drugs purchased, administered, and dispensed. (BPC 4081, BPC 4190[b].)

☐☐☐ 10.2.1 Purchase invoices for all prescription drugs. (BPC 4081[a])

☐☐☐ 10.2.2 Biennial controlled substance inventory. (21 CFR 1304.11[c], CCR 1718.)

☐☐☐ 10.2.3 U.S. Official Order Forms (DEA Form 222). (21 CFR 1305.13)

☐☐☐ 10.2.4 Power of Attorney for completion of DEA Forms 222. (21 CFR 1305.05)

☐☐☐ 10.2.5 Theft and loss reports (DEA Form 106). (BPC 4081, 21 CFR 1301.74[c])

☐☐☐ 10.2.6 Records documenting return of drugs to wholesaler or manufacturer. (BPC 4081[a].)

☐☐☐ 10.2.7 Records documenting transfers or sales to other clinics or reverse distributors. (BPC 4081, 4105, CCR 1718.)

☐☐☐ 10.2.8 Records of receipt and shipment. (BPC 4081.)

☐☐☐ 10.3 All records or other documentation of the acquisition and disposition of dangerous drugs and dangerous devices by the clinic is retained on the licensed premises in a readily retrievable form. (BPC 4105.)

☐☐☐ 10.4 Each completed quarterly written certification by the consulting pharmacist is kept on file in the clinic for three years. (BPC 4192[b])

☐☐☐ 10.5 Completed Surgical Clinic self-assessments signed under penalty of perjury are kept on file in the clinic for three years. (BPC 4192[b])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

_____

CONSULTING PHARMACIST CERTIFICATION:

I, (please print) _____, RPH # _____ hereby certify that I have read, reviewed and completed the self-assessment of this clinic of which I am the Consulting Pharmacist. Any deficiency identified herein will be corrected by _____(date). The self-assessment was completed to the best of my professional ability and acknowledge failure to correct any deficiency identified could result in action by the board. 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 _____
(Consulting Pharmacist)

PROFESSIONAL DIRECTOR CERTIFICATION:

I, (please print) _____, Professional License # _____ hereby certify that I have read and reviewed the completed self-assessment of this clinic of which I am the Professional Director. Any deficiency identified herein will be corrected by _____(date). The self-assessment was completed to the best of my professional ability and acknowledge failure to correct any deficiency identified could result in action by the board. 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 is provided in this self-assessment form is true and correct.

Signature _____ Date _____
(Professional Director)

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 9 – Pharmacy
- California Code of Regulation (CCR), Title 16, Division 17 – California State Board of Pharmacy
- 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 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
- 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
- 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
- United States Pharmacopeia, Chapters 795, 797, 800, and 825

Attachment 3

Attachment 3a
Proposed New Form

Proposed New Form

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8614
www.pharmacy.ca.gov

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

PETITION FOR REINSTATEMENT OR MODIFICATION OF PENALTY (INCLUDING MODIFICATION OR TERMINATION OF PROBATION)

Business and Professions Code section 4309 permits a person whose license has been revoked or suspended or who has been placed on probation to petition the Board for reinstatement or modification of penalty, including modification or termination of probation, after not less than the following minimum periods have elapsed from the effective date of the decision ordering disciplinary action:

(1) At least three years for reinstatement of a revoked license.
(2) At least two years for early termination of probation of three years or more.
(3) At least one year for modification of a condition, or reinstatement of a license revoked for mental or physical illness, or termination of probation of less than three years.

TYPE OF PETITION

____ **PETITION FOR REINSTATEMENT OF REVOKED LICENSE: LICENSE NO. _____**

____ **PETITION FOR REDUCTION (MODIFICATION) OF PENALTY OF PROBATION OF LICENSE NO. _____**

____ **PETITION FOR EARLY TERMINATION OF PROBATION OF LICENSE NO. _____**

Petitioner Information - Please Type or Print

_____ _____ _____
Full Legal Name - Last Name | First Name | Middle Name

_____
Previous Name(s) (AKA, Maiden Name, Alias, etc.)

_____
*Official Mailing/Public Address of Record – Street/PO Box | City | State | Zip Code

_____
Residence Address – Street | City | State | Zip Code

_____ _____ _____
Telephone Numbers – Home | Cell | Work

_____ _____
Date of Birth (Month/Day/Year) | Email Address

XXX - XX - _____
Last 4 digits of US Social Security Number or Individual Tax ID Number

Education

Name(s) of University, College, or School of Pharmacy	Country	Date of Graduation	Degree
_____	_____	_____	_____
_____	_____	_____	_____

License Information List all state(s) where you are or have previously been licensed as a pharmacist, intern pharmacist, pharmacy technician, any type of designated representative, and/or other healthcare professional, including California.

State	License Type and Number	Active or Inactive	Issue Date	Expiration Date
_____	_____	_____	_____	_____
_____	_____	_____	_____	_____
_____	_____	_____	_____	_____

Experience

List years, location, and type of practice for last five (5) years, prior to the revocation of your California State Board of Pharmacy License.

Dates			
From	**To**	**Location**	**Type of Practice**
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

Provide a written explanation for all affirmative answers below. Failure to provide any of the requested information may result in the application being deemed incomplete. Falsification of the information on this application may constitute grounds for denial of the petition.

1. If your license is restored, what type of setting do you intend to practice in?

2. Are you currently or have you previously been listed as a corporate officer, partner, owner, manager, member, administrator, or medical director on a license to conduct a pharmacy, wholesaler, third-party logistics provider, or any other entity licensed in any state, territory, foreign country, or other jurisdiction?
   Yes ____ No____ If "yes," attach a statement of explanation.

3. Have you even been diagnosed with an emotional, mental, or behavioral disorder that may impair your ability to practice safely?
   Yes ____ No____ If "yes," attach a statement of explanation.

4. Have you ever been diagnosed with a physical condition that may impair your ability to practice safely?
   Yes ____ No____ If "yes," attach a statement of explanation.

5. Do you have any other condition that may in any way impair or limit your ability to practice safely?
   Yes ____ No____ If "yes," attach a statement of explanation.

6. Have you participated in, been enrolled in, or required to enter into any drug, alcohol, or other substance abuse recovery program?
   Yes ____ No____ If "yes," attach a statement of explanation.

7. If you answered "Yes" to questions 3 through 6 above, have you received treatment or participated in any program that improves your ability to practice safely?
   Yes ____ No____ N/A ____ If "yes," attach a statement of explanation.

8. Have you ever had disciplinary action taken against your healthcare professional license in this state or any other state, other than the license for which you are petitioning?
   Yes ____ No____ If "yes," attach a statement of explanation.

9. List the date in which your license was disciplined and explain fully the cause of the disciplinary action.

10. Explain fully why you feel your license should be restored or why the disciplinary penalty should be reduced or terminated.

11. Describe fully your activities and occupation since the date of the disciplinary action of your license; include dates, employers, and locations.

12. Describe any rehabilitative or corrective measures you have taken since your license was disciplined to support your petition. List dates, nature of programs, and current status. You may include any community service or volunteer work.

13. List all post-graduate or refresher courses, with dates, location, and type of course, you have taken since your license was disciplined.

14. List all pharmaceutical literature you have studied during the last year.

15. List all continuing education courses you have completed since your license was disciplined. Attach copies of the certificates.

16. List names, addresses, and telephone numbers of persons submitting the letters of recommendation accompanying this petition.

NOTICE

Pursuant to Business and Professions Code section 4309(b) et seq., all items of information requested in this application are mandatory. Failure to provide any of the requested information will result in the petition being rejected as incomplete. The information will be used to evaluate the petition under the California Pharmacy Law. The official responsible for information maintenance is the Executive Officer, telephone (916) 518-3100, 2720 Gateway Oaks Drive, Suite 100, Sacramento, California 95833. The information may be transferred to another governmental agency, if necessary, for it to perform its duties. Each individual has the right to review the files or records maintained on them by our agency in accordance with applicable law.

PETITIONER AFFIDAVIT
(must be signed and dated by the petitioner)

I, _____, hereby attest to the fact that I am the
(Print Full Legal Name)
petitioner whose signature appears below. I hereby certify to the truth and accuracy of all statements, answers, and representations made in this application, including all supplementary statements. I understand that my application may be denied, or any license disciplined, for fraud or misrepresentation.

_____ _____
Signature of Petitioner Date
(Signed and dated within 60 days of submission to the Board)

Attachment 3b
Current Forms (recently updated)

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8614
www.pharmacy.ca.gov

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

PETITION FOR REINSTATEMENT OF LICENSE REVOKED BY ADMINISTRATIVE ACTION

Pursuant to Section 4309 of the Business and Professions Code, a person whose license, permit, registration, certificate, or exemption has been revoked or suspended may petition the Board to reinstate the license, permit, registration, certificate, or exemption after a period of not less than three years has elapsed from the date of the revocation or suspension.

In determining whether the discipline penalty should be set aside and the terms and conditions, if any, which should be imposed if the disciplinary penalty is set aside, the board may investigate and consider all activities of the petitioner since the disciplinary action was taken, the offense for which discipline was imposed, activity during the time the license, permit, registration, certificate, or exemption was in good standing and the petitioner's general reputation for truth, professional ability and good character.

Petitioner Information - Please Type or Print

_____ _____ _____
Full Legal Name - Last Name First Name Middle Name

_____
Previous Names (AKA, Maiden Name, Alias, etc.)

_____
*Official Mailing/Public Address of Record – Street/PO Box City State Zip Code

_____
Residence Address – Street City State Zip Code

_____ _____ _____
Telephone Numbers – Home Cell Work

_____ _____
Date of Birth (Month/Day/Year) ** US Social Security Number or ITIN

_____
Email Address

_____
California Board of Pharmacy License Number

Education

Name(s) of University, College, or School of Pharmacy	Country	Date of Graduation	Degree
_____	_____	_____	_____
_____	_____	_____	_____

License Information List all state(s) where you are or have previously been licensed as a pharmacist, intern pharmacist, pharmacy technician, any type of designated representative, and/or other healthcare professional, including California.

State	License Type and Number	Active or Inactive	Issue Date	Expiration Date
_____	_____	_____	_____	_____
_____	_____	_____	_____	_____
_____	_____	_____	_____	_____

List years, location, and type of practice for five (5) years, prior to the revocation of your California License.

Dates From	To	Location	Type of Practice
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

1. If your license is restored, what type of practice do you intend to practice?

_____

_____

_____

2. Are you or have you ever been addicted to the use of narcotics or hypnotics?
   Yes ____ No____ If Yes, attach a statement of explanation.

3. Are you or have you *ever* been habitually intemperate in the use of alcohol or other drugs?
   Yes ____ No____ If Yes, attach a statement of explanation.

4. Have you *ever* been or are you currently under observation or treatment for mental disorders, alcoholism, narcotic or hypnotic drug addiction?
   Yes ____ No____ If Yes, attach a statement of explanation.

5. Have you ever been convicted of or pled no contest to a violation of any law of a foreign country, the United States, any state or a local ordinance? You must include all misdemeanor and felony convictions, regardless of the age of the offense, including those which have been set aside under Penal Code section 1203.4 (which includes diversion programs).
   Yes ____ No____ If Yes, attach a statement of explanation.

6. Are you now on probation or parole for any criminal or administrative violations in this state or any other state? (Attach certified copies of all disciplinary or court documents.)
   Yes ____ No____ If Yes, attach a statement of explanation.

7. Have you ever had disciplinary action taken against your license in this state or any other state, other than the license for which you are petitioning?
   Yes ____ No____ If Yes, attach a statement of explanation.

8. List the date of revocation of your license and explain fully the cause of the disciplinary action.

9. Explain fully why you feel your license should be restored.

10. Describe fully your activities and occupation since the date of the revocation of your license; include dates, employers, and locations.

11. Describe any rehabilitative or corrective measures you have taken since your license revocation to prepare yourself for reinstatement. List dates, nature of programs, and current status. You may include any community service or volunteer work.

12. List all post-graduate or refresher courses, with dates, location and type of course, you have taken since your license was revoked.

13. List all pharmaceutical literature you have studied during the last year.

14. List all continuing education courses you have completed since your license was revoked. Attach copies of the certificates.

15. List names, addresses, and telephone numbers of persons submitting the letters of recommendation accompanying this petition.

PETITIONER AFFIDAVIT

Provide a written explanation for all affirmative answers. Failure to provide any of the requested information may result in the application being deemed incomplete. Falsification of the information on this application may constitute grounds for denial or revocation of the license.

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

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

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

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

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

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

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

MANDATORY REPORTER

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

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

NOTICE

Pursuant to Business and Professions Code section 4309(b) et seq., all items of information requested in this application are mandatory. Failure to provide any of the requested information will result in the petition being rejected as incomplete. The information will be used to determine qualifications for reinstatement under the California Pharmacy Law. The official responsible for information maintenance is the Interim Executive Officer, telephone (916) 518-3100, 2720 Gateway Oaks Drive, Suite 100, Sacramento, California 95833. The information may be transferred to another governmental agency, if necessary, for it to perform its duties. Each individual has the right to review the files or records maintained on them by our agency, unless the records are identified as confidential information and exempted by Section 1798.3 of the Civil Code.

PETITIONER AFFIDAVIT
(must be signed and dated by the petitioner)

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

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

_____ _____

Original Signature of Petitioner Date

(please sign and date within 60 days of submittal to the board)

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8614
www.pharmacy.ca.gov

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

PETITION FOR REDUCTION (MODIFICATION) OF PROBATION

No petition to modify the terms of probation will be entertained until one year after the effective date of the Board's disciplinary action. The decision will be made by the full Board in accordance with Section 11522 of the Government Code.

Modification of the terms of probation will be provided only in exceptional circumstances, such as when the board determines that the penalty imposed have been excessive, considering both the violation of law charged and the supporting evidence, or when there is substantive evidence that there is no more need for the degree of probationary supervision as set forth in the original terms and conditions. As a rule, no reduction of penalty will be granted unless the probationer has at all times been in compliance with the terms of probation.

Petitioner Information - Please Type or Print

_____ _____ _____
Full Legal Name - Last Name | First Name | Middle Name

_____
Previous Names (AKA, Maiden Name, Alias, etc.)

_____
*Official Mailing/Public Address of Record – Street/PO Box | City | State | Zip Code

_____
Residence Address – Street | City | State | Zip Code

_____ _____ _____
Telephone Numbers – Home | Cell | Work

_____ _____
Date of Birth (Month/Day/Year) | ** US Social Security Number or ITIN

_____
Email Address

_____
California Board of Pharmacy License Number

1. Describe any rehabilitative or corrective measures you have taken since your license was placed on probation. List dates, nature of programs, and current status. You may include any community service or volunteer work.

2. List all pharmaceutical literature you have studied during the last year.

3. List names, addresses, and telephone numbers of persons submitting the letters of recommendation accompanying this petition.

PETITIONER AFFIDAVIT

Provide a written explanation for all affirmative answers. Failure to provide any of the requested information may result in the application being deemed incomplete. Falsification of the information on this application may constitute grounds for denial or revocation of the license.

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

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

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

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

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

****Disclosure of your U.S. Social Security Number or Individual Taxpayer Identification Number (ITIN) is mandatory.** Section 30 of the Business and Professions Code, section 17520 of the Family Code, and Public Law 94-455 (42 USC § 405(c)(2)(C)) authorize collection of your social security number or individual taxpayer identification number. Your social security number or individual taxpayer identification number will be used exclusively for tax enforcement purposes, for purposes of compliance with any judgment or order for child or

family support in accordance with section 17520 of the Family Law Code, or for verification of license or examination status by a licensing or examination entity, which utilizes a national examination and where licensure is reciprocal with the requesting state. If you fail to disclose your social security number or individual taxpayer identification number, your application will not be processed, and you may be reported to the Franchise Tax Board, which may assess a $100 penalty against you.

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

MANDATORY REPORTER

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

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

NOTICE

Pursuant to Business and Professions Code section 4309(b) et seq., all items of information requested in this application are mandatory. Failure to provide any of the requested information will result in the petition being rejected as incomplete. The information will be used to determine qualifications for reinstatement under the California Pharmacy Law. The official responsible for information maintenance is the Interim Executive Officer, telephone (916) 518-3100, 2720 Gateway Oaks Drive, Suite 100, Sacramento, California 95833. The information may be transferred to another governmental agency, if necessary, for it to perform its duties. Each individual has the right to review the files or records maintained on them by our agency, unless the records are identified as confidential information and exempted by Section 1798.3 of the Civil Code.

PETITIONER AFFIDAVIT
(must be signed and dated by the petitioner)

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

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

_____ _____
Original Signature of Petitioner Date
(please sign and date within 60 days of submittal to the board)

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8614
www.pharmacy.ca.gov

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

PETITION FOR EARLY TERMINATION OF PROBATION

No petition for early release from probation will be entertained until one year after the effective date of the Board's disciplinary action. The decision will be made by the full board in accordance with Section 4309 of the Business and Professions Code.

Early release from probation will be provided only in exceptional circumstances, such as when the board determines that the probationary terms imposed have been excessive, considering both the violation of law charged and the supporting evidence, or when there is substantive evidence that there is no more need for probationary supervision. As a rule, no early termination will be granted unless the probationer has at all times been in compliance with the terms of probation

Petitioner Information - Please Type or Print

_____ _____ _____
Full Legal Name - Last Name First Name Middle Name

_____
Previous Names (AKA, Maiden Name, Alias, etc.)

_____
*Official Mailing/Public Address of Record – Street/PO Box City State Zip Code

_____
Residence Address – Street City State Zip Code

_____ _____ _____
Telephone Numbers – Home Cell Work

_____ _____
Date of Birth (Month/Day/Year) ** US Social Security Number or ITIN

_____
Email Address

_____
California Board of Pharmacy License Number

1. Describe any rehabilitative or corrective measures you have taken since your license was placed on probation. List dates, nature of programs, and current status. You may include any community service or volunteer work.

2. List all pharmaceutical literature you have studied during the last year.

3. List names, addresses, and telephone numbers of persons submitting the letters of recommendation accompanying this petition.

PETITIONER AFFIDAVIT

Provide a written explanation for all affirmative answers. Failure to provide any of the requested information may result in the application being deemed incomplete. Falsification of the information on this application may constitute grounds for denial or revocation of the license.

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

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

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

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

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

****Disclosure of your U.S. Social Security Number or Individual Taxpayer Identification Number (ITIN) is mandatory.** Section 30 of the Business and Professions Code, section 17520 of the Family Code, and Public Law 94-455 (42 USC § 405(c)(2)(C)) authorize collection of your social security number or individual taxpayer identification number. Your social security number or individual taxpayer identification number will be used exclusively for tax enforcement purposes, for purposes of compliance with any judgment or order for child or

family support in accordance with section 17520 of the Family Law Code, or for verification of license or examination status by a licensing or examination entity, which utilizes a national examination and where licensure is reciprocal with the requesting state. If you fail to disclose your social security number or individual taxpayer identification number, your application will not be processed, and you may be reported to the Franchise Tax Board, which may assess a $100 penalty against you.

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

MANDATORY REPORTER

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

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

NOTICE

Pursuant to Business and Professions Code section 4309(b) et seq., all items of information requested in this application are mandatory. Failure to provide any of the requested information will result in the petition being rejected as incomplete. The information will be used to determine qualifications for reinstatement under the California Pharmacy Law. The official responsible for information maintenance is the Interim Executive Officer, telephone (916) 518-3100, 2720 Gateway Oaks Drive, Suite 100, Sacramento, California 95833. The information may be transferred to another governmental agency, if necessary, for it to perform its duties. Each individual has the right to review the files or records maintained on them by our agency, unless the records are identified as confidential information and exempted by Section 1798.3 of the Civil Code.

PETITIONER AFFIDAVIT
(must be signed and dated by the petitioner)

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

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

_____ _____
Original Signature of Petitioner Date
(please sign and date within 60 days of submittal to the board)

Attachment 3c
Previous Forms

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8614
www.pharmacy.ca.gov

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

PETITION FOR REINSTATEMENT OF CERTIFICATE TO PRACTICE PHARMACY REVOKED THROUGH ADMINISTRATIVE DISCIPLINARY ACTION

Pursuant to section 4309 of the Business and Professions Code, a person whose certificate, license, permit, registration or exemption has been revoked or suspended may petition the Board to reinstate the certificate, license, permit, registration or exemption after a period of not less than three years has elasped from the date of the revocation or suspension.

In determining whether the disciplinary penalty should be set aside and the terms and conditions, if any, which should be imposed if the disciplinary penalty is set aside, the board may investigate and consider all activities of the petitioner since the disciplinary action was taken, the offense for which discipline was imposed, activity during the time the certificate, license, permit, registration or exemption was in good standing and the petitioner's general reputation for truth, professional ability and good character.

Please print or type

1. Name	2. Date of Birth	3. California License Number

4. Residence Address — Street and Number — City — State — Zip Code

5. Telephone Number

Hm ( ) _____

Wk ( ) _____

6. Are you licensed in any other state? yes ☐ no ☐

State	Date of Issuance	Status of License

7. University, College or School of Pharmacy you attended.

Name of School	Dates Attended		Graduation Date	Degree
	From	To		

8. List years, location, and type of practice for 5 years prior to the revocation of your California License.

Dates		Location	Type of Practice
From	To		

9. If your license is restored, what type of pharmacy to you intend to practice?

_____

_____

Are you or have you ever been addicted to the use of narcotics or hypnotics? Yes ____ No ____

Are you or have you ever been habitually intemperate in the use of alcohol or other drugs? Yes ____ No ____

Have you ever been or are you currently under observation or treatment for mental disorders, alcoholism, narcotic or hypontic drug addiction? Yes ____ No ____

Have you ever been convicted of or pled no contest to a violation of any law of a foreign country, the United States, any state or a local ordinance? You must include all misdemeanor and felony convictions, regardless of the age of the offense, including those which have been set aside under Penal Code section 1203.4 (which includes diversion programs). Yes ____ No ____

Are you now on probation or parole for any criminal or administrative violations in this state or any ıer state? (Attach certified copies of all disciplinary or court documents.) Yes ____ No ____

Have you ever had disciplinary action taken against your pharmacist license in this state or any other state? Yes ____ No ____

he answer to any questions, 10 through 15, is yes you must attach a statement of explanation giving full details.

ON AN ATTACHED SHEET OF PAPER ANSWER THE FOLLOWING QUESTIONS

. List the date of revocation of your license and explain fully the cause of the disciplinary action.

. Explain fully why you feel your license should be restored.

. Describe fully your activites and occupation since the date of the revocation of your license; include dates, employers, and locations.

. Describe any rehabilitative or corrective measures you have taken since your license revocation to prepare yourself for reinstatement. List dates, nature of programs, and current status. You may include any community service or volunteer work.

: List all post-graduate or refresher courses, with dates, location and type of course, you have taken since your license was revoked.

1. List all pharmaceutical literature you have studied during the last year.

2. List all continuing education courses you have completed since your license was revoked. Attach copies of the certificates.

3. List names, addresses, and telephone numbers of persons submitting the letters of recommendation accompanying this petition.

declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

)ATE _____ Signature _____

NOTICE

Pursuant to Business and Professions Code section 4309(b) et seq., all items of information requested in this application are mandatory. Failure to provide any of the requested information will result in the petition being rejected as incomplete. The information will be used to determine qualifications for reinstatement under the California Pharmacy Law. The official responsible for information maintenance is the Interim Executive Officer, telephone (916) 518-3100, 2720 Gateway Oaks Drive, Suite 100, Sacramento, California 95833. The information may be transferred to another governmental agency, if necessary, for it to perform its duties. Each individual has the right to review the files or records maintained on them by our agency, unless the records are identified as confidential information and exempted by Section 1798.3 of the Civil Code.

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Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8614
www.pharmacy.ca.gov

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

PETITION FOR REDUCTION OF PENALTY

No petition to modify the terms of probation will be entertained until one year after the effective date of the Board's disciplinary action. The decision on the petition will be made by the full Board and in accordance with Government Code section 11522.

Modification of the terms of probation will be provided only in exceptional circumstantces, such as when the board determines that the penalty imposed has been excessive, considering both the violation of the law charged and the supporting evidence, or when there is substantive evidence that there is no more need for the degree of probationary supervision as set forth in the original terms and conditions. As a rule, no reducation of penalty will be granted unless the probationer has at all times been in compliance with the terms of probation.

Please print or type

1. Name	2. Date of Birth	3. California License Number

4. Residence Address	Street and Number	City	State	Zip Code

5. Telephone Number

Hm ( ) _____

Wk ( ) _____

6. Are you licensed in any other state? yes ☐ no ☐

State	Date of Issuance	Status of License

7. University, College or School of Pharmacy you attended.

Name of School	Dates Attended		Graduation Date	Degree
	From	To		

8. List years, location, and type of practice for 5 years prior to the revocation of your California License.

Dates		Location	Type of Practice
From	To		

9. How should the penalty be reduced/modified?

_____

_____

. Are you or have you ever been addicted to the use of narcotics or hypnotics? Yes ____ No ____

. Are you or have you ever been habitually intemperate in the use of alcohol or other drugs? Yes ____ No ____

. Have you ever been or are you currently under observation or treatment for mental disorders, alcoholism, narcotic or hypontic drug addiction? Yes ____ No ____

. Have you ever been convicted of or pled no contest to a violation of any law of a foreign country, the United States, any state or a local ordinance? You must include all misdemeanor and felony convictions, regardless of the age of the offense, including those which have been set aside under Penal Code section 1203.4 (which includes diversion programs). Yes ____ No ____

. Are you now on probation or parole for any criminal or administrative violations in this state or any other state? (Attach certified copies of all disciplinary or court documents.) Yes ____ No ____

. Have you ever had disciplinary action taken against your pharmacist license in this state or any other state? Yes ____ No ____

If the answer to questions 10 through 15 is yes, you must attach a statement of explanation giving full details.

ON AN ATTACHED SHEET OF PAPER ANSWER THE FOLLOWING QUESTIONS

. List the date of disciplinary action taken against your license and explain fully the cause of the disciplinary action.

. Explain fully why you feel your license should be restored, or the disciplinary penatly reduced.

. Describe fully your activites and occupation since the date of the disciplinary action; include dates, employers, and locations.

. Describe any rehabilitative or corrective measures you have taken since your license was disciplined to support your petition. List dates, nature of programs, and current status. You may include any community service or volunteer work.

0. List all post-graduate or refresher courses, with dates, location and type of course, you have taken since your license was disciplined.

1. List all pharmaceutical literature you have studied during the last year.

2. List all continuing education courses you have completed since your license was disciplined. Attach copies of the certificates.

3. List names, addresses, and telephone numbers of persons submitting the letters of recommendation accompanying this petition.

declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

)ATE _____ SIGNATURE _____

NOTICE

Pursuant to Business and Professions Code section 4309(b) et seq., all items of information requested in this application are mandatory. Failure to provide any of the requested information will result in the petition being rejected as incomplete. The information will be used to determine qualifications for reinstatement under the California Pharmacy Law. The official responsible for information maintenance is the Interim Executive Officer, telephone (916) 518-3100, 2720 Gateway Oaks Drive, Suite 100, Sacramento, California 95833. The information may be transferred to another governmental agency, if necessary, for it to perform its duties. Each individual has the right to review the files or records maintained on them by our agency, unless the records are identified as confidential information and exempted by Section 1798.3 of the Civil Code.

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8614
www.pharmacy.ca.gov

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

PETITION FOR EARLY TERMINATION OF PROBATION

No petition for early release from probation will be entertained until one year after the effective date of the Board's disciplinary action. The decision will be made by the full board in accordance with section 4309 of the Business and Professions Code.

Early release from probation will be provided only in exceptional circumstances, such as when the baord determines that the probationary terms imposed have been excessive, considering both the violation of law charged and the supporting evidence, or when there is sustantive evidence that there is no more need for probationary supervision. As a rule, no early termination will be granted unless the probationer has at all times been in compliance with the terms of probation.

Please print or type

1. Name	2. Date of Birth	3. California License Number

4. Residence Address — Street and Number — City — State — Zip Code

5. Telephone Number

Hm ( ) _____

Wk ( ) _____

6. Are you licensed in any other state? yes ☐ no ☐

State	Date of Issuance	Status of License

7. University, College or School of Pharmacy you attended.

Name of School	Dates Attended		Graduation Date	Degree
	From	To		

8. List years, location, and type of practice for 5 years prior to the revocation of your California License.

Dates		Location	Type of Practice
From	To		

9. If your license is restored, what type of pharmacy do you intend to practice?

. Are you or have you ever been addicted to the use of narcotics or hypnotics? Yes ____ No ____

. Are you or have you ever been habitually intemperate in the use of alcohol or other drugs? Yes ____ No ____

. Have you ever been or are you currently under observation or treatment for mental disorders, alcoholism, narcotic or hypontic drug addiction? Yes ____ No ____

. Have you ever been convicted of or pled no contest to a violation of any law of a foreign country, the United States, any state or a local ordinance? You must include all misdemeanor and felony convictions, regardless of the age of the offense, including those which have been set aside under Penal Code section 1203.4 (which includes diversion programs). Yes ____ No ____

. Are you now on probation or parole for any criminal or administrative violations in this state or any other state? (Attach certified copies of all disciplinary or court documents.) Yes ____ No ____

. Have you ever had disciplinary action taken against your pharmacist license in this state or any other state? Yes ____ No ____

If the answer to questions 10 through 15 is yes, you must attach a statement of explanation giving full details.

ON AN ATTACHED SHEET OF PAPER ANSWER THE FOLLOWING QUESTIONS

. List the date of disciplinary action taken against your license and explain fully the cause of the disciplinary action.

. Explain fully why you feel your license should be restored, or the disciplinary penatly reduced.

. Describe fully your activites and occupation since the date of the disciplinary action; include dates, employers, and locations.

. Describe any rehabilitative or corrective measures you have taken since your license was disciplined to support your petition. List dates, nature of programs, and current status. You may include any community service or volunteer work.

. List all post-graduate or refresher courses, with dates, location and type of course, you have taken since your license was disciplined.

1. List all pharmaceutical literature you have studied during the last year.

2. List all continuing education courses you have completed since your license was disciplined. Attach copies of the certificates.

3. List names, addresses, and telephone numbers of persons submitting the letters of recommendation accompanying this petition.

declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

)ATE _____ SIGNATURE _____

NOTICE

Pursuant to Business and Professions Code section 4309(b) et seq., all items of information requested in this application are mandatory. Failure to provide any of the requested information will result in the petition being rejected as incomplete. The information will be used to determine qualifications for reinstatement under the California Pharmacy Law. The official responsible for information maintenance is the Interim Executive Officer, telephone (916) 518-3100, 2720 Gateway Oaks Drive, Suite 100, Sacramento, California 95833. The information may be transferred to another governmental agency, if necessary, for it to perform its duties. Each individual has the right to review the files or records maintained on them by our agency, unless the records are identified as confidential information and exempted by Section 1798.3 of the Civil Code.

Attachment 4

Board of Pharmacy

Enforcement Workload Statistics FY 2024/25

Complaint Investigations	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Received	758	778	563	0	2,099
Closed	770	730	471	0	1,971
					Quarter Ending
Pending	1,918	1,977	2,074	0	2,074
Average Days for Investigation	236	225	233	0	233

Cases Under Investigation (By Team)	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Quarter Ending
Compliance / Routine	830	835	940	0	940
Drug Diversion / Fraud	242	245	255	0	255
Prescription Drug Abuse	178	113	143	0	143
Compounding	56	61	76	0	76
Outsourcing	7	5	6	0	6
Probation / PRP	36	52	36	0	36
Enforcement	59	65	60	0	60
Criminal Conviction	510	601	558	0	558

Application Investigations	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Received	41	64	42	0	147
Closed					
Approved	29	20	22	0	71
Denied	17	9	5	0	31
Total Closed (includes withdrawn)	***50***	***34***	***30***	***0***	***114***
Pending	90	113	123	0	123

Complaint Closure Outcomes Not Resulting in Further Action	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Insufficient Evidence	359	304	166	0	829
Non-Jurisdictional	88	86	79	0	253
No Violation	37	25	29	0	91
No Further Action	47	33	31	0	111
Other / Non-Substantiated	39	35	17	0	91
Subject Educated	19	47	37	0	103

Letter of Admonishments / Citations	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
LOA Issued	44	35	38	0	117
Citations Issued	156	193	121	0	470
Proof of Abatement Requested	12	16	14	0	42
Appeals Referred to AG's Office	63	30	14	0	107
Dismissed	7	5	8	0	20
Total Fines Collected	***$612,872***	***$569,232***	***$290,416***	***$0***	***$1,472,520***

Administrative Cases	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Referred to the AG's Office	43	38	19	0	100
Pleadings Filed	65	39	20	0	124
Total Closed	68	61	50	0	179
Pending					Quarter Ending
Pre-Accusation	123	118	101	0	101
Post-Accusation	181	164	153	0	153
Total Pending	**304**	**282**	**254**	**0**	**254**

Administrative Case Outcomes	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Revocation					
Pharmacist	4	2	2	0	8
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	20	17	16	0	53
Designated Representative	1	0	0	0	1
Wholesaler	0	0	0	0	0
Clinic	0	0	0	0	0
Pharmacy	0	1	0	0	1
Sterile Compounding	0	0	0	0	0
Outsourcing	0	0	0	0	0
Total	***25***	***20***	***18***	***0***	***63***

Administrative Case Outcomes	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Revocation, stayed, suspension/probation					
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	0	0	0	0	0
Clinic	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	***0***	***0***	***0***	***0***	***0***

Administrative Case Outcomes	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Revocation, stayed, probation					
Pharmacist	11	6	7	0	24
Intern Pharmacist	1	1	0	0	2
Pharmacy Technician	3	7	5	0	15
Designated Representative	0	0	1	0	1
Wholesaler	0	0	0	0	0
Clinic	0	0	0	0	0
Pharmacy	5	0	2	0	7
Sterile Compounding	0	0	0	0	0
Outsourcing	0	0	0	0	0
Total	***20***	***14***	***15***	***0***	***49***

Administrative Case Outcomes	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Surrender / Voluntary Surrender					
Pharmacist	0	0	2	0	2
Intern Pharmacist	0	1	0	0	1
Pharmacy Technician	5	4	2	0	11
Designated Representative	0	0	0	0	0
Wholesaler	2	0	0	0	2
Clinic	0	1	0	0	1
Pharmacy	1	4	2	0	7
Sterile Compounding	0	0	0	0	0
Outsourcing	0	1	0	0	1
Total	***8***	***11***	***6***	***0***	***25***

Administrative Case Outcomes	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Public Reproval / Reprimand					
Pharmacist	7	2	1	0	10
Intern Pharmacist	1	1	0	0	2
Pharmacy Technician	1	2	0	0	3
Designated Representative	1	0	0	0	1
Wholesaler	0	0	0	0	0
Clinic	0	0	0	0	0
Pharmacy	3	4	2	0	9
Sterile Compounding	1	0	0	0	1
Outsourcing	0	0	0	0	0
Total	***14***	***9***	***0***	***0***	***23***

Administrative Case Outcomes	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Licenses Granted (with or w/o conditions)					
Pharmacist	0	1	2	0	3
Intern Pharmacist	2	0	0	0	2
Pharmacy Technician	0	1	1	0	2
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Clinic	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	***2***	***2***	***3***	***0***	***7***

Administrative Case Outcomes	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	2	0	0	0	2
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Clinic	0	0	0	0	0
Pharmacy	0	1	2	0	3
Sterile Compounding	0	0	0	0	0
Outsourcing	0	0	0	0	0
Total	***2***	***1***	***2***	***0***	***5***

Administrative Case Cost Recovery Efforts	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Cost Recovery Requested	***$281,598***	***$304,775***	***$524,959***	***$0***	***$1,111,332***
Cost Recovery Collected	***$198,145***	***$434,568***	***$113,174***	***$0***	***$745,886***

Immediate Public Protection Sanctions	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Interim Suspension Orders	5	4	2	0	11
Automatic Suspension Orders	0	0	0	0	0
Penal Code 23 Restrictions	1	0	2	0	3
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	166	153	150	0	150
Advanced Practice Pharmacist	0	0	2	0	2
Intern Pharmacist	4	4	4	0	4
Pharmacy Technician	29	37	36	0	36
Designated Representative	1	0	1	0	1
Wholesaler / 3PL	3	1	1	0	1
Pharmacy	54	49	48	0	48
Sterile Compounding	9	9	9	0	9
Outsourcing	0	0	0	0	0
Total	***266***	***253***	***251***	***0***	***251***
Probation Compliance Measures					Total
Probation Office Conferences	21	23	13	0	57
Probation Interviews / Site Inspections	183	109	101	0	393
Probation Terminated / Completed	16	28	18	0	62
Referred to AG for Non-Compliance	0	1	3	0	4

As of 2/28/2025

Board of Pharmacy

Citation and Fine Statistics FY 2024/25

Citation Outcomes	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Pharmacist with Fine	15	15	6	0	36
Pharmacist-in-Charge with Fine*	9	12	5	0	26
Pharmacist no Fine	24	32	25	0	81
Pharmacist-in-Charge no Fine*	24	23	19	0	66
Pharmacy with Fine	56	98	32	0	186
Pharmacy no Fine	29	23	25	0	77
Pharmacy Technician with Fine	9	7	5	0	21
Pharmacy Technician no Fine	11	10	14	0	35
Wholesalers	0	2	0	0	2
Designated Representative	1	1	3	0	5
Clinics	0	0	0	0	0
Drug Room	0	0	1	0	1
Exempt Hospital	0	0	0	0	0
Hospital Pharmacy	2	3	1	0	6
Miscellaneous**	20	14	9	0	43
Unlicensed Premises	1	4	6	0	11
Unlicensed Person	0	0	0	0	0

*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

As of 2/28/2025

Top Ten Violations by License Type

Pharmacists	%	Pharmacies	%	Pharmacists In Charge	%
1714(d) - Operational Standards and Security; Pharmacist responsible for pharmacy security	20%	1714(b) - Operational Standards and Security; pharmacy responsible for pharmacy security	27%	1714(d) - Operational Standards and Security; Pharmacist responsible for pharmacy security	24%
4301(f) - Unprofessional Conduct - Acts of moral turpitude, dishonesty, fraud, deceit or corruption	17%	1714(d) - Operational Standards and Security; Pharmacist responsible for pharmacy security	12%	4115(f) - The board may adopt regulations establishing the ratio of pharmacy technicians performing the tasks specified in subdivision (a)	20%
4301(l) - Unprofessional Conduct - Conviction of a crime substantially related to the practice of pharmacy	13%	1716 - Variation from prescription	12%	4081(a) - Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory	12%
4081(a) - Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory	10%	4113(E) - Pharmacist-in-Charge: Notification to Board; Responsibilities; If a pharmacy is unable, in the exercise of reasonable diligence, to identify within 30 days a permanent replacement pharmacist	10%	4301(f) - Unprofessional Conduct - Acts of moral turpitude, dishonesty, fraud, deceit or corruption	12%
1715(a)(b) - Self-assessment form of a pharmacy by the pharmacist in charge; shall complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law/ in addition to the self-	7%	4115(f) - The board may adopt regulations establishing the ratio of pharmacy technicians performing the tasks specified in subdivision (a)	8%	1715(b) - In addition to the self-assessment required in (a), the pharmacist-in-charge shall complete a self- assessment within 30 days whenever: there is a change in permit or pharmacist-in-charge	8%
1716 - Variation from prescription	7%	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	8%	1735.8(c) - Compounding Quality Assurance requires the pharmacy to have qualitative and quantitative reports on the integrity, potency, quality of its compounded drug products	8%
4115(f) - The board may adopt regulations establishing the ratio of pharmacy technicians performing the tasks specified in subdivision (a)	7%	1764/56.10(a) - Unauthorized disclosure of prescription and medical information	6%	1735.5(b) - Policy and Procedure Manual shall be reviewed on an annual basis by the pharmacist-in-charge and shall be updated whenever changes in processes are implemented	4%
1735.8(c) - Compounding Quality Assurance requires the pharmacy to have qualitative and quantitative reports on the integrity, potency, quality of its compounded drug products	7%	56.10/4301(o) - Unauthorized release of protected healthcare information/Unprofessional conduct; assist in violation	6%	1715(a)(b) - Self-assessment form of a pharmacy by the pharmacist in charge; shall complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law/ in addition to the self-	4%
4301(h) - Unprofessional Conduct – The administering to oneself, of any controlled substance, or the use of any dangerous drug or of alcoholic beverages to the extent or in a manner as to be dangerous	7%	1707(g) - Waiver requirements for Off-Site Storage of Records: (g) Notwithstanding the requirements of this section, any entity licensed by the board may store the records described in subdivision (	6%	1735.2(e)(3) - Compounding limitations and requirements; written master formula	4%
1304.11(b)(c) - Inventory requirements-initial inventory date; biennial inventory date	7%	4113(d) - Every pharmacy shall notify the board in writing within 30 days of the date of a change in pharmacist-in- charge	4%	1735.3(a) - Records of Compounded Drug Products- For each compounded drug product, the pharmacy records shall include…	4%

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 2024 through February 2025.

Board of Pharmacy	July -Sep	Oct Dec	Jan Mar*	Apr Jun	24/25
PRP Intakes					
PRP Self-Referrals					
PRP Probation Referrals	3	4	3		10
PRP Under Investigation	1	2			3
PRP In Lieu Of (investigation conducted)					
Total Number of PRP Intakes	4	6	3		13
New Probationers					
Pharmacists	5	3	2	2	12
Intern Pharmacists		1			1
Pharmacy Technicians	4	8	2	5	19
Total New Probationers	9	12	4	7	32
PRP Participants and Recovery Agreements					
Total PRP Participants	29	24	25		N/A
Recovery Agreements Reviewed	26	26	21		73
Probationers and Inspections					
Total Probationers	54	56	54		N/A
Inspections Completed	28	20	22		70
Referrals to Treatment					
Referrals to Treatment (PRP and Probationers)	1	3	1		5
Drug Tests					
Drug Test Ordered (PRP and Probationers)	433	485	321		1239
Drug Tests Conducted (PRP and Probationers)	421	444	309		1174
Relapses (Break in Sobriety)					
Relapsed (PRP and Probationers)		1	1		2
Major Violation Actions					
Cease Practice/Suspension (PRP and Probationers)	6	9	1		16
Termination from PRP	1				1
Probationers Referred for Discipline			3		3
Closure or Noncompliance					
Successful Completion (PRP and Probationers)	1	7	1		9
Termination (Probation)		1	2		3
Voluntary Surrender (Probation)		4	6		10
Surrender as a result of PTR (Probation)					
Closed Public Risk (PRP)	1				1
Non-compliance in PRP or Probation	19	6	7		32
Other (PRP)		3	2		5
Patients Harmed					
Number of Patients Harmed (PRP and Probationers)					Zero

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 2024 through February 2025.

Board of Pharmacy	July -Sep	Oct Dec	Jan Mar*	Apr Jun	24/25
Drug of Choice at PRP Intake or Probation					
Pharmacists	**July-Sep**	**Oct-Dec**	**Jan-Mar***	**Apr-Jun**	**Total 24/25**
Alcohol	2		3		5
Ambien	1				1
Opiates		1			1
Hydrocodone	1				1
Oxycodone					
Morphine					
Benzodiazepines		3			3
Barbiturates					
Marijuana		1			1
Heroin					
Cocaine					
Methamphetamine					
Pharmaceutical Amphetamine			1		1
Phentermine					
Methadone					
Zolpidem Tartrate					
Hydromorphone					
Clonazepam					
Tramadol					
Carisprodol					
Phendimetrazine					
Promethazine w/Codeine					
Intern Pharmacists	**July-Sep**	**Oct-Dec**	**Jan-Mar***	**Apr-Jun**	**Total 24/25**
Alcohol	1	2			3
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 24/25**
Alcohol	2	8	5		15
Opiates					
Hydrocodone					
Oxycodone					
Benzodiazepines					
Barbiturates					
Marijuana	2				2
Heroin					
Cocaine	1				1
Methamphetamine					
Pharmaceutical Amphetamine	1				1
Phentermine					
Methadone					
Zolpidem Tartrate					
Hydromorphone					
Clonazepam					
Tramadol					
Carisprodol					
Phendimetrazine					
Promethazine w/Codeine					