California State Board of Pharmacy
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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

Enforcement and Compounding Committee Report
January 18, 2022

Maria Serpa, Licensee Member, Chair
Jignesh Patel, Licensee Member, Vice-Chair
Seung Oh, Licensee Member, President
Ricardo Sanchez, Public Member
Debbie Veale, 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 October 20, 2021, Enforcement and Compounding Committee Meeting Minutes

A draft version of the minutes is provided in **Attachment 1.**

IV. Discussion and Consideration of Board's Disciplinary Guidelines

Relevant Law

Title 16, California Code of Regulations section 1760 provides that the board, in reaching a decision on a disciplinary matter, shall consider the Disciplinary Guidelines (Rev. 2/2017), which are incorporated by reference.

Background

As part of its July 2021, the Committee initiated assessment of the Disciplinary Guidelines. (This review was initiated following action at the April 2021 Board Meeting, where such a review was requested specified to underlying actions involving driving under the influence convictions.) As part of the July 2021 meeting, members decided to discuss the guidelines at a future meeting and requested that staff bring forward recommendations for the Committee's consideration.

For Committee Consideration and Discussion

Subsequent to the July meeting, staff and counsel have undertaken review of the Guidelines and are offering recommendations for the Committee's Consideration. Below is a summary of the types of

recommended changes.

1. Updates to reflect the current version and Board information and includes requirements to disclosure of a respondent's email address.
2. Transition to gender-inclusive language
3. Updating terms to ensure consistency throughout the document and ensuring consistency with language used in Pharmacy Law. As an example, replace the word "psychologist" with "mental health practitioner"
4. Language to provide that any new licenses issued while an individual respondent remains on probation shall also be placed on probation under specified conditions.
5. Require a licensee whose license is surrendered to seek reinstatement from the Board in lieu of the current process of seeking licensure through reapplication.
6. Changes to the Categories for some violations. The changes are primarily relating to scope of practice violations, violations involving sterile compounding of drug preparations, use of policies and procedures that violate Pharmacy Law, and repeated failure to provide patient consultation.
7. New Optional Terms
    a. New Optional Term 41: Individual Licenses to include a requirement to complete the Board's one-day training program on prescription drug abuse prevention and pharmacy law.
    b. New Optional Term 43 for Individual Licenses and Term 26 Business Licenses to include an optional term establishing an administrative fine.
    c. New Optional Term 27 for Business Licenses to include an optional term establishing a consultant review of business operations.
8. Clarifying relevant terms relating to the consultant requirement, to explicitly state that the proposed consultant shall have appropriate education, training and professional experience. (Refer to language is Term 8, Option 2 for Individual Licenses)
9. Require a release authorizing a mental health practitioner to share information when such a term is required. (Refer to Optional Term 21 for Individual Licenses)
10. Include optional language under the posted notice of probation term to specify how such a notice shall be provided. (Refer to Standard Term 14 for Business Licenses
11. Where appropriate, provide specific timeframes within which actions must be taken. As an example, clarify the necessary reporting requirement for notification of departure.

Attachment 2 includes a copy of the recommended changes to the Title 16, CCR Section 1760 and the Disciplinary Guidelines. Should the Committee agree with the recommendations, the following motion could be used to recommend action by the Board.

> Recommend initiation of a rulemaking to amend CCR section 1760 and the Disciplinary Guidelines incorporated by reference, as presented. Authorize the executive officer to make any non-substantive changes prior to initiation of the rulemaking. Further, if no adverse comments are received during the 45-day comment period and no hearing is requested,

authorize the executive officer to take all steps necessary to complete the rulemaking and adopt the proposed regulation at section 1760 as presented.

V. Discussion and Consideration of Frequently Asked Questions Developed to Discuss Requirements for Outsourcing Facilities Providing Patient Specific Prescriptions

Relevant Law
Recent amendments to BPC 4129 provide authority for a California licensed outsourcing facility to dispense patient-specific compounded preparations pursuant to a prescription under specified conditions.

Background
Assembly Bill 1533, expanded authority for licensed outsourcing facilities to dispense patient-specific compounding medications under specified conditions, including that such dispensing be done consistent with the dispensing requirements for a pharmacy.

As part of its discussion on the recently enacted legislation, the Committee noted that education on the requirements would be appropriate to ensure harmony with federal law and ensure patients have access to pharmacist care, including drug utilization reviews, patient consultation, etc.

For Committee Consideration and Discussion
During the meeting members will have the opportunity to review draft FAQs intended to provide education on the necessary requirements.

Attachment 3 includes a copy of the FAQs.

VI. Discussion and Consideration of Senate Bill 311 (Hueso, Chapter 384, Statutes of 2021) Compassionate Access to Medical Cannabis Act or Ryan's Law

Background
During its October 2021 Committee meeting, members discussed the provisions contained in Senate Bill 311 and what appears to be conflicts within the measure relating the requirements for patient-provided medicinal cannabis to comply with provisions related to schedule II-IV medications.

Subsequent to this discussion, staff have confirmed with the author's office that amendments will be pursued to clarify the intent of the law consistent with the letter to the Senate Journal. Specifically, the letter to the journal provides that the intent of the late amendments were not to subject medicinal cannabis to all requirements applicable to controlled substances, not to require that a pharmacy or pharmacist be involved in the use, storage, management, or dispensing of medicinal cannabis at a health facility.

For Committee Consideration and Discussion
During the meeting members will have the opportunity to review the matter.

Attachment 4 includes a job of the letter published in the Senate Journal and information provided to the author's office from CMS.

VII. Discussion and Consideration of Self-Assessment Forms

a. **Community Pharmacy/Hospital Out-Patient Self-Assessment (17M-13)**
b. **Compounding Self-Assessment (17M-39)**
c. **Hospital Pharmacy Self-Assessment (17M-14)**
d. **Wholesaler Dangerous Drugs & Devices Self-Assessment (17M-26)**
e. **Automated Drug Delivery System Self-Assessment (17M-112)**

Background

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

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

Several of the Board's current self-assessments are currently in various stages of review and promulgation to make permanent prior versions of the assessment forms. Staff recommend that identified updates to the self-assessment forms that have occurred since the Board's initial approval of the forms could be achieved through the formal rulemaking process currently underway. Such an approach would hopefully mitigate any further delays in the regulation process.

For Committee Discussion

During the meeting members will have the opportunity to review the draft updates to the self-assessment forms and provide feedback to staff. Should the committee agree with the edits and or offer changes, Board staff will work to incorporate the additional changes for consideration by Board during the January meeting. Provided below are possible motions that could be used to recommend action to the Board to update the pending rulemakings for the various self-assessments forms.

Attachment 5 includes copies of the updated draft self-assessment forms.

Possible Motion for Compounding Self-Assessment (17M-39)

Recommend approval of the proposed amendments to self-assessment form 17M-39 and incorporate the proposed amendments into the rulemaking package currently undergoing pre-notice review. Authorize the chair and executive officer to further refine the language consistent with the policy discussions as may be required by control agencies (DCA or Agency). If no adverse comments are received during the 45-day comment period, authorize the Executive Officer to take

all steps necessary to complete the rulemaking, make any non-substantive changes to the package, and adopt self-assessment form 17M-39 as noticed for public comment.

Possible Motion for Community Pharmacy/Hospital Out-Patient (17M-13), Hospital Pharmacy Self-Assessment (17M-14), and Wholesaler Dangerous Drugs & Devices Self-Assessment (17M-26)

Recommend approval of the proposed amendments to self-assessment forms 17M-13, 17M-14, and 17M-26. Authorize the chair and executive officer to further refine the language consistent with the policy discussions as may be required by control agencies (DCA or Agency) and notice the proposed amendments for a 15-day comment period. If no adverse comments are received during the 15-day comment period, authorize the Executive Officer to take all steps necessary to complete the rulemaking, make any non-substantive changes to the package, and adopt self-assessment forms 17M-13, 17M-14, and 17M-26 as noticed.

Possible Motion for Automated Drug Delivery System Self-Assessment (17M-112)

Recommend approval of the proposed self-assessment form 17M-112. Authorize the chair and executive officer to further refine the language consistent with the policy discussions as may be required by control agencies (DCA or Agency). Further, authorize the Executive Officer to take all steps necessary to initiate the rulemaking process, make any non-substantive changes to the package, and set the matter for a hearing if requested. If no adverse comments are received during the 45-day comment period and no hearing is requested, authorize the Executive Officer to take all steps necessary to complete the rulemaking and adopt the proposed self-assessment form 17M-112 as noticed.

VIII. Review and Discussion of Enforcement Statistics

Since July 1, 2021, the board received 1,475 complaints and has closed 1,610 investigations. The board has issued 165 Letters of Admonishment, 691 Citations and referred 65 cases to the Office of the Attorney General. The board has secured one interim suspension orders and one automatic suspension order. Further, the board has revoked 22 licenses, accepted the disciplinary surrender of 37 licenses, denied 4 applications, and imposed other levels of discipline against 70 licensees and/or applicants.

As of January 3, 2022, the board had 960 field investigations pending. Below is a breakdown providing more detail in the various investigation process:

	July 3, 2021		October 1, 2021		Jan 3, 2022	
	Volume	Average Days	Volume	Average Days	Volume	Average Days
Awaiting Assignment	41	18	71	14	43	29
Cases Under Investigation	631	150	560	146	626	136

Pending Supervisor Review	141	40	134	40	135	41
Pending Second Level Review	30	16	42	47	90	53
Awaiting Final Closure	410	70	167	75	66	60

Attachment 6 includes the current fiscal year enforcement statistics.

IX. Future Committee Meeting Dates

- April 20, 2022
- July 19, 2022
- October 19, 2022

Attachment 1

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Business, Consumer Services and Housing Agency
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ENFORCEMENT COMMITTEE
Draft MEETING MINUTES

DATE:	October 20, 2021
LOCATION:	Teleconference Public Committee Meeting Note: Pursuant to the provisions of Government Code section 11133, neither a public location nor teleconference locations are provided.
COMMITTEE MEMBERS PRESENT:	Maria Serpa, Licensee Member Chair Jig Patel, Licensee Member Vice Chair Seung Oh, Licensee Member Debbie Veale, Licensee Member Ricardo Sanchez, Public Member
STAFF MEMBERS PRESENT:	Anne Sodergren, Executive Officer Eileen Smiley, DCA Staff Counsel Sheila Tatayon, DCA Staff Counsel

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

Chairperson Maria Serpa called the meeting to order at 9:01 a.m.

The meeting moderator provided updated WebEx instructions.

Chairperson Serpa took roll call. Members present included; Jignesh Patel, Seung Oh, Ricardo Sanchez, Maria Serpa. A quorum was established.

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

Members of the public were provided the opportunity to provide comments for items not on the agenda.

Public comment included a request for the Committee to discuss an enforcement issue related to e-prescribing and the upcoming California requirements related to forwarding an electronic controlled substances prescription to another pharmacy. Comments noted challenges created because of the lack of National Council for Prescription Drug Programs (NCPDP) standards in this area. As part of the

comments members were advised that standards are under development but will not be completed until 2024 and requested a delay in enforcement until NCPDP standards.

Public comment also suggest that the Board perform education on the requirement for e-prescribing for pharmacists that prescribe medications.

Debbie Veale joined the meeting at 9:10.

Members agreed to agendize this issue as part of the December 2021 Board Meeting.

III. Approval of July 15, 2021, Enforcement and Compounding Committee Meeting Minutes

Members were provided an opportunity to provide comments on the draft minutes. Members identified changes to the minutes to correct references made to Member Oh as Vice Chair; correct references made to Member Veale as "Dr."; amend page 5, last paragraph on section 5 to, "*In response, Dr Serpa stated that the current checklist provides information for all licensed categories, however, some items may not apply to all.*"; amend page 13, item 9, last sentence, "*Dr. Serpa requested language clarification be added for hospitals that are using ADDS for discharge prescriptions after hours.*"

Motion: Approve the July 15, 2021 Committee Meeting minutes with changes noted.

M/S: Sanchez/Patel

Members of the public were provided with an opportunity to provide public comment; however, none were offered.

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

Committee Member	Vote
Oh	Support
Patel	Support

Sanchez	Support
Serpa	Support
Veale	Support

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

Dr. Serpa referenced the meeting materials. Several measures were recently signed that impact the practice of pharmacy. For each bill a summary was provided as well as information on implementation.

Assembly Bill 107

Dr. Serpa informed members that Assembly Bill 107 is related to veterans and military spouses. This measure will require the Board to issue a temporary license to practice within 30 days of the Board receiving the results of a fingerprint background check. The measure does require an applicant for a pharmacist license to take and pass the CPJE as a precursor to issuance of the temporary license.

Dr. Serpa advised members that the provisions take effect July 1, 2023, which will provide the Board time to complete necessary implementation activities including changes to application and instruction updates, changes and changes to data systems and develop of regulations.

As part of its discussion the Committee indicated referral to the Licensing Committee for development of the regulations would be appropriate.

Members of the public were provided with the opportunity to provide public comment; however, none were provided.

Assembly Bill 527

Chairperson Serpa noted that Assembly Bill 527 includes the Board's sponsored provision to exempt specified non-narcotic combination product controlled substances from the California controlled substances. Members noted that implementation efforts should be minimal and include education on the change.

Members of the Committee and public were provided with the opportunity to provide comments; however, none were provided.

Assembly Bill 1064

Dr. Serpa highlighted that Assembly Bill 1064 expands authority to allow a pharmacist to independently initiate and administer any vaccine that has been approved or authorized by the FDA and received a recommendation by the Advisory Committee on Immunization Practices. Chairperson Serpa noted that implementation efforts will focus primarily on education of the change.

Members of the Committee and public were provided with the opportunity to provide comments.

Public comment was received from the California Pharmacists Association, the sponsor of the bill, expressing appreciation of the Board's support and noted the expanded role for pharmacists.

Assembly Bill 1533

Chairperson Serpa advised members that Assembly Bill 1533 (our Sunset bill), contains a number of changes in Pharmacy Law.

Dr. Serpa noted that the measure extends the operations of the Board until January 1, 2026. The Committee agreed that the Board should receive an annual report of many of the reporting elements of the Sunset Report which could be reviewed as part of the July meeting.

Members did not have comments on this provision.

Dr. Serpa informed members that Section 4052(a)(13) amends 4052 to expand authority to pharmacists to initiate, adjust or discontinue drug therapy for a patient under a collaborative practice agreement and also expands authority for pharmacists to provide medication assisted treatment pursuant to a state protocol.

Implementation efforts will include the Board's development of a state protocol to facilitate implementation of the MAT authority.

Members noted that it was appropriate for the Licensing Committee to develop the regulations for MAT. Members also noted that the expansion of collaborative practice was appropriate.

Dr. Serpa advised members that Business and Professions Code Section 4052.6 was amended to expand the authority for an advanced practice pharmacist to initiate, adjust, or discontinue drug therapy beyond health care facilities. The Committee discussion included that implementation efforts will focus primarily on education about the provision and should reiterate the provisions for coordination for care and education with the diagnosing prescriber.

Dr. Serpa highlighted the changes in Business and Professions Code Sections 4110 and 4126.10 are changes sought to implement provisions of the FDA MOU addressing certain distributions of compounded drugs. Specifically, pharmacy license renewal requirements will include notification of compounding practices for pharmacies distributing compounding human preparations as well as reporting requirements established in the MOU. Implementation efforts will include updating renewal forms and data systems as well as the development of educational materials.

Members did not have comments to the changes to the sections.

Dr. Serpa advised that Pharmacy Law was also amended to allow outsourcing facilities licensed by the Board to dispense patient-specific compounded drug preparations under specified conditions, including that such dispensing shall comply with the same requirements of a pharmacy.

Chairperson Serpa indicated that implementation efforts will include development of educational materials and it is anticipated that extensive education to outsourcing facilities will be required noting that such education is necessary to allow harmony with federal allowances while ensuring patients have access to pharmacist care, including drug utilization review, patient-centered labeling, and patient consultation requirements.

Members did not have comments to the changes to the sections.

Dr. Serpa summarized the change to Section 4161 which was amended to create alternative pathways to licensure for nonresident third-party logistics providers. Implementation efforts will include updating application instructions and forms. Dr. Serpa referenced the meeting materials which included that staff will need to begin working with facilities granted temporary licenses to those entities currently under the Board's waiver process for purposes of distributing ventilators and vaccines into California. This work will need to be completed prior to the expiration of the temporary licenses to ensure continuity to the effective date of this new law, January 1, 2022.

Members did not have comments to the changes to the Section 4161.

Chairperson Serpa highlighted that changes to Section 4210 alter application requirements for an advance practice pharmacist recognition to allow for qualification under a single pathway, if that pathway includes completion of a second criterion. Dr. Serpa noted that the change clarifies the requirements and eliminates the current confusing language. Dr. Serpa summarized implementation efforts which include updating application instructions and forms as well as development of educational materials. In addition, staff will review pending applications to determine if the changes in the requirements will impact applicant eligibility.

Members did not have comments to the changes to the Section 4210.

Dr, Serpa notified members that Business and Professions Code Section 4232.5 was amended to require a pharmacist with authority to prescribe a controlled substance to complete an educational course on the risks of addiction to Schedule II drugs. Implementation efforts will include updating the renewal application requirements via regulation. The regulation will give notice of the requirement and how an individual will demonstrate compliance.

The Committee determined that the Licensing Committee would be well suited to develop the regulations and should include other CE topics that are required as well.

Dr. Serpa noted under the provisions of this bill, the Board will be required to convene a working group of interested stakeholders to discuss whether moving to a standard of care model is feasible and appropriate. Chairperson Serpa continued that as included in the measure, the Board will be required to submit a report with recommendations to the Legislature by July 1, 2023 following completion of the workgroup.

President Oh advised members that education will be provided in January and members will be provided the opportunity to elect to participate in the ad hoc committee to consider the matter.

Dr. Serpa noted that under the provisions established in Section 4317.5 the Board will have new fine authority to address repeated violations under specified conditions including that the violations occurred in community chain pharmacies operating under common ownership. Chairperson Serpa highlighted that the measure provides for an opportunity for the pharmacy to cure a violation, as long as the violation did not result in actual harm to any consumer or pose serious potential harm to the public.

It was noted that implementation will include education about the provisions and the Committee will be provided with data on implementation of this new fine included as part of the annual presentation the Committee receives on the Board's citation and fine program.

Members did not have comments on BPC 4317.5

Dr. Serpa reviewed Section 4427.65 which expands the locations where unit-dose automated drug delivery systems may be located, noting that implementation will include education on the provisions.

Members did not have comments on BPC 4427.65

Members of the public were provided with the opportunity to provide public comment on AB 1533.

Public comment included comments related to changes in Section 4126.10. Comments noted that information required to be reported indicated the MOU may be pushed back beyond October 2022, suggesting that the Committee should consider delaying enforcement or enforcement discretion on the reporting comments.

Senate Bill 306

Dr. Serpa highlighted that under the provisions a pharmacist will be allowed to dispense a medication without an individual name if the prescription includes "expedited partner therapy" or EPT. Chairperson noted that the bill requires a pharmacist to provide a written notice that describes the right of an individual receiving EPT to consult with a pharmacist about the therapy and potential drug interactions. Implementation efforts will focus primarily on education of the measure.

Members did not have comments on the provisions of Senate Bill 306.

Members of the public were provided with an opportunity to provide public comment; however, none were provided.

Senate Bill 310

Chairperson Serpa informed members that Senate Bill 310 creates a medication collection and distribution program that allows for patients to donate previously dispensed medication back to a participating practitioner or physician for redistribution to other patients of the same practitioner. Dr. Serpa noted that under the provisions of the measure the Board has the authority to request records to evaluate for compliance with the provisions and has the authority to prohibit a practitioner from participating in this program under specified conditions. Implementation will focus on education about the provisions as well an extensive education of identified Board staff to assure practitioners have appropriate policies and procedures, documentation of drug manufacturing requirements and to ensure appropriate patient protections exist. Data on this new program will be collected and reported to our Committee.

Members did not have comments on the provisions of Senate Bill 310.

Members of the public were provided with an opportunity to provide public comment; however, none were provided.

Senate Bill 311

Dr. Serpa noted that Senate Bill 311 requires health care facilities to allow a terminally ill patient to use medical cannabis under specified conditions. Late amendments to the measure specified that health care facilities permitting such use must comply with

drug and medication requirements applicable to Schedule II – IV drugs and shall be subject to enforcement actions by the California Department of Public Health.

Dr. Serpa advised members that late amendments to the bill created conflicts within the measure itself. Specifically, the amendments to require the medicinal cannabis to comply with provisions related to Schedule II-IV medication creates a number of questions about the applicability of Board regulations including storage, inventory control, acquisition and the role of Pharmacy in these facilities.

The Committee considered if it was appropriate to determine what the Board's role should be in resolving these conflicts along with other regulators and stakeholders noting there are other challenges with this measure that may be outside of the Board's purview, but problematic for health systems. Concerns included federal implications to allowing the use of medicinal cannabis in health care facilities that could negatively impact their licensure, accreditations or reimbursement.

Members sought clarification on the measure and the applicability and were advised the medicinal cannabis was not rescheduled under the provisions of the bill.

Members of the public were provided with the opportunity to provide public comment.

Linda Panofsky, UCSF, was read into the record because of technology challenges. Ms. Panofsky suggested the Board, in conjunction with CDPH, consider strengthening patient medication regulations.

Dr. Stein advised the Committee that late amendments included in Section 1649.3 seemed to be contradictory to other provisions of the bill and indicated that it may not have much applicability. Dr. Stein also noted it is interesting that the California Department of Public Health is charged with enforcement of the provision.

Lori Hensic, Scripps Health, shared with members that conversations with the author's office confirm medicinal cannabis was not rescheduled and noted conflicts were previously discussed. The author clarified that it was not their intent to hold the pharmacy responsible and requested a letter be published in the journal. [**Note**: A letter published in the assembly or daily journal is a tool authors use to clarify ambiguity in a bill or clarify intent.] Dr. Hensic continued that the measure raises several questions, including questions of acquisition, disposition, and inventory control and offered to assist the Committee in its further discussion.

Keith Yoshizuka noted agreement with the Board's assessment and the need to further refine the requirements. Dr. Yoshizuka highlighted the potential consequences of the bill including that hospitals could lose their federal funding.

Steven Gray commented that the medical cannabis law in California is very old. He noted that certain hospitals appear to allow the use of medical cannabis. Dr. Gray noted that Federal law prohibits DEA from taking action against a hospital that allows the use of medical cannabis.

Following public comments, members requested that staff come back to the Committee with recommendations on education of the measure.

Senate Bill 362

Dr. Serpa advised members that Senate Bill 362 will prohibit a community chain pharmacy from using a quota to evaluate the performance of a pharmacist or pharmacy technician. Dr. Serpa noted that implementation efforts will include education about the provisions as well as the process a pharmacist or pharmacy technician may use to file a complaint and education about whistleblower protections. Members were advised that the Committee will receive data on implementation of this new law.

Members did not have any additional comments on Senate Bill 362.

Members of the public were provided the opportunity to provide public comment. Public comment was received from a representative from UFCW indicating that UCFW looks forward to working with the Board to implement the provisions and thanked the Board for its support of the measure.

Chairperson Serpa advised members that Senate Bill 409 expands authority for pharmacists to provide CLIA-waived tests under specified conditions. Implementation will include education on the provisions and that the Board's Health Services Registry should be updated to include these additional patient care services.

Members did not have any additional comments on Senate Bill 409.

Members of the public were provided the opportunity to provide public comment; however, none were provided.

The meeting was in recess from 10:13 to 10:23. Roll call was taken upon resumption of the meeting. Members present: Jignesh Patel, Seung Oh, Ricardo Sanchez, Debbie Veale and Maria Serpa.

V. Discussion and Consideration of Released Revised Proposed Changes to USP Chapters 795 and 797 and the Board's Current Policy Statement

Dr. Serpa indicated relevant law sections are detailed in the meeting materials, and highlighted that under Section 4127, the Board is required to review any formal revisions to USP Chapter 797 no later than 90 days after the revisions become official to determine whether amendments are necessary for Board regulations. Chairperson Serpa noted that in 2019 during many stakeholder meetings to update current pharmacy regulations, review and consideration of the USP Chapters requires a significant amount of member time. This work was put on hold when USP paused their implementation date to look at additional changes to their proposed language.

Given that, with the release of the newly revised proposed chapters, Dr. Serpa suggested it is appropriate to resume work on updating compounding regulations. Dr. Serpa referenced the meeting materials included high level comparison charts to USP 795 and 797 noting that the information will assist the Committee in future efforts.

Dr. Serpa suggested the first step for the Committee is to review the Board's current policy statement and update it, followed by monitoring the USP process in finalizing the standards and restart stakeholder meetings on compounding in 2022.

Members were provided the opportunity to comment on the plan moving forward.

Dr. Serpa transitioned to discussion on the need and text of the draft policy statement noting it is important to provide stakeholders with an update on the status of compounding to ensure the Board's regulated public has a clear understanding of the applicable laws and standards that must be followed to compound drug preparations.

Members considered the updated draft policy statement.

Motion: Recommend to the Board approval of the draft policy statement.

M/S: Oh/Veale

Members of the public were provided with an opportunity to provide public comment; however, none were provided.

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

Committee Member	**Vote**
Oh	Support

Patel	Support
Sanchez	Support
Serpa	Support
Veale	Support

VI. Updates on FDA Actions Related to Human Compounding

Dr. Serpa noted that the meeting materials included two items for information only. The information was provided not only for the Committee's information, but to inform stakeholders.

Dr. Serpa advised members of the notice of extension released by the FDA relating to the MOU on Interstate Distribution of Compounded Drug Products. As included in the notice, the FDA is extending the period for a state to enter the MOU until October 27, 2022. Dr. Serpa noted that the extension will allow the Board time to implement necessary provisions.

Dr. Serpa informed members of the October 7, 2021 release by the FDA of a draft guidance document titled, Hospital and Health System Compounding Under Section 503 of the Federal Food, Drug, and Cosmetic Act Guidance for Industry. The guidance describes how the FDA intends to apply certain provisions of Section 503 A to human drug products that are compounded by state-licensed pharmacies for distribution within a hospital or health-system. Dr. Serpa advised members that written comments must be submitted by December 6.

Members did not have additional comments.

Members of the public were provided with the opportunity to provide public comments. Public comment questioned what other steps are necessary for the Board to sign the MOU. Counsel advised that the Committee has previously discussed this issue and the commenter was referred back to those previous discussions.

VII. Review and Discussion of Enforcement Statistics

Dr. Serpa referenced the enforcement statistics provided in the meeting materials.

Members were provided the opportunity to provide comments; however, none were provided.

Members of the public were provided with the opportunity to provide public

comment; however, none were provided.

VIII. Future Committee Meeting Dates

The Committee was reminded that future Committee meeting dates were included in the meeting materials.

IX. Adjournment

Chairperson Serpa adjourned the meeting at 10:35 a.m.

Attachment 2

Title 16. Board of Pharmacy
Proposed Text

Proposed changes to current regulation text are indicated with ~~single strikethrough~~ for deletions and single underline for additions.

Amend Sections 1760 of Article 4 of Division 17 of Title 16 of the California Code of Regulations to read:

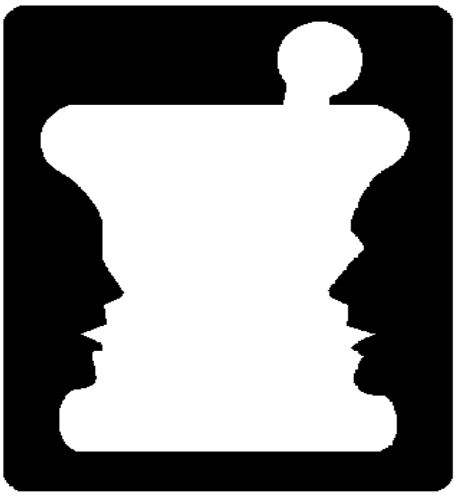
§ 1760. Disciplinary Guidelines.

In reaching a decision on a disciplinary action under the Administrative Procedure Act (Government Code section 11400 et seq.) the board shall consider the disciplinary guidelines entitled "Disciplinary Guidelines" (Rev. ~~2/2017~~ 1/2022), which are hereby incorporated by reference.
Deviation from these guidelines and orders, including the standard terms of probation, is appropriate where the board, in its sole discretion, determines that the facts of the particular case warrant such a deviation -the presence of mitigating factors; the age of the case; evidentiary problems.

Note: Authority cited: Sections 315, 315.2, 315.4 and 4005, Business and Professions Code; and Section 11400.20, Government Code. Reference: Sections 315, 315.2, 315.4 and 4300-4313, Business and Professions Code; and Sections 11400.20 and 11425.50(e), Government Code.

DISCIPLINARY GUIDELINES

A Manual of Disciplinary Guidelines
and Model Disciplinary Orders



BE AWARE & TAKE CARE:
Talk to your pharmacist!

California State Board of Pharmacy
Department of Consumer Affairs
(Rev. ~~2/2017~~1/2022)

STATE BOARD OF PHARMACY

DEPARTMENT OF CONSUMER AFFAIRS

~~**Amy Gutierrez**~~
Seung Oh
PRESIDENT

~~**Virginia K. Herold**~~**Anne Sodergren**
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Additional copies of these disciplinary guidelines may be downloaded from the board's website

BOARD OF PHARMACY

DISCIPLINARY GUIDELINES

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STATE BOARD OF PHARMACY

DISCIPLINARY GUIDELINES
(Rev. ~~2/2017~~1/2022)

INTRODUCTION

The Board of Pharmacy (board) is responsible for the enforcement of statutes and regulations related to the practice of pharmacy (the Pharmacy Law) and to the regulation of controlled substances (the Uniform Controlled Substances Act). The board serves the public by:

- protecting the health, safety, and welfare of the people of California with integrity and honesty;
- advocating the highest quality of affordable pharmaceutical care;
- providing the best available information on pharmaceutical care; and
- promoting education, wellness and quality of life.

Pharmacists and intern pharmacists are patient advocates and vital members of the clinical care team who provide pharmaceutical care and exercise clinical judgment for their patients. They also exercise critical vigilance and control over medication stocks, drug inventories, and quality assurance protocols. Pharmacy technicians provide crucial assistance to pharmacists and intern pharmacists in all of their pharmacy tasks. Pharmacists and intern pharmacists enlighten their patients about their drug therapies through effective communicating and listening, assessing, collaborating, understanding and intervening. They also, under appropriate conditions, initiate or terminate drug therapies, compound drug preparations, ensure safety and security of drug stocks, and otherwise contribute to clinical safety and performance. Also, pharmacists and intern pharmacists are always vigilant to ensure that drug therapies are being appropriately and effectively utilized. When a pharmacist takes on the responsibility of a pharmacist-in-charge, the pharmacist also ensures the pharmacy's compliance with state and federal law, quality assurance responsibilities, and inventory controls. Likewise, the premises and other individuals licensed by the board help to ensure the reliability, safety, and security of the dangerous drug and/or dangerous device supply chain, so that patients and prescribers can be confident in the drugs or devices prescribed. Enforcement officials act quickly, consistently and efficiently in the public's interest to ensure the safe, effective delivery of these services.

The board recognizes the importance of ensuring the safe and effective delivery of dangerous drugs and controlled substances for therapeutic purposes. At the same time, and given the historical and current abuse and diversion of drugs, particularly controlled substances, the board believes there should be no tolerance for licensees who traffic in drugs or who, in the absence of appropriate evidence of rehabilitation, personally abuse drugs or alcohol.

In accordance with Section 1760 of the California Code of Regulations, the board has produced this booklet for those involved in and affected by the disciplinary process: the general public, , attorneys from the Office of the Attorney General, administrative law judges from the Office of Administrative Hearings, defense attorneys, the courts, board staff, and board members who review and vote on proposed decisions and stipulations.

These guidelines are to be followed in Board of Pharmacy disciplinary actions. Subject to judicial review, the board has the final authority over the disposition of its cases, and, to complete its work, it uses the services of the Office of the Attorney General and the Office of Administrative Hearings. The board recognizes that individual cases may necessitate a departure from these guidelines. In such cases, the mitigating or aggravating circumstances shall be detailed in any proposed decision or any transmittal memorandum accompanying a proposed stipulation, especially where Category III or IV- violations are involved.

In general, the position of the board is that revocation should always be an option whenever grounds for discipline are found to exist. Board policy is that revocation is generally an appropriate order where a respondent is in default, such as when ~~he or she fails~~they fail to file a notice of defense or fails to appear at a disciplinary hearing.

Board policy is that a suspension, where imposed, should be at least 30 days for an individual and at least 14 days for a licensed premises.

The board seeks recovery of all investigative and prosecution costs up to the hearing in all disciplinary cases. This includes all charges of the Office of the Attorney General, including, but not limited to, those for legal services, and includes charges by expert consultants. The board believes that the burden of paying for disciplinary cases should fall on those whose conduct requires investigation and prosecution, not on the profession as a whole.

The board recognizes there may be situations where an individual licensee deserves a stronger penalty than the pharmacy for which ~~he or she works~~they work. Similarly, the board recognizes that in some cases a licensed premises may well be more culpable than any individual licensed by or registered with the board. Typically, the board also believes in holding a pharmacy owner, manager, and/or pharmacist-in-charge responsible for the acts of pharmacy personnel.

For purposes of these guidelines “board” includes the board and/or its designees.

FACTORS TO BE CONSIDERED IN DETERMINING PENALTIES

Section 4300 of the Business and Professions Code provides that the board may discipline the holder of, and suspend or revoke, any certificate, license or permit issued by the board.

In determining whether the minimum, maximum, or an intermediate penalty is to be imposed in a given case, factors such as the following should be considered:

1. actual or potential harm to the public
2. actual or potential harm to any consumer
3. prior disciplinary record, including level of compliance with disciplinary order(s)
4. prior warning(s), including but not limited to citation(s) and fine(s), letter(s) of admonishment, and/or correction notice(s)
5. number and/or variety of current violations
6. nature and severity of the act(s), offense(s) or crime(s) under consideration
7. aggravating evidence
8. mitigating evidence
9. rehabilitation evidence
10. compliance with terms of any criminal sentence, parole, or probation
11. overall criminal record
12. if applicable, evidence of proceedings for case being set aside and dismissed pursuant to Section 1203.4 of the Penal Code
13. time passed since the act(s) or offense(s)
14. whether the conduct was intentional or negligent, demonstrated incompetence~~, or, if the respondent is being held to account for conduct committed by another, the respondent had knowledge of or knowingly participated in such conduct~~
15. financial benefit to the respondent from the misconduct.
16. other licenses held by the respondent and license history of those licenses.
17. Uniform Standards Regarding Substance-Abusing Healing Arts Licensees (see Business and Professions Code Section 315)
18. if the respondent is being held to account for conduct committed by another, whether or not the respondent had knowledge of or knowingly participated in such conduct

No single one or combination of the above factors is required to justify the minimum and/or maximum penalty in a given case, as opposed to an intermediate ~~one~~penalty.

MITIGATING EVIDENCE

A respondent is permitted to present mitigating circumstances at a hearing or in the settlement process and has the burden of demonstrating any rehabilitative or corrective measures ~~he, she, or it has~~they have taken. The board does not intend, by the following references to written statements, letters, and reports, to waive any evidentiary objections to the form or admissibility of such evidence. The respondent must produce admissible evidence in the form required by law in the absence of a stipulation to admissibility by the complainant.

The following are examples of appropriate evidence a respondent may submit to demonstrate ~~his or her~~their rehabilitative efforts and competency:

a. Recent, dated, written statements and/or performance evaluations from persons in positions of authority who have on-the-job knowledge of the respondent's current competence in the practice relevant to the disciplinary proceeding, including the period of time and capacity in which the person worked with the respondent. Such reports must be signed under penalty of perjury and will be subject to verification by board staff.
b. Recent, dated, letters from counselors regarding the respondent's participation in a rehabilitation or recovery program, which should include at least a description and requirements of the program, a ~~psychologist's~~ mental health practitioner's diagnosis of the condition and current
state of recovery, and the ~~psychologist's~~ mental health practitioner's basis for determining rehabilitation. Such letters and reports will be subject to verification by board staff.
c. Recent, dated letters describing the respondent's participation in support groups, (e.g., Alcoholics Anonymous, Narcotics Anonymous, professional support groups, etc.). Such letters and reports will be subject to verification by board staff.
d. Recent, dated, laboratory analyses or drug screen reports, confirming abstention from drugs and alcohol. Such analyses and reports will be subject to verification by board staff.
e. Recent, dated~~,~~ , physical examination~~/ or~~ assessment report(s) by a licensed ~~physician~~health care practitioner, confirming the absence of any physical impairment that would prohibit the respondent
from practicing safely. Such report(s) will be subject to verification by board staff.
f. Recent, dated~~,~~ , letters from probation or parole officers regarding the respondent's participation in and/or compliance with terms and conditions of probation or parole, which should include at least a description of the terms and conditions, and the officer's basis for determining compliance. Such letters and reports will be subject to verification by board staff.
g. Recent, dated, letters from persons familiar with respondent in either a personal or professional capacity regarding their knowledge of: the respondent's character; the respondent's rehabilitation, if any; the conduct of which the respondent is accused; or any other pertinent facts that would enable the board to better decide the case. Such letters must be signed under penalty of perjury and will be subject to verification by board staff.
h. For premises licensees, recent, dated letters from appropriate licensees or representatives of licensees of the board in good standing, or from appropriate consultants and/or experts in the field, written by persons familiar with respondent in either a personal or professional capacity regarding their knowledge of: the character and rehabilitation, if any, of respondent's owner(s), officer(s), or managerial employee(s); the conduct of which the respondent is accused; the details of respondent's operation(s); or any other pertinent facts that would enable the board to

better decide the case. Such letters must be signed under penalty of perjury and will be subject to verification by board staff.

TERMS OF PROBATION – INDIVIDUAL LICENSEES ~~(PHARMACIST, ADVANCED PRACTICE PHARMACIST, INTERN PHARMACIST, PHARMACY TECHNICIAN, DESIGNATED REPRESENTATIVE AND DESIGNATED REPRESENTATIVE-3PL)~~

A minimum three-year probation period has been established by the board as appropriate in most cases where probation is imposed. A minimum five-year probation period has been established by the board as appropriate in cases involving self-administration or diversion of controlled substances or dangerous drugs and/or dangerous devices, or abusive use of alcohol. Terms and conditions are imposed to provide consumer protection and to allow the probationer to demonstrate rehabilitation. A suspension period may also be required as part of the probation order. The board prefers that any stayed order be for revocation rather than for some period of suspension. The board also uses the Uniform Standards Regarding Substance-Abusing Licensees developed by the Substance Abuse Coordinating Committee of the Department of Consumer Affairs (2011).

Probation conditions are divided into two categories: (1) standard conditions that shall appear in all probation cases, and (2) optional conditions that depend on the nature and circumstances of a particular case. These conditions may vary depending on the nature of the offense(s).

The board may also impose any other condition appropriate to the case where the condition is not contrary to public policy.

CATEGORIES OF VIOLATIONS AND RECOMMENDED PENALTIES

The California Pharmacy Law identifies offenses for which the board may take disciplinary action against the license. Included among grounds for discipline are violations of the Pharmacy Law itself, violations of regulations promulgated by the board, and violations of other state or federal statutes or regulations.

For those licenses issued to individuals ~~(pharmacists, intern pharmacists, pharmacy technicians, and designated representatives, designated representatives-3PL, and advanced practice pharmacists)~~, the board has identified four (4) categories of violations and their associated recommended minimum and maximum penalties. These categories of violations are arranged in ascending order from the least serious (Category I) to the most serious (Category IV), although any single violation in any category, or any combination of violation(s) in one or more categories, may merit revocation. For pharmacy technicians and designated representatives, the board believes an order of revocation is typically the appropriate penalty when any grounds for discipline are established, and that if revocation is not imposed that a minimum Category III level of discipline should be imposed.

For each violation category, the board has given ~~offense~~ descriptions and examples where violations would typically merit the recommended range of minimum to maximum penalties for that category. These descriptions and examples are representative, and are not intended to be comprehensive or exclusive. Where a violation not included in these lists is a basis for disciplinary action, the appropriate penalty for that violation may be best derived by comparison to any analogous violation(s) that are included. Where no such analogous violation is listed, the category descriptions may be consulted.

These categories ~~assume~~ presume a single violation. For multiple violations, the appropriate penalty shall increase accordingly. Moreover, if an individual has committed violations in more than one category, the minimum and maximum penalties shall be those recommended in the highest category.

The board also has the authority, pursuant to Business and Professions Code section 4301(n), to impose discipline based on disciplinary action taken by another jurisdiction. The discipline imposed by the board will depend on the discipline imposed by the other jurisdiction, the extent of the respondent's compliance with the terms of that discipline, the nature of the conduct for which the discipline was imposed, and other factors set forth in these guidelines.

CATEGORY I

Minimum: Revocation; Revocation stayed; two years probation. All standard terms and conditions shall be included and optional terms and conditions as appropriate.

Maximum: Revocation

Category I discipline is recommended for violations that are less serious than Category ~~2~~ II through ~~4~~ IV but are potentially harmful. These may include:

- violations of recordkeeping requirements, ~~scope of practice requirements,~~ or inventory control requirements;
- smaller or isolated failure(s) to abide by or enforce prescription or refill requirements, drug-substitution requirements, or labeling requirements;
- violation(s) of obligations to supply or update information to the board, or to other enforcement or regulatory agencies;
- failure(s) to adequately supervise staff or ensure security and sanitation of premises, dangerous drugs and/or dangerous devices, or controlled substances; and
- violation(s) of packaging requirements, security control requirements, or reporting requirements.
- violation(s) involving the improper compounding of drug products
- violation(s) resulting from the misuse of education or licensing privileges irrespective of whether it occurs outside of an entity licensed by the board.

CATEGORY II

Minimum: Revocation; Revocation stayed, three years probation (five years probation in cases involving self-administration or diversion of controlled substances or dangerous drugs and/or dangerous devices, or abusive use of alcohol). All standard terms and conditions shall be included and optional terms and conditions as appropriate.

Maximum: Revocation

Category II discipline is recommended for violation(s) with serious potential for harm, as well as for violations involving disregard for public safety or for the laws or regulations pertaining to pharmacy and/or to dispensing or distributing of dangerous drugs and/or dangerous devices or controlled substances, violations that reflect on ethics, competence, or diligence, and criminal convictions not involving alcohol, dangerous drugs and/or dangerous devices, or controlled substances. Violations in this category may include:

- failure(s) to abide by prohibitions on referral rebates or discounts (kickbacks) and/or volume or percentage-based lease agreements;
- violation(s) of advertising or marketing limitations, including use of false or misleading advertising or marketing;
- repeat or serious violation(s) of recordkeeping requirements, scope of practice requirements, or inventory control requirements;
- violation(s) of controlled substance secure prescription requirements, inventory controls, or security requirements;
- failure(s) to meet compliance requirements, including pharmacist-in-charge or designated representative-in-charge designation and duties;

- violation(s) of monitoring and reporting requirements with regard to chemically, mentally, or physically impaired licensees or employees;
- repeat or serious failure(s) to adequately supervise staff or ensure security and sanitation of premises, dangerous drugs and/or dangerous devices, or controlled substances;
- violation(s) of law governing controlled substances, dangerous drugs and/or dangerous devices, or alcohol, including smaller cases of diversion or self-administration or abusive use of a controlled substance, dangerous drug and/or dangerous device, or alcohol;
- unlawful possession(s) of dangerous drugs and/or dangerous devices, controlled substances, hypodermic needles and syringes, or drug paraphernalia;
- smaller scale dispensing or furnishing of dangerous drug(s) and/or dangerous device(s) via the internet without valid prescription(s);
- purchasing, trading, selling, or transferring dangerous drug(s) and/or dangerous device(s) to or from unauthorized person(s);
- failure(s) to make required reports to the board or other regulatory agencies, including CURES obligations and reporting to DEA;
- violation(s) of quality assurance and self-assessment obligations, failure(s) to clarify erroneous or uncertain prescription(s);
- gross immorality, incompetence, gross negligence, excessive furnishing of controlled substances, moral turpitude, dishonesty, or fraud;
- criminal conviction(s) not involving alcohol, dangerous drugs and/or dangerous devices, or controlled substances;
- violating, or assisting in or abetting violation of, or conspiring to violate the laws and regulations governing pharmacy; and
- subverting or attempting to subvert an investigation conducted by the board.
- repeated violation(s) involving the improper compounding of drug ~~products~~preparations
- repeated violation(s) involving the improper sterile compounding of drug preparations
- violations resulting from the misuse of education or licensing privileges irrespective of whether these violations occur in an entity regulated by the board.

CATEGORY III

Minimum: Revocation; Revocation stayed, 90 days actual suspension, three to five years probation (five years probation in cases involving self-administration or diversion of controlled substances or dangerous drugs and/or dangerous devices, or abusive use of alcohol). All standard terms and conditions and optional terms and conditions as appropriate.

Maximum: Revocation

Category III discipline is recommended for violations where potential for harm is greater, more imminent, or more serious than it is for Category II violations, as well as for violations that involve knowingly or willfully violating laws or regulations pertaining to pharmacy and/or to the dispensing or distributing of dangerous drugs and/or dangerous devices or controlled substances, and most criminal convictions involving alcohol, dangerous drugs and/or dangerous devices or controlled substances. Violations in this category may include:

- violation(s) involving creation, manipulation, perpetuation, or disregard of drug shortages;
- failure(s) to deploy or abide by Drug Supply Chain Security Act requirements, and other similar requirements for dangerous drugs and/or dangerous devices;

- violation(s) of licensee’s corresponding responsibility to ensure the proper prescribing and dispensing of controlled substances;

- dispensing or furnishing without valid prescription, dispensing or furnishing to unauthorized person(s);
- violation(s) involving fraudulent acts committed in connection with the licensee's practice;
- repeat or serious violation(s) of controlled substance secure prescription requirements, inventory controls, or security requirements;
- violation(s) of laws governing controlled substances, dangerous drugs and/or dangerous devices, or alcohol, including repeat or serious diversion or self-administration, or abuse;
- violation(s) of law governing self-administration of controlled substances that create a potential infection control risk.
- repeat or serious unlawful possession(s) of dangerous drugs and/or dangerous devices, controlled substances, hypodermic needles or syringes, or drug paraphernalia;
- larger scale dispensing or furnishing of dangerous drug(s) and/or dangerous device(s) via the internet, without valid prescription(s);
- purchasing, trading, selling, or transferring adulterated, misbranded, or expired dangerous drug(s) and/or dangerous device(s);
- removal, sale, or disposal of embargoed dangerous drug(s) and/or dangerous device(s);
- failing to maintain record(s) of acquisition and disposition of dangerous drug(s) and/or dangerous device(s);
- resale(s) of preferentially priced drugs, contract bid diversion, or other instances of improper sale(s) or resale(s);
- repeat or serious violation(s) of quality assurance and self-assessment obligations, failure(s) to ensure properly trained staff and conduct practice safely;
- repeat or serious failure(s) to perform drug utilization reviews, monitor patient medication profiles, or promote safety and efficacy of prescribed drugs;
- forgery of prescriptions, passing of forged prescriptions, or other unlawful means of acquiring dangerous drug(s) and/or dangerous device(s) or controlled substance(s);
- repeat or serious acts violating, assisting in or abetting violation of, or conspiring to violate the laws and regulations governing pharmacy; and
- violation(s) involving providing or offering to provide controlled substance(s) to addict(s).
- repeat or serious violation(s) involving the improper compounding of drug products
- repeat or serious violation(s) resulting from the misuse of education or licensing privileges irrespective of whether ~~is~~ it occurs outside of an entity licensed by the board.

CATEGORY IV

Penalty: Revocation

Category IV discipline (revocation) is recommended for the most serious violations of laws or regulations pertaining to pharmacy and/or to the dispensing or distributing of dangerous drugs and/or dangerous devices or controlled substances. Violations in this category may include:

- violations involving possession for sale, transportation, importation, and/or use of a minor for unlawful sale of controlled substances;
- criminal convictions involving the above, or repeat convictions involving diversion or abuse of alcohol, dangerous drugs and/or dangerous devices, or controlled substances;
- repeated or serious example(s) of conduct described in Category I, Category II, or Category III.
- violation(s) of law governing self-administration of controlled substances that create a potential infection control risk.

Revocation is also recommended where a respondent fails to file a notice of defense to an Accusation or Petition to Revoke Probation or to appear at a disciplinary hearing, where a respondent violates the terms and conditions of probation from a previous disciplinary order, or where prior discipline has been imposed on the license.

MODEL DISCIPLINARY LANGUAGE - INDIVIDUAL LICENSEES ~~(PHARMACIST, INTERN PHARMACIST, PHARMACY TECHNICIAN, DESIGNATED REPRESENTATIVE, DESIGNATED REPRESENTATIVE – 3PL, ADVANCED PRACTICE PHARMACIST)~~

The following standardized language shall be used in every decision where the order or condition is imposed. Where brackets appear, drafters should choose the appropriate term or consider the text instructional.

Revocation

License number _____, issued to respondent _____,is

revoked. Respondent shall relinquish ~~[his/her]~~their license, including any indicia of licensure issued by the board, to the board within 10 days of the effective date of this decision. Respondent may not reapply or petition the board for reinstatement of ~~[his/her]~~their revoked license for three years from the effective date of this decision.

As a condition precedent to reinstatement of ~~[his/her]~~their revoked license, respondent shall reimburse the board for its costs of investigation and prosecution in the amount of $_____. Said amount shall be paid in full prior to the reinstatement of ~~his or her~~their license unless otherwise ordered by the board.

Option: Respondent shall pay to the board its costs of investigation and prosecution in the amount of $ _____within fifteen (15) days of the effective date of this decision.

Suspension

As part of probation, respondent is suspended from ~~the~~ practice as a [insert license type] for [day(s)/month(s)/year(s)] beginning the effective date of this decision.

During suspension, respondent shall not enter any pharmacy area or any portion of any board ~~the~~ licensed premises ~~of a wholesaler, third-party logistics provider, veterinary food-animal drug retailer, or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area~~ where dangerous drugs and/or dangerous devices or controlled substances are maintained.

Respondent shall not ~~practice pharmacy~~ exercise any of the privileges conveyed by the board nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs and/or dangerous devices or controlled substances.

During suspension, respondent shall not engage in any activity that requires the professional judgment of and/or licensure as a [insert license type]. Respondent shall not direct or control any aspect of any board licensed premises~~the practice of pharmacy or of the manufacturing, distributing, wholesaling, or retailing of dangerous drugs and/or dangerous devices or controlled substances~~.

Failure to comply with this suspension shall be considered a violation of probation.

Revocation, stayed, Probation Order

License number _____, issued to respondent is revoked; however, the revocation is stayed and respondent is placed on probation for _____ years upon the following terms and conditions:

It is further ordered that any new license(s) issued while Respondent remains on probation shall also be placed on probation subject to the same terms and conditions applicable to Respondent's _____ license.

Issuance of Probationary License (In cases where a Statement of Issues has been filed.)

Upon satisfaction of all statutory and regulatory requirements for issuance of a [insert license type] license, a [insert license type] license shall be issued to respondent and immediately revoked; the order of revocation is stayed and respondent is placed on probation for _____ years upon the following terms and conditions:

Option: (Intern Pharmacist Only)
Should the board subsequently issue a license to practice as a pharmacist to respondent during the period of probation, the intern license shall be cancelled and the pharmacist license shall be immediately revoked. The revocation of such license shall be stayed, and the probation imposed by this decision and order will continue. Respondent shall remain subject to the same terms and conditions imposed by this disciplinary order. Notwithstanding this provision, the board reserves the right to deny respondent's application for the pharmacist licensure exam. If the board issues a pharmacist license to respondent, the following additional terms and conditions shall be included as part of the disciplinary order:

Surrender

Respondent surrenders license number _____as of the effective date of this decision. Respondent shall relinquish ~~[his/her]~~their license, including any indicia of licensure issued by the board, to the board within ten (10) days of the effective date of this decision.

The surrender of respondent's license and the acceptance of the surrendered license by the board shall constitute the imposition of discipline against respondent. This decision constitutes a record of discipline and shall become a part of respondent's license history with the board. Respondent understands and agrees that for purposes of Business and Professions Code section 4307, this surrender shall be construed the same as revocation.

Respondent may only seek a new or reinstated license from the board by way of a ~~new application for licensure~~reinstatement. Respondent understands and agrees that if ~~he or she [he/she]~~they ever file~~s~~ an application for licensure or a petition for reinstatement in the State of California, the board shall treat it as a ~~new application for licensure shall not be eligible to~~ petition for reinstatement of licensure.

Respondent may not ~~apply~~ petition for any license, permit, or registration from the board for three years from the effective date of this decision. Respondent stipūlates that should ~~he or she [he/she]~~ they apply for any license from the board on or after the effective date of this decision, all allegations set forth in the [accusation or petition to revoke probation] shall be deemed to be true, correct and admitted by respondent when the board determines whether to grant or deny the ~~application~~petition. ~~Respondent shall satisfy all requirements applicable to that license as of the date the application is submitted to the board, including, but not limited to, taking and passing licensing examination(s) as well as fulfilling any education or~~

~~experience requirements prior to the issuance of a new license.~~

Respondent is required to report this surrender as disciplinary action.

Respondent further stipulates that ~~[he/she]~~they shall reimburse the board for its costs of investigation and prosecution in the amount of $_____within_____days of the effective date of this decision.

Option: Respondent stipulates that should ~~[he/she]~~they ~~apply~~ petition for ~~any license~~reinstatement of licensure from the board on or after the effective date of this decision the investigation and prosecution costs in the amount of $_____shall be paid to the board prior to ~~issuance of the new license~~reinstatement.

Public Reproval

~~It is hereby ordered that a public reproval be issued against licensee, _____.~~
It is hereby ordered that license number _____ issued to Respondent shall be publicly reproved by the Board of Pharmacy under Business and Professions Code section 495 in resolution to Accusation No. _____, attached as Exhibit A.

Respondent is required to report this reproval as a disciplinary action.

License Reinstatement with Conditions Precedent (Pharmacists and Pharmacy Technicians Only)

It is hereby ordered that the petition for reinstatement is granted. Upon satisfaction of the following conditions precedent to licensure, Petitioner's License No. _____ will be reinstated:

OPTION (Pharmacists Only)

a. Petitioner must satisfy licensure requirements as defined by Business and Professions Code section 4200, subdivision (a)~~Examination (NAPLEX) and/or the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE)]~~ within one (1) year of the effective date of this order. Failure to take and pass the examination(s) within one (1) year of the effective date of this order shall invalidate the order granting the petition for reinstatement~~,~~. Petitioner shall be deemed to have failed the conditions precedent for re-licensure, and Petitioner's License No. _____ shall remain [revoked or surrendered]

b. Petitioner must pay the fee(s) in place at the time for [this/these] examinations.

c. Petitioner must pay all applicable application and licensing fees as well as any cost recovery owed from the prior action.

Option (Pharmacy Technicians Only)

a. Petitioner shall ~~take and pass the Pharmacy Technician Certification Board exam]~~become certified as defined by Business and Professions Code section 4202, subdivision (a)(4) within one (1) year of the effective date of

this order. Failure to ~~take and pass the examinations~~become certified within one (1) year of the effective date of this order shall invalidate the order granting the petition for reinstatement, Petitioner shall be deemed to have failed the conditions precedent for re-licensure, and Petitioner's License No. _____shall remain [revoked or surrendered]."

b. Petitioner must pay the fee(s) in place at the time for [this/these] examinations.

c. Petitioner must pay all applicable application and licensing fees as well as any cost recovery owed from the prior action.

Upon completion of the foregoing conditions precedent, Petitioner's license shall be reinstated and immediately revoked, with revocation stayed and Petitioner placed on probation for a period of _____ year(s) on the following terms and conditions:

License Reinstatement

It is hereby ordered that the petition for reinstatement filed by _____ is hereby granted and Petitioner's license shall be reinstated. Petitioner's license shall be reinstated and immediately revoked, with revocation stayed and Petitioner placed on probation for a period of _____year(s)~~]~~ on the following terms and conditions:

STANDARD CONDITIONS - To be included in all probation decisions/orders.

1. Obey All Laws
2. Report to the Board
3. Interview with the Board
4. Cooperate with Board Staff
5. Continuing Education
6. Reporting of Employment and Notice to Employers
7. Notification of Change(s) in Name, Employment, Address(es), or Phone Number(s)
8. Restrictions on Supervision and Oversight of Licensed Facilities
9. Reimbursement of Board Costs
10. Probation Monitoring Costs
11. Status of License
12. License Surrender While on Probation/Suspension
13. Certification Prior to Resuming Work
14. Practice Requirement – Extension of Probation
15. Violation of Probation
16. Completion of Probation

OPTIONAL CONDITIONS

17. Suspension
18. Restricted Practice
19. Pharmacist Examination
20. Clinical Diagnostic Evaluation
21. Psychotherapy
22. Medical Evaluation
23. Pharmacists Recovery Program (PRP)
24. Drug and Alcohol Testing
25. Notification of Departure
26. Abstain from Drugs and Alcohol
27. Prescription Coordination and Monitoring of Prescription Use
28. Facilitated Group Recovery and/or Support Meetings
29. Attend Substance Abuse Recovery Relapse Prevention and Support Groups
30. Work Site Monitor
31. Community Service Program
32. Restitution
33. Remedial Education
34. Ethics Course
35. Supervised Practice
36. No Ownership or Management of Licensed Premises
37. Separate File of Controlled Substances Records
38. Report of Controlled Substances
39. No Access to Controlled Substances
40. Criminal Probation/Parole Reports
41. ~~Tolling of Suspension~~Board's One-Day Training Program
42. Surrender of DEA Permit
43. Administrative Fine

STANDARD CONDITIONS: TO BE INCLUDED IN ALL PROBATIONS

1. Obey All Laws

Respondent shall obey all state and federal laws and regulations.

Respondent shall report any of the following occurrences to the board, in writing, within seventy-two (72) hours of such occurrence:

- an arrest or issuance of a criminal complaint, information or indictment ~~for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws~~
- a plea of guilty, or nolo contendere, no contest, or similar, in any state or federal criminal proceeding to any criminal complaint, information or indictment
- a conviction of any crime
- the filing of a disciplinary pleading, issuance of a citation, or initiation of another administrative action filed by any state or federal agency ~~which involves respondent's license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling, distributing, billing, or charging for any drug, device or controlled substance.~~

Failure to timely report such occurrence shall be considered a violation of probation.

2. Report to the Board

Respondent shall report to the board quarterly, on a schedule as directed by the board ~~or its designee~~. The report shall be made either in person or in writing, as directed. Among other requirements, respondent shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation.

Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the board.

3. Interview with the Board

Upon receipt of reasonable prior notice, respondent shall appear ~~in person~~ for interviews with the board ~~or its designee~~, at such intervals and locations as are determined by the board ~~or its designee~~. Failure to appear for any scheduled interview without prior notification to board staff, or failure to appear for two (2) or more scheduled interviews with the board ~~or its designee~~ during the period of probation, shall be considered a violation of probation.

4. Cooperate with Board Staff

Respondent shall timely cooperate with the board's inspection program and with the board's monitoring and investigation of respondent's compliance with the terms and conditions of ~~[his/her]~~their probation, including but not limited to: timely responses to requests for information by board staff; timely compliance with directives from board staff regarding requirements of any term or condition of probation; and timely completion of documentation pertaining to a term or condition of probation. Failure to timely cooperate shall be considered a violation of probation.

5. Continuing Education (Pharmacists Only)

Respondent shall provide evidence of efforts to maintain skill and knowledge as a pharmacist as directed by the board ~~or its designee~~that complies with Title 16 California Code of Regulations section 1732.3.

6. Reporting of Employment and Notice to Employers

During the period of probation, respondent shall notify all present and prospective employers of the decision in case number _____and the terms, conditions and restrictions imposed on respondent by the decision, as follows:

Within thirty (30) days of the effective date of this decision, and within ten (10) days of undertaking any new employment, respondent shall report to the board in writing the name, physical address, and mailing address of each of ~~[his/her]~~their employer(s), and the name(s) and telephone number(s) and email address(es) of all of ~~[his/her]~~their direct supervisor(s), as well as any pharmacist(s)-in- charge, designated representative(s)-in-charge, responsible manager, or other compliance supervisor(s) and the work schedule, if known. Respondent shall also include the reason(s) for leaving the prior employment and the last day worked. Respondent shall sign and return to the board a written consent authorizing the board ~~or its designee~~ to communicate with all of respondent's employer(s) and supervisor(s), and authorizing those employer(s) or supervisor(s) to communicate with the board~~ or its designee~~, concerning respondent's work status, performance, and monitoring. Failure to comply with the requirements or deadlines of this condition shall be considered a violation of probation.

Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment, respondent shall cause (a) ~~[his/her]~~their direct supervisor, (b) ~~[his/her]~~their pharmacist-in-charge, designated representative-in-charge, responsible manager, or other compliance supervisor, and (c) the owner or owner representative of ~~[his/her]~~their employer, to report to the board in writing acknowledging that the listed individual(s) has/have read the decision in case number _____, and terms and conditions imposed thereby. If one person serves in more than one role described in (a), (b), or (c), the acknowledgment shall so state. It shall be the respondent's responsibility to ensure that these acknowledgment(s) are timely submitted to the board. In the event of a change in the person(s) serving the role(s) described in (a), (b), or (c) during the term of probation, respondent shall cause the person(s) taking over the role(s) to report to the board in writing within fifteen (15) days of the change acknowledging that ~~he or she has~~they have read the decision in case number
_____, and the terms and conditions imposed thereby.

If respondent works for or is employed by or through an employment service, respondent must notify the person(s) described in (a), (b), and (c) above at every entity licensed by the board of the decision in case number _____, and the terms and conditions imposed thereby in advance of respondent commencing work at such licensed entity. A record of this notification must be provided to the board upon request.

Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment by or through an employment service, respondent shall cause the person(s) described in (a), (b), and (c) above at the employment service to report to the board in writing acknowledging that ~~he or she has~~they have read the decision in case number_____, and the terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that these acknowledgment(s) are timely submitted to the board.

Failure to timely notify present or prospective employer(s) or failure to cause the identified

person(s) with that/those employer(s) to submit timely written acknowledgments to the board shall be considered a violation of probation.

"Employment" within the meaning of this provision includes any full-time, part-time, temporary, relief, or employment/management service position as a [insert license type], or any position for which a [insert license type] license is a requirement or criterion for employment, whether the respondent is an employee, independent contractor or volunteer.

7. Notification of Change(s) in Name, Address(es), or Phone Number(s)

Respondent shall further notify the board ~~in writing~~as directed within ten (10) days of any change in name, residence address, mailing address, e-mail address or phone number.

Failure to timely notify the board of any change in employer, name, address, email address, or phone number, within 10 days, shall be considered a violation of probation.

8. Restrictions on Supervision and Oversight of Licensed Facilities (Not appropriate for Pharmacy Technicians)

During the period of probation, respondent shall not supervise any intern pharmacist, be the pharmacist-in-charge, designated representative-in-charge, responsible manager, supervising pharmacist, quality manager, designated individual (as defined in USP Chapter 797, including as an individual responsible and accountable for the performance and operations of the facility and personnel in the preparation of compounded sterile products) or other ~~compliance~~ supervisor, nor serve as a consultant of any entity licensed by the board~~, nor serve as a consultant~~. Assumption of any such unauthorized supervision responsibilities shall be considered a violation of probation.

Option 1 (To be included along with standard language when appropriate): During the period of probation, respondent shall not supervise any ancillary personnel, including, but not limited to, pharmacy technicians, designated representatives, designated representative-3PL, , designated individual (as defined in USP Chapter 797, including as an individual responsible and accountable for the performance and operations of the facility and personnel in the preparation of compounded sterile products), production operators in any entity licensed by the board. Assumption of any such unauthorized ancillary personnel supervision responsibilities shall be considered a violation of probation.

Option 2 (To be used in place of standard language when appropriate): During the period of probation, respondent shall not supervise any intern pharmacist or serve as a consultant to any entity licensed by the board. Respondent may be a pharmacist-in-charge, designated representative-in-charge, responsible manager, designated individual (as defined in USP Chapter 797, including as an individual responsible and accountable for the performance and operations of the facility and personnel in the preparation of compounded sterile products), or other compliance supervisor of any single entity licensed by the board, but only if respondent or that entity retains, at ~~[his/her]~~their own expense, an independent consultant who shall be responsible for reviewing the operations of the entity on a [monthly/quarterly] basis for compliance by respondent and the entity with state and federal laws and regulations governing the practice of the entity, and compliance by respondent with the obligations of ~~[his/her]~~their supervisory position. The consultant shall have sufficient education, training, and professional experience to be able to provide guidance to Respondent related to the causes for discipline in Case No. . Respondent may serve in such a position at only one entity licensed by the board, and only upon approval by the board ~~or its designee~~. Any such approval shall be site specific. The consultant shall be a pharmacist licensed by and not on probation with the board or other professional as appropriate and not on probation with the board, who has been approved by the board ~~or its designee~~ to serve in this position. Respondent shall submit the

name of the proposed consultant to the board ~~or its designee~~ for approval within thirty (30) days of the effective date of the decision or prior to assumption of duties allowed in this term. Assumption of any unauthorized supervision responsibilities shall be considered a violation of probation. In addition, failure to timely seek approval for, timely retain, or ensure timely reporting by the consultant shall be considered a violation of probation.

9. Reimbursement of Board Costs

As a condition precedent to successful completion of probation, respondent shall pay to the board its costs of investigation and prosecution in the amount of $_____. Respondent shall make said payments as follows:

There shall be no deviation from this schedule absent prior written approval by the board ~~or its designee~~. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

Option Respondent shall be permitted to pay these costs in a payment plan approved by the board ~~or its designee~~, so long as full payment is completed no later than one (1) year prior to the end date of probation.

10. Probation Monitoring Costs

Respondent shall pay any costs associated with probation monitoring as determined by the board each and every year of probation. Such costs shall be payable to the board on a schedule as directed by the board ~~or its designee~~. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

11. Status of License

Respondent shall, at all times while on probation, maintain an active, current [insert license type] license with the board, including any period during which suspension or probation is tolled. Failure to maintain an active, current [insert license type] license shall be considered a violation of probation.

If respondent's [insert license type] license expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof due to tolling or otherwise, upon renewal or reapplication respondent's license shall be subject to all terms and conditions of this probation not previously satisfied.

12. License Surrender While on Probation/Suspension

Following the effective date of this decision, should respondent cease practice due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, respondent may relinquish ~~[his/her]~~their license, including any indicia of licensure issued by the board, along with a request to surrender the license. The board ~~or its designee~~ shall have the discretion whether to accept the surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondent will no longer be subject to the terms and conditions of probation. This surrender constitutes a record of discipline and shall become a part of the respondent's license history with the board.

Upon acceptance of the surrender, respondent shall relinquish ~~[his/her]~~their pocket and/or wall license, including any indicia of licensure not previously provided to the board within ten (10) days of notification by the board that the surrender is accepted if not already provided. Respondent may not reapply for any license from the board for three (3) years from the

effective date of the surrender. Respondent shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board, including any outstanding costs.

13. Certification Prior to Resuming Work (Pharmacy Technicians Only)

Respondent shall be suspended, and shall not work as a pharmacy technician, until ~~[he/she] has~~they have been certified as defined by Business and Professions Code section 4202, subdivision (a)(4), and has submitted proof of certification to the board, and has been notified by the board ~~or its designee~~ that ~~[he/she]~~they may begin work. Failure to achieve certification within six (6) months of the effective date shall be considered a violation of probation.

During suspension, respondent shall not enter any pharmacy area or any portion of any other board licensed premises ~~of a wholesaler, third-party logistics provider, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area~~ where dangerous drugs and/or dangerous devices or controlled substances are maintained.

Respondent shall not ~~do any act involving drug selection, selection of stock, manufacturing, compounding or dispensing; nor shall respondent manage, administer,~~exercise any of the privileges conveyed by the board or assist any licensee of the board. Respondent shall not have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs and/or dangerous devices or controlled substances.

During this suspension, respondent shall not engage in any activity that requires licensure as a pharmacy technician. Respondent shall not direct or control any aspect of any board licensed premises~~the practice of pharmacy or of the manufacture, distribution, wholesaling, or retailing of dangerous drugs and/or dangerous devices, or controlled substances~~.

Failure to comply with any such suspension shall be considered a violation of probation.

Option: Respondent shall maintain an active, current certification as defined by Business and Professions Code section 4202, subdivision (a)(4), for the entire period of probation, and shall submit proof of re-certification or renewal of certification to the board within ten (10) days of receipt. Failure to maintain active, current certification or to timely submit proof of same shall be considered a violation of probation.

14. Practice Requirement – Extension of Probation

Except during periods of suspension, respondent shall, at all times while on probation, be employed as a [insert license type] in California for a minimum of _____hours per calendar month. Any month during which this minimum is not met shall extend the period of probation by one month. During any such period of insufficient employment, respondent must nonetheless comply with all terms and conditions of probation, unless respondent receives a waiver in writing from the board ~~or its designee~~.

If respondent does not practice as a [insert license type] in California for the minimum number of hours in any calendar month**,** for any reason (including vacation), respondent shall notify the board in writing within ten (10) days of the conclusion of that calendar month. This notification shall include at least: the date(s), location(s), and hours of last practice; the reason(s) for the interruption or reduction in practice; and the anticipated date(s) on which respondent will resume practice at the required level. Respondent shall further notify the board in writing within

ten (10) days following the next calendar month during which respondent practices as a [insert license type] in California for the minimum of hours. Any failure to timely provide such notification(s) shall be considered a violation of probation.

It is a violation of probation for respondent's probation to be extended pursuant to the provisions of this condition for a total period, counting consecutive and non-consecutive months, exceeding thirty-six (36) months. The board ~~or its designee~~ may post a notice of the extended probation period on its website.

Option: **(Pharmacist interns only)** During respondent's enrollment in a school or college of pharmacy, no minimum practice hours shall be required. Instead, respondent shall report to the board quarterly in writing, in a format and schedule as directed by the board ~~or its designee~~, on ~~[his/her]~~their compliance with academic and vocational requirements, and on ~~[his/her]~~their academic progress. Respondent must comply with all other terms and conditions of probation, unless notified in writing by the board ~~or its designee~~.

15. Violation of Probation

If respondent has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondent, and the board shall provide notice to respondent that probation shall automatically be extended, until all terms and conditions have been satisfied or the board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed. The board ~~or its designee~~ may post a notice of the extended probation period on its website.

If respondent violates probation in any respect, the board, after giving respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. If a petition to revoke probation or an accusation is filed against respondent during probation, or the preparation of an accusation or petition to revoke probation is requested from the Office of the Attorney General, the board shall have continuing jurisdiction and the period of probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided.

16. Completion of Probation

Upon written notice by the board ~~or its designee~~ indicating successful completion of probation, respondent's license will be fully restored.

OPTIONAL CONDITIONS OF PROBATION

17. Suspension

As part of probation, respondent is suspended from practice as a [insert license type] for [day(s)/month(s)/year(s)] beginning the effective date of this decision.

During suspension, respondent shall not enter any pharmacy area or any portion of any board ~~the~~ licensed premises ~~of a wholesaler, third-party logistics provider, veterinary food-animal drug retailer, or any other distributor of drugs that is licensed by the board, or any manufacturer, or any area~~ where dangerous drugs and/or dangerous devices or controlled substances are maintained.

Respondent shall not ~~practice pharmacy~~exercise any of the privileges conveyed by the board nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing

or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs and/or dangerous devices or controlled substances.

During this suspension, respondent shall not engage in any activity that requires the professional judgment of and/or licensure as a [insert license type]. Respondent shall not direct or control any aspect of any board licensed premises~~the practice of pharmacy or of the manufacturing, distributing, wholesaling, or retailing of dangerous drugs and/or dangerous devices or controlled substances~~.

Failure to comply with this suspension shall be considered a violation of probation.

Option: During the period of suspension, respondent shall not leave California for any period exceeding ten (10) days, regardless of purpose (including vacation). Any such absence in excess of ten (10) days during the period of suspension shall be considered a violation of probation, and shall toll the suspension, i.e., the suspension shall be extended by one day for each day over ten (10) days respondent is absent from California. During any such period of tolling of suspension, respondent must nonetheless comply with all terms and conditions of probation, unless respondent is notified otherwise in writing by the board ~~or its designee~~.

Respondent shall notify the board ~~or its designee~~ in writing within ten (10) days of any departure from California, for any period, and shall further notify the board ~~or its designee~~ in writing within ten (10) days of return. Failure to timely provide such notification(s) shall be considered a violation of probation. Upon such departure and return, respondent shall not resume practice until notified by the board ~~or its designee~~ that the period of suspension has been satisfactorily completed.

18. Restricted Practice

Respondent's practice as a [insert license type] shall be restricted to [specify setting or type of practice] for the first _____year(s) of probation. Respondent shall submit proof satisfactory to the board ~~or its designee~~ of compliance with this term of probation.

Option: Respondent shall not [sterile] ~~prepare~~compound, supervise ~~oversee, or participate in the preparation of~~ [sterile] ~~compounds~~ compounding, or be involved in [sterile] compounding during the first _____year(s) of probation. Upon request, respondent shall submit to the board ~~or its designee on~~in writing, satisfactory proof of compliance with this restriction, including but not limited to a written acknowledgment of this restriction signed by (a) respondent's direct supervisor, (b) the pharmacist-in-charge, and (c) the owner or owner representative of ~~his or her~~their employer, which explains whether the workplace in question compounds drug ~~preparations~~ products and how this restriction will be enforced. Failure to abide by this restriction or to timely submit proof to the board ~~or its designee~~ shall be considered a violation of probation.

19. Pharmacist Examination (Pharmacists Only)

Respondent ~~shall~~ must pass the examinations required for licensure as defined by Business and Professions Code section 4200, subdivision (a)~~take and pass the [California Pharmacist Jurisprudence Examination (CPJE) [and/or] the North American Pharmacist Licensure Examination (NAPLEX)]~~ within six (6) months of the effective date of this decision. If respondent fails to take and pass the examination(s) within six (6) months of the effective of this decision, respondent shall be automatically suspended from practice. Respondent shall not resume the practice of pharmacy until ~~[he/she]~~they take~~s~~ and pass~~es~~ the ~~[CPJE and/or NAPLEX]~~examination(s) and is notified, in writing, that ~~[he/she] has~~they have passed the examination(s) and may resume practice. Respondent shall bear all costs of the examination(s) required by the board.

During any- suspension, respondent shall not enter any pharmacy area or any portion of any boardthe licensed premises ~~of a wholesaler, third-party logistics provider, veterinary food-animal drug retailer, or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area~~ where dangerous drugs and/or dangerous devices or controlled substances are maintained. Respondent shall not ~~practice pharmacy~~exercise any of the privileges conveyed by the board nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs and/or dangerous devices and controlled substances.

During any suspension, respondent shall not engage in any activity that requires the professional judgment of and/or licensure as a pharmacist. Respondent shall not direct or control any aspect of any board licensed premises~~the practice of pharmacy or of the manufacturing, distributing, wholesaling, or retailing of dangerous drugs and/or dangerous devices and controlled substances~~.

Failure to comply with any suspension shall be considered a violation of probation.

Failure to take and pass the examination(s) within twelve (12) months of the effective date of this decision shall be considered a violation of probation.

If respondent fails to comply with licensure requirements as defined by Business and Professions Code section 4200, subdivision (a)~~take and pass the [CPJE and/or NAPLEX]~~ after four attempts, respondent shall successfully complete, at a minimum, sixteen (16) additional semester units of pharmacy education as approved by the board. Respondent shall complete the coursework, and submit proof of completion satisfactory to the board ~~or its designee~~, within three (3) months of the fourth failure of the examination. Failure to complete coursework or provide proof of such completion as required shall be considered a violation of probation.

20. Clinical Diagnostic Evaluation (Appropriate for those cases where evidence demonstrates that psychiatric disorders, mental ~~illness~~health issues, emotional disturbance, gambling addiction), diversion, self-administration, or ~~ab~~use of alcohol or drugs, or disability was a contributing cause of the violation(s).)

Within thirty (30) days of the effective date of this decision, and on a periodic basis thereafter if required by the board ~~or its designee~~, respondent shall undergo, at ~~[his/her]~~their own expense, clinical diagnostic evaluation(s) by a practitioner selected or approved prior to the evaluation by the board ~~or its designee~~. The approved evaluator shall be provided with a copy of the board's [accusation, petition to revoke probation, or other pleading] and decision. Respondent shall sign a release ~~authorizing~~ authorizing the evaluator to furnish the board with a current diagnosis and a written report regarding the respondent's judgment and ability to function independently as a [insert license type] with safety to the public. If the evaluator recommends restrictions or conditions on respondent's practice, including but not limited to other terms and ~~conditions~~ conditions listed in these guidelines (e.g., required psychotherapy, inpatient treatment, prescription coordination and monitoring, restricted practice), the board ~~or its designee~~ may by written notice to respondent adopt any such restrictions or conditions as additional probation terms and conditions, violation of which shall be considered a violation of probation. Failure to comply with any requirement or deadline stated by this paragraph shall be considered a violation of probation.

If at any time the approved evaluator or therapist determines that respondent is unable to practice safely or independently, the licensed mental health practitioner shall notify the board immediately by telephone and follow up by written letter or email within three (3) working days.

Upon notification from the board ~~or its designee~~ of this determination, respondent shall be automatically suspended and shall not resume practice until notified by the board ~~or its designee~~ that practice may resume.

Failure to comply with any requirement or deadline stated by this term shall be considered a violation of probation.

Option 1: (Appropriate for those cases where evidence demonstrates ~~ab~~use of alcohol or drugs. Option language to be used in addition to standard language**)**:
Commencing on the effective date of this decision, respondent is suspended from practice and shall not practice as a [insert license type] until:

- Respondent has undergone and completed clinical diagnostic evaluation(s);
- The report(s) of the evaluation(s) has/have been received by the board ~~or its designee~~;
- One or more report(s) has concluded that respondent is safe to return to practice as a [insert license type];
- The board ~~or its designee~~ is satisfied that respondent is safe to return to practice as a [insert license type];
- Respondent receives written notice from the board ~~or its designee~~ that practice may resume.

For all such evaluations, a final written report shall be provided to the board no later than ten (10) days from the date the evaluator is assigned the matter unless the evaluator requests additional information to complete the evaluation, not to exceed thirty (30) days.

During any suspension, respondent shall not enter any pharmacy area or any portion of any board ~~the~~ licensed premises ~~of a wholesaler, third-party logistics provider, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area~~ where dangerous drugs and/or dangerous devices or controlled substances are maintained. Respondent shall not ~~practice pharmacy~~exercise any of the privileges conveyed by the board nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs and/or dangerous devices or controlled substances.

During any suspension, respondent shall not engage in any activity that requires the professional judgment of and/or licensure as a [insert license type]. Respondent shall not direct or control any aspect of any board licensed premise~~the practice of pharmacy, or of the manufacturing, distributing, wholesaling, or retailing of dangerous drugs and/or dangerous devices or controlled substances~~.

Failure to comply with any requirement, including any suspension or deadline stated by this term shall be considered a violation of probation.

Option 2 Option language to be used in addition to standard language when deemed appropriate: Commencing on the effective date of this decision, respondent is suspended from practice and shall not practice as a [insert license type] until the evaluator recommends that respondent return to practice, this recommendation is accepted by the board ~~or its designee~~, and respondent receives written notice from the board ~~or its designee~~ that practice may resume.

The final written report of the evaluation shall be provided to the board no later than ten (10) days from the date the evaluator is assigned the matter unless the evaluator requests additional information to complete the evaluation, not to exceed thirty (30) days.

During any suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises ~~of a wholesaler, third-party logistics provider, veterinary food-animal drug retailer, or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area~~ where dangerous drugs and/or dangerous devices or controlled substances are maintained.

Respondent shall not ~~practice pharmacy~~exercise any of the privileges conveyed by the board nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs and/or dangerous devices or controlled substances.

During any suspension, respondent shall not engage in any activity that requires the professional judgment of and/or licensure as a [insert license type]. Respondent shall not direct or control any aspect of any board licensed premises~~the practice of pharmacy, or of the manufacturing, distributing, wholesaling, or retailing of dangerous drugs and/or dangerous devices or controlled substances~~.

Failure to comply with any requirement or deadline stated by this term shall be considered a violation of probation.

Option 3: If recommended by evaluator, the board ~~or its designee~~ may suspend respondent from practice as a [insert license type] by providing written notice of suspension to the respondent. Upon suspension, respondent shall not resume practice as a [insert license type] until: 1) another evaluation is done at respondent's expense by a licensed practitioner selected or approved by the board ~~or its designee~~; 2) the evaluator recommends that respondent return to practice; 3) the board ~~or its designee~~ accepts the recommendation; 4) and the board notifies the respondent in writing that practice may resume.

The report(s) from any such additional evaluation(s) shall be provided to the board ~~or its designee~~ in writing by the evaluator no later than ten (10) days from the date the evaluator is assigned the matter unless the evaluator requests additional information to complete the evaluation, not to exceed thirty (30) days.

During any suspension, respondent shall not enter any pharmacy area or any portion of any board ~~the~~ licensed premises ~~of a wholesaler, third-party logistics provider, veterinary food-animal drug retailer, or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area~~ where dangerous drugs and/or dangerous devices or controlled substances are maintained.

Respondent shall not ~~practice pharmacy~~exercise any of the privileges conveyed by the board nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs and/or dangerous devices or controlled substances.

During any suspension, respondent shall not engage in any activity that requires the professional judgment of and/or licensure as a [insert license type]. Respondent shall not direct or control any aspect of any board licensed premises~~the practice of pharmacy, or of the manufacturing,~~
~~distributing, wholesaling, or retailing of dangerous drugs and/or dangerous devices or controlled substances~~.

Failure to comply with any requirement or deadline stated by this term shall be considered a violation of probation.

21. Psychotherapy (Appropriate for those cases where the evidence demonstrates psychiatric disorders (mental ~~illness~~health issues, emotional disturbance, gambling addiction,) ~~or~~ alcohol or drug ~~ab~~use was involved in the violation(s).)

Within thirty (30) days of the effective date of this decision, respondent shall submit to the board ~~or its designee~~, for prior approval, the name and qualifications of a licensed mental health practitioner of respondent's choice. Within thirty (30) days of approval thereof, respondent shall submit documentation to the board demonstrating the commencement of psychotherapy with the approved licensed mental health practitioner. Respondent shall sign a release authorizing the mental health practitioner to furnish the board with a current diagnosis and a written report regarding the respondent's ability to function independently as a [insert license type] with no harm to the public. Should respondent, for any reason, cease treatment with the approved licensed mental health practitioner, respondent shall notify the board immediately and, within thirty (30) days of ceasing treatment, submit the name of a replacement psychotherapist or licensed mental health practitioner of respondent's choice to the board for its prior approval. Within thirty (30) days of approval thereof, respondent shall submit documentation to the board demonstrating the commencement of psychotherapy with the approved replacement. Failure to comply with any requirement or deadline stated by this paragraph shall be considered a violation of probation.

Upon approval of the initial or any subsequent licensed mental health practitioner, respondent shall undergo and continue treatment with that therapist, at respondent's own expense, until the therapist recommends in writing to the board, and the board ~~or its designee~~ agrees by way of a written notification to respondent, that no further psychotherapy is necessary. Upon receipt of such recommendation from the treating therapist, and before determining whether to accept or reject said recommendation, the board ~~or its designee~~ may require respondent to undergo, at respondent's own expense, a mental health evaluation by a board-appointed or board-approved psychiatrist or psychologist. If the approved evaluator recommends that respondent continue psychotherapy, the board ~~or its designee~~ may require respondent to continue psychotherapy.

Psychotherapy shall be at least once a week unless otherwise approved by the board. Respondent shall provide the therapist with a copy of the board's accusation and decision no later than the first therapy session. Respondent shall take all necessary steps to ensure that the treating therapist submits written quarterly reports to the board concerning respondent's fitness to practice, progress in treatment, and such other information required by the board ~~or its designee~~.

If at any time the treating therapist determines that respondent cannot practice safely or independently, the therapist shall notify the board immediately by telephone and follow up by written letter or email within three (3) working days. Upon notification from the board ~~or its designee~~ of this determination, respondent shall be automatically suspended and shall not resume practice

until notified by the board that practice may be resumed.

During any suspension, respondent shall not enter any pharmacy area or any portion of any board ~~the~~ licensed premises ~~of a wholesaler, third-party logistics provider, veterinary food-animal drug retailer, or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area~~ where dangerous drugs and/or dangerous devices or controlled substances are maintained.

Respondent shall not ~~practice pharmacy~~exercise any of the privileges conveyed by the board nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing

or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs and/or dangerous devices or controlled substances. Respondent shall not resume practice until notified by the board.

During any suspension, respondent shall not engage in any activity that requires the professional judgment of and/or licensure as a [insert license type]. Respondent shall not direct or control any aspect of any board licensed premises~~the practice of pharmacy, or of the manufacturing, distributing, wholesaling, or retailing of dangerous drugs and/or dangerous devices or controlled substances~~.

Failure to comply with any requirement or deadline stated by this term shall be considered a violation of probation.

22. Medical Evaluation (Appropriate for those cases where the evidence demonstrates that the respondent has had a physical problem/disability which was a contributing cause of the violations and which may affect the respondent's ability to practice.)

Within thirty (30) days of the effective date of this decision, and on a periodic basis thereafter as may be required by the board ~~or its designee~~, respondent shall undergo a medical evaluation, at respondent's own expense, by a board-appointed or board-approved ~~physician~~ health care practitioner who shall
furnish a medical report to the board. The approved ~~physician~~ practitioner shall be provided with a copy of the board's [accusation, petition to revoke probation, or other pleading] and decision. A
record of this notification must be provided to the board upon request. Respondent shall sign a release authorizing the ~~physician~~ practitioner to furnish the board with a current diagnosis and a written report regarding the respondent's ability to function independently as [insert license type] with ~~safety~~ no harm to the public. If the ~~physician~~ practitioner recommends restrictions or conditions on respondent's practice, including but not limited to other terms and conditions listed in these guidelines (e.g., required ~~psychotherapy~~mental health treatment, inpatient treatment, prescription coordination and monitoring, restricted practice), the board ~~or its designee~~ may by written notice to respondent adopt any such restrictions or conditions as additional probation terms and conditions, violation of which shall be considered a violation of probation.

If the physician recommends, and the board ~~or its designee~~ directs, that respondent undergo medical treatment, respondent shall, within thirty (30) days of written notice from the board, submit to the board ~~or its designee~~, for prior approval, the name and qualifications of a licensed ~~physician~~ health care practitioner of respondent's choice. Within thirty (30) days of approval thereof, respondent shall submit documentation to the board demonstrating the commencement of treatment with the
approved ~~physician~~practitioner. Should respondent, for any reason, cease treatment with the approved ~~physician~~practitioner, respondent shall notify the board immediately and, within thirty (30) days of ceasing treatment, submit the name of a replacement ~~physician~~ practitioner of respondent's choice to the board ~~or its designee~~ for prior approval. Within thirty (30) days of approval thereof, respondent shall submit documentation to the board demonstrating the commencement of treatment with the approved replacement. Failure to comply with any deadline stated by this paragraph shall be considered a violation of probation.

Upon approval of the initial or any subsequent ~~physician~~practitioner, respondent shall undergo and continue treatment with that ~~physician~~practitioner, at respondent's own expense, until the treating ~~physician~~ practitioner recommends in writing to the board, and the board ~~or its designee~~ agrees by way of a written notification to respondent, that no further treatment is necessary.

Upon receipt of such recommendation from the treating ~~physician~~practitioner, and before determining whether to accept or reject said recommendation, the board ~~or its designee~~ may require respondent to undergo, at respondent's own expense, a medical evaluation by a separate board-appointed or board- approved ~~physician~~health care practitioner. If the approved evaluating ~~physician~~ practitioner recommends that respondent continue treatment, the board ~~or its designee~~ may require respondent to continue treatment.

Respondent shall take all necessary steps to ensure that any treating ~~physician~~ practitioner submits written quarterly reports to the board concerning respondent's fitness to practice, progress in treatment, and other such information as may be required by the board ~~or its designee~~.

If at any time an approved evaluating ~~physician~~ practitioner or respondent's approved treating ~~physician~~ practitioner determines that respondent is unable to practice safely or independently as a [insert license type], the evaluating or treating ~~physician~~ practitioner shall notify the board immediately by telephone and follow up by written letter or email within three (3) working days. Upon notification from the board ~~or its designee~~ of this determination, respondent shall be automatically suspended and shall not resume practice until notified by the board that practice may be resumed.

During any suspension, respondent shall not enter any pharmacy area or any portion of any board~~the~~ licensed premises ~~of a wholesaler, third-party logistics providers, veterinary food-animal drug retailer, or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area~~ where dangerous drugs and/or dangerous devices or controlled substances are maintained.

Respondent shall not ~~practice pharmacy~~exercise any of the privileges conveyed by the board nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs and/or dangerous devices or controlled substances.

During any suspension, respondent shall not engage in any activity that requires the professional judgment of and/or licensure as a [insert license type]. Respondent shall not direct or control any aspect of any board licensed premises~~the practice of pharmacy, or of the manufacturing, distributing, wholesaling, or retailing of dangerous drugs and/or dangerous devices or controlled substances~~.

Failure to comply with any requirement or deadline stated by this term shall be considered a violation of probation.

(Option language to be used in addition to standard language when suspension is warranted until the evaluation is completed.)
Option 1: Commencing on the effective date of this decision, respondent shall not engage in the practice as a [insert license type] until notified in writing by the board that respondent has been deemed medically fit to practice safely and independently, and the board ~~or its designee~~ approves said recommendation.

During this suspension, respondent shall not enter any pharmacy area or any portion of any board ~~the~~ licensed premises ~~of a wholesaler, third-party logistics provider, veterinary food-animal~~ drug retailer, ~~or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area~~ where dangerous drugs and/or dangerous devices or controlled

substances are maintained.

Respondent shall not ~~practice as a [insert license type]~~exercise any of the privileges conveyed by the board nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs and/or dangerous devices or controlled substances. Respondent shall not resume practice until notified by the board.

During this suspension, respondent shall not engage in any activity that requires the professional judgment of and/or licensure as a [insert license type]. Respondent shall not direct or control any aspect of any board licensed premises~~the practice of pharmacy, or of the manufacturing, distributing, wholesaling, or retailing of dangerous drugs and/or dangerous devices or controlled substances~~.

Failure to comply with any requirement or deadline stated by this term shall be considered a violation of probation.

23. **Pharmacists Recovery Program (PRP)** (Appropriate for those cases where evidence demonstrates substance abuse or psychiatric disorders (mental ~~illness~~health issues, emotional disturbance, gambling addiction or substance abuse or misuse) (Pharmacists and Pharmacist Interns Only)

By no later than ten (10) days after the effective date of this decision, respondent shall have completed all of the following: contacted the Pharmacists Recovery Program (PRP) for evaluation; enrolled in the PRP; completed, signed, and returned the treatment contract as well as any addendums required or suggested by the PRP; successfully completed registration for any drug or alcohol testing mandated by the treatment contract and/or by enrollment in the PRP; and begun compliance with the drug or alcohol testing protocol(s). Respondent shall successfully participate in the PRP and complete the treatment contract and any addendums required or suggested by the PRP. The costs for PRP participation shall be borne by the respondent.

If respondent is currently enrolled in the PRP, said participation is now mandatory and as of the effective date of this decision is no longer considered a self-referral under Business and Professions Code section 4362 (a)(2). Respondent shall successfully participate in and complete ~~his or her~~their current contract and any subsequent addendums with the PRP.

Respondent shall pay administrative fees as invoiced by the PRP or its designee. Fees not timely paid to the PRP shall constitute a violation of probation. The board will collect unpaid administrative fees as part of the annual probation monitoring costs if not submitted to the PRP.

Any of the following shall result in the automatic suspension of practice by respondent and shall be considered a violation of probation:

- Failure to contact, complete enrollment, and execute and return the treatment contract with the PRP, including any addendum(s), within ten (10) days of the effective date of the decision as directed by the PRP;
- Failure to complete registration for any drug or alcohol testing mandated by the treatment contract and/or by the PRP, and begin compliance with the testing protocol(s), within ten (10) days of the effective date of the decision as directed by the PRP;

- Failure to comply with testing protocols regarding daily check-in and/or failure to complete a mandated test as directed by the PRP;
- Any report from the PRP of material non-compliance with the terms and conditions of the treatment contract and/or any addendum(s); or
- Termination by the PRP for non-compliance, failure to derive benefit, or as a public risk.

Respondent may not resume the practice of pharmacy until notified by the board in writing.

Probation shall be automatically extended until respondent successfully completes the PRP. The board will provide notice of any such suspension or extension of probation.

During any suspension, respondent shall not enter any pharmacy area or any portion of any board ~~the~~ licensed premises ~~of a wholesaler, third-party logistics provider, veterinary food-animal drug retailer, or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area~~ where dangerous drugs and/or dangerous devices or controlled substances are maintained. Respondent shall not ~~practice as a [insert license type]~~exercise any of the privileges conveyed by the board nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs and/or dangerous devices or controlled substances.

During any suspension, respondent shall not engage in any activity that requires the professional judgment of and/or licensure as a [insert license type]. Respondent shall not direct or control any aspect of any board licensed premises~~the practice of pharmacy, or of the manufacturing, distributing, wholesaling, or retailing of dangerous drugs and/or dangerous devices or controlled substances~~.

Failure to comply with any requirement or deadline stated by this term shall be considered a violation of probation.

(Option language to be used in addition to standard language when appropriate to ensure licensee works in an access position while being monitored.)
Option: Respondent shall work in a pharmacy setting with access to controlled substances for six (6) consecutive months before successfully completing the PRP. If respondent fails to do so, probation shall be automatically extended until this condition has been met. Failure to satisfy this condition within six (6) months beyond the original date of expiration of the term of probation shall be considered a violation of probation.

24. Drug and Alcohol Testing (Appropriate for those cases where the evidence demonstrates substance use.)

Respondent, at ~~[his/her]~~their own expense, shall participate in testing as directed by the board ~~or its designee~~ for the detection of alcohol, controlled substances, and dangerous drugs and/or dangerous devices. Testing protocols may include biological fluid testing (urine, blood), breathalyzer, hair follicle testing, or other testing protocols as directed by the board ~~or its designee~~. All testing must be pursuant to an observed testing protocol, unless respondent is informed otherwise in writing by the board ~~or its designee~~. Respondent may be required to participate in testing for the entire probation period and frequency of testing will be determined

by the board ~~or its designee~~.

By no later than thirty (30) days after the effective date of this decision, respondent shall have completed all of the following tasks: enrolled and registered with an approved drug and alcohol testing vendor; provided that vendor with any documentation, and any information necessary for payment by respondent; commenced testing protocols, including all required contacts with the testing vendor to determine testing date(s); and begun testing. At all times, respondent shall fully cooperate with the testing vendor, and with the board ~~or its designee~~, with regard to enrollment, registration, and payment for, and compliance with, testing. Any failure to cooperate timely shall be considered a violation of probation.

Respondent may be required to test on any day, including weekends and holidays. Respondent is required to make daily contact with the testing vendor to determine if a test is required, and if a test is required must submit to testing on the same day.

Prior to any vacation or other period of absence from the area where the approved testing vendor provides services, respondent shall seek and receive approval from the board ~~or its designee~~ to use an alternate testing vendor to ensure testing can occur. Upon approval, respondent shall enroll and register with the approved alternate drug testing vendor, provide to that alternate vendor any documentation required by the vendor, including any necessary payment by respondent. During the period of absence of the area, respondent shall commence testing protocols with the alternate vendor, including required daily contacts with the testing vendor to determine if testing is required, and required testing. Any failure to timely seek or receive approval from the board ~~or its designee~~, or to timely enroll and register with, timely commence testing protocols with, or timely undergo testing with, the alternate testing vendor, shall be considered a violation of probation.

Upon detection of an illicit drug, controlled substance or dangerous drug, the board ~~or its designee~~ may require respondent to timely provide documentation from a licensed practitioner authorized to prescribe the detected substance demonstrating that the substance was administered or ingested pursuant to a legitimate prescription issued as a necessary part of treatment. All such documentation shall be provided by respondent within ten (10) days of being requested.

Any of the following shall be considered a violation of probation and shall result in respondent being immediately suspended from practice as a [insert license type] until notified by the board in writing that ~~[he/she]~~they may resume practice: failure to timely complete all of the steps required for enrollment/registration with the drug testing vendor, including making arrangements for payment; failure to timely commence drug testing protocols; failure to contact the drug testing vendor as required to determine testing date(s); failure to test as required; failure to timely supply documentation demonstrating that a detected substance was taken pursuant to a legitimate prescription issued as a necessary part of treatment; and/or detection through testing of alcohol, or of an illicit drug, or of a controlled substance or dangerous drug absent documentation that the detected substance was taken pursuant to a legitimate prescription and a necessary treatment. In the event of a suspension ordered after detection through testing of alcohol, an illicit drug, or of a controlled substance or dangerous drug absent documentation that the detected substance was taken pursuant to a legitimate prescription and a necessary treatment, the board ~~or its designee~~ shall inform respondent of the suspension and inform ~~[him/her]~~them to immediately leave work, and shall notify respondent's employer(s) and work site monitor(s) of the suspension.

During any such suspension, respondent shall not enter any pharmacy area or any portion of any board
~~the~~ licensed premises ~~of a wholesaler, third-party logistics provider, veterinary food-animal drug retailer, or any other distributor of drugs which is licensed by the board, or any manufacturer, or~~

~~any area~~ where dangerous drugs and/or dangerous devices or controlled substances are maintained. Respondent shall not ~~practice pharmacy~~exercise any of the privileges by the board nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs and/or dangerous devices and controlled substances.

During any such suspension, respondent shall not engage in any activity that requires the professional judgment of and/or licensure as a [insert license type]. Respondent shall not direct or control any aspect of any board licensed premises~~the practice of pharmacy, or of the manufacturing, distributing, wholesaling, or retailing of dangerous drugs and/or dangerous devices~~.

Failure to comply with any such suspension shall be considered a violation of probation. Failure to comply with any requirement or deadline stated by this term shall be considered a violation of probation.

25. Notification of Departure

Within three (3) business days, ~~Prior~~ prior to leaving the probationary geographic area designated by the board ~~or its designee~~ for a period greater than twenty-four (24) hours, respondent shall notify the board verbally and in writing of the dates of departure and return. Failure to comply with this provision shall be considered a violation of probation.

26. Abstain from Drugs and Alcohol
(Appropriate for those cases where the evidence demonstrates substance use.)

Respondent shall completely abstain from the possession or use of alcohol, controlled substances, illicit drugs, dangerous drugs and/or dangerous devices, or their associated paraphernalia, except when possessed or used pursuant to a legitimate prescription issued as a necessary part of treatment. Respondent shall ensure that ~~[he/she] is~~they are not in the same physical location as individuals who are using illicit substances even if respondent is not personally ingesting the drugs. Any possession or use of alcohol, dangerous drugs and/or dangerous devices or controlled substances, or their associated paraphernalia for which a legitimate prescription has not been issued as a necessary part of treatment, or any physical proximity to persons using illicit substances, shall be considered a violation of probation.
Respondent shall sign an acknowledgment confirming receipt of a list of examples of prohibited substances.

27. Prescription Coordination and Monitoring of Prescription Use (Appropriate for those cases where the evidence demonstrates substance use or psychiatric disorders (mental ~~illness~~health, emotional disturbance, gambling addiction)

Within thirty (30) days of the effective date of this decision, respondent shall submit to the board, for its prior approval, the name and qualifications of a single ~~physician, nurse practitioner, physician assistant, or psychiatrist~~practitioner of respondent's choice, who shall be aware of the respondent's history [with the use of alcohol, illicit drugs, controlled substances, and/or dangerous drugs, and/or of mental ~~illness~~health issues, and/or of gambling addiction] and who will coordinate and monitor any prescriptions for respondent for dangerous drugs and/or dangerous devices, controlled substances or mood-altering drugs. The approved practitioner shall be provided with a copy of the board's [accusation, petition to revoke probation, or other pleading] and decision. A record of this notification must be provided to the board ~~or its designee~~ upon request. Respondent shall sign a release authorizing the practitioner to

communicate with the board ~~or its designee~~ about respondent's treatment(s). The coordinating ~~physician, nurse practitioner, physician assistant, or psychiatrist~~practitioner shall report to the board on a quarterly basis for the duration of probation regarding respondent's compliance with this condition. If any substances considered addictive have been prescribed, the report shall identify a program for the time limited use of any such substances. The board ~~or its designee~~ may require that the single coordinating ~~physician, nurse practitioner, physician assistant or psychiatrist~~practitioner be a specialist in addictive medicine, or consult a specialist in addictive medicine. Should respondent, for any reason, cease supervision by the approved practitioner, respondent shall notify the board ~~or its designee~~ immediately and, within thirty (30) days of ceasing supervision, submit the name of a replacement ~~physician, nurse practitioner, physician assistant, or psychiatrist~~practitioner of respondent's choice to the board ~~or its designee~~ for its prior approval. Failure to timely submit the selected practitioner or replacement practitioner to the board ~~or its designee~~ for approval, or to ensure the required quarterly reporting thereby, shall be considered a violation of probation.

If at any time an approved practitioner determines that respondent is unable to practice safely or independently as a [insert license type], the practitioner shall notify the board ~~or its designee~~ immediately by telephone and follow up by written letter or email within three (3) working days. Upon notification from the board ~~or its designee~~ of this determination, respondent shall be automatically suspended and shall not resume practice as a [insert license type] until notified by the board ~~or its designee~~ that practice may be resumed.

During ~~any~~ suspension, respondent shall not enter any pharmacy area or any portion of any board ~~the~~ licensed premises ~~of a wholesaler, third-party logistics provider, veterinary food-animal drug retailer, or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area~~ where dangerous drugs and/or dangerous devices or controlled substances are maintained. Respondent shall not ~~practice pharmacy~~exercise any of the privileges conveyed by the board nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs and/or dangerous devices and controlled substances. Respondent shall not resume practice until notified by the board.

During ~~any~~ suspension, respondent shall not engage in any activity that requires the professional judgment and/or licensure as a [insert license type]. Respondent shall not direct or control any aspect of any board licensed premises~~the practice of pharmacy or of the manufacturing, distributing, wholesaling, or retailing of dangerous drugs and/or dangerous devices or controlled substances~~.

Failure to comply with any requirement or deadline stated by this term shall be considered a violation of probation.

28. Facilitated Group Recovery and/or Support Meetings (Appropriate for those cases where the evidence demonstrates substance use. Pharmacists and Pharmacist Interns Only)

Within thirty (30) days of the effective date of this decision, respondent shall begin regular attendance at a group recovery and/or support meeting that is run by a trained facilitator approved in advance by the board~~ or its designee~~. The required frequency of group meeting attendance shall be determined by the board~~ or its designee~~. Respondent shall continue regular attendance as directed at an approved facilitated group meeting until the board ~~or its designee~~ advises the respondent in writing that ~~[he/she]~~they may cease regular attendance.

Respondent shall provide signed and dated documentation of attendance as required with each quarterly report. Failure to attend as required or to submit documentation of attendance shall be

considered a violation of probation.

If respondent is required to participate in the PRP, compliance with this term can be demonstrated through that program. Where respondent is enrolled in the PRP, participation as required in a facilitated group meeting approved by the PRP shall be sufficient for satisfaction of this requirement. Any deviation from participation requirements for the PRP-approved group shall be considered a violation of probation.

29. Attend Substance Abuse Recovery Relapse Prevention and Support Groups (Appropriate for those cases where the evidence demonstrates substance use.)

Within thirty (30) days of the effective date of this decision, respondent shall begin regular attendance at a recognized and established substance abuse recovery support group in California (e.g., Alcoholics Anonymous, Narcotics Anonymous, etc.) which has been approved by the board ~~or its designee~~. Respondent must attend the number of group meetings per week or month directed by the board ~~or its designee~~, which shall typically be at least one per week. Respondent shall continue regular attendance and submit signed and dated documentation confirming attendance with each quarterly report for the duration of probation. Failure to attend or submit documentation thereof shall be considered a violation of probation.

Where respondent is enrolled in the PRP, participation as required in a recovery group meeting approved by the PRP shall be sufficient for satisfaction of this requirement. Any deviation from participation requirements for the PRP-approved group shall be considered a violation of probation.

30. Work Site Monitor (Appropriate for those cases where the evidence demonstrates substance use.)

Within ten (10) days of the effective date of this decision, respondent shall identify a work site monitor, for prior approval by the board ~~or its designee~~, who shall be responsible for supervising respondent during working hours. Respondent shall be responsible for ensuring that the work site monitor reports in writing to the board monthly or on another schedule as directed by the board ~~or its designee~~. Should the designated work site monitor suspect at any time during the probationary period that respondent has abused alcohol or drugs, ~~he or she~~they shall notify the board immediately.

In the event of suspected abuse, the monitor shall make at least oral notification within one (1) business day of the occurrence, and shall be followed by written notification within two (2) business days of the occurrence. If, for any reason, including change of employment, respondent is no longer able to be monitored by the approved work site monitor, within ten (10) days respondent shall designate a new work site monitor for approval by the board ~~or its designee~~. Failure to timely identify an acceptable initial or replacement work site monitor, or to ensure monthly reports are submitted to the board by the monitor, shall be considered a violation of probation.

Within thirty (30) days of being approved by the board ~~or its designee~~, the work site monitor shall sign an affirmation that ~~he or she has~~they have reviewed the terms and conditions of respondent's disciplinary order and agrees to monitor respondent. The work site monitor shall at least:

1) Have regular face-to-face contact with respondent in the work environment, at least once per week or with greater frequency if required by the board ~~or its designee~~;
2) Interview other staff in the office regarding respondent's behavior, if applicable; and
3) Review respondent's work attendance.

The written reports submitted to the board ~~or its designee~~ by the work site monitor shall include at least the following information: respondent's name and license number; the monitor's name, license number (if applicable) and work site location; the date(s) the monitor had face-to-face contact with respondent; the staff interviewed, if applicable; an attendance report; notes on any changes in respondent's behavior or personal habits; notes on any indicators that may lead to substance abuse; and the work site monitor's signature.

Respondent shall complete the required consent forms and sign an agreement with the work site monitor and the board to allow the board to communicate with the work site monitor.

Option (Alternate language that is appropriate for respondents enrolled in PRP or who are given the PRP enrollment term: It is a condition of respondent's enrollment in the Pharmacists Recovery Program (PRP) that ~~[he/she] is~~they are required to have a work site monitor approved by the PRP who shall be responsible for supervising respondent during working hours. Respondent shall be responsible for ensuring that the work site monitor reports in writing to the PRP monthly or on another schedule as directed by the PRP. Should the designated work site monitor suspect at any time during the probationary period that respondent has abused alcohol or drugs, ~~he or she~~they shall notify the PRP immediately. The initial notification shall be made orally within one (1) business day of the occurrence, which shall be followed by written notification within two (2) business days of the occurrence. If, for any reason, including change of employment, respondent is no longer able to be monitored by the approved work site monitor, within ten (10) days of commencing new employment for prior approval by the PRP. Failure to identify an acceptable initial or replacement work site monitor, or to ensure monthly reports are submitted to the PRP by the work site monitor, shall be considered a violation of probation.

Within thirty (30) days of being approved by the PRP, the work site monitor shall sign an affirmation that ~~he or she has~~they have reviewed the terms and conditions of respondent's disciplinary order and agrees to monitor respondent. The work site monitor shall at least:

1) Have regular face-to-face contact with respondent in the work environment, at least once per week or with greater frequency if required by the board ~~or its designee~~;
2) Interview other staff in the office regarding respondent's behavior, if applicable; and
3) Review respondent's work attendance.

The written reports submitted to the PRP by the work site monitor shall include at least the following information: respondent's name and license number; the monitor's name, license number (if applicable) and work site location; the date(s) the monitor had face-to-face contact with respondent; the staff interviewed, if applicable; an attendance report; notes on any changes in respondent's behavior or personal habits; notes on any indicators that may lead to substance abuse; and the work site monitor's signature.

Respondent shall complete the required consent forms and sign an agreement with the work site monitor and the board to allow the board to communicate with the work site monitor.

31. Community Service~~s~~ Program

Within sixty (60) days of the effective date of this decision, respondent shall submit to the board ~~or its designee~~, for prior approval, a community service program in which respondent shall provide free [insert type of service, e.g., health-care related services] on a regular basis to a community or charitable facility or agency for at least _____hours per _____for the first _____of probation. Within thirty (30) days of board approval thereof, respondent shall submit documentation to the board ~~or its designee~~ demonstrating commencement of the community service program. Respondent shall report on progress with the community service program in the quarterly reports and provide satisfactory documentary evidence of such

progress to the board ~~or its designee~~ upon request. Failure to timely submit, commence, or comply with the program shall be considered a violation of probation.

32. Restitution (Appropriate in cases of drug diversion, theft, fraudulent billing, or patient harm resulting from negligence or incompetence.)

Within _____ days of the effective date of this decision, respondent shall pay restitution to _____ in the amount of $_____. Failure to make restitution by this deadline shall be considered a violation of probation.

33. Remedial Education

Within [thirty (30), sixty (60), ninety (90)] days of the effective date of this decision, respondent shall submit to the board ~~or its designee~~, for prior approval, an appropriate program of remedial education related to [the grounds for discipline]. The program of remedial education shall consist of at least _____hours, which shall be completed within _____months/year at respondent's own expense. All remedial education shall be in addition to, and shall not be credited toward, continuing education (CE) courses used for license renewal purposes for pharmacists.

Failure to timely submit for approval or complete the approved remedial education shall be considered a violation of probation. The period of probation will be automatically extended until such remedial education is successfully completed and written proof, in a form acceptable to the board, is provided to the board ~~or its designee~~.

Following the completion of each course, the board ~~or its designee~~ may require the respondent, at ~~[his/her]~~their own expense, to take an approved examination to test the respondent's knowledge of the course. If the respondent does not achieve a passing score, as determined by the provider, on the examination that course shall not count towards satisfaction of this term. Respondent shall take another course approved by the board in the same subject area.

Option: Respondent shall be restricted from the practice of [areas where a serious deficiency has been identified] until the remedial education program has been successfully completed.

34. Ethics Course (Pharmacists, Advanced Practice Pharmacists and Pharmacist Intern Only)

Within sixty (60) calendar days of the effective date of this decision, respondent shall enroll in a course in ethics, at respondent's expense, approved in advance by the board ~~or its designee~~ that complies with Title 16 California Code of Regulations section 1773.5. ~~Respondent~~ Within five (5) days of enrollment, respondent shall provide proof of enrollment ~~upon request~~to the board. Within five (5) days of completion, respondent shall submit a copy of the certificate of completion to the board ~~or its designee~~. Failure to timely enroll in an approved ethics course, to initiate the course during the first year of probation, to successfully complete it before the end of the second year of probation, or to timely submit proof of completion to the board ~~or its designee~~, shall be considered a violation of probation.

35. Supervised Practice (See Option for Pharmacy Technicians.)

Within thirty (30) days of the effective date of this decision, respondent shall submit to the board ~~or its designee~~, for prior approval, the name of a [insert license type] licensed by and not on probation with the board, to serve as respondent's practice supervisor. As part of the documentation submitted, respondent shall cause the proposed practice supervisor to report to the board in writing acknowledging that ~~he or she has~~they have read the decision in case

number [insert case number], and is familiar with the terms and conditions imposed thereby, including the level of supervision required by the board ~~or its designee~~. This level will be determined by the board ~~or its designee~~, will be communicated to the respondent on or before the effective date of this decision and shall be one of the following:

Continuous – At least 75% of a work week
Substantial - At least 50% of a work week
Partial - At least 25% of a work week
Daily Review - Supervisor's review of probationer's daily activities within 24 hours

Respondent may practice only under the required level of supervision by an approved practice supervisor. If, for any reason, including change of employment, respondent is no longer supervised at the required level by an approved practice supervisor, within ten (10) days of this change in supervision respondent shall submit to the board ~~or its designee~~, for prior approval, the name of a [insert license type] licensed by and not on probation with the board, to serve as respondent's replacement practice supervisor. As part of the documentation submitted, respondent shall cause the proposed replacement practice supervisor to report to the board in writing acknowledging that ~~he or she has~~they have read the decision in case number [insert case number], and is familiar with the terms and conditions imposed thereby, including the level of supervision required.

Any of the following shall result in the automatic suspension of practice by a respondent and shall be considered a violation of probation:

- Failure to nominate an initial practice supervisor, and to have that practice supervisor report to the board in writing acknowledging the decision, terms and conditions, and supervision level, within thirty (30) days;
- Failure to nominate a replacement practice supervisor, and to have that practice supervisor report to the board in writing acknowledging the decision, terms and conditions, and supervision level, within ten (10) days;
- Practicing in the absence of an approved practice supervisor beyond the initial or replacement nomination period; or
- Any failure to adhere to the required level of supervision.

Respondent shall not resume practice until notified in writing by the board ~~or its designee~~.

During any suspension, respondent shall not enter any pharmacy area or any portion of any board ~~the~~ licensed premises ~~of a wholesaler, third-party logistics provider, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area~~ where dangerous drugs and/or dangerous devices or controlled substances are maintained. Respondent shall not ~~practice pharmacy~~exercise any of the privileges conveyed by the board nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs and/or dangerous devices or controlled substances.

During any suspension, respondent shall not engage in any activity that requires the professional judgment and/or licensure as a [insert license type]. Respondent shall not direct or control any aspect of any board licensed premises~~the practice of pharmacy or of the manufacture, distribution, wholesaling, or retailing of dangerous drugs and/or dangerous devices or controlled substances~~.

Failure to comply with any suspension shall be considered a violation of probation.

Option: (For Pharmacy Technicians Only)

Within thirty (30) days of the effective date of this decision, respondent shall submit to the board ~~or its designee~~, for prior approval, the name of a pharmacist licensed by and not on probation with the board, to serve as respondent's practice supervisor. As part of the documentation submitted, respondent shall cause the proposed practice supervisor to report to the board in writing acknowledging that ~~her or she has~~they have read the decision in case number [insert case number], and is familiar with the terms and conditions imposed thereby, including the level of supervision required by the board ~~or its designee~~. Respondent may have multiple supervisors approved by the board if necessary to meet respondent's work requirements.

Any of the following shall be considered a violation of probation: failure to timely nominate either an initial or a replacement practice supervisor; failure to cause the practice supervisor to timely report to the board in writing acknowledging the decision, terms and conditions, and supervision level; practicing in the absence of an approved practice supervisor after lapse of the nomination period; and/or failure to adhere to the level of supervision required by the board ~~or its designee~~. If any of these obligations or prohibitions is not met, respondent shall be prohibited from practice as a [insert license type] and may not resume such practice until notified by the board ~~or its designee~~ in writing.

36. No Ownership or Management of Licensed Premises

Respondent shall not own, have any legal or beneficial interest in, nor serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board. Respondent shall sell or transfer any legal or beneficial interest in any entity licensed by the board within ninety (90) days following the effective date of this decision and shall immediately thereafter provide written proof thereof to the board. Failure to timely divest any legal or beneficial interest(s) or provide documentation thereof shall be considered a violation of probation.

Option (To be used in place of the standard language in those circumstances where respondent is permitted to continue existing ownership of a licensed entity): Respondent shall not acquire any new ownership, legal or beneficial interest nor serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any additional business, firm, partnership, or corporation licensed by the board. If respondent currently owns or has any legal or beneficial interest in, or serves as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board, respondent may continue to serve in such capacity or hold that interest, but only to the extent of that position or interest as of the effective date of this decision. Violation of this restriction shall be considered a violation of probation.

37. Separate File of Controlled Substances Records (Pharmacist owners and pharmacists-in-charge)

Respondent shall maintain and make available for inspection a separate file of all records pertaining to the acquisition or disposition of all controlled substances. Failure to maintain such file or make it available for inspection shall be considered a violation of probation.

38. Report of Controlled Substances (Pharmacist owners and pharmacists-in-charge)

Respondent shall submit reports to the board detailing the total acquisition and disposition of such controlled substances as the board ~~or its designee~~ may direct. Respondent shall specify the manner of disposition (e.g., by prescription, due to burglary, etc.) or acquisition (e.g., from a manufacturer, from another retailer, etc.) of such controlled substances. Respondent shall report on a quarterly basis or as directed by the board ~~or its designee~~. The report shall be delivered or mailed to the board no later than ten (10) days following the end of the reporting period as determined by the board ~~or its designee~~. Failure to timely prepare or submit such reports shall be considered a violation of probation.

39. No Access to Controlled Substances

During the period of probation and as directed by the board ~~or its designee~~, respondent shall not order, possess, dispense or otherwise have access to any controlled substance(s) in Schedules I, II, III, IV or V (Health and Safety Code sections 11054 -11058 inclusive). Respondent shall not order, receive or retain any security prescription forms. Failure to comply with this restriction shall be considered a violation of probation.

40. Criminal Probation/Parole Reports

Within ten (10) days of the effective date of this decision, or within ten (10) days of the issuance or assignment/replacement of same, whichever is earlier, respondent shall provide the board ~~or its designee~~ in writing: a copy of the conditions of any criminal probation/parole applicable to respondent; and the name and contact information of any probation, parole or similar supervisory officer assigned to respondent. Respondent shall provide a copy of all criminal probation/parole reports to the board within ten (10) days after such report is issued. Failure to timely make any of the submissions required hereby shall be considered a violation of probation.

41. Board's One-Day Training Program

Within the first year of probation, respondent shall enroll in the board's one-day, six (6) hour, training program, *"Preventing Prescription Drug Abuse and Drug Diversion."* Respondent shall provide proof of enrollment within five (5) days of enrollment. Within five (5) days of completion, Respondent shall submit a copy of the certificate of completion to the board. Failure to timely enroll in the training program, to initiate the training program during the first year of probation, to successfully complete it before the end of the second year of probation, or to timely submit proof of completion to the board, shall be considered a violation of probation.

42. Surrender of DEA Permit (Pharmacists, Advanced Practice Pharmacists and Pharmacist Intern Only)

Within thirty (30) days of the effective date of this decision, respondent shall surrender ~~[his/her]~~their federal Drug Enforcement Administration (DEA) permit to the DEA, for cancellation. Respondent shall provide documentary proof of such cancellation to the board ~~or its designee~~. Respondent is prohibited from dispensing, furnishing, or otherwise providing dangerous drugs

and/or dangerous devices or controlled substances until the board has received satisfactory proof of cancellation. Thereafter, respondent shall not apply/reapply for a DEA registration number without the prior written consent of the board ~~or its designee~~.

Option 1: Respondent may obtain a DEA permit restricted to Schedule(s) _____ controlled substance(s).

Option 2: Respondent shall not order, receive, or retain any federal order forms, including DEA form 222 forms, for controlled substances.

43. Administrative Fine

Respondent shall pay an administrative fine to the board in the amount of _____. Respondent shall have [insert timeframe] from the effective date of this Decision and Order to pay the administrative fine. Failure to pay the administrative fine as ordered, shall be considered a violation of probation.

TERMS OF PROBATION – PREMISES

A three-year probation period has been established by the board as the minimum appropriate length in most cases where probation is imposed. A minimum five-year probation period has been established by the board as appropriate where self-administration or diversion of dangerous drugs or devices or controlled substances has occurred at a licensed premises. Terms and conditions are imposed to provide consumer protection. A suspension period may also be required as part of the probation order. The board prefers that any stayed order be for revocation rather than for some period of suspension.

Probation conditions are divided into two categories: (1) standard conditions that shall appear in all probation cases, and (2) optional conditions that depend on the nature and circumstances of a particular case. These conditions may vary depending on the nature of the offense(s).

The board may also impose any other condition appropriate to the case where the condition is not contrary to public policy.

CATEGORIES OF VIOLATIONS AND RECOMMENDED PENALTIES

The California Pharmacy Law identifies offenses for which the board may take disciplinary action against a license. Included among grounds for discipline are violations of the Pharmacy Law itself, violations of regulations promulgated by the board, and violations of other state or federal statutes or regulations.

For those licenses issued to premises the board has identified four (4) categories of violations and associated recommended minimum and maximum penalties for each. These categories of violations are arranged in ascending order from the least serious (Category I) to the most serious (Category IV), although any violation in any category, or any combination of violation(s) in one or more categories, may merit revocation.

For each violation category, the board has given offense descriptions and examples where violations would typically merit the recommended range of minimum to maximum penalties for that category. These descriptions and examples are representative, and are not intended to be comprehensive or exclusive. Where a violation not included in these lists is a basis for disciplinary action, the appropriate penalty for that violation may be best derived by comparison to any analogous violation(s) that are included. Where no such analogous violation is listed, the category descriptions may be consulted.

These categories ~~assume~~ presume a single violation. For multiple violations, the appropriate penalty shall increase accordingly. Moreover, if respondent has committed violations in more than one category, the minimum and maximum penalties shall be those recommended in the highest category.

The board also has the authority, pursuant to Business and Professions Code section 4301(n), to impose discipline based on disciplinary action taken by another jurisdiction. The discipline imposed by the board will depend on the discipline imposed by the other jurisdiction, the extent of the respondent's compliance with the terms of that discipline, the nature of the conduct for which the discipline was imposed, and other factors set forth in these guidelines.

CATEGORY I

Minimum: Revocation; Revocation stayed; two years probation. All standard terms and conditions shall be included and the disciplinary order may include optional terms and conditions, as appropriate.

Maximum: Revocation

Category I discipline is recommended for violations which are less serious than Categories II through IV but are potentially harmful:

- violation(s) of recordkeeping requirements, ~~scope of practice requirements,~~ or inventory control requirements;
- smaller or isolated failure(s) to abide by or enforce prescription or refill requirements, drug-substitution requirements, or labeling requirements;
- violation(s) of obligations to supply or update information to the board, or to other enforcement or regulatory agencies;
- failure(s) to adequately supervise staff to ensure security and sanitation of premises, dangerous drugs and/or dangerous devices or controlled substances;
- violation(s) of packaging requirements, security control requirements, or reporting requirements; and
- failure(s) to display original license(s), or to supply name(s) of owner(s), manager(s), or employee(s).
- violation(s) involving the improper compounding of drug products
- institution or use of policies and procedures that are in violation of laws or regulations governing pharmacy

CATEGORY II

Minimum: Revocation; Revocation stayed, three years probation (five years probation where self-administration or diversion of dangerous drugs and/or dangerous devices or controlled substances occurred at the licensed premises). All standard terms and conditions shall be included and the disciplinary order may include optional terms and conditions, as appropriate.

Maximum: Revocation

Category II discipline is recommended for violations with serious potential for harm, as well as for violations involving disregard for public safety or for laws or regulations pertaining to pharmacy and/or to the dispensing or distributing of dangerous drugs and/or dangerous devices or controlled substances, violations that reflect on ethics, competency, or diligence, and criminal convictions not involving alcohol, dangerous drugs and/or dangerous devices, or controlled substances. Violations in this category may include:

- failure(s) to abide by prohibitions on referral rebates or discounts (kickbacks) and/or volume or percentage-based lease agreements;
- violation(s) of advertising or marketing limitations, including use of false or misleading advertising or marketing;
- repeat or serious violation(s) of recordkeeping requirements, scope of practice requirements, or inventory control requirements;
- violation(s) of controlled substance secure prescription requirements, inventory controls, or security requirements;
- failure(s) to meet compliance requirements, including pharmacist-in-charge or designated representative-in-charge designation and duties;
- violation(s) of monitoring and reporting requirements with regard to chemically,

mentally, or physically impaired licensees or employees;

- repeat or serious failure(s) to adequately supervise staff or ensure security and sanitation of premises, dangerous drugs and/or dangerous devices or controlled substances;
- violation(s) of laws governing dangerous drugs and/or dangerous devices and controlled substances, including smaller cases of diversion or self-administration;
- unlawful possession(s) of dangerous drugs and/or dangerous devices, controlled substances, hypodermic needles or syringes, or drug paraphernalia;
- smaller scale dispensing or furnishing of dangerous drugs and/or dangerous devices via the internet, without a valid prescription;
- purchasing, trading, selling, or transferring dangerous drugs and/or dangerous devices to or from unauthorized person(s);
- failure(s) to make required reports to the board or to other regulatory agencies, including CURES obligations and reporting to the DEA;
- violation(s) of quality assurance and self-assessment obligations, failure(s) to ensure properly trained staff and conduct practice safely;
- failure(s)~~(s)~~ to perform drug utilization reviews, monitor patient medication profiles, or promote safety and efficacy of prescribed drugs or devices or controlled substances; repeat failure(s) to provide patient consultation
- repeat or serious deviation(s) from the requirements of prescription(s) or failure(s) to clarify erroneous or uncertain prescription(s);
- gross immorality, incompetence, gross negligence, clearly excessive furnishing of controlled substances, moral turpitude, dishonestly, or fraud;
- criminal conviction(s) not involving alcohol, dangerous drugs and/or dangerous devices or controlled substances;
- violating, assisting in or abetting violation of, or conspiring to violate the laws and regulations governing pharmacy; and
- subverting or attempting to subvert an investigation conducted by the board.
- repeat or serious violation(s) involving the improper compounding of drug products

CATEGORY III

Minimum: Revocation; Revocation stayed, 90 days actual suspension, three to five years probation (five years probation where self-administration or diversion of dangerous drugs and/or dangerous devices or controlled substances, or abusive use of alcohol, occurred at the licensed premises). All standard terms and conditions shall be included and the disciplinary order may include optional terms and conditions, as appropriate. For a licensed premises, a minimum of 14-28 days actual suspension.

Maximum: Revocation

Category III discipline is recommended for violations where potential for harm is greater, more imminent, or more serious than it is for Category II violations, as well as for violations that involve knowingly or willfully violating laws or regulations pertaining to pharmacy and/or to the dispensing or distributing of dangerous drugs and/or dangerous devices or controlled substances, and most criminal convictions involving alcohol, dangerous drugs and/or dangerous devices or controlled substances. Violations in this category may include:

- violation(s) involving creation, manipulation, perpetuation, or disregard of drug shortages;
- failure(s) to deploy or abide by Drug Supply Chain Security Act requirements;
- violation(s) of licensee's corresponding responsibility to ensure the proper prescribing and dispensing of controlled substances;

- dispensing or furnishing without valid prescription, dispensing or furnishing to unauthorized person(s);
- violation(s) involving fraudulent acts committed in connection with the licensee's practice;
- repeat or serious unlawful possession(s) of dangerous drugs and/or dangerous devices,
  controlled substances, hypodermic needles or syringes, or drug paraphernalia;
- larger scale dispensing or furnishing of dangerous drug(s) and/or dangerous device(s) via the internet, without valid prescription(s);
- purchasing, trading, selling, or transferring adulterated, misbranded, or expired dangerous drug(s) and/or dangerous device(s);
- removal, sale, or disposal of embargoed dangerous drug(s) and/or dangerous device(s);
- failing to maintain record(s) of acquisition and disposition of dangerous drug(s) and/or dangerous devise(s) or controlled substances
- resale(s) of preferentially prices drugs, contract bid diversion, or other instances of improper sale(s) or resale(s);
- repeat or serious violation(s) of quality assurance and self-assessment obligations, failure(s) to ensure properly trained staff and conduct practice safely;
- repeat or serious failure(s) to perform drug utilization reviews, monitor patient medication profiles, or promote safety and efficacy of prescribed drugs;
- forgery of prescriptions, passing of forged prescriptions, or other unlawful means of acquiring dangerous drug(s) and/or dangerous device(s) or controlled substances(s);
- repeat or serious acts violating, assisting in or abetting violation of, or conspiring to violate the laws and regulations governing pharmacy; and
- violation(s) involving providing or offering to provide controlled substance(s) to addict(s).
- repeat or serious violation(s) involving the improper compounding of drug products

CATEGORY IV

Penalty: Revocation

Category IV discipline (revocation) is recommended for the most serious violations of laws or regulations pertaining to pharmacy and/or to the dispensing or distributing of dangerous drugs and/or dangerous devices or controlled substances. Violations in this category may include:

- violation(s) involving possession for sale, transportation, importation, and/or use of a minor for unlawful acquisition of sale, of controlled substances;
- criminal conviction(s) involving the above, or repeat convictions involving diversion or abuse of alcohol, dangerous drugs and/or dangerous devices, or controlled substances; and
- repeat or serious example(s) of conduct described in Category I, Category II, or Category III.

Revocation is also recommended where a respondent fails to file a notice of defense to a pleading requiring a timely notice of defense or to appear at a disciplinary hearing, where a respondent violates the terms and conditions of probation from a previous disciplinary order, or where prior discipline has been imposed on the license.

MODEL DISCIPLINARY LANGUAGE - PREMISES

The following standardized language shall be used in every decision where the order or condition is imposed.

Revocation

License number _____, issued to respondent _____, is revoked.

Respondent shall, by the effective date of this decision, arrange for the destruction of, the transfer to, sale of or storage in a facility licensed by the board of all dangerous drugs and/or dangerous devices or controlled substances and dangerous drugs and/or dangerous devices. Respondent shall further arrange for the transfer of all records of acquisition and disposition of dangerous drugs to premises licensed and approved by the board. Respondent shall provide written proof of such disposition, submit a completed Discontinuance of Business form and return the wall and renewal license to the board within five (5) days of disposition.

Respondent shall also, by the effective date of this decision, arrange for the continuation of care for ongoing patients of the pharmacy by, at minimum, providing a written notice to ongoing patients that specifies the anticipated closing date of the pharmacy and that identifies one or more area pharmacies capable of taking up the patients' care, and by cooperating as may be necessary in the transfer of records or prescriptions for ongoing patients. Within five (5) days of its provision to the pharmacy's ongoing patients, Respondent shall provide a copy of the written notice to the board. For the purposes of this provision, "ongoing patients" means those patients for whom the pharmacy has on file a prescription with one or more refills outstanding, or for whom the pharmacy has filled a prescription within the preceding sixty (60) days.

Suspension

License number _____, issued to respondent _____is suspended for a period of _____days beginning the effective of this decision.

Respondent shall cease all operations as a [insert license type] during the period of suspension. Failure to comply with this suspension shall be considered a violation of probation.

Standard Stay/Probation Order

License number _____, issued to respondent, is revoked; however, the revocation is stayed and respondent is placed on probation for _____years on the following terms and conditions:

Issuance of Probationary License (In cases where a Statement of Issues has been filed.)

Upon satisfaction of all statutory and regulatory requirements for issuance of a [insert license type] license, a license shall be issued to respondent and immediately revoked; the order of revocation is stayed and respondent is placed on probation for _____years on the following terms and conditions:

Surrender

Respondent surrenders license number _____as of the effective date of this decision. Respondent shall relinquish the premises wall license and renewal license to the board within ten (10) days of the effective date of this decision.

The surrender of respondent's license and the acceptance of the surrendered license by the board shall constitute the imposition of discipline against respondent. This decision constitutes a record of discipline and shall become a part of respondent's license history with the board. Respondent understands and agrees that for purposes of Business and Professions Code section 4307, this surrender shall be construed the same as revocation.

Respondent shall, within ten (10) days of the effective date, arrange for the destruction of, the transfer to, sale of or storage in a facility licensed and approved by the board of all controlled substances and dangerous drugs and/or dangerous devices. Respondent shall further arrange for the transfer of all records of acquisition and disposition of dangerous drugs to premises licensed and approved by the board. Respondent shall further provide written proof of such disposition and submit a completed Discontinuance of Business form according to board guidelines.

Respondent may only seek a new or reinstated license from the board by way of a new application for licensure. Respondent shall not be eligible to petition for reinstatement of licensure.

Respondent may not reapply for any license from the board for three (3) years from the effective date of this decision. Respondent stipulates that should ~~[he/she]~~they apply for any license from the board on or after the effective date of this decision, all allegations set forth in the [accusation or petition to revoke probation] shall be deemed to be true, correct and admitted by respondent when the board determines whether to grant or deny the application. Respondent shall satisfy all requirements applicable to that license as of the date the application is submitted to the board. Respondent is required to report this surrender as disciplinary action.

Respondent further stipulates that ~~[he/she]~~they shall reimburse the board for its costs of investigation and prosecution in the amount of $_____within _____days of the effective date of this decision.

(To be included if the respondent is a pharmacy.) Respondent shall also, by the effective date of this decision, arrange for the continuation of care for ongoing patients of the pharmacy by, at minimum, providing a written notice to ongoing patients that specifies the anticipated closing date of the pharmacy and that identifies one or more area pharmacies capable of taking up the patients' care, and by cooperating as may be necessary in the transfer of records or prescriptions for ongoing patients. Within five days of its provision to the pharmacy's ongoing patients, Respondent shall provide a copy of the written notice to the board. For the purposes of this provision, "ongoing patients" means those patients for whom the pharmacy has on file a prescription with one or more refills outstanding, or for whom the pharmacy has filled a prescription within the preceding sixty (60) days.

Option 2: Respondent stipulates that should ~~[he/she]~~they apply for any license from the board on or after the effective date of this decision the investigation and prosecution costs in the amount of $_____shall be paid to the board prior to issuance of the new license.

Public Reproval

It is hereby ordered that a public reproval be issued against licensee, _____.
Respondent is required to report this reproval as a disciplinary action.

STANDARD CONDITIONS - To be included in all probation decisions/orders.

1. Definition: Respondent
2. Obey All laws
3. Report to the Board
4. Interview with the Board
5. Cooperate with Board Staff
6. Reimbursement of Board Costs
7. Probation Monitoring Costs
8. Status of License
9. License Surrender While on Probation/Suspension
10. Sale or Discontinuance of Business
11. Notice to Employees
12. Owners and Officers: Knowledge of the Law
13. Premises Open for Business
14. Posted Notice of Probation
15. Violation of Probation
16. Completion of Probation

OPTIONAL CONDITIONS

17. Suspension
18. Community Services Program
19. Restitution
20. Separate File of Records
21. Report of Controlled Substances
22. Surrender of DEA Permit
23. Posted Notice of Suspension
24. Destruction of Dangerous Drugs and/or Dangerous Devices
25. No Additional Ownership or Management of Licensed Premises
26. Administrative Fine
27. Consultant Review of Facility Operations

STANDARD CONDITIONS: TO BE INCLUDED IN ALL PROBATIONS

1. Definition: Respondent

For the purposes of these terms and conditions, "respondent" shall refer to [insert name]. All terms and conditions stated herein shall bind and be applicable to the licensed premises and to all owners, managers, officers, administrators, members, directors, trustees, associates, or partners thereof. For purposes of compliance with any term or condition, any report, submission, filing, payment, or appearance required to be made by respondent to or before the board ~~or its designee~~ shall be made by an owner or executive officer with authority to act on

behalf of and legally bind the licensed entity.

2. Obey All Laws

Respondent shall obey all state and federal laws and regulations.

Respondent shall report any of the following occurrences to the board, in writing, within seventy-two (72) hours of such occurrence:

- an arrest or issuance of a criminal complaint, information or indictment ~~for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws;~~
- a plea of guilty, or nolo contendere, no contest, or similar, in any state or federal criminal proceeding to any criminal complaint, information or indictment;
- a conviction of any crime; or
- discipline, citation, or other administrative action filed by any state or federal agency ~~which involves respondent's _____ license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling or distributing, billing, or charging for any dangerous drug, and/or dangerous device or controlled substance.~~

Failure to timely report any such occurrence shall be considered a violation of probation.

3. Report to the Board

Respondent shall report to the board quarterly, on a schedule as directed by the board ~~or its designee~~. The report shall be made either in person or in writing, as directed. Among other requirements, respondent shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation.

Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the board.

4. Interview with the Board

Upon receipt of reasonable prior notice, respondent shall appear ~~in person~~ for interviews with the board ~~or its designee~~, at such intervals and locations as are determined by the board ~~or its designee~~. Failure to appear for any scheduled interview without prior notification to board staff, or failure to appear for two (2) or more scheduled interviews with the board ~~or its designee~~ during the period of probation, shall be considered a violation of probation.

5. Cooperate with Board Staff

Respondent shall timely cooperate with the board's inspection program and with the board's monitoring and investigation of respondent's compliance with the terms and conditions of the probation, including but not limited to: timely responses to requests for information by board staff; timely compliance with directives from board staff regarding requirements of any term or condition of probation; and timely completion of documentation pertaining to a term or condition

of probation. Failure to timely cooperate shall be considered a violation of probation.

6. Reimbursement of Board Costs

As a condition precedent to successful completion of probation, respondent shall pay to the board its costs of investigation and prosecution in the amount of $_____. Respondent shall make said payments as follows: _____.

There shall be no deviation from this schedule absent prior written approval by the board ~~or its designee~~. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

Option Respondent shall be permitted to pay these costs in a payment plan approved by the board ~~or its designee~~, so long as full payment is completed no later than one (1) year prior to the end date of probation.

7. Probation Monitoring Costs

Respondent shall pay any costs associated with probation monitoring as determined by the board each and every year of probation. Such costs shall be payable to the board on a schedule as directed by the board ~~or its designee~~. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

Option (additional language to be used for out of state premises) Probation monitoring costs include travel expenses for an inspector to inspect the premises on a scheduled as determined by the board.

8. Status of License

Respondent shall, at all times while on probation, maintain a current [insert license type] with the board. Failure to maintain current licensure shall be considered a violation of probation.

If respondent's license expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof or otherwise, upon renewal or reapplication respondent's license shall be subject to all terms and conditions of this probation not previously satisfied.

9. License Surrender While on Probation/Suspension

Following the effective date of this decision, should respondent wish to discontinue business, respondent may tender the premises license to the board for surrender. The board ~~or its designee~~ shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondent will no longer be subject to the terms and conditions of probation.

Respondent may not apply for any new license from the board for three (3) years from the effective date of the surrender. Respondent shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board.

Respondent further stipulates that it shall reimburse the board for its costs of investigation and prosecution prior to the acceptance of the surrender.

OPTION: Upon acceptance of the surrender, respondent shall relinquish the premises wall and renewal license to the board within ten (10) days of notification by the board that the surrender is accepted. Respondent shall further submit a completed Discontinuance of Business form according to board guidelines and shall notify the board of the records inventory transfer within five (5) days. Respondent shall further arrange for the transfer of all records of acquisition and disposition of dangerous drugs and/or devices to premises licensed and approved by the board.

Respondent shall also, by the effective date of this decision, arrange for the continuation of care for ongoing patients of the pharmacy by, at minimum, providing a written notice to ongoing patients that specifies the anticipated closing date of the pharmacy and that identifies one or more area pharmacies capable of taking up the patients' care, and by cooperating as may be necessary in the transfer of records or prescriptions for ongoing patients. Within five days of its provision to the pharmacy's ongoing patients, Respondent shall provide a copy of the written notice to the board. For the purposes of this provision, "ongoing patients" means those patients for whom the pharmacy has on file a prescription with one or more refills outstanding, or for whom the pharmacy has filled a prescription within the preceding sixty (60) days.

Respondent may not apply for any new license from the board for three (3) years from the effective date of the surrender. Respondent shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board.

Respondent further stipulates that it shall reimburse the board for its costs of investigation and prosecution prior to the acceptance of the surrender.

10. Sale or Discontinuance of Business

During the period of probation, should respondent sell, trade or transfer all or part of the ownership of the licensed entity, discontinue doing business under the license issued to respondent, or should practice at that location be assumed by another full or partial owner, person, firm, business, or entity, under the same or a different premises license number, the board ~~or its designee~~ shall have the sole discretion to determine whether to exercise continuing jurisdiction over the licensed location, under the current or new premises license number, and/or carry the remaining period of probation forward to be applicable to the current or new premises license number of the new owner.

11. Notice to Employees

Respondent shall, upon or before the effective date of this decision, ensure that all employees involved in permit operations are made aware of all the terms and conditions of probation, either by posting a notice of the terms and conditions, circulating such notice, or both. If the notice required by this provision is posted, it shall be posted in a prominent place and shall remain posted throughout the probation period. Respondent shall ensure that any employees hired or used after the effective date of this decision are made aware of the terms and conditions of probation by posting a notice, circulating a notice, or both. Additionally, respondent shall submit written notification to the board, within fifteen (15) days of the effective date of this decision, that this term has been satisfied. Failure to timely provide such notification to employees, or to timely submit such notification to the board shall be considered a violation of probation.

> "Employees" as used in this provision includes all full-time, part-time, volunteer, temporary and relief employees and independent contractors employed or hired at any time during probation.

12. Owners and Officers: Knowledge of the Law

Respondent shall provide, within thirty (30) days after the effective date of this decision, signed and dated statements from its owners, including any owner or holder of ten percent (10%) or more of the interest in respondent or respondent's stock, and all of its officer, stating under penalty of perjury that said individuals have read and are familiar with state and federal laws and regulations governing the practice of pharmacy. The failure to timely provide said statements under penalty of perjury shall be considered a violation of probation.

13. Premises Open for Business

Respondent shall remain open and engaged in its ordinary business as a [insert license type] in California for a minimum of ~~_____~~[insert number] hours per calendar month. Any month during which this
minimum is not met shall toll the period of probation, i.e., the period of probation shall be extended by one month for each month during with this minimum is not met. During any such period of tolling of probation, respondent must nonetheless comply with all terms and conditions of probation, unless respondent is informed otherwise in writing by the board ~~or its designee~~.

If respondent is not open and engaged in its ordinary business as a [insert license type] for a minimum of ~~_____~~[insert number] hours in any calendar month, for any reason (including vacation),
respondent shall notify the board in writing within ten (10) days of the conclusion of that calendar month. This notification shall include at minimum all of the following: the date(s) and hours respondent was open; the reason(s) for the interruption or why business was not conducted; and the anticipated date(s) on which respondent will resume business as required. Respondent shall further notify the board in writing with ten (10) days following the next calendar month during which respondent is open and engaged in its ordinary business as a [insert license type] in California for a minimum ~~of~~ ~~_____~~of[insert number] hours. Any failure to timely provide such notification(s) shall be considered a violation of probation.

14. Posted Notice of Probation

Respondent shall prominently post a probation notice provided by the board ~~or its designee~~ in a place conspicuous to and readable by the public within two (2) days of receipt thereof from the board ~~or its designee~~. Failure to timely post such notice, or to maintain the posting during the entire period of probation, shall be considered a violation of probation.

In addition, respondent shall prominently post a probation notice similar to that provided by the board on respondent's website in a place that is likely to be frequented by California consumers and health care providers.

Respondent shall not, directly or indirectly, engage in any conduct or make any statement which is intended to mislead or is likely to have the effect of misleading any patient, customer, member of the public, or other person(s) as to the nature of and reason for the probation of the licensed entity.

Option (include additional language for mail order pharmacies)
Respondent shall also provide a copy of the notice of probation in all shipments to California.

15. Violation of Probation

If ~~a~~ respondent has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondent, and probation shall be automatically extended, until all terms and conditions have been satisfied or the board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed. The board may post a notice of the extended probation period on its website.

If respondent violates probation in any respect, the board, after giving respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. If a petition to revoke probation or an accusation is filed against respondent during probation, or the preparation of an accusation or petition to revoke probation is requested from the Office of the Attorney General, the board shall have continuing jurisdiction and the period of probation shall be
automatically extended until the petition to revoke probation or accusation is heard and decided.

16. Completion of Probation

Upon written notice by the board ~~or its designee~~ indicating successful completion of probation, respondent's license will be fully restored.

OPTIONAL CONDITIONS OF PROBATION

17. Suspension

As part of probation, respondent's license to operate a [insert license type] is suspended for _____[day(s)/month(s)/year(s)] beginning the effective date of this decision. Respondent shall cease all operations as a [insert license type] during the period of suspension. Failure to comply with this suspension shall be considered a violation of probation.

18. Community Service~~s~~ Program

Within sixty (60) days of the effective date of this decision, respondent shall submit to the board ~~or its designee~~, for prior approval, a community service program in which respondent shall provide free health-care related services to a community or charitable facility or agency for at least _____hours per _____for the first _____of probation.

Within thirty (30) days of board approval thereof, respondent shall submit documentation to the board demonstrating commencement of the community service program. Respondent shall report on progress with the community service program in the quarterly reports.

Failure to timely submit, commence, or comply with the program shall be considered a violation of probation.

19. Restitution (Appropriate in cases of drug diversion, theft, fraudulent billing, or patient harm resulting from negligence or incompetence.)

Within _____days of the effective date of this decision, respondent shall pay restitution to _____in the amount of $ _____. Failure to make restitution by this deadline shall be considered a violation of probation.

20. Separate File of Controlled Substances Records

Respondent shall maintain and make available for inspection a separate file of all records pertaining to the acquisition or disposition of all controlled substances. Failure to maintain such file or make it available for inspection shall be considered a violation of probation.

21. Report of Controlled Substances

Respondent shall submit reports to the board detailing the total acquisition and disposition of such controlled substances as the board ~~or its designee~~ may direct. Respondent shall specify the manner of disposition (e.g., by prescription, due to burglary, etc.) or acquisition (e.g., from a manufacturer, from another retailer, etc.) of such controlled substances. Respondent shall report on a quarterly basis or as directed by the board ~~or its designee~~. The report shall be delivered or mailed to the board no later than ten (10) days following the end of the reporting period as determined by the board ~~or its designee~~. Failure to timely prepare or submit such reports shall be considered a violation of probation.

22. Surrender of DEA Permit

Within thirty (30) days of the effective date of this decision, respondent shall surrender its federal Drug Enforcement Administration (DEA) permit to the DEA, for cancellation. Respondent shall provide documentary proof of such cancellation to the board ~~or its designee~~. Thereafter, respondent shall not apply/reapply for a DEA registration number without the prior written consent of the board ~~or its designee~~.

Option**:** Respondent may obtain a DEA permit restricted to Schedule(s) _____ controlled substance(s).

Option**:** Respondent shall not order, receive, or retain any federal order forms, including DEA Form 222, for controlled substances.

23. Posted Notice of Suspension

Respondent shall prominently post a suspension notice provided by the board in a place conspicuous and readable to the public within two (2) days of receipt thereof from the board ~~or its designee~~. The suspension notice shall remain posted during the entire period of suspension ordered by this decision. Failure to timely post such notice, or to maintain the posting during the entire period of suspension, shall be considered a violation of probation.

Respondent shall not, directly or indirectly, engage in any conduct or make any statement, orally, electronically or in writing, which is intended to mislead or is likely to have the effect of misleading any patient, customer, member of the public, or other person(s) as to the nature of and reason for the closure of the licensed entity.

24. Destruction of Dangerous Drugs and/or Dangerous Devices [To be used when the violations include misbranded or adulterated drugs.]

Respondent shall, by the effective date of this decision, arrange for the destruction of all dangerous drugs and/or dangerous devices or controlled substances and dangerous drugs and devices by a waste management company or reverse distributor. All products must be inventoried with an exact count prior to destruction. Respondent shall provide written proof of such destruction within five days of disposition.

Option: [To be used when the integrity, quality and strength of compounded drug products is at issue]

Respondent shall, by the effective date of this decision, arrange for the destruction of all compounded drug products and the components used to compound drug products by a waste management company. Respondent shall provide written proof of such destruction within five days of disposition. The Board ~~or its designee~~ shall have the right to retain a sample(s) of any and all compounded drug products or components used to compound drug products by Respondent.

25. No Additional Ownership or Management of Licensed Premises

Respondent shall not acquire any additional ownership, legal or beneficial interest in, nor serve as a manager, administrator, member, officer, director, associate, partner or any business, firm , partnership, or corporation currently or hereinafter licensed by the board except as approved by the board ~~or its designee~~. Violations of this restriction shall be considered a violation of probation.

26. Administrative Fine

Respondent shall pay an administrative fine to the board in the amount of . Respondent shall have [insert timeframe] from the effective date of this Decision and Order to pay the administrative fine. Failure to pay the administrative fine as ordered, shall be considered a violation of probation.

27. Consultant Review of Facility Operations

Respondent shall retain, at its own expense, an independent consultant who shall review the operations of the facility, during the period of probation, on a [monthly/quarterly] basis for compliance of the facility with state and federal laws and regulations governing the practice of pharmacy, and compliance by respondent. The consultant shall provide the board with an inspection agenda for approval prior to conducting the inspection. Any inspection conducted without prior approval of the inspection agenda shall not be accepted. The consultant shall also provide the board with reports documenting the inspection. The reports shall be provided directly to the board, and receive confirmation of receipt from the board, prior to providing to the respondent. Should the board determine that the consultant is not appropriately assessing the operations of respondent, or providing the appropriate written reports, the board shall require respondent to obtain a different consultant through the same process outlined above, by submitting a new name of an expert within sixty (60) days of respondent being notified of the need for a new consultant. During the period of probation, the board shall retain discretion to reduce the frequency of the consultant's review.

Respondent shall submit the name of the proposed consultant for approval within thirty (30) days of the effective date of this decision. The consultant shall be a pharmacist licensed by and not on probation with the board or other professional as appropriate and not on probation with the board, who has been approved by the board to serve in this position. The consultant shall have sufficient education, training, and professional experience to be able to provide guidance to respondent related to the causes for discipline in Case No. . Assumption of any unauthorized supervision responsibilities shall be considered a violation of probation.

Failure to timely seek approval for, timely retain, or ensure timely reporting by the consultant shall

be considered a violation of probation.

~~2/2017~~1/2022

Attachment 3

DRAFT FAQ Patient Specific Prescriptions Dispensed by a California Licensed Outsourcing Facility within or into California.

A new statute effective January 1, 2022, allows for California licensed outsourcing facilities to dispense patient specific prescriptions. To qualify, an outsourcing facility must: 1) be licensed with the federal Food and Drug Administration as an outsourcing facility; 2) be licensed with the Board of Pharmacy in the State of California as a resident or nonresident outsourcing facility; and 3) comply with same requirements of a pharmacy when dispensing patient-specific prescriptions. The purpose of these FAQs is to generally describe the requirements under California law governing patient-specific dispensing by licensed outsourcing facilities. For a full understanding of the requirements, please read the cited sections of California Pharmacy Law.

A California licensed outsourcing facility, when dispensing patient-specific prescriptions in or into California, will need to comply with California law governing the dispensing of patient-specific prescriptions that a pharmacy would have to comply with including, but not limited to, the duty to provide consultation, requirements regarding prior review of drug therapy and labeling of prescriptions and other miscellaneous requirements.

References to BPC refers to California's Business and Professions Code, references to HSC refers to California's Health and Safety Code, references to CCR refers to sections of Title 16 of the California Code of Regulations, and references to CFR refers to sections of Title 21 of the Code of Federal Regulations. Additionally, the provisions of law can be found on the Board's website.

1) **Is patient consultation required?**
   Yes, under specified conditions including:
   - (1) upon request;
   - (2) whenever the pharmacist deems it warranted in the exercise of their professional judgment;
   - (3) whenever the prescription drug has not previously been dispensed to a patient;
   - (4) whenever a prescription drug not previously dispensed to a patient in the same dosage form, strength or with the same written directions, is dispensed.

   Note: The pharmacist must review a patient's drug therapy and medication record prior to consultation. Further, consultation must be performed in a manner suitable for patient confidentiality (Civil Code 56.10, CCR 1714(a), 1764)).
   Reference: CCR sections 1707.2 & 1707.3

2) **What is the required information on the prescription document?**
   BPC sections 4040 and 4070 detail the required information on the prescription.

3). How can I receive a prescription?

- Effective January 1, 2022, most prescriptions must be sent and received electronically subject to certain exemptions. The Board has FAQs available that provide further information on those requirements.
- Prescriptions that are orally transmitted can only be received and reduced to writing by a pharmacist or a pharmacist intern, working under the direct supervision of a pharmacist.
- A faxed or electronically submitted prescription must be received only from a prescriber's office unless otherwise provided in the law.

Note: Records must include identification of the pharmacist and be retained for a period of three years.
Reference: BPC 688, 4040, 4070, 4071 and CCR 1712, 1717.

3) Can we accept written prescriptions for a controlled substance for a California patient?
Yes, under specified conditions. The prescriptions must be comply with Division 10, Chapter 4 of the HSC. [Add link]. Prescriptions must be on forms with certain security features as specified in this chapter. Also, California law imposes a duty of corresponding responsibility on pharmacists who dispense a controlled substance that it is issued for a legitimate medical purpose.

Note: Controlled substances prescriptions are valid for a limited period of time and have additional requirements if e-prescribed.
Reference: HSC sections 11153, 11159.2, 11159.3, 11162.1, HSC 11164(a), 11166, 21 CFR 1306.08, 1306.11, 1311.100

4) Do we have to follow California requirements for the prescription label?
Yes. Requirements for prescription labeling are established in provisions of state and federal law described below.

- The prescription label must contain all the required information established in BPC section 4076, the prescription label must be formatted in accordance with patient-centered labeling requirements. Also, the expiration date of a drug's effectiveness must be accurately identified on the label. (Reference: BPC 4076 and CCR 1707.5.)
- The trade name or generic name and manufacturer of the prescription drug must be 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. (Reference: BPC 4076, CCR 1717[b][2], CCR 1707.5[a][1][B])
- The federal warning label prohibiting transfer of controlled substances must be on the prescription container. (Reference: 21 CFR section 290.5)
- If the prescription is filled by a pharmacy technician or a pharmacy technician trainee, before dispensing, the prescription must be checked for accuracy by a pharmacist and

that pharmacist must initials the prescription label or records by their identity as the reviewing pharmacist in a computer system by a secure means. (Reference: BPC 4115, 4115.5, CCR 1793.7, CCR 1712)

- Prescriptions must be 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. (Reference: 15 USC section 1473[b], 16 CFR section 1700.15, CCR section 1717)
- The label must include a physical description of the dispensed medication, including its color, shape, and any identification code that appears on the tablets or capsules. (Reference: BPC 4076)

5) Are there are other requirements for patient specific prescriptions?

Yes

- Patient package inserts must be dispensed with all estrogen medications. (Reference: 21 CFR section 310.515)
- The pharmacy must provide patients with Black Box Warning Information in conformance with 21 CFR section 201.57[c].
- Medication guides must be provided on required medications. (Reference: 21 CFR, Part 208, Section 208.24[e])
- The drug container must contain a written label 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. (Reference: BPC 4074, 4076.7, and CCR 1744)
- The written label on the drug container must 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. (Reference: BPC 4074, CCR 1744)
- Whenever an opioid prescription drug is dispensed to patient for outpatient use, the label or container must contain a flag or other notification on the container, with a notice that states, "Caution: Opioid. Risk of overdose and addiction." (Reference: BPC 4076.7)
- When requested by a patient or a patient's representative, the outsourcing facility must provide translated directions for use, printed on the prescription container, label, or on a supplemental document. If the translated directions for use appears on the prescription container or label, the English-language version of the directions for use should also appear on the container or label, whenever possible, and may appear on other areas of the label outside the patient-centered area. If the English-language directions are not able to appear on the container or label, the English-language directions must be provided on a supplemental document. (Reference: BPC 4076.6)
- No drug preparation may be compounded prior to receipt by the outsourcing facility of a valid prescription for an individual patient where the prescriber has approved use of a compounded drug preparation either orally or in writing. Where approval is given orally by the prescriber, that approval shall be noted on the prescription prior to

compounding. There are two exceptions to this prohibition of prior compounding of a drug preparation of: 1) a limited quantity to ensure continuity of care for an identified population of patients of the outsourcing facility based on a documented history of prescriptions for that patient population; and 2) a reasonable quantity that may be compounded for prescriber office use as authorized by BPC section 4052(a)(1). (Reference: CCR 1735.2).

6) **Is there a limit on the days' supply or quantity of a non-controlled medication we can send pursuant to a patient specific prescription?**
No, generally prescriptions for non-controlled substances can be filled for more than the prescription allows; however, there are several exceptions. Please see the referenced law section for more information about the specific provisions conditions.

Reference: BPC 4064.5

7) **Is there a limit on the day's supply or quantity that can be dispensed for a controlled substance.?**
Yes, there are limits. Requirements vary based on the schedule.

Reference: HSC 11200

8) **We have an auto ship option; can we use this for patient specific prescriptions?**
- Refill authorization from the prescriber must be obtained before refilling a prescription (BPC section 4063) and refills must be documented. (Reference: CCR 1717).
- Refills for Schedule II controlled substances are prohibited. (Reference: HSC 11200)
- 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 may not exceed a 120-day supply. (Reference: HSC 11200)

Note: Effective July 1, 2022, Board regulations will establish parameters for automatic refill programs generally related to obtaining informed patient consent to enroll in such programs and how to withdraw from such programs.

9) **Are there required actions that must be done in the event of a medication error?**
Yes, a quality assurance process is necessary to meet the requirements of California Law.

Reference: BPC 4125, CCR 1711

10) **Is there a requirement to exercise corresponding responsibility before dispensing a controlled substance?**
Yes, a pharmacist must fulfill their corresponding responsibility.

Note: The Board has issued a precedential decision on this point, the *Pacifica Pharmacy* matter, which can be found on the Board's website in addition to educational information and a video on corresponding responsibility.
Reference: HSC 11153, CCR 1761

11) Do we need to report our controlled substance prescription dispensing to the California Department of Justice?
Yes, schedule II-V controlled substances must be reported to the CURES system.

Note: The Board has information on the CURES system on its website, including how to register for access to the CURES system.
Reference: HSC 11165, 21 CFR 1308.12, 1308.13, 1308.14, 11308.15.

12) Can we advertise our products directly to consumers?
Yes. There is no express prohibition against advertising per se. *See* Business and Professions Code section 17500.1. However, false and misleading advertising by any licensee of the Board could constitute violations of BPC sections 17500, 651 and 4301. Also, California law regulates different arrangements including rebates and referrals and you should consult California law, including but not limited to, BPC sections 650 through 657 in structuring arrangements to ensure compliance with California law.

Reference: BPC 650, 4301, 17500 and CCR 1766

13) Is there any other information guides to assist us with the requirements under California law?

Yes. The Board of Pharmacy has adopted self-assessment forms to assist pharmacists in maintaining compliance with Pharmacy Law. Review of the form may provide additional information and guidance on requirements for dispensing prescriptions to California patients.

Revised 1.7.2022

Attachment 4

CAPITOL OFFICE
STATE CAPITOL, ROOM 4035
SACRAMENTO, CA 95814
TEL (916) 651-4040
FAX (916) 651-4940

SD40.SENATE.CA.GOV

California State Senate

SENATOR
BEN HUESO
FORTIETH SENATE DISTRICT

STANDING COMMITTEES
ENERGY, UTILITIES & COMMUNICATIONS
CHAIR
INSURANCE
LATINO LEGISLATIVE CAUCUS
NATURAL RESOURCES & WATER
GOVERNMENTAL ORGANIZATION
BANKING & FINANCIAL INSTITUTIONS

SELECT COMMITTEES
CALIFORNIA-MEXICO COOPERATION
CHAIR
MENTAL HEALTH
STATUS OF BOYS AND MEN OF COLOR

JOINT COMMITTEE
JOINT LEGISLATIVE COMMITTEE ON
CLIMATE CHANGE POLICIES

September 10, 2021

Ms. Erika Contreras
Secretary of the Senate

VIA HAND DELIVERY

Dear Ms. Contreras:

I respectfully request this letter be entered into the Senate Journal to clarify the Legislature's intent with respect to SB 311, the Compassionate Access to Medical Cannabis Act.

The September 1, 2021 amendments to this bill were taken at the request of the California Department of Public Health (CDPH). One of these amendments requires health facilities, with regard to medical cannabis, to comply with drug and medication requirements applicable to Schedule II, III, and IV drugs [§1649.2(a)(4)]. Concerns have been raised by health facilities and pharmacists that this amendment would require health facilities to treat cannabis as a Schedule II, III, or IV drug, therefore subject to existing requirements that include: acquiring physician orders, pharmacist verification of such orders, and pharmacy oversight of management and use.

This letter is to clarify that it is not the intent of this bill or of these amendments to subject medicinal cannabis to all requirements applicable to controlled substances, nor to require that a pharmacy or pharmacist be involved in the use, storage, management, or dispensing of medicinal cannabis at a health facility.

According to the California Department of Public Health, the intent of this amendment was specific to the use, storage, and tracking of medicinal cannabis only, and to require facilities to create policies and procedures for checking in and storage of the cannabis. CDPH states that the storage and tracking requirements pertaining to health facilities are the same for all schedules of the Controlled Substances Act. As CDPH has stated, nothing in this bill requires the health facility to provide the medicinal cannabis, nor does this bill require the facility to dispense the cannabis from the pharmacy, and it is not the intent of the Legislature for this bill to be interpreted in such a way as to impose such requirements. Rather, this amendment is intended to require health facilities to ensure proper storage and tracking of the medication, and to allow CDPH to monitor this storage and tracking.

CHULA VISTA DISTRICT OFFICE
303 H STREET, SUITE 200
CHULA VISTA, CA 91910
TEL (619) 409-7690
FAX (619) 409-7688

EL CENTRO DISTRICT OFFICE
1224 STATE STREET, SUITE D
EL CENTRO, CA 92243
TEL (760) 335-3442
FAX (760) 335-3444

Thank you for the opportunity to clarify this intent.

Sincerely,

Ben Hueso
Senator, 40th District

Hickey, Erin

From: CMS ROSFOORA <ROSFOORA@cms.hhs.gov>
Sent: Friday, March 19, 2021 10:49 AM
To: Hickey, Erin
Subject: RE: Legislative Meeting Request - California Senator Ben Hueso SB 311

Follow Up Flag: Flag for follow up
Flag Status: Flagged

Good Morning,

I apologize for the delay in our response.
CMS and States have received questions from Medicare-participating providers about the impact of marijuana use on their participation in Medicare and Medicaid reimbursement. The Medicare or Medicaid regulations do not address the use of medical marijuana or CBD oil. Surveyors do look at topics such as medication storage, appropriate self-administration of medications, and safe smoking policies, fire safety, etc. – but there is nothing explicitly in the Medicare/Medicaid survey and certification process related to the use of marijuana or CBD oil.

CMS regulations generally require compliance with federal, state, and local laws. CMS would not cite this unless that other body (the authority having jurisdiction-in this case the DOJ) has made an adverse finding.

We are not aware of a provider that has specifically lost funding or been penalized for permitting the use of marijuana or CBD oil; however, there have been citations cited when there has been non-compliance related to the other areas above (fire safety issues in smoking marijuana in a resident/patient room, safe storage, etc.).

Please let us know if you have any questions,

Thank you

From: Hickey, Erin <Erin.Hickey@sen.ca.gov>
Sent: Monday, March 15, 2021 1:55 PM
To: CMS SFCMSFOIA <SFCMSFOIA@cms.hhs.gov>
Subject: Legislative Meeting Request - California Senator Ben Hueso SB 311

Good afternoon,

I work for California State Senator Ben Hueso and am reaching out with a legislative meeting request.

The senator is carrying legislation this year that would require that hospitals and certain types of healthcare facilities in the State of California allow a terminally-ill patient to use medical cannabis for treatment and/or pain relief. The bill number is SB 311 (Hueso): Compassionate Access to Medical Cannabis Act or Ryan's Law: https://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=202120220SB311

We recently met with the California Department of Public Health, which previously opposed this bill out of the concern that, as the enforcing agency for CMS, they would be required to cite hospitals that permitted this. The California Hospital Association also has an oppose-unless-amended stance due to a possible risk of losing Medicare/Medicaid reimbursement from CMS.

We were hoping to further discuss with your office to see exactly what the process is like when you receive reports from CDPH and what the enforcement action might be if the report is only detailing that the facility is allowing a terminally-ill patient to access cannabis in a state where it is legal and the patient has a valid prescription (also, the hospital does not have to administer or provide it -- only not interfere with the patient's use). I'm hoping this doesn't result in a loss of funding but, again, we're just trying to better understand the actual risks involved here. This will greatly help as we decide if and how to amend the bill to ensure that hospitals do not lose funding in our attempt to provide compassionate access to those who most need it.

I've attached the fact sheet for your review. You'll notice we have included a safe harbor clause that allows facilities to suspend compliance based on actions from fed agencies including CMS. We would love to discuss that with you, as well, to see if there are ways to strengthen that.

Are there any days in the coming week(s) that might work for our teams to jump on a Zoom meeting?

Thanks so much!
Erin

Erin Hickey
Communications Director
Office of State Senator Ben Hueso, 40th District
Work: 619-409-7690

Click on the button to receive Senator Hueso's newsletter, and the Twitter and Instagram logos to follow Senator Hueso on social media.

Attachment 5

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 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 underline for added language. In cases where the original text contains underlined text, the underline text has been double underlined for emphasis that the original text contains underline and is not being added.

Amendments to the proposed changes are shown by ~~double strikethrough~~ for deleted language and wave 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 ~~and~~ may be completed online, printed, initialed, signed, and readily available ~~and retained~~ in the pharmacy. Signatures and initials shall be an original handwritten signature or initial on the self-assessment form. Do not copy a previous assessment.

Notes: If a hospital pharmacy dispenses prescriptions for outpatient use, this Community Pharmacy Self-Assessment/Hospital Outpatient Pharmacy Self-Assessment must be completed in addition to the Hospital Pharmacy Self-Assessment (17M-14 Rev. ~~10/14~~ ~~07/18~~ 12/21). Any pharmacy that compounds drug products must also complete the Compounding Self-Assessment (17M-39 Rev. 02/12).

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

Pharmacy Name: _____

Address: _____ Phone: _____

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

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

Licensed Sterile Compounding ~~Permit~~ License#_____ ~~Expiration~~ Exp Date: _____

Licensed Remote Dispensing Site Pharmacy License # _____ Exp Date: _____

_____
PIC Initials

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

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

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

PIC: _____ RPH # _____ Exp. Date: _____

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

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

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

10. _____ TCH # _____ Exp. Date: _____

11. _____ TCH # _____ Exp. Date: _____

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

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

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

1. Facility

Yes No N/A

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

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

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

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

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

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

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

☐☐☐ 1.8. "Point to Your Language" poster is posted or provided in a place conspicuous to and readable by a prescription drug consumer or adjacent to each counter in a pharmacy where drugs are dispensed. (CCR 1707.6[c])

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

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

Yes No N/A

☐☐☐ ~~1.10~~ 1.11. Does the pharmacy compound sterile drugs? (If yes, complete ~~section 27 –~~ the "Compounding Self-Assessment as required by CCR 1735.2(k).)

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

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

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

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

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

Date Last Notification Received: _____

E~~-~~mail address registered with the board: _____

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

Date Last Notification Received: _____

E~~-~~mail address registered with the board: _____

☐☐☐ 1.17. The pharmacy informs the customer at the point of sale for a covered prescription drug whether the retail price is lower than the applicable cost-sharing amount for the prescription drug unless the pharmacy automatically charges the customer the lower

price. Additionally, the pharmacy submits the claim to the health care service plan or insurer. (BPC 4079, BPC 4079.5)

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 box, locking medicine cabinet, locking medication bags, prescription locking vials, etc.) in a place on the premise that is located close to the pharmacy unless the pharmacy is owned and managed by pharmacists and owns 4 or less pharmacy. (BPC 4106.5)

☐☐☐ 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 Is 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. For prescriptions for controlled substances, as defined by Section 4021 generation and transmission of the electronic data transmission prescription complies with Parts 1300, 1304, and 1311 or Title 21 of the Code of Federal Regulations (BPC 688 (c)).

☐ 1.20.2. 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). Unfulfilled controlled substance prescriptions are transferred or forwarded in compliance with Federal Law.

☐ 1.20.3. 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).

☐☐☐ 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 (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, accesses compliance with its policies, and 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]).

CORRECTIVE ACTION OR ACTION PLAN: _____

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2. Delivery of Drugs

Yes No N/A

☐☐☐ 2.1. Dangerous drugs and dangerous devices are only delivered to the licensed premises, and signed for and received by a pharmacist. (B~~&~~PC 4059.5[a], H~~&~~SC 1120~~([~~a]~~)~~)

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

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

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

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

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

CORRECTIVE ACTION OR ACTION PLAN: _____

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3. Drug Stock

Yes No N/A

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

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

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

☐☐☐ 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-l(g)

CORRECTIVE ACTION OR ACTION PLAN: _____

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

Yes No N/A

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

(If yes, complete Section ~~29~~ 30 [donate drugs] or Section 31 [operate program] of this Self-Assessment.)

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. (B~~&~~PC 4101, 4113, 4305, 4330, CCR 1709, 1709.1)

☐☐☐ 5.2. The PIC has adequate authority to assure the pharmacy's compliance with laws governing the operation of a pharmacy. (BPC 4113[c], CCR 1709.1[b])

☐☐☐ 5.3. The PIC has completed a biennial pharmacy self-assessment before July 1 of each odd numbered year. An additional self-assessment will be completed within 30 days if a new ~~permit~~ license is issued or a new PIC employed. Each self-assessment will be maintained in the pharmacy for three years. (CCR 1715)

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

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

Name of the other pharmacy _____

☐☐☐ 5.6. Any change of PIC is reported by the pharmacy and the departing PIC to the board in writing within 30 days. (B~~&~~PC 4101, 4113)

~~☐☐☐ 5.7. Is the PIC serving concurrently as the designated representative-in-charge for a wholesaler or veterinary food-animal retailer? (CCR 1709.1[d])~~

~~If yes, name the wholesaler or veterinary food-animal retailer. _____~~

☐☐☐ ~~5.8~~ 5.7. The PIC is responsible for directing and overseeing the performance of waived clinical laboratory tests, if the pharmacy holds a registration from CDPH to conduct such tests. (~~H&SC~~BPC 1206.5, 1209, 1265)

CORRECTIVE ACTION OR ACTION PLAN: _____

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6. Duties of a Pharmacist

Yes No N/A

☐☐☐ 6.1. ~~The pharmacist furnishes a reasonable quantity of compounded drug products to a prescriber office for office use by the prescriber; transmits a valid prescription to another pharmacist; administers drugs and biological products ordered by the prescriber; manufactures, measures, fits to the patient or sells and repairs dangerous devices or furnishes instructions to the patient or patient representative concerning the use of the dangerous devices; provides consultation, training and education to patients about drug therapy disease management and disease prevention; provides professional information and participates in multidiscipline review of patient progress;~~

~~furnishes medication including emergency contraception drug therapy and self-administered hormonal contraceptives, nicotine replacement products, prescription medication not requiring a diagnosis recommended by the Centers for Disease Control when traveling outside of the US; administers immunizations pursuant to a protocol; orders and interprets tests for monitoring and managing efficacy and toxicity of drug therapies. (B&PC 4052)~~

Only a pharmacist:

- transmits a valid prescription to another pharmacist; (BPC 4052[a][2])
- administers drugs and biological products ordered by the prescriber; (BPC 4052[a][3])
- manufactures, measures, fits to the patient or sells and repairs dangerous devices or furnishes instructions to the patient or patient representative concerning the use of the dangerous devices; (BPC 4052[a][7])
- provides consultation, training and education to patients about drug therapy disease management and disease prevention; (BPC 4052[a][8])
- provides professional information and participates in multidiscipline review of patient progress; (BPC 4052[a][9])
- furnishes medication including emergency contraception drug therapy, self-administered hormonal contraceptives, nicotine replacement products, naloxone, or prescription medication not requiring a diagnosis recommended by the Centers for Disease Control when traveling outside of the US; administers immunizations, HIV preexposure prophylaxis, HIV postexposure prophylaxis pursuant to a protocol; (BPC 4052 [a][10], ~~BPC~~ 4052[a][11], ~~BPC~~ 4052.01, 4052.02, 4052.03, ~~BPC~~ 4052.3, ~~BPC~~ 4052.8, ~~BPC~~ 4052.9)
- dispenses aid-in-dying drugs; (HSC 443.5 [b][2]) and
- orders and interprets tests for monitoring and managing efficacy and toxicity of drug therapies (BPC 4052 [a][12]).
- Initiate, adjust, or discontinue drug therapy for a patient under a collaborative practice agreement with any health care provider with prescriptive authority (BPC 4052 [a][13]).
- Provide medication-assisted treatment pursuant to a state protocol, to the extent authorized by federal law (BPC 4052 [a][14]).

PIC Initials

☐☐☐ 6.2. ~~The pharmacist receives a new prescription order from the prescriber, consults with the patient, identifies, evaluates and interprets a prescription, interprets the clinical data in a patient medication record, consults with any prescriber, nurse, health professional or agent thereof, supervises the packaging of drugs, checks the packaging procedure and product upon completion, is responsible for all activities of pharmacy technicians to ensure that all such activities are performed completely, safely and without risk of harm to patients, performs any other duty which federal or state law or regulation authorizes only a registered pharmacist to perform and performs all functions which require professional judgment. (CCR 1707.2, 1793.1, B&PC 4052, 4052.1, 4052.2, 4052.3, 4052.4, 4070(a))~~

In addition, ~~O~~ only a pharmacist:

- receives a new prescription order from the prescriber; (BPC 4070 [a]), CCR 1793.1 [a])
- consults with the patient; (BPC 4052 [a][8], CCR 1707.2, CCR 1793.1[b])
- identifies, evaluates and interprets a prescription; (CCR 1793.1 [c])
- interprets the clinical data in a patient medication record; (CCR 1793.1 [d])
- consults with any prescriber, nurse, health professional or agent thereof; (CCR 1793.1 [e])
- supervises the packaging of drugs; (CCR 1793.1 [f])
- checks the packaging procedure and product upon completion; (CCR 1793.1 [f])
- is responsible for all activities of pharmacy technicians to ensure that all such activities are performed completely, safely and without risk of harm to patients; (CCR 1793.7 [e]) or
- performs any other duty which federal or state law or regulation authorizes only a registered pharmacist to perform and performs all functions which require professional judgment. (BPC 4052, 4052.02, 4052.03, 4052.1, 4052.2, 4052.3, 4052.4, CCR 1793.1 [g])

☐☐☐ 6.3. The pharmacist as part of the care provided by a health care facility, a licensed clinic and a licensed home health agency in which there is physician oversight, or a provider who contracts with a licensed health care service plan with regard to the care or services provided to the enrollees of that health care service plan, is performing the following functions, in accordance with policies, procedures, or protocols of that facility, licensed clinic, or health care service plan that were developed by health professionals, including physicians and surgeons, pharmacists and registered nurses. The functions are: ordering or performing routine drug therapy related patient assessment procedures; ordering drug therapy related laboratory tests; administering drugs or biologicals by injection; initiating and adjusting the drug regimen of a patient; and performing moderate or waived laboratory tests. (B&PC 4052, 4052.1, 4052.2, 4052.3, 4052.4)

☐☐☐ 6.4. Pharmacists ~~are able to~~ have obtained approval to access ~~information on the Internet that is maintained by the California Department of Justice regarding controlled substance history of a patient who is under the care of the pharmacy based on data~~

~~obtained through~~ the CURES Prescription Drug Monitoring Program (PDMP). (H~~&~~SC 11165.1)

☐☐☐ 6.5. The pharmacist dispenses emergency contraceptive only pursuant to the statewide protocol found in 16 CCR 1746. (4052.3[a][1])

☐☐☐ 6.6. Only a pharmacist performs blood glucose, hemoglobin A1c, or cholesterol tests that are waived under CLIA. ~~(No CDPH registration required.)~~ (B~~&~~PC 1206.6)

~~Yes No N/A~~

☐☐☐ 6.7. Only a pharmacist performs FDA-approved or authorized CLIA waived clinical laboratory tests specified in BPC 4052.4~~, where the pharmacy is registered with CDPH to perform such services.~~ (B~~&~~PC 1206.6)

CDPH (CLIA) Registration #:_____ Expiration: _____

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

☐☐☐ 6.9. Effective July 1, 2022, a pharmacist who is authorized to an order 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)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

7. Duties of an Advanced Practice Pharmacist

Yes No N/A

~~☐☐☐~~ ~~7.1. The pharmacist who is authorized to issue an order to initiate or adjust a controlled substance therapy is personally registered with the federal Drug Enforcement Administration. (B&PC 4052[b])~~

☐☐☐ ~~7.2~~ 7.1. The advanced practice pharmacist has received an advanced practice pharmacist ~~recognition~~ license ~~by~~ from the board and may do the following: (B~~&~~PC 4016.5, 4210)

- ☐ ~~7.2.1~~ 7.1.1Perform patient assessments, order and interpret drug therapy-related tests, and refer patients to other health care providers; (B~~&~~PC 4052.6[a])
- ☐ ~~7.2.2~~ 7.1.2 Participate in the evaluation and management of diseases and health conditions in collaboration with other health care providers; (B~~&~~PC 4052.6[a])
- ☐ ~~7.2.3~~ 7.1.3 Initiate drug therapy and promptly transmit written notification to, or enter the appropriate information in to a patient record system shared with the patient's primary care provider or diagnosing provider; (B~~&~~PC 4052.6[b])

☐ ~~7.2.4~~ 7.1.4 Adjust or discontinue drug therapy and promptly transmit written notification to the patient's diagnosing prescriber or enters the appropriate information in a patient's record system shared with the prescriber; (B~~&~~PC 4052.6[b])

☐ ~~7.2.5~~ 7.1.5 Prior to initiating or adjusting a controlled substance therapy, the advance practice pharmacist is personally registered with the federal Drug Enforcement Administration; (B~~&~~PC 4052.6[d])

☐ ~~7.2.6~~ 7.1.6 Ordering of tests is done in coordination with the patient's primary care provider or diagnosing prescriber, including promptly transmitting written notification to the prescriber or entering information in a patient record system shared with the prescriber. (B~~&~~PC 4052.6[e])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

8. Duties of an Intern Pharmacist

Yes No N/A

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

Yes No N/A

☐☐☐ 8.2. All prescriptions filled or refilled by an intern are, prior to dispensing, checked for accuracy by a licensed pharmacist and the prescription label initialed by the checking pharmacist. (CCR 1717[b][1], CCR 1712)

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

☐☐☐ 8.4. During a temporary absence of a pharmacist or duty free breaks or meal periods, an intern pharmacist may not perform any discretionary duties nor act as a pharmacist. (CCR 1714.1[d])

☐☐☐ 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. ~~Registered~~ ~~p~~Pharmacy technicians ~~are performing~~ only perform packaging, manipulative, repetitive, or other nondiscretionary tasks, while assisting and under the direct supervision and control of a pharmacist. The pharmacist is responsible for the duties performed by the pharmacy technician under the pharmacist's supervision. (B~~&~~PC 4023.5, 4038, 4115, CCR 1793, 1793.2, 1793.7)

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

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

☐☐☐ 9.4. The pharmacy has a job description for the pharmacy technician and written policies and procedures to ensure compliance with technician requirements. (CCR 1793.7[~~e~~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 ~~120~~ 140 hours. (B~~&~~PC 4115.5)

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

CORRECTIVE ACTION OR ACTION PLAN: _____

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10. Duties of Non-Licensed Personnel

Yes No N/A

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

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

CORRECTIVE ACTION OR ACTION PLAN: _____

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PHARMACY PRACTICE

11. Consultation/Patient Profile/Review of Drug Therapy

Yes No N/A

☐☐☐ 11.1. Pharmacists provide oral consultation: (~~B&PC 4052[a][7],~~ BPC 4052[a][8], CCR 1707.2)~~:~~

- ☐ 11.1.1. whenever the prescription drug has not been previously dispensed to the patient;
- ☐ 11.1.2. whenever a refill prescription drug is dispensed in a different dosage form, strength, or with new written directions;
- ☐ 11.1.3. upon request; ~~and~~
- ☐ 11.1.4. whenever the pharmacist deems it is warranted in the exercise of his or her professional judgment~~.~~; and
- ☐ 11.1.5. all of the above, unless a patient or patient's agent declines the consultation directly to the pharmacist.

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

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

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

☐☐☐ 11.5. Appropriate drug warnings are provided orally or in writing. (B~~&~~PC 4074, CCR 1744)

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

CORRECTIVE ACTION OR ACTION PLAN: _____

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12. Prescription Requirements

Yes No N/A

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

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

PIC Initials _____

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

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

☐☐☐ 12.5. The security and confidentiality of electronically transmitted prescriptions are maintained. (B&PC 4070[c], CCR 1717.4[h])

☐☐☐ 12.6. Facsimile prescriptions are received only from a prescriber's office. (B&PC 4040[c])

☐☐☐ 12.7. Internet prescriptions for patients (human or animal) in this state are only dispensed or furnished pursuant to a prior good faith examination. (B&PC 2290.5, 2242, 2242.1, 4067[a])

☐☐☐ 12.8. With the exception of those prescriptions written under H&SC 11159.2, 11159.3 and ~~H&SC~~ 11167.5, all written controlled substances prescriptions (Schedules II – V) are on California Security Prescription forms. (H&SC 11164[a], ~~H&SC~~ 11167.5, 11162.1)

☐☐☐ 12.9. All controlled substance prescriptions are valid for six months and are signed and dated by the prescriber. (H&SC 11164[a][1], 11166)

☐☐☐ 12.10. All controlled substance prescriptions that are e-prescribed conform to provisions of federal law. (21 CFR 1300, 1306, 1311~~6.08, 1306.11, 1311.100~~)

CORRECTIVE ACTION OR ACTION PLAN: _____

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13. Prescription Labeling, Furnishing and Dispensing

Yes No N/A

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

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

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

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

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

~~☐ 13.4.1 The name of the patient, name of the drug and strength of the drug, the directions for use of the drug, the condition or purpose for which the drug was~~

~~prescribed, if indicated on the prescription, are clustered into one area of the label and comprise at least 50 percent of the label.~~

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

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

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

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

☐☐☐ 13.~~6~~3. The ~~E~~expiration date~~s~~ of a ~~drugs'~~ drug's effectiveness is accurately identified on the label ~~are~~ ~~consistent with those of the manufacturer~~ ~~if the information is required on the original manufacturer's label~~. (B&PC 4076)

☐☐☐ 13.~~7~~4. The trade name or generic name and manufacturer of the prescription drug is accurately identified on the label and prescription record 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. (B&PC 4076, CCR 1707.5[a][1], 1717[b][2])

☐☐☐ 13.~~8~~5. Generic substitution is communicated to the patient. (B&PC 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.~~9~~~~e~~7. If the prescription is filled by a pharmacy technician or a pharmacy technician trainee, before dispensing the prescription is checked for accuracy by a licensed pharmacist and that pharmacist initials the prescription label or by recording the identity of the reviewing pharmacist in a computer system by a secure means~~or as otherwise allowed for those filled by a pharmacy technician trainee~~. (B&PC 4115, 4115.5, CCR 1793.7, CCR 1712)

☐☐☐ 13.~~10~~~~f~~8. The federal warning label prohibiting transfer of controlled substances is on the prescription container. (21 CFR 290.5)

☐☐☐ 13.~~11~~~~e~~9. Prescriptions are dispensed in a new and child-resistant container, or senior-adult ease-of-opening tested container, or in a non-complying package only pursuant to the prescriber or when requested by the purchaser. (15 USC 1473[b], 16 CFR 1700.15, CCR 1717)

☐☐☐ 13.~~12~~~~g~~10. Patient package inserts are dispensed with all estrogen medications. (21 CFR 310.515)

☐☐☐ 13.~~13~~~~h~~11. The pharmacy provides patients with Black Box Warning Information in conformance with 21 CFR 201.57[c].

☐☐☐ 13.~~14~~12. Medication guides are provided on required medications. (21 CFR, Part 208, Section 208.24[e])

☐☐☐ 13.~~14~~12~~12~~13. The pharmacy furnishes dangerous drugs in compliance with:

☐ BPC 4119 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)

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

☐☐☐ 13.~~15~~13~~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. (B~~&~~PC 4076)

Yes No N/A

☐☐☐ 13.~~16~~14~~14~~15. Controlled substance prescriptions are not filled or refilled more than six months from the date written. (H~~&~~SC 11200[a])

☐☐☐ 13.~~15~~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. (H~~&~~SC 11200[b])

☐☐☐ 13.~~17~~16~~16~~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: ~~with the following exceptions (other than controlled substances, or psychotropic medication or drugs)~~: (B~~&~~PC 4064.5)

- Controlled substances
- Psychotropic medications
- Self-administered hormonal contraception

☐ 13.17~~16~~.1 Where the prescription specifies an initial quantity of less than a 90-day supply followed by periodic refills; and where: (B&PC 4064.5[a])

☐ 13. 17~~16~~.1.1 The prescriber has not indicated “no change to quantity” or words of similar meaning; (B&PC 4064.5[d])

☐ 13. 17~~16~~.1.2. The patient has completed an initial 30 day supply; (B&PC 4064.5[a][1]) (This is not required where the prescription continues the same medication as previously dispensed in a 90 day supply. B&PC 4064.5[b])

☐ 13. 17~~16~~.1.3. The total quantity dispensed does not exceed the total quantity authorized on the prescription, including refills; (B&PC 4064.5[a][2])

☐ 13. 17~~16~~.1.4. The prescriber has not specified on the prescription that dispensing the prescription in an initial amount, followed by periodic refills, is medically necessary; and (B&PC 4064.5[a][3])

☐ 13. 17~~16~~.1.5. The pharmacist is exercising his or her professional judgment. (B&PC 4064.5[a][4])

☐ 13. 17~~16~~.2. The pharmacist notifies the prescriber of the increase in quantity dispensed. (B&PC 4064.5[c])

☐ 13.-17~~16~~.2. The pharmacist notifies the prescriber of the increase in quantity dispensed. (B~~&~~PC 4064.5[c])

☐ 13.17.3. When requested by the patient, the pharmacist dispenses up to a 12-month supply of an FDA-approved, self-administered hormonal contraceptive pursuant to a valid prescription that specifies an initial quantity followed by periodic refills. (BPC 4064.5)

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

☐☐☐ 13.~~18~~17~~7~~8. The pharmacist includes a written label on the drug container indicating that the drug may impair a person's ability to operate a vehicle or vessel. The label may be printed on an auxiliary label affixed to the prescription container. (B~~&~~PC 4074[a],[b], 4076.7, CCR 1744)

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

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

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

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

☐☐☐ 13.23. When the pharmacy furnished naloxone or another opioid antagonist to a school district, county office of education, or charter school pursuant to Section 49414.3 of the

Education Code, it is furnished exclusively for use at a school district school site, county office of education school site, or charter school, and a physician or surgeon provides a written order specifying the quantity to be furnished. (BPC 4119.8)

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

☐☐☐ 13.25. For each vaccine administered by a pharmacist, a patient vaccine administration record is maintained in an automated data processing or manual record mode such that information required under section 300aa-25 of Title 42 of the United States Code is readily retrievable during the pharmacy's normal operating hours, provides each patient with a vaccine administration record, and reports to the immunization registry, in accordance with BPC 4052.8(b)(3), the information described in HSC 120440(c) within 14 days of the administration of any vaccine (includes informing each patient or patient's guardian of immunization record sharing preferences detailed in HSC 120440(e). (CCR 1746.4)

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

☐☐☐ 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)

☐☐☐ 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).

☐☐☐ 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]).

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

14. Refill Authorization

Yes No N/A

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

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

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

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

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

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

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

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 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 or 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: _____

_____

~~15~~16. Quality Assurance and Medication Errors

Yes No N/A

☐☐☐ ~~15~~16.1. Pharmacy has established quality assurance program that documents medication errors attributable, in whole or in part, to the pharmacy or its personnel. (B&PC 4125, CCR 1711)

☐☐☐ ~~15~~16.2. Pharmacy quality assurance policies and procedures are maintained in the pharmacy and are immediately retrievable. (CCR 1711[c])

☐☐☐ ~~15~~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], 1711[c][3])

☐☐☐ ~~15~~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])

☐☐☐ ~~15~~16.5. Investigation of pharmacy medication errors is initiated within two business days from the date the medication error is discovered. (CCR 1711[d])

☐☐☐ ~~15~~16.6. The record for quality assurance review for a medication error contains: (CCR 1711[e])

☐ ~~15~~16.6.1. Date, location, and participants in the quality assurance review;

☐ ~~15~~16.6.2. Pertinent data and other information related to the medication error(s) reviewed;

☐ ~~15~~16.6.3. Findings and determinations; and

☐ ~~15~~16.6.4. Recommended changes to pharmacy policy, procedure, systems or processes, if any.

☐☐☐ ~~15~~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])

☐☐☐ ~~15~~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 B~~&~~PC 4073 (generic substitution). (CCR 1716)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

~~16~~17. Erroneous or Uncertain Prescriptions / Corresponding Responsibility for Filling Controlled Substance Prescriptions

Yes No N/A

☐☐☐ ~~16~~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])

☐☐☐ ~~16~~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. (H~~&~~SC 11153)

☐☐☐ ~~16~~17.3. Even after conferring with the prescriber, the pharmacist does not dispense a controlled substance prescription if he or she knows or has objective reason to know that the prescription was not issued for a legitimate medical purpose. (CCR 1761[b], HSC 11153)

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

☐☐☐ ~~16~~17.~~5~~ 4. Internet prescriptions for controlled substances are only dispensed if in compliance with the Ryan Haight Online Pharmacy Consumer Protection Act of 2008. (21 USC 829, 21 USC 802.)

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

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

~~17~~18. Prescription Transfer

Yes No N/A

☐☐☐ ~~17~~18.1. Only pharmacists transfer prescriptions from pharmacy to pharmacy, and records of prescription transfers are kept as required. (CCR 1717 [e][1-6])

☐☐☐ ~~17~~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). Unfulfilled controlled substance prescriptions received as electronic data transmission prescriptions are transferred or forwarded in compliance with Federal Law.

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

☐☐☐ ~~17~~18.3. For the **transferring pharmacy**: the prescription hard copy is pulled and "void" is written on its face. The name of the pharmacy to which the prescription is transferred is written on the back of the voided prescription and all other information is recorded as required. The prescription can be transferred only once unless the pharmacies electronically share a real-time, on-line database, in which case the prescription is transferred up to the maximum refills permitted by law and the prescriber's authorization. (CFR 1306.25, CCR 1717[f])

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

☐☐☐ ~~17~~18.4. For the **receiving pharmacy**: the prescription is reduced to writing by the pharmacist and "transfer" is written on the face of the transferred prescription and all other information is recorded as required. (CCR 1717[e], CFR 1306.25)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

~~18~~19. Confidentiality of Prescriptions

Yes No N/A

☐☐☐ ~~18~~19.1. Patient information is maintained to safeguard confidentiality. (Civil Code 56.10 et seq.)

☐☐☐ ~~18~~19.2. All prescriptions are kept confidential and only disclosed as authorized by law. (CCR 1764)

☐☐☐ ~~18~~19.3. The pharmacy ensures electronically transmitted prescriptions are received, maintained and transmitted in a secure and confidential manner. (CCR 1717.4[h])

☐☐☐ ~~18~~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])

☐☐☐ ~~18~~19.5. If pharmacy has established and utilizes common electronic prescription files to maintain required dispensing information, the system shall not permit disclosure of confidential medical information except as authorized by law. (CCR 1717.1)

☐☐☐ ~~18~~19.6. Destruction or disposal of patient records preserves the confidentiality of the information contained therein. (Civil Code 56.101)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

~~19~~20. Record Keeping Requirements

Yes No N/A

☐☐☐ ~~19~~20.1. ~~A~~ All completed ~~biennial~~ pharmacy self-assessments ~~is~~ are on file in the pharmacy and maintained for three years. (CCR 1715)

☐☐☐ ~~19~~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 maintained electronically. These records include (B~~&~~PC 4081, 4105, 4169, 4333):

- ☐ ~~19~~20.2.1. Prescription records (B~~&~~PC 4081[a])
- ☐ ~~19~~20.2.2. Purchase Invoices for all prescription drugs (B~~&~~PC 4081[b])
- ☐ 20.2.3. Purchase Invoices and sales records for non-prescription diabetic test devices dispensed pursuant to a prescription (B&PC 4081[d])
- ☐ ~~19~~20.2.~~3~~4. Biennial controlled substances inventory (21 CFR 1304.11, CCR 1718)
- ☐ ~~19~~20.2.~~4~~5. U.S. Official Order Forms (DEA Form 222) (21 CFR 1305.13)
- ☐ ~~19~~20.2.~~5~~6. Power of Attorney for completion of DEA 222 forms (21 CFR 1305.07)
- ☐ ~~19~~20.2.~~6~~7. Theft and Loss Reports (DEA Form 106) (21 CFR 1301.74[c])
- ☐ ~~19~~20.2.~~7~~8. Record documenting return of drugs to wholesaler or manufacturer (B~~&~~PC 4081)
- ☐ ~~19~~20.2.~~8~~9. Record documenting transfers or sales to other pharmacies, licensees, ~~and~~ prescribers, and reverse distributors (B~~&~~PC 4081, 4105, CCR 1718)
- ☐ 20.2.10. Records of receipt and shipment (B&PC 4081)

~~Yes No N/A~~

☐☐☐ ~~19~~20.3. ~~Hypodermic needle and syringe sales by a pharmacist to a person without~~A pharmacist may sell hypodermic needles and syringes to a person with a prescription ~~are~~ is limited to: (B~~&~~PC 4145.5)

- ☐ ~~19~~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;
- ☐ ~~19~~20.3.2. Use on animals, provided the person is known to the pharmacist or the person's identity can be properly established.
- ~~☐ 19.3.3. The sale of hypodermic needles or syringes at any one time to a person 18 or older **only** if the pharmacy is registered in their local county or city with the Disease Prevention Demonstration Project, and complies with the requirements of that project. (H&S 121285, B&PC 4145.5)~~
- ☐ ~~19~~20.3.~~4~~3. For industrial use, as determined by the board. (B~~&~~PC 4144.5)
- ☐ ~~19~~20.3.~~5~~4. As a public health measure intended to prevent the transmission of HIV, viral hepatitis, and other bloodborne diseases, furnishing of ~~30 or fewer~~ hypodermic needles and syringes for human use to a person 18 years of age or older for personal use. (B~~&~~PC 4145.5)

☐☐☐ ~~19~~20.4. When hypodermic needles and syringes are furnished by a pharmacy ~~or hypodermic needle and exchange program~~ without a prescription, the pharmacy provides the consumer with written information or verbal counseling on how to access drug treatment, testing and treatment for HIV and hepatitis C and safe disposal of sharps waste; and provide one or more of the following disposal options: (B~~&~~PC 4145.5[e],[f])

- ☐ ~~19~~20.4.1. Onsite, safe, hypodermic needle and syringe collection and disposal program.
- ☐ ~~19~~20.4.2. Furnish or make available mail-back sharps containers.
- ☐ ~~19~~20.4.3. Furnish or make available sharps containers.

☐☐☐ ~~19~~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, B~~&~~PC 4105)

Date Waiver Approved _____ Waiver Number _____

Address of offsite storage location: _____

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

☐ 20.6.1. The epinephrine auto-injectors are furnished for use at a school district site, county office or 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]).

☐☐☐ ~~19.6~~20.7. The pharmacy ~~dispenses~~ furnishes an epinephrine auto-injector to an authorized entity ~~a prehospital emergency medical care person or lay rescuer~~ for the purpose of rendering emergency care in accordance with H~~&~~SC 1797.197a. (B~~&~~PC 4119.3, 4119.4)

☐ ~~19.6~~20.7.1. An ~~physician/surgeon~~ authorized healthcare provider provides a written order that specifies the quantity of epinephrine auto-injectors to be dispensed. (B~~&~~PC 4119.3[a][1], 4119.4[a][2])

☐ ~~19.6~~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. (B~~&~~PC 4119.3[a][1], 4119.4[b])

☐ ~~19.6~~20.7.3. Each dispensed prescription includes the manufacturer's product information sheet for epinephrine auto-injectors. (B~~&~~PC 4119.3[a][2], 4119.4[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

~~20~~21. DEA Controlled Substances Inventory

Inventory:

Yes No N/A

☐☐☐ ~~20~~21.1. Is completed biennially (every two years).
Date completed: _____ (21 CFR 1304.11[~~b~~ c])

☐☐☐ ~~20~~21.2. Schedule II inventory is separate from Schedule III, IV and V. See also Section 21. (21 CFR 1304.04[h][1]~~, 1304.04[h][2]~~)

☐☐☐ ~~20~~21.3. All completed inventories are ~~Is~~ available for inspection for three years. (CCR 1718)

☐☐☐ ~~20~~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])

☐☐☐ ~~20~~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])

☐☐☐ ~~20~~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][~~2~~4])

☐☐☐ ~~20~~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)

☐☐☐ ~~20~~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 Form222. (21 CFR 1305.03, 1305.12, 1305.13, 1305.21, 1305.22[g])

☐☐☐ ~~20~~21.9. When a pharmacy distributes schedule II controlled substances to a DEA registrant (pharmacies, wholesales, manufacturers, prescribers) a DEA Form222 is prepared by the purchasing registrant and provided to the pharmacy selling the schedule II controlled substances. (21 CFR 1305.12)

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

☐☐☐ ~~20~~21.10. When the pharmacy distributes Schedule II controlled substances to other DEA registrants, such as those listed above, Copy 2 of the DEA Form222, is properly completed by the pharmacy selling the controlled substances and that copy is submitted at the end of each month to the DEA regional office. (21 CFR 1305.13)

☐☐☐ ~~20~~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[b], ~~Prescription Drug Marketing Act of 1987 [Pub. L. 100-293, Apr. 22, 1988] 503.~~ Drug Supply Chain Security Act, B~~&~~PC 4160)

☐☐☐ ~~20~~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 Bureau of Narcotic Enforcement within 144 hours of the failure to provide prescription. (H~~&~~SC 11167[d])

☐☐☐ ~~20~~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.

☐☐☐ ~~20~~21.14. Any controlled substances drug loss is reported ~~upon~~ within one business day of discovery to the DEA and within 30 days of discovery to the Board of Pharmacy. (21 CFR 1301.74[c], CCR 1715.6)

☐☐☐ ~~20~~21.15. Do pharmacy staff hand initial prescription records or prescription labels, or

☐☐☐ ~~20~~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])

☐☐☐ ~~20~~21.17. All Schedule II through IV controlled substance dispensing data is successfully transmitted to CURES ~~weekly. (H&SC 11165[d])~~ within one working day from the date the controlled substance is released to be patient. [HSC 11165(d)])

☐☐☐ ~~20~~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) ~~When furnishing controlled substances for physician office use, a prescription is not issued in order for an individual practitioner to obtain controlled substances for supplying the practitioner's general dispensing to patients. (21 CFR 1306.04[b])~~

☐☐☐ 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 administration and the Special Agent in charge of DEA in their area. (21 USC 832).

CORRECTIVE ACTION OR ACTION PLAN: _____
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~~21~~22. Inventory Reconciliation Report of Controlled Substances

Yes No N/A

☐☐☐ ~~21~~22.1. The pharmacy performs periodic inventory and inventory reconciliation functions to detect and prevent the loss of controlled substances. (CCR 1715.65 [a])

☐☐☐ ~~21~~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])

☐☐☐ ~~21~~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])

- ☐ ~~21~~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])
- ☐ ~~21~~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])

☐ ~~21~~22.3.3. A comparison of the two above-mentioned items to determine if there are any variances; (CCR 1715.65[c][3])

☐ ~~21~~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])

☐ ~~21~~22.3.5. Possible causes of overages shall be identified in writing and incorporated into the inventory reconciliation report. (CCR 1715.65[c][5])

☐☐☐ ~~21~~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])

☐☐☐ ~~21~~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])

☐☐☐ ~~21~~22.6. A new pharmacist-in-charge of the pharmacy completes an inventory reconciliation report as identified in CCR 1715.65 (c) within 30 days of becoming pharmacist-in-charge. When possible, the outgoing pharmacist-in-charge also completes an inventory reconciliation report as required in CCR 1715.65 (c). (CCR 1715.65 [f])

CORRECTIVE ACTION OR ACTION PLAN: _____

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~~21~~22~~2~~3. Oral/Electronic Transmission and ~~Fractionation~~ Partial Fill of Schedule II Controlled Substance Prescriptions

Yes No N/A

☐☐☐ ~~21~~22~~3~~.1. A faxed prescription for a Schedule II controlled substance is dispensed only **after** the original written prescription is received from the prescriber. (21 CFR 1306.11[a], H~~&~~SC 11164)

☐☐☐ ~~21~~22~~3~~.2. An oral or electronically transmitted prescription for a Schedule II controlled substance for a patient in a licensed skilled nursing facility, licensed intermediate care facility, licensed home health agency or a licensed hospice care is dispensed only **after** the pharmacist has reduced the prescription to writing on a pharmacy-generated prescription form, and: (21 CFR 1306.11, 21 CFR 1306.11[f], H~~&~~SC 11167.5)

☐ ~~21~~22~~3~~.2.1. The licensed facility provides the pharmacy with a copy of the prescriber's signed order, when available.

PIC Initials

☐ ~~21~~23.2.2. The prescription is endorsed by the pharmacist with the pharmacy's name, license, and address.

☐ ~~21~~23.2.3. The physician has signed the original prescription or provides a facsimile signature on the prescription.

☐ ~~21~~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], H~~&~~SC 11167.5)

☐☐☐ ~~21~~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])

☐☐☐ ~~21~~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)

☐☐☐ ~~22~~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. (H&SC 11159.2, 21 CFR 1306.11[a], CCR 1745)

☐☐☐ ~~212.56~~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 H~~&~~SC 11162.1 by the seventh day following the transmission of the initial order. (21 CFR 1306.11[d], H~~&~~SC 11167)

☐☐☐ ~~212.67~~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)

☐☐☐ ~~212.78~~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])

☐☐☐ ~~212.89~~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])

~~Yes No N/A~~

☐☐☐ ~~212.910~~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])

☐☐☐ ~~212.1011~~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)

~~☐☐☐ 212.1112. Controlled substances written with the "11159.2 exemption" for the terminally ill are only dispensed when the original prescription is received, is tendered and partially filled within 60 days and no portion is dispensed more than 60 days from the date issued. (H&SC 11159.2, 21 CFR 1306.11[a], CCR 1745)~~

☐☐☐ ~~212.12~~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:

☐ 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 CURE PDMP before dispensing the medication.

☐ If the prescription is a Schedule II controlled substance, 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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~~223~~24. Automated Drug Delivery Systems ~~Dispensing/Delivery Devices~~

Yes No N/A

☐☐☐ ~~223~~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 annual self-assessment for automated drug delivery systems.

~~automated dispensing/delivery device and/or prescription drop box? (CCR 1713)~~

☐☐☐ 223.2. The drugs in an automated dispensing drug delivery system unit are properly labeled and identified with at least the following information: name of drug, strength and dosage form, manufacturer and manufacturer's lot number, and expiration date. (21 CFR Parts 201.17, 210, 211, B&PC 4342, HSC 111355)

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

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

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

- ☐ 223.4.1. Drugs are restocked by a pharmacist or by an intern or technician working under the supervision of a pharmacist except when statute authorizes exceptions. (H&SC 1261.6[f][1], 1261.6[g])
- ☐ 223.4.2. Removable pockets or drawers are transported between the pharmacy and the facility in a secure tamper-evident container. (H&SC 1261.1[f][2])

CORRECTIVE ACTION OR ACTION PLAN: _____

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23425. Repackaging by the Pharmacy

Yes No N/A

☐☐☐ 23425.1. Drugs are repackaged (precounted or poured) in quantities suitable for dispensing to patients of the pharmacy. Such repackaging is performed according to the Current Good Manufacturing Practice (CGMP), and the drugs are properly labeled with at least the following information: name of drug, strength, dosage form, manufacturer's name and lot number, expiration date, and quantity per repackaged unit. (21 CFR Part 210, 211 [CGMP], B&PC 4342, H&SC 110105, 111430, CCR 1707.5)

☐☐☐ 23425.2. A log is maintained for drugs pre-packed for future dispensing. (CCR 1751.1, 21 CFR Parts 210, 211)

☐☐☐ 23425.3. Drugs previously dispensed by another pharmacy are re-packaged at the patient's request in compliance with and includes the name and address of both pharmacies and complies with the other requirements of B&PC 4052.7.

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

CORRECTIVE ACTION OR ACTION PLAN: _____

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~~24~~5526. Refill Pharmacy

Yes No N/A

☐☐☐ ~~24~~526.1. Pharmacy processes refills for another California licensed pharmacy (CCR 1707.4[a])

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

☐☐☐ ~~24~~526.2. Does the pharmacy employ the use of a common electronic file? If yes, are there policies and procedures in place to prevent unauthorized disclosures? (CCR 1717.1)

☐☐☐ ~~24~~526.3. Some or all pharmacy refill orders are processed by another California licensed pharmacy. (CCR 1707.4[a])

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

If the answer to both questions above is “no” or “not applicable” go to section ~~23~~276~~6~~.

☐☐☐ ~~24~~526.4. Originating pharmacy and refill pharmacy have a contract outlining the refill arrangement, or the pharmacies have the same owner. (CCR 1707.4[a][1])

☐☐☐ ~~24~~526.5. Refill prescription label meets requirements of B~~&~~PC 4076 and CCR 1707.5 and shows the name and address of the refilling and or originating pharmacy. (CCR 1707.4[a][2])

☐☐☐ ~~24~~526.6. Patient is provided with written information, either on the prescription label or prescription container that describes which pharmacy to contact for questions. (CCR 1707.4[a][3])

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

☐☐☐ ~~24~~526.7. Both pharmacies maintain complete and accurate records of refill. (CCR 1707.4[a][4])

☐☐☐ ~~24~~526.8. Both pharmacies are responsible for accuracy of the refilled prescription. (CCR 1707.4[a][5])

☐☐☐ ~~24~~526.9. 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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~~256~~27. Standards of Service for Providers of Blood Clotting Products for Home Use (HSC 125286.10)

Yes No N/A

☐☐☐ ~~256~~27.1. The pharmacy is a provider of blood clotting products for home use. (HSC 125286.20)

- ☐ ~~256~~27.1.1. Health system pharmacy. (HSC 125286.20[j][1][B])
- ☐ ~~256~~27.1.2. Pharmacy affiliated with hemophilia treatment centers. (HSC 125286.20[j][1][C])
- ☐ ~~256~~27.1.3. Specialty home care pharmacy. (HSC 125286.20[j][1][D])
- ☐ ~~256~~27.1.4. Retail pharmacy. (HSC 125286.20[j][1][E])

☐☐☐ ~~256~~27.2. The pharmacy meets the following requirements:

- ☐ ~~256~~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])
- ☐ ~~256~~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])
- ☐ ~~256~~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])
- ☐ ~~256~~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])
- ☐ ~~256~~27.2.5. Supplies all necessary ancillary infusion equipment and supplies with each prescription, as needed. (HSC 125286.25[e])
- ☐ ~~256~~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])
- ☐ ~~256~~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])

☐ ~~25~~6~~2~~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])

☐ ~~25~~6~~2~~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])

☐ ~~25~~6~~2~~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])

☐ ~~25~~6~~2~~27.2.11. Provides language interpretive services over the telephone or in person, as needed by the patient. (HSC 125286.25[k])

☐ ~~25~~6~~2~~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])

~~26~~7~~2~~8. Policies and Procedures

Yes No N/A

☐☐☐ ~~26~~7~~2~~8.1. There are written policies and procedures in place for:

☐ ~~26.1.1. The pharmacist's administration of immunizations by injection pursuant to a prescriber's order or state protocol for immunizations; (B&PC 4052.1[a][3])~~

☐ ~~26~~7~~2~~8.1.~~2~~1. Action to be taken to protect the public when a licensed individual employed by or with the pharmacy is known to be chemically, mentally, or physically impaired to the extent that it affects his or her ability to practice the profession or occupation authorized by his or her license, including the reporting to the board within 14 days of receipt or development; (B~~&~~PC 4104[a],[c])

☐ ~~26~~7~~2~~8.1.~~3~~2. Action to be taken to protect the public when a licensed individual employed by or with the pharmacy is known to have engaged in the theft or diversion or self-use of prescription drugs belonging to the pharmacy, including the reporting to the board within 14 days of receipt or development; (B~~&~~PC 4104[b],[c])

☐ ~~26~~7~~2~~8.1.~~4~~3. Oral consultation for discharge medications to an inpatient of a health care facility licensed pursuant to H~~&~~SC 1250, or to an inmate of an adult correctional facility or juvenile detention facility; (B~~&~~PC 4074, CCR 1707.2[b][3])

☐ ~~26~~7~~2~~8.1.~~5~~4. Operation of the pharmacy during the temporary absence of the pharmacist for breaks and meal periods including authorized duties of personnel, pharmacist's responsibilities for checking all work performed by ancillary staff,

and pharmacist's responsibility for maintaining the security of the pharmacy; (CCR 1714.1[f])

☐ ~~26~~7~~.~~28.1.~~6~~5. Assuring confidentiality of medical information if your pharmacy maintains the required dispensing information for prescriptions, other than controlled substances, in a shared common electronic file; (CCR 1717.1[e])

☐ ~~26~~7~~.~~28.1.~~7~~6. The delivery of dangerous drugs and dangerous devices to a secure storage facility, if the pharmacy accepts deliveries when the pharmacy is closed and there is no pharmacist present; (B~~&~~PC 4059.5[f][1])

☐ ~~26~~7~~.~~28.1.~~8~~7. Compliance with Title VII of Public Law 109-177 – Combat Methamphetamine Epidemic Act of 2005;

~~☐ 26.7.1.98. Reporting requirements to protect the public; (B&PC 4104)~~

☐ ~~26~~7~~.~~28.1.~~109~~108. ~~Preventing the dispensing of a prescription drug that is contrary to the law;~~ A policy to establish how a patient will receive a medication when a pharmacist has a conscientious objection. (B~~&~~PC 733)

☐ ~~26~~7~~.~~28.1.~~11~~10~~11~~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; and (B~~&~~PC 733)

☐ ~~26~~7~~.~~28.1.~~12~~11~~12~~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. (CCR 1707.5)

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

~~Yes No N/A~~

☐☐☐ ~~26~~7~~.~~28.2. Does your pharmacy employ the use of a common electronic file?

☐ ~~26~~28.2.1. If yes, are there policies and procedures in place to prevent unauthorized disclosures? (CCR 1717.1[e])

☐☐☐ ~~26~~7~~.~~28.3. Does your pharmacy furnish emergency contraceptives pursuant to B~~&~~PC 4052.3[a][1]? (B~~&~~PC 4052, CCR 1746) If yes, does the pharmacy

☐ ~~26~~7~~.~~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)

☐ ~~26~~7~~.~~28.3.2. Provide the patient with a copy of the current EC Fact Sheet approved by the Board of Pharmacy? (CCR 1746)

☐ ~~26~~7~~.~~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)

☐ ~~26~~7~~.~~28.3.4. Prior to furnishing EC, the pharmacist has completed a minimum of one hour of continuing education specific to emergency contraception. (CCR 1746)

☐ ~~26~~7~~/~~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? (CCR 1746, 1746.1[b][9])

☐ ~~26~~7~~/~~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? (B~~&~~PC 733[b])

☐ ~~26~~7~~/~~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 his or her employer in writing? (B~~&~~PC 733[b], B~~&~~PC 4052.3)

☐ ~~26~~7~~/~~28.3.8. If no, EC services are not immediately available or any pharmacist declines to furnish pursuant to a conscience clause, does the pharmacist refer the patient to another emergency contraception provider? (CCR 1746)

☐☐☐ ~~26~~7~~/~~28.4. Furnishes naloxone hydrochloride in accordance with standardized procedures or protocols developed and approved by both the Board of Pharmacy and the Medical Board of California. (B~~&~~PC 4052.01[a], CCR 1746.3)

☐ ~~26~~7~~/~~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.

☐ ~~26~~7~~/~~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.

☐☐☐ ~~27~~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)

☐☐☐ ~~27~~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), and incorporate by reference, completion of the CDC Yellow Fever Vaccine Course and current basic life support certification. (CCR 1746.5[c])

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

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

☐ 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 or facility's normal operating hours and the pharmacist provides the patient with written documentation that reflects the clinical assessment and travel medication plan. (CCR 1746.5[g])

CORRECTIVE ACTION OR ACTION PLAN: _____

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~~27~~8~~29~~. Compounding

Yes No N/A

☐☐☐ ~~27~~8~~29~~.1. Prior to allowing any drug product to be compounded in a pharmacy, the pharmacist-in-charge must complete the "Compounding Self-Assessment" ~~Form 17M-39 (Rev. 02/12)~~ required by ~~(~~CCR 1735.2~~[j]~~[k]~~)~~.

~~28~~9~~30~~. Nuclear Pharmacy

Yes No N/A

☐☐☐ ~~28~~9~~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)

☐☐☐ ~~28~~9~~.~~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)

☐☐☐ ~~28~~9~~.~~30.3. The pharmacy possesses a current Sterile Compounding Permit (B~~&~~PC 4127) and is compliant with CCR 1751. (Must also complete Compounding Self-Assessment, ~~17M-39 Rev. 02/12.)~~ required by ~~(~~CCR 1735.2[k]~~ et al.)~~.

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

31. Telepharmacy Systems and Remote Dispensing Site Pharmacies

Yes No N/A

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

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

Name:_____ License No.:_____

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

TCH Name:_____ License No._____

TCH Name:_____ License No._____

TCH Name:_____ License No._____

TCH Name:_____ License No._____

TCH Name:_____ License No._____

If the answer to the question above is “no” or “not applicable” go to section ~~26~~32.

☐☐☐ 31.2. The supervising pharmacy uses a telepharmacy system for the dispensing of prescription drugs and providing related drug regimen review and patient counseling services at the remote dispensing site pharmacy. (BPC 4130, 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 will become a full-service pharmacy licensed under Section 4110 with a pharmacist onsite if it meets all the requirements for licensure for a pharmacy, if the remote dispensing pharmacy dispenses more than 225 prescriptions per day, calculated each calendar year. (BPC 4130 [h])

Yes No N/A

☐☐☐ 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 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 qualifications promulgated by the board as required by BPC 4132. (BPC 4132[a]). The regulations developed by the board only apply to pharmacy technicians working at remote dispensing sites. BPC 4132(a)

☐ Possess a pharmacy technician license that is in good standing.

PIC Initials

☐ 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.

Yes No N/A

☐☐☐ 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])

Yes No N/A

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

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

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

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

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

☐☐☐ 31.31. 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])

☐☐☐ 31.31. 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. 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; and (BPC 4134[f][4])

Yes No N/A

☐☐☐ 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 shall be made within 14 days of discovery. If the remote dispensing site pharmacy is unable to identify the cause of the loss, further investigation is undertaken to identify the cause and actions necessary to prevent additional losses of controlled substances. (BPC 4134[g])

☐☐☐ 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 be readily retrievable in the pharmacy for three years. A countersignature is not required if the pharmacist-in-charge personally completed the inventory reconciliation report. (BPC 4134 [i])

☐☐☐ 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 or 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 this section is stored separately from existing inventory until the time the controlled substance is reviewed and countersigned by a pharmacist. (BPC 4059.5[g])

Yes No N/A

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

Yes No N/A

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

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

☐☐☐ 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])

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])

Date the board was notified: _____

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

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

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

Date reported: _____

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

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

Yes No N/A

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

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

☐☐☐ 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 D179 standard test for impact resistance of 165 grams (drop dart test) and the ASTM D1922 standards for tear resistance of 480 grams in both parallel and perpendicular planes. (CCR 1776.3[f])

☐ 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.

☐ 32.23.2. The liner is clearly marked to display the maximum contents (for example, in gallons). (CCR 1776.3[f][2]

☐ 32.23.3. The liner bears a permanent, unique identification number established by the pharmacy or pre-entered onto the liner by the liner's manufacturer or distributor. (CCR 1776.3[f][2])

☐ 32.23.4. The liner is removable as specified pursuant to CCR 1776.3.

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

Yes No N/A

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

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

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

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

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

Pharmacies with Drug Take-Back Services in Skilled Nursing Facilities

Yes No N/A

☐☐☐ 32.32. 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])

☐☐☐ 32.33. 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])

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

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

If yes, continue answering the questions in this section.

List the location(s) of the collection receptacle:

_____

_____

_____

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

Yes No N/A

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

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

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

☐☐☐ 32.38. 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])

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

☐☐☐ 32.40. 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])

☐☐☐ 32.41. 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])

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

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

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

Yes No N/A

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

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

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

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

Record Keeping Requirements for Board Licensees Providing Drug Take Back Services

Yes No N/A

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

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

☐ 32.50.1. 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])

☐ 32.50.2. 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])

☐ 32.50.3. 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])

☐ 32.50.4. 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])

☐ 32.50.5. 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: _____

_____

~~2930~~33. Pharmacies That Donate Drugs to a Voluntary County-Approved Drug Repository and Distribution Program

Yes No N/A

☐☐☐ ~~2930~~33.1. The pharmacy donates medications to a county-approved drug repository and distribution program, and meets the following requirements: (H~~&~~SC 150202.5, 150204, B~~&~~PC 4169.5)

☐ ~~2930~~33.1.1. The pharmacy is licensed by and is not on probation with the California State Board of Pharmacy, **and** (H~~&~~SC 150202.5)

☐ ~~2930~~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. (H~~&~~SC 150202.5)

☐☐☐ ~~2930~~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. (B~~&~~PC 4169.5)

☐☐☐ ~~2930~~33.3. No controlled substances shall be donated. (H~~&~~SC 150204[c][1])

☐☐☐ ~~293~~33.4. Drugs that are donated are unused, unexpired and meet the following requirements: (H~~&~~SC 150202.5, 150204[c])

- ☐ ~~293~~33.4.1. Have not been adulterated, misbranded, or stored under conditions contrary to standards set by the USP or the product manufacturer. (H~~&~~SC 150204[c][2])
- ☐ ~~293~~33.4.2. Were received directly from a manufacturer or wholesaler. (H~~&~~SC 150202.5[a])
- ☐ ~~293~~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. (H~~&~~C 150202.5[b], 150204[c][3])
- ☐ ~~293~~33.4.4. Are in unopened, tamper-evident packaging or modified unit dose containers with lot numbers and expiration dates affixed. (H~~&~~SC 105204[d])
- ☐ ~~293~~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. (H~~&~~SC 150204[m])

~~30~~1~~34~~. Pharmacies That Operate a Voluntary County-Approved Drug Repository and Distribution Program

Yes No N/A

☐☐☐ ~~30~~1~~34~~.1. The pharmacy conducts a county-approved drug repository and distribution program. (H~~&~~SC 150201, 150204)

- ☐ ~~30~~1~~34~~.1.1. The pharmacy is licensed by and is not on probation with the California State Board of Pharmacy, **and:** (H~~&~~SC 150201[a][1])
  - ☐ ~~30~~1~~34~~.1.1.1. Is county owned (H~~&~~SC 150201[b][1]) or
  - ☐ ~~30~~1~~34~~.1.1.2. Contracts with the county to establish a voluntary drug repository and distribution program. (H~~&~~SC 150201[b][1], 150200)
- ☐ ~~30~~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. (H~~&~~SC 150201[a][2])

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

☐☐☐ ~~30~~1~~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. (H~~&~~SC 150204[a][5])

Issued By: _____ Date: _____

☐☐☐ ~~30~~1~~34~~.3. Date that the county health department confirmed receipt of the pharmacy's "notice of intent" to participate in the program: _____ (H~~&~~SC 150204[a][3])

☐☐☐ ~~301~~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. (H~~&~~SC 150204[a][4][A])

Date last quarterly report was submitted: _____

☐☐☐ ~~301~~34.5. The pharmacy complies with the county's established written procedures. (H~~&~~SC 150204[b])

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

☐☐☐ ~~301~~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. (H~~&~~SC 150204[j])

☐☐☐ ~~301~~34.7. Records of acquisition and disposition of donated medications are kept separate from the participating entity's other drug acquisition and disposition records. (H~~&~~SC 150204[k])

☐☐☐ ~~301~~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. (H~~&~~SC 150204[n])

☐☐☐ ~~301~~34.9. Donated medications received are unused, unexpired and meet the following requirements: (H~~&~~SC 150202, 150202.5, 150204[c])

- ☐ ~~301~~34.9.1. Are received from authorized sources. (H~~&~~SC 150202, 150203)
- ☐ ~~301~~34.9.2. No controlled substances are received. (H~~&~~SC 150204[c][1])
- ☐ ~~301~~34.9.3. Are not adulterated, misbranded, or stored under conditions contrary to USP standards or the product manufacturer. (H~~&~~SC 150204[c][2])
- ☐ ~~301~~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. (H~~&~~SC 150204[c][3])
- ☐ ~~301~~34.9.5. Are received in unopened, tamper-evident packaging or modified unit dose containers with lot numbers and expiration dates affixed. (H~~&~~SC 150204[d])
- ☐ ~~301~~34.9.6. Are maintained in the donated packaging until dispensed to an eligible patient under the program, who presents a valid prescription. (H~~&~~SC 150204[i])
- ☐ ~~301~~34.9.7. For donated medications that require refrigeration, there are specific procedures to ensure that the medications are packaged, transported, stored, and dispensed at appropriate temperatures and in accordance with USP standards and pharmacy law. (H~~&~~SC 150204[m])

~~Yes No N/A~~

☐☐☐ ~~301~~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. (H&SC 150204[d], 150204[h])

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

☐☐☐ ~~30~~134.11. The pharmacy transfers donated medications to another participating county-owned pharmacy within an adjacent county. (H&SC 150204[g][4])

☐☐☐ ~~30~~134.12. The pharmacy has a written agreement outlining the protocols and procedures for the transfer of donated medications. (H&SC 150204[g][4][A])

Adjacent counties to which donated medications are transferred:

_____

☐☐☐ ~~30~~134.13. Donated medication is not transferred by any participating entity more than once. (H&SC 150204[g][4][B])

☐☐☐ ~~30~~134.14. When transferring donated medications, documentation accompanies the medication that identifies the drug name, strength, quantity of medication, and the donating facility from where the medication originated. (H&SC 150204[g][4][C])

☐☐☐ ~~30~~134.15. When transferring donated medication, documentation includes a statement that the medication may not be transferred to another participating entity. (H&SC 150204[g][4][C])

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

☐☐☐ ~~30~~134.16. Donated medications that are dispensed to an eligible patient that presents a valid prescription are dispensed in a new and properly labeled container, specific to the eligible patient. (H&SC 150204[i])

☐☐☐ ~~30~~134.17. The pharmacist adheres to standard pharmacy practices, as required by state and federal law, when dispensing donated medications under this program. (H&SC 150204[f])

PHARMACIST-IN-CHARGE CERTIFICATION:

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

Signature _____ _____ Date
(Pharmacist-in-Charge)

ACKNOWLEDGEMENT BY PHARMACY OWNER OR HOSPITAL ADMINISTRATOR:

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

Signature _____ _____ Date
Pharmacy Owner or Hospital Administrator

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.

California Code of Regulations (CCR), Title 16 and Title 24
Business and Professions Code (B&PC), Chapter 9, Division 2
Health and Safety Code (H&SC), Division 10, Uniform Controlled Substances Act
California Code of Regulations (CCR), Chapter 1, Division 5, Title 22
Code of Federal Regulations (CFR), Title 21, Chapter II, Drug Enforcement Administration (www.dea.gov)

California Board of Pharmacy
1625 N. Market Blvd., Suite N219
Sacramento, CA 95834
Phone: (916) 574-7900
Fax: (916) 574-8618
www.pharmacy.ca.gov
Pharmacy Law may be obtained by contacting:
Law Tech Publishing Co.
1060 Calle Cordillera, Suite 105
San Clements, CA 92673
Phone: (800) 498-0911 Ext. 5
www.lawtechpublishing.com

Pharmacist Recovery Program
(800) 522-9198 (24 hours a day)

Atlantic Associates, Inc. (CURES)
Prescription Collection
8030 S. Willow Street, Bldg 3 Unit 3
Manchester, NH 03103
Phone: (888) 492-7341
Fax: 877-508-6704

CURES
4949 Broadway
Sacramento, CA 95820
Phone: (916) 319-9062
Fax: (916) 319-9448
http://www.ag.ca.gov/bne

CURES Patient Activity Report Request Forms:
http://www.ag.ca.gov/bne/trips.php

PRESCRIBER BOARDS:

Medical Board of California
2005 Evergreen St., Suite 1200
Sacramento, CA 95815
Phone: (800) 633-2322
Phone: (916) 263-2382
Fax: (916) 263-2944
http://www.mbc.ca.gov

Dental Board of California
2005 Evergreen St., Suite 1550
Sacramento, CA 95815
Phone: (916) 263-2300
Fax: (916) 263-2140
http://www.dbc.ca.gov

Board of Registered Nursing
1625 N. Market Blvd., Suite N217
Sacramento, CA 95834
Phone: (916) 322-3350
Fax: (916) 574-7697
http://www.rn.ca.gov/

Board of Optometry
2420 Del Paso Road, Suite 255
Sacramento, CA 95834
Phone: (916) 575-7170
Fax: (916) 575-7292
http://www.optometry.ca.gov/

Osteopathic Medical Board of California
1300 National Drive, Suite 150
Sacramento, CA 95834
Phone: (916) 928-8390

Fax: (916) 928-8392
http://www.ombc.ca.gov

Physician Assistant Committee
2500 Evergreen St., Suite 1100
Sacramento, CA 95815
Phone: (916) 561-8780
Fax: (916) 263-2671
http://www.pac.ca.gov

Board of Podiatric Medicine
2005 Evergreen St., Suite 1300
Sacramento, CA 95815
Phone: (916) 263-2647
Fax: (916) 263-2651
http://www.bpm.ca.gov

Veterinary Medical Board
2005 Evergreen St., Suite 2250
Sacramento, CA 95815
Phone: (916) 263-2610
Fax: (916) 263-2621
http://www.vmb.ca.gov

FEDERAL AGENCIES:

Food and Drug Administration – Industry Compliance
http://www.fda.gov/oc/industry/centerlinks.html#drugs

The **Drug Enforcement Administration** may be contacted at:

DEA Website:
http://www.deadiversion.usdoj.gov

Online Registration – New Applicants:
http://www.deadiversion.usdoj.gov/drugreg/reg_apps/onlineforms_new.htm

Online Registration - Renewal:
www.deadiversion.usdoj.gov/drugreg/reg_apps/onlineforms.htm

Registration Changes (Forms):
http://www.deadiversion.usdoj.gov/drugreg/change_requests/index.html

DEA Registration Support (all of CA):
(800) 882-9539

Online DEA 106 Theft/Loss Reporting:
https://www.deadiversion.usdoj.gov/webforms/app106Login.jsp

Online DEA 222 Controlled Substance Ordering System (CSOS): http://www.deaecom.gov/

DEA - Fresno
2444 Main Street, Suite 240
Fresno, CA 93721
Registration: (888) 304-3251 or (415) 436-7900
Diversion or Investigation: (559) 487-5406

DEA - Los Angeles
255 East Temple Street, 20th Floor
Los Angeles, CA 90012
Registration: (888) 415-9822 or (213) 621-6960
Diversion or Investigation: (213) 621-6942

DEA – Oakland
1301 Clay Street, Suite 460N
Oakland, CA 94612
Registration: (888) 304-3251
Diversion or Investigation: (510) 637-5600

DEA – Redding
310 Hensted Drive, Suite 310
Redding, CA 96002
Registration: (888) 304-3251 or (415) 436-7900
Diversion or Investigation: (530) 246-5043

DEA - Riverside
4470 Olivewood Avenue
Riverside, CA 92501-6210
Registration: (888) 415-9822 or (213) 621-6960
Diversion or Investigation: (951) 328-6200

DEA - Sacramento
4328 Watt Avenue
Sacramento, CA 95821
Registration: (888) 304-3251 or (415) 436-7900
Diversion or Investigation: (916) 480-7250

DEA – San Diego and Imperial Counties
4560 Viewridge Avenue
San Diego, CA 92123-1637
Registration: (800) 284-1152
Diversion or Investigation: (858) 616-4100

DEA – San Francisco

~~450 Golden Gate Avenue, 14th Floor~~
~~San Francisco, CA 94102~~
~~Registration: (888) 304-3251~~
~~Theft Reports or Diversion: (415) 436-7900~~
~~**DEA – San Jose**~~
~~One North First Street, Suite 405~~
~~San Jose, CA 95113~~
~~Registration: (888) 304-3251~~
~~Diversion or Investigation: (408) 291-2631~~

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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

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

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

Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment

The California Code of Regulations section 1735.2 requires the pharmacist-in-charge of each pharmacy licensed under section 4037 or 4029 of the Business and Professions Code that compounds drug preparations 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; 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 and may be completed online, printed, readily retrievable and retained in the pharmacy. Do not copy a previous assessment.

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

Pharmacy Name: _____

Address: _____ Phone: _____

Fax: _____

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

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

Licensed Sterile Compounding License # _____ Expiration: _____

Accredited by: _____ From: _____ To: _____

Centralized Hospital Packaging License #: _____ Exp. Date: _____

Hours: Weekdays _____ Sat_____ Sun. _____ 24 Hours _____

PIC: _____ RPH # _____ Exp. Date: _____

Website address (optional): _____

Pharmacy Staff (pharmacists, intern pharmacists, pharmacy technicians assigned to compounding duties): (Please use additional sheets if necessary)

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

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

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

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

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

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

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

8. _____ INT # _____ Exp. Date: _____

9. _____ INT # _____ Exp. Date: _____

10. _____ INT # _____ Exp. Date: _____

11. _____ TCH # _____ Exp. Date: _____

12. _____ TCH # _____ Exp. Date: _____

13. _____ TCH # _____ Exp. Date: _____

14. _____ TCH # _____ Exp. Date: _____

15. _____ TCH # _____ Exp. Date: _____

_____
PIC Initials

Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment

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

Please mark the appropriate box for each question. 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.

ALL COMPOUNDING PHARMACIES Complete Sections 1 through 10.

1. Definitions (CCR 1735 and 1735.1)

Yes No N/A

☐ ☐ ☐ 1.1 The pharmacy compounds as defined in CCR 1735(a).

☐ ☐ ☐ 1.2 Each pharmacist, intern pharmacist, and pharmacy technician involved with compounding understands the definitions in CCR 1735.1.

2. Compounding Limitations and Requirements (CCR 1735.2)

Yes No N/A

☐ ☐ ☐ 2.1. The pharmacy does not compound drug preparations prior to receipt of a valid prescription unless under the following conditions, as allowed in CCR 1735.2 (b-c) (CCR 1735.2(a)). See sections 2.2 and 2.3

☐ ☐ ☐ 2.2. The pharmacy prepares and stores a limited quantity of a compounded drug preparations in advance of receipt of a patient specific prescription solely in such quantity as is necessary to ensure continuity of care of an identified population as defined in CCR 1735.2(b).

☐ ☐ ☐ 2.3. The pharmacy compounds a reasonable quantity of drug preparations which is furnished to a prescriber for office use upon prescriber order as allowed in CCR 1735.2(c) and under all of the following requirements:

- ☐ 2.3.1. Is ordered by the prescriber or the prescribers' agent on a purchase order or other documentation received by the pharmacy prior to furnishing that lists the number of patients seen or to be seen in the prescriber's office for whom the drug is needed or anticipated, and the quantity for each patient sufficient for office administration; (CCR 1735.2[c][1]) **AND**
- ☐ 2.3.2. Is delivered to the prescriber's office and signed for by the prescriber or the prescriber's agent; (CCR 1735.2[c][2]) **AND**
- ☐ 2.3.3. Is sufficient for administration or application to patients in the prescriber's office or for distribution of not more than a 120-hour supply for veterinary medical practices; (CCR 1735.2[c][3]) **AND**
- ☐ 2.3.4. The pharmacist has a credible basis for concluding it is a reasonable quantity for office use considering the intended use of the compounded preparation and the nature of the prescriber's practice; (CCR 1735.2[c][4]) **AND**

☐ 2.3.5. Is an amount which the pharmacy is capable of compounding in compliance with pharmaceutical standards for integrity, potency, quality and strength of the compounded drug preparation; (CCR 1735.2[c][5]) **AND**

☐ 2.3.6. Does not exceed an amount the pharmacy can reasonably and safely compound. (CCR 1735.2[c][6])

Yes No N/A

☐ ☐ ☐ 2.4. The pharmacy does NOT compound drug preparations that: (CCR 1735.2[d])

☐ 2.4.1. Are classified by the FDA as demonstrably difficult to compound; (CCR 1735.2[d][1])

☐ 2.4.2. Appear on an FDA list of drugs that have been withdrawn or removed from the market; (CCR 1735.2[d][2]) or

☐ 2.4.3. Are copies or essentially copies of one or more commercially available drug products. (CCR 1735.2[d][3])

☐ ☐ ☐ 2.5. The pharmacy does not compound drug preparations until it has prepared a written master formula document that includes the following elements: (CCR 1735.2[e][1-8])

☐ 2.5.1. Active ingredients used.

☐ 2.5.2. Equipment to be used.

☐ 2.5.3. Beyond use date (BUD).

☐ 2.5.4. Inactive ingredients used.

☐ 2.5.5. Specific and essential compounding steps.

☐ 2.5.6. Quality reviews required at each step.

☐ 2.5.7. Post-compounding process or procedures, if required.

☐ 2.5.8. Instructions for storage and handling.

☐ ☐ ☐ 2.6. The master formula for a drug preparation not routinely compounded by the pharmacy may be recorded on the prescription document itself. (CCR 1735.2[f])

☐ ☐ ☐ 2.7. The pharmacists performing or supervising compounding understand they are responsible for the integrity, potency, quality, and labeled strength of a compounded drug preparation until the BUD indicated on the label, so long as label instructions for storage and handling are followed after the preparation is dispensed. (CCR 1735.2[g])

☐ ☐ ☐ 2.8. All chemicals, bulk drug substances, drug preparations and other components used for drug compounding are stored and used according to compendia and other applicable requirements to maintain their integrity, potency, quality and labeled strength. (CCR 1735.2[h])

☐ ☐ ☐ 2.9. Every compounded drug preparation is given a BUD representing the date or date and time beyond which the compounded drug preparation should not be used, stored, transported or administered, and is determined based on the professional judgment of the pharmacist performing or supervising the compounding. (CCR 1735.2[i])

☐ 2.9.1. For non-sterile compounded drug preparations, the BUD does not exceed any of the following: (CCR 1735.2[i][1][A-F])

- ☐ 2.9.1.1. The shortest expiration date or BUD of any ingredient in the compounded drug preparation,
- ☐ 2.9.1.2. The chemical stability of any one ingredient in the compounded drug preparation;
- ☐ 2.9.1.3. The chemical stability of the combination of all ingredients in the compounded drug preparation,
- ☐ 2.9.1.4. For non-aqueous formulations, 180 days or an extended date established by the pharmacist's research, analysis, and documentation,
- ☐ 2.9.1.5. For water-containing oral formulations, 14 days or an extended date established by the pharmacist's research, analysis, and documentation, and
- ☐ 2.9.1.6. For water-containing topical/dermal and mucosal liquid and semisolid formulations, 30 days or an extended date established by the pharmacist's research, analysis, and documentation.
- ☐ 2.9.1.7. The pharmacist, using his or her professional judgment establishes an extended date as provided in (D), (E), and (F), if the pharmacist researched(s) by consulting and applying drug-specific and general stability documentation and literature; analyzes such documentation and literature as well as the other factors set forth in this subdivision, and maintains documentation of the research, analysis and conclusion. The factors pharmacist analyzed included: i) the nature of the drug and its degradation mechanism, (ii) the dosage form and its components, (iii) the potential for microbial proliferation in the preparation, (iv) the container in which it is packaged, (v) the expected storage conditions, and (vi) the intended duration of therapy. Documentation of the pharmacist's research and analysis supporting an extension must be maintained in a readily retrievable format as part of the master formula.

☐ 2.9.2. For sterile compounded drug preparations, the BUD does not exceed any of the following: (CCR 1735.2[i][2][A-D])

- ☐ 2.9.2.1. The shortest expiration date or BUD of any ingredient in the sterile compounded drug preparation,
- ☐ 2.9.2.2. The chemical stability of any one ingredient in the sterile compounded drug preparation,
- ☐ 2.9.2.3. The chemical stability of the combination of all ingredients in the sterile compounded drug preparation, and
- ☐ 2.9.2.4. The BUD assigned for sterility in CCR 1751.8.

☐ 2.9.3. For sterile compounded drug preparations, extension of a BUD is supported by the following: (CCR 1735.2[i][3][A-C])

- ☐ 2.9.3.1. Method Suitability Test,
- ☐ 2.9.3.2. Container Closure Integrity Test, and
- ☐ 2.9.3.3. Stability Studies.

☐ 2.9.4. The finished drugs or compounded drug preparations tested and studied are compounded using the same identical components or ingredients,

PIC Initials _____

specific and essential compounding steps, quality reviews, and packaging as the finished drug or compounded drug preparation. (CCR 1735.2[i][4])

☐ 2.9.5. Shorter dating is used if it is deemed appropriate in the professional judgment of the responsible pharmacist. (CCR 1735.2[i][5])

Yes No N/A

☐ ☐ ☐ 2.10. The pharmacist performing, or supervising compounding is responsible for the proper preparation, labeling, storage, and delivery of the compounded drug preparation. (CCR 1735.2[j])

☐ ☐ ☐ 2.11. Self-assessment is completed, as required, prior to compounding a drug preparation. (CCR 1735.2[k])

☐ ☐ ☐ 2.12. Packages of ingredients, both active and inactive, which lack a supplier's expiration date are subject to the following limitations: (CCR 1735.2[l])

- ☐ 2.12.1. Ingredients are not used for any non-sterile compounded drug preparation more than three (3) years after the date of receipt by the pharmacy.
- ☐ 2.12.2. Ingredients are not used for any sterile compounded drug preparation more than one (1) year after the date of receipt by the pharmacy.

☐ ☐ ☐ 2.13. The Pharmacy compounds Human drug preparation for interstate and complies with the following conditions: (BPC 4126.10[a][1-3])

- ☐ 2.13.1. The pharmacy reports all required data for the previous calendar year into the Information Sharing Network established by the National Association of Boards of Pharmacy in conjunction with the United States Food and Drug Administration (FDA)
- ☐ 2.13.2. On an annual basis, in connection with and as a condition of renewal of the pharmacy's license, the pharmacist-in-charge of the pharmacy certifies that the reporting requirements of above have been satisfied.
- ☐ 2.13.3. The pharmacy reports any adverse drug experience and product quality issue for any compounded product to the board within 12 hours after the pharmacy receives notice of the adverse drug experience or product quality issue.

☐ ☐ ☐ 2.14. Pharmacy and pharmacist-in-charge understand the Information reported by the board to the FDA directly or through the Information Sharing Network established by the National Association of Boards of Pharmacy in conjunction with the FDA to implement the Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products is not subject to public disclosure under the California Public Records Act (Chapter 3.5 (commencing with Section 6250) of Division 7 of Title 1 of the Government Code). (BPC 4126.10[b])

CORRECTIVE ACTION OR ACTION PLAN: _____

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PIC Initials

3. Recordkeeping for Compounded Drug Preparation (CCR 1735.3)

Yes No N/A

☐ ☐ ☐ 3.1. The pharmacy makes and retains a record for each compounded drug preparation which includes, at least, the following: (CCR 1735.3[a][1-2])

- ☐ 3.1.1. The master formula document.
- ☐ 3.1.2. A compounding log consisting of a single document containing all of the following:
- ☐ 3.1.2.1. The name and strength of the compounded drug preparation.
- ☐ 3.1.2.2. The date the drug preparation was compounded.
- ☐ 3.1.2.3. The identity of the pharmacy personnel who compounded the drug preparation.
- ☐ 3.1.2.4. The identity of the pharmacist reviewing the final drug preparation.
- ☐ 3.1.2.5. The quantity of each component used in compounding the drug preparation.
- ☐ 3.1.2.6. The manufacturer or supplier, expiration date and lot number of each component.
- ☐ 3.1.2.7. The pharmacy assigned reference or lot number for the compounded drug preparation.
- ☐ 3.1.2.8. The BUD or BUD and time of the final compounded drug preparation.
- ☐ 3.1.2.9. The final quantity or amount of drug preparation compounded.
- ☐ 3.1.2.10. Documentation of quality reviews and required post-compounding process and procedures.

Yes No N/A

☐ ☐ ☐ 3.2. The pharmacy maintains records of the proper acquisition, storage, and destruction of chemicals, bulk drug substances, components and drug preparations used in compounding. (CCR 1735.3[b])

☐ ☐ ☐ 3.3. Active ingredients are obtained from a supplier registered with the Food and Drug Administration (FDA). All other chemicals, bulk drug substances, and drug components used to compound drug preparations are to be obtained, whenever possible, from FDA-registered suppliers. The pharmacy acquires and retains certificates of purity or analysis, either written in English or translated into English, for chemicals, bulk drug substances, and drug products used in compounding. (CCR 1735.3[c])

☐ ☐ ☐ 3.4. The pharmacy maintains and retains all records required in the pharmacy in a readily retrievable form for at least three years (CCR 1735.3[d]).

CORRECTIVE ACTION OR ACTION PLAN: _____

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4. Labeling of Compounded Drug Preparation (CCR 1735.4)

Yes No N/A

☐ ☐ ☐ 4.1. Each compounded drug preparation has at least the following affixed to the container on a label prior to dispensing: (CCR 1735.4[a][1-6])
- ☐ 4.1.1. Name of the compounding pharmacy and dispensing pharmacy (if different);
- ☐ 4.1.2. Name (brand or generic) and strength, volume, or weight of each active ingredient. For admixed intravenous (IV) solutions, the IV solution utilized shall be included;
- ☐ 4.1.3. Instructions for storage, handling, and administration. For admixed IV solutions, the rate of infusion shall be included;
- ☐ 4.1.4. The BUD for the drug preparation;
- ☐ 4.1.5. The date compounded; and
- ☐ 4.1.6. The lot number or pharmacy reference number.

☐ ☐ ☐ 4.2. Any compounded drug preparation dispensed to a patient or readied for dispensing to a patient is labeled with the information required under Business and Professions Code section 4076 and California Code of Regulations, title 16, section 1707.5. (CCR 1735.4[b])

☐ ☐ ☐ 4.3. Any compounded drug preparation dispensed to a patient or readied for dispensing to a patient also includes, on the container label or on a receipt provided to the patient, a statement the drug preparation has been compounded by the pharmacy. (CCR 1735.4[c])

Yes No N/A

☐ ☐ ☐ 4.4. Drug preparations compounded into unit-dose containers that are too small or otherwise impractical for full compliance with the requirements of CCR 1735.4(a), (b), and (c) are labeled with at least the name(s) of the active ingredient(s), concentration of strength, volume or weight, pharmacy reference or lot number, and BUD. (CCR 1735.4[d])

☐ ☐ ☐ 4.5. All hazardous agents bear a special label which states “Chemotherapy - Dispose of Properly” or “Hazardous – Dispose of Properly. (CCR 1735.4[e])

CORRECTIVE ACTION OR ACTION PLAN: _____

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5. Compounding Policies and Procedures (CCR 1735.5)

Yes No N/A

☐ ☐ ☐ 5.1. The pharmacy maintains written policies and procedure for compounding which establish procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding. (CCR 1735.5[a])

PIC Initials _____

☐ ☐ ☐ 5.2. The policy and procedures are reviewed on an annual basis by the pharmacist-in-charge and are updated whenever changes are implemented. (CCR 1735.5[b])

☐ ☐ ☐ 5.3. The policies and procedures include at least the following: (CCR 1735.5[c][1-11])

- ☐ 5.3.1. Procedures for notifying staff assigned to compounding duties of any changes in policies or procedures.
- ☐ 5.3.2. A written plan for recall of a dispensed compounded drug preparation where subsequent information demonstrates the potential for adverse effects with continued use. The plan ensures all affected doses can be accounted for during the recall and shall provide steps to identify which patients received the affected lot or compounded drug preparation(s).
- ☐ 5.3.3. Procedures for maintaining, storing, calibrating, cleaning, and disinfecting equipment used in compounding, and for training on these procedures as part of the staff training and competency evaluation process.
- ☐ 5.3.4. Procedures for evaluating, maintaining, certifying, cleaning, and disinfecting the facility (physical plant) used for compounding, and for training on these procedures as part of the staff training and competency evaluation process.
- ☐ 5.3.5. Documentation of the methodology used to validate integrity, potency, quality, and labeled strength of compounded drug preparations. The methodology must be appropriate to compounded drug preparations.
- ☐ 5.3.6. Documentation of the methodology and rationale or reference source used to determine appropriate BUDs for compounded drug preparations.
- ☐ 5.3.7. Dates and signatures reflecting all annual reviews of the policies and procedures by the pharmacist-in-charge.
- ☐ 5.3.8. Dates and signatures accompanying any revisions to the policies and procedures approved by the pharmacist-in-charge.
- ☐ 5.3.9. Policies and procedures for storage of compounded drug preparations in the pharmacy and daily documentation of all room, refrigerator, and freezer temperatures within the pharmacy.
- ☐ 5.3.10. Policies and procedures for ensuring appropriate functioning of refrigeration devices, monitoring refrigeration device temperatures, and actions to take regarding any out of range temperature variations within the pharmacy.
- ☐ 5.3.11. Policies and procedures for proper garbing when compounding with hazardous products; including when to utilize double shoe covers.

CORRECTIVE ACTION OR ACTION PLAN: _____

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6. Compounding Facilities and Equipment (CCR 1735.6)

Yes No N/A

☐ ☐ ☐ 6.1. The pharmacy maintains written documentation regarding the facilities and equipment necessary for safe and accurate compounding of compounded drug

preparations which includes records of certification of facilities or equipment, if applicable. (CCR 1735.6[a])

☐ ☐ ☐ 6.2. All equipment used to compound a drug preparation is stored, used and maintained in accordance with manufacturers' specifications. (CCR 1735.6[b])

☐ ☐ ☐ 6.3. All equipment used to compound a drug preparation is calibrated prior to use to ensure accuracy. (CCR 1735.6[c])

☐ 6.3.1. Documentation of each calibration is recorded in a form which is not alterable and is maintained and retained in the pharmacy.

☐ ☐ ☐ 6.4. When engaged in hazardous drug compounding, the pharmacy maintains written documentation regarding appropriate cleaning of facilities and equipment to prevent cross-contamination with non-hazardous drugs. (CCR 1735.6[d])

☐ ☐ ☐ 6.5. Hazardous drug compounding is completed in an externally exhausted physically separate room with the following requirements: (CCR 1735.6[e])

☐ 6.5.1. Minimum of 30 air changes per hour except that 12 air changes per hour are acceptable for segregated compounding areas with a BSC or CACI when preparations are assigned a BUD of 12 hours or less or when nonsterile products are compounded; and

☐ 6.5.2. Maintained at a negative pressure of 0.01 to 0.03 inches of water column relative to all adjacent spaces (rooms, above ceiling, and corridors); and

☐ 6.5.3. For sterile compounding, each BSC or CACI shall be externally exhausted.

☐ 6.5.3. For nonsterile compounding, a BSC, a CACI, or other containment ventilated enclosure shall be used and shall either use a redundant-HEPA filter in series or be externally exhausted,

☐ 6.5.4. All surfaces within the room are smooth, seamless, impervious, and non-shedding.

CORRECTIVE ACTION OR ACTION PLAN:

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7. Training of Compounding Staff (CCR 1735.7)

Yes No N/A

☐ ☐ ☐ 7.1. The pharmacy maintains documentation demonstrating personnel involved in compounding have the skills and training required to properly and accurately perform their assigned responsibilities and documentation demonstrating all personnel involved in compounding are trained in all aspects of policies and procedures. This training includes, but is not limited to, support personnel (e.g. institutional environmental services, housekeeping), maintenance staff, supervising pharmacists and all others whose jobs are related to the compounding process. (CCR 1735.7[a])

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PIC Initials

☐ ☐ ☐ 7.2. The pharmacy has developed and maintains an ongoing competency evaluation process for pharmacy personnel involved in compounding and shall maintain documentation of any and all training related to compounding undertaken by pharmacy personnel. (CCR 1735.7[b])

☐ ☐ ☐ 7.3. Pharmacy personnel assigned to compounding duties demonstrate knowledge about processes and procedures used in compounding prior to compounding any drug preparation. (CCR 1735.7[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

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8. Compounding Quality Assurance (CCR 1735.8)

Yes No N/A

☐ ☐ ☐ 8.1. The pharmacy maintains, as part of its written policies and procedures, a written quality assurance plan to monitor and ensure the integrity, potency, quality and labeled strength of compounded drug preparation. (CCR 1735.8[a])

Yes No N/A

☐ ☐ ☐ 8.2. The pharmacy's quality assurance plan includes the written procedures and standards for at least the following:

- ☐ 8.2.1. Verification, monitoring and review of the adequacy of the compounding processes as well as documentation of review of those processes by qualified pharmacy personnel. (CCR 1735.8[b])
- ☐ 8.2.2. Qualitative and quantitative analysis of compounded drug preparations to ensure integrity, potency, quality and labeled strength, including the frequency of testing. Frequency of routine testing and analysis is done on an annual basis. (CCR 1735.8[c])
- ☐ 8.2.3. Such reports are retained by the pharmacy and collated with the compounding record and master formula document. (CCR 1735.8[c])
- ☐ 8.2.4. Scheduled action in the event any compounded drug preparation is ever discovered to be below minimum standards for integrity, potency, quality or labeled strength. (CCR 1735.8[d])
- ☐ 8.2.5. Response to out-of-range temperature variations within the pharmacy and within patient care areas of a hospital where furnished drug is returned for redispensing. (CCR 1735.8[e])

CORRECTIVE ACTION OR ACTION PLAN: _____

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9. Compounding Consistent with United States Pharmacopeia – National Formulary (Business and Professions Code (BPC) 4126.8)

Yes No N/A

☐ ☐ ☐ 9.1. The compounding of drug preparation is consistent with standards established in the pharmacy compounding chapters of the current version of the United States Pharmacopeia-National Formulary, including relevant testing and quality assurance.

CORRECTIVE ACTION OR ACTION PLAN: _____

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10. Duties of a Pharmacy Issuing a Compounded Drug Recall (BPC 4126.9)

Yes No N/A

☐ ☐ ☐ 10.1. When the pharmacy issues a recall notice regarding a nonsterile compounded drug product, in addition to any other duties, all of the following take place, contact the recipient pharmacy, prescriber, or patient of the recalled drug and the board within 12 hours of the recall notice if both of the following apply: (BPC 4126.9[a][1-2])

- ☐ 10.1.1. Use of or exposure to the recalled drug may cause serious adverse health consequences or death.
- ☐ 10.1.2. The recalled drug was dispensed, or is intended for use, in this state.

Yes No N/A

☐ ☐ ☐ 10.2. A recall notice issued pursuant to subdivision (a) is made as follows: (BPC 4126.9[b][1-3])

- ☐ 10.2.1. If the recalled drug was dispensed directly to the patient, the notice is be made to the patient.
- ☐ 10.2.2. If the recalled drug was dispensed directly to the prescriber, the notice is be made to the prescriber, who shall ensure the patient is notified.
- ☐ 10.2.3. If the recalled drug was dispensed directly to a pharmacy, the notice is be made to the pharmacy, which shall notify the prescriber or patient, as appropriate. If the pharmacy notifies the prescriber, the prescriber ensures the patient is notified.

☐ ☐ ☐ 10.3. If the pharmacy has been advised that a patient has been harmed by using a nonsterile compounded product potentially attributable to the pharmacy, the pharmacy reports the event to MedWatch within 72 hours of the pharmacy being advised. (BPC 4126.9[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

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COMPOUNDING STERILE DRUGS

Does the pharmacy compound sterile drug preparations? (BPC 4127)

☐ **Yes** ☐ **No**

If yes, complete Sections 11 through 27.
If no, proceed to the certification on page 30.

FOR PHARMACIES THAT COMPOUND STERILE DRUG preparations:

11. Compounding Drug for Other Pharmacy for Parenteral Therapy

Yes No N/A

☐ ☐ ☐ 11.1. Any pharmacy that contracts to compound a drug for parenteral therapy, pursuant to a prescription, for delivery to another pharmacy shall report that contractual arrangement to the board. (BPC 4123)

- ☐ 11.1.1. The contractual arrangement is reported to the board within 30 days of commencing that compounding.

CORRECTIVE ACTION OR ACTION PLAN: _____

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12. Sterile Compounding; Compounding Area (CCR 1751)

Yes No N/A

☐ ☐ ☐ 12.1. The pharmacy conforms to the parameters and requirements stated by Article 4.5 (Section 1735 et seq.), applicable to all compounding, and shall also conform to the parameters and requirements stated by this Article 7 (Section 1751 et seq.), applicable solely to sterile compounding. (CCR 1751[a])

☐ ☐ ☐ 12.2. The pharmacy has a compounding area designated for the preparation of sterile drug preparations in a restricted location where traffic has no impact on the performance of the Primary Engineering Control(s) (PEC). (CCR 1751[b])

- ☐ 12.2.1. The cleanroom, including the walls, ceilings, and floors, are constructed in accordance with Section 1250.4 of Title 24, Part 2, Chapter 12, of the California Code of Regulations.
- ☐ 12.2.2. The pharmacy is ventilated in a manner in accordance with Section 505.5 of Title 24, Part 4, Chapter 5 of the California Code of Regulations.
- ☐ 12.2.3. The environments within the pharmacy meet at least the following standards: (CCR 1751[b])
- ☐ 12.2.3.1. Each ISO environment is certified at least every six months by a qualified technician in accordance with Section 1751.4.
  - ☐ 12.2.3.1.1. Certification records must be retained in the pharmacy.
- ☐ 12.2.3.2. Items related to the compounding of sterile drug preparations within the compounding area are stored in such a way as to maintain the integrity of an aseptic environment.

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PIC Initials

☐ 12.2.3.3. A sink is included in accordance with Section 1250.4 of Title 24, Part 2, Chapter 12, of the California Code of Regulations. Sinks and drains are not present in any ISO Class 7 or better cleanroom, nor in a segregated sterile compounding area within three feet of an ISO Class 5 or better PEC, with the exception of emergency eye-rinsing stations. A sink may be located in an ante-area.

☐ 12.2.3.4. There is a refrigerator and where appropriate, a freezer, of sufficient capacity to meet the storage requirements for all material requiring refrigeration or freezing, and a backup plan is in place to ensure continuity of available compounded drug preparations in the event of a power outage.

CORRECTIVE ACTION OR ACTION PLAN: _____

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13. Sterile Compounding; Compounding Area (CCR 1250.4, 505.5 and 505.5.1)

TITLE 24, PART 2, CHAPTER 12, REGULATIONS

Yes No N/A

☐ ☐ ☐ 13.1. The pharmacy has a designated area for the preparation of sterile products for dispensing which meets at least the following: (24 CCR 1250.4)

- ☐ 13.1.1. In accordance with Federal Standard 209(b), Clean Room and Work Station Requirements, Controlled Environment, as approved by the Commission, Federal Supply Service, General Services Administration meet standards for class 100 HEPA (high efficiency particulate air) filtered air such as laminar air flow hood or clean room. (24 CCR 1250.4[1])
- ☐ 13.1.2. Has non-porous and cleanable surfaces, walls, floors, ceilings and floor coverings. (24 CCR 1250.4[2])
- ☐ 13.1.3. The pharmacy is arranged in such a manner that the laminar-flow hood (PEC) is located in an area which is exposed to minimal traffic flow, and is separate from any area used for bulk storage of items not related to the compounding of parenteral preparations. There is sufficient space, well separated from the laminar-flow hood area, for the storage of bulk materials, equipment, and waste materials. (24 CCR 1250.4[3])
- ☐ 13.1.4. A sink with hot and cold running water is within the parenteral preparation compounding area or adjacent to it. (24 CCR 1250.4[4])
- ☐ 13.1.5. The pharmacy compounding sterile injectable preparations from one or more nonsterile ingredients, compounds the preparations in one of the following environments: (24 CCR 1250.4[5])
  - ☐ 13.1.5.1. An ISO Class 5 laminar airflow hood within an ISO Class 7 cleanroom. The cleanroom must have a positive air pressure differential relative to adjacent areas.
  - ☐ 13.1.5.2. An ISO Class 5 cleanroom.
  - ☐ 13.1.5.3. A barrier isolator that provides an ISO Class 5 environment for compounding.

Yes No N/A

☐ ☐ ☐ 13.2. The pharmacy has a designated area for the compounding of sterile preparations for dispensing which shall: (24 CCR 505.5)

☐ 13.2.1. Be ventilated in a manner not interfering with laminar air flow.

☐ ☐ ☐ 13.3. Pharmacies preparing parenteral cytotoxic agents, all compounding is conducted within a certified Class II Type A or Class II Type B vertical laminar air flow hood with bag in-bag out design. The pharmacy ensures that contaminated air plenums under positive air pressure are leak tight. (24 CCR 505.5.1)

CORRECTIVE ACTION OR ACTION PLAN: _____

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14. Sterile Compounding Recordkeeping Requirements. (CCR 1751.1)

Yes No N/A

☐ ☐ ☐ 14.1. In addition to the records required by section 1735.3 the pharmacy maintains at least the following records, which are in a readily retrievable, within the pharmacy: (CCR 1751.1[a][1-11])

- ☐ 14.1.1. Documents evidencing training and competency evaluations of employees in sterile drug preparation policies and procedures.
- ☐ 14.1.2. Results of hand hygiene and garbing assessments with integrated gloved fingertip testing.
- ☐ 14.1.3. Results of assessments of personnel for aseptic techniques including results of media-fill tests and gloved fingertip testing performed in association with media-fill tests.
- ☐ 14.1.4. Results of viable air and surface sampling.
- ☐ 14.1.5. Biannual video of smoke studies in all ISO Class 5 certified spaces.
- ☐ 14.1.6. Documents indicating daily documentation of room, refrigerator, and freezer temperatures appropriate for sterile compounded drug preparations consistent with the temperatures listed in section 1735.1 for:
  - ☐ 14.1.6.1. Controlled room temperature.
  - ☐ 14.1.6.2. Controlled cold temperature.
  - ☐ 14.1.6.3. Controlled freezer temperature.
- ☐ 14.1.7. Certification(s) of the sterile compounding environment(s).
- ☐ 14.1.8. Documents indicating daily documentation of air pressure differentials or air velocity measurements between all adjoining ISO rooms or areas, including those associated with compounding aseptic (containment) isolators, and air pressure differentials or air velocity measurements between all rooms or spaces with an immediate entry or opening to ISO rooms or areas.
- ☐ 14.1.9. Other facility quality control records specific to the pharmacy's policies and procedures (e.g., cleaning logs for facilities and equipment, incubator temperatures).
- ☐ 14.1.10. Logs or other documentation of inspections for expired or recalled chemicals, bulk drug substances, drug products, or other ingredients.

☐ 14.1.11. Preparation records including the master formula document, the preparation compounding log, and records of end-product evaluation testing and results.

Yes No N/A

☐ ☐ ☐ 14.2. The pharmacy compounds for future use pursuant to section 1735.2, and in addition to those records required by section 1735.3, the pharmacy makes and keeps records indicating the name, lot number, and amount of any drug preparation compounded for future use, the date on which any preparation was provided to a prescriber, and the name, address, license type and number of the prescriber. (CCR 1751.1[b])

☐ ☐ ☐ 14.3. The pharmacy maintains and retains all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was created. If only recorded and stored electronically, on magnetic media, or in any other computerized form, the records are maintained as specified by Business and Professions Code section 4070 subsection (c). (CCR 1751.1[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

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15. Sterile Labeling Requirements (CCR 1751.2)

Yes No N/A

☐ ☐ ☐ 15.1 In addition to the labeling information required under Business and Professions Code section 4076 and California Code of Regulations, title 16, sections 1707.5 and 1735.4, the pharmacy labels each compounded sterile drug preparation with at least the following information: (CCR 1751.2[a-c])

- ☐ 15.1.1. The telephone number of the pharmacy.
- ☐ 15.1.2. Instructions for storage, handling, and administration.
- ☐ 15.1.3. All hazardous agents shall bear a special label which states "Chemotherapy - Dispose of Properly" or "Hazardous – Dispose of Properly.":

CORRECTIVE ACTION OR ACTION PLAN: _____

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16. Sterile Policies and Procedures (CCR 1751.3)

Yes No N/A

☐ ☐ ☐ 16.1 The pharmacy maintains written policies and procedures for compounding and understands any material failure to follow the pharmacy's written policies and procedures shall constitute a basis for disciplinary action. (CCR 1751.3[a])

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PIC Initials

☐ ☐ ☐ 16.2 In addition to the elements required by section 1735.5, there are written policies and procedures regarding at least the following: (CCR 1751.3[a][1-24])

- ☐ 16.2.1. Action levels for colony-forming units (CFUs) detected during viable surface sampling, glove fingertip, and viable air sampling and actions to be taken when the levels are exceeded.
- ☐ 16.2.2. Airflow considerations and pressure differential monitoring.
- ☐ 16.2.3. An environmental sampling plan and procedures specific to viable air, surface and gloved fingertip sampling as well as nonviable particle sampling.
- ☐ 16.2.4. Cleaning and maintenance of ISO environments and segregated compounding areas.
- ☐ 16.2.5. Compounded sterile drug preparation stability and beyond use dating.
- ☐ 16.2.6. Compounding, filling, and labeling of sterile drug preparations.
- ☐ 16.2.7. Daily and monthly cleaning and disinfection schedule for the controlled areas and any equipment in the controlled area as specified in section 1751.4.
- ☐ 16.2.8. Depyrogenation of glassware (if applicable)
- ☐ 16.2.9. Facility management including certification and maintenance of controlled environments and related equipment.
- ☐ 16.2.10. For compounding aseptic isolators and compounding aseptic containment isolators, documentation of the manufacturer's recommended purge time.
- ☐ 16.2.11. Hand hygiene and garbing.
- ☐ 16.2.12. Labeling of the sterile compounded drug preparations based on the intended route of administration and recommended rate of administration.
- ☐ 16.2.13. Methods by which the supervising pharmacist will fulfill his or her responsibility to ensure the quality of compounded drug preparations.
- ☐ 16.2.14. Orientation, training, and competency evaluation of staff in all aspects of the preparation of sterile drug preparations including didactic training and knowledge/competency assessments which include at minimum: hand hygiene and garbing; decontamination (where applicable); cleaning and disinfection of controlled compounding areas; and proper aseptic technique demonstrated through the use of a media-fill test performed by applicable personnel; and aseptic area practices.
- ☐ 16.2.15. Preparing sterile compounded drug preparations from non-sterile components (if applicable). This shall include sterilization method suitability testing for each master formula document.
- ☐ 16.2.16. Procedures for handling, compounding and disposal of hazardous agents. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.
- ☐ 16.2.17. Procedures for handling, compounding and disposal of infectious materials. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.
- ☐ 16.2.18. Proper use of equipment and supplies.

PIC Initials _____

- ☐ 16.2.19. Quality assurance program compliant with sections 1711, 1735.8, and 1751.7.
- ☐ 16.2.20. Record keeping requirements.
- ☐ 16.2.21. Temperature monitoring in compounding and controlled storage areas.
- ☐ 16.2.22. The determination and approval by a pharmacist of ingredients and the compounding process for each preparation before compounding begins.
- ☐ 16.2.23. Use of automated compounding devices (if applicable).
- ☐ 16.2.24. Visual inspection and other final quality checks of sterile drug preparations.

Yes No N/A

☐ ☐ ☐ 16.3. For lot compounding, the pharmacy maintains written policies and procedures that include at least the following: (CCR 1751.3[b][1-3])
- ☐ 16.3.1. Use of master formula documents and compounding logs.
- ☐ 16.3.2. Appropriate documentation.
- ☐ 16.3.3. Appropriate sterility and potency testing.

☐ ☐ ☐ 16.4 For non-sterile-to-sterile batch compounding, the pharmacy maintains written policies and procedures for compounding that include at least the following. (CCR 1751.2[c][1-2])
- ☐ 16.4.1. Process validation for chosen sterilization methods.
- ☐ 16.4.2. End-product evaluation, quantitative, and qualitative testing.

Yes No N/A

☐ ☐ ☐ 16.5. All personnel involved have read the policies and procedures before compounding sterile drug preparations. All personnel involved have read all additions, revisions, and deletions to the written policies and procedures. Each review is documented by a signature and date. (CCR 1751.3[e])

CORRECTIVE ACTION OR ACTION PLAN: _____

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17. Facility & Equipment Standards for Sterile Compounding (CCR 1751.4)

Yes No N/A

☐ ☐ ☐ 17.1. No sterile drug preparation is compounded if it is known, or reasonably should be known, that the compounding environment fails to meet criteria specified in the pharmacy's written policies and procedures for the safe compounding of sterile drug preparations (CCR 1751.4[a])

☐ ☐ ☐ 17.2 During the compounding of sterile drug preparations, access to the areas designated for compounding is limited to those individuals who are properly attired (CCR 1751.4[b])

☐ ☐ ☐ 17.3 All equipment used in the areas designated for compounding is made of a material that can be easily cleaned and disinfected. (CCR 1751.4[c])

☐ ☐ ☐ 17.4 Cleaning is done using a germicidal detergent and sterile water. A sporicidal agent is used at least monthly (CCR 1751.4[d][1-4])

- ☐ 17.4.1. All ISO Class 5 surfaces, work table surfaces, carts, counters, and the cleanroom floor are cleaned at least daily. After each cleaning, disinfection using a suitable sterile agent occurs on all ISO Class 5 surfaces, work table surfaces, carts, and counters.
- ☐ 17.4.2. Walls, ceilings, storage shelving, tables, stools, and all other items in the ISO Class 7 or ISO Class 8 environment are cleaned at least monthly.
- ☐ 17.4.3. Cleaning shall also occur after any unanticipated event that could increase the risk of contamination.
- ☐ 17.4.4. All cleaning materials, such as wipers, sponges, and mops, shall be non-shedding and dedicated to use in the cleanroom, or ante-area, and segregated sterile compounding areas and shall not be removed from these areas except for disposal.

☐ ☐ ☐ 17.5 Disinfection, using a suitable sterile agent, occurs on all surfaces in the ISO Class 5 PEC frequently, including: (CCR 1751.4[e])

- ☐ 17.5.1. At the beginning of each shift;
- ☐ 17.5.2. At least every 30 minutes when compounding involving human staff is occurring or before each lot;
- ☐ 17.5.3. After each spill; and
- ☐ 17.5.4. When surface contamination is known or suspected.

Yes No N/A

☐ ☐ ☐ 17.6 Pharmacies preparing sterile compounded preparations are using a PEC that provides ISO Class 5 air or better air quality (CCR 1751.4[f])

- ☐ 17.6.1. Certification and testing of primary and secondary engineering controls are performed no less than every six months and whenever the device or area designated for compounding is relocated, altered or a service to the facility is performed which would impact the device or area.
- ☐ 17.6.2. Certification is completed by a qualified technician who is familiar with certification methods and procedures in accordance with CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006-13, Revised May 20, 2015).
  - ☐ 17.6.2.1. Certification records are retained for at least 3 years.
- ☐ 17.6.3. Unidirectional compounding aseptic isolators or compounding aseptic containment isolators used outside of an ISO Class 7 cleanroom if the isolators are certified to meet the following criteria: (CCR 1751.4[f][1-3])
  - ☐ 17.6.3.1. Particle counts sampled approximately 6-12 inches upstream of the critical exposure site shall maintain ISO Class 5 levels during compounding operations.
  - ☐ 17.6.3.2. Not more than 3520 particles (0.5 um and larger) per cubic meter shall be counted during material transfer, with the particle counter probe located as near to the transfer door as possible without obstructing transfer.
  - ☐ 17.6.3.3. Recovery time to achieve ISO Class 5 air quality shall be documented and internal procedures developed to ensure that adequate

PIC Initials _____

recovery time is allowed after material transfer before and during compounding operations.

☐ 17.6.4. Compounding aseptic isolators that do not meet the requirements as outlined in this subdivision or are not located within an ISO Class 7 cleanroom are only used to compound preparations that meet the criteria specified in accordance with subdivision (d) of Section 1751.8 of Title 16, Division 17, of the California Code of Regulations.

☐ ☐ ☐ 17.7. Pharmacies preparing sterile hazardous agents shall do so in accordance with Section 505.5.1 of Title 24, Chapter 5, of the California Code of Regulations, requiring a negative pressure PEC.

☐ 17.7.1. Additionally, each PEC used to compound hazardous agents shall be externally vented.

☐ 17.7.2. The negative pressure PEC is certified every six months by a qualified technician who is familiar with CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006-13, Revised May 20, 2015).

☐ 17.7.3. Any drug preparation compounded in a PEC where hazardous drugs are prepared are labeled as hazardous, regardless of whether the drug ingredients are considered hazardous. (CCR 1751.4[g])

☐ 17.7.4. During hazardous drug compounding performed in a compounding aseptic containment isolator, full hand hygiene and garbing occurs. Garbing shall include hair cover, facemask, beard cover (if applicable), polypropylene or low shedding gown that closes in the back, shoe covers, and two pairs of sterile ASTM D6978-05 standard gloves. (CCR 1751.4[g][1])

Yes No N/A

☐ ☐ ☐ 17.8. If a compounding aseptic isolator is certified by the manufacturer to maintain ISO Class 5 air quality during dynamic operation conditions during compounding as well as during the transfer of ingredients into and out of the compounding aseptic isolator, then it may be placed into a non-ISO classified room. Individuals who use compounding aseptic isolators in this manner must ensure appropriate garbing, which consists of donning sterile gloves over the isolator gloves immediately before non-hazardous compounding. These sterile gloves must be changed by each individual whenever continuous compounding is ceased and before compounding starts again. (CCR 1751.4[h])

☐ ☐ ☐ 17.9. Compounding aseptic isolators and compounding aseptic containment isolators used in the compounding of sterile drug preparations shall use non-turbulent unidirectional air flow patterns. A smoke patterned test shall be used to determine air flow patterns. (CCR 1751.4[i])

☐ ☐ ☐ 17.10. Viable surface sampling is done at least every six months for all sterile-to-sterile compounding and quarterly for all non-sterile-to-sterile compounding. (CCR 1751.4[j])

☐ 17.10.1. Viable air sampling is done by volumetric air sampling procedures which test a sufficient volume of air (400 to 1,000 liters) at each location and is done at least once every six months.

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☐ 17.10.2. Viable surface and viable air sampling are performed by a qualified individual who is familiar with the methods and procedures for surface testing and air sampling.

☐ 17.10.3. Viable air sampling is performed under dynamic conditions which simulate actual production.

☐ 17.10.4. Viable surface sampling is performed under dynamic conditions of actual compounding.

☐ 17.10.5. When the environmental monitoring action levels are exceeded, the pharmacy identifies the CFUs at least to the genus level in addition to conducting an investigation pursuant to its policies and procedures. Remediation includes, at minimum, an immediate investigation of cleaning and compounding operations and facility management.

☐ ☐ ☐ 17.11. The sterile compounding area in the pharmacy has a comfortable and well-lighted working environment, which typically includes a room temperature of 20 degrees Celsius (68 degrees Fahrenheit) or cooler to maintain comfortable conditions for compounding personnel when attired in the required compounding garb. (CCR 1751.4[k])

CORRECTIVE ACTION OR ACTION PLAN: _____

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18. Sterile Compounding Attire (CCR 1751.5)

Yes No N/A

☐ ☐ ☐ 18.1. When compounding sterile drug preparations, the following standards are met: (CCR 1751.5[a][1-6])

☐ 18.1.1. Personal protective equipment consisting of a low non-shedding coverall gown, head cover, face mask, facial hair covers (if applicable), and shoe covers are worn inside the designated area at all times. For hazardous compounding, double shoe covers are worn.

☐ 18.1.2. Personal protective equipment is donned and removed in an ante-area or immediately outside the segregated compounding area.

☐ 18.1.3. Personnel dons personal protective equipment in an order that proceeds from those activities considered the dirtiest to those considered the cleanest.

☐ 18.1.4. Compounding personnel does not wear any wrist, hand, finger, or other visible jewelry, piercing, headphones, earbuds, or personal electronic devices.

☐ 18.1.5. Sterile gloves that have been tested for compatibility with disinfection by isopropyl alcohol are worn.

☐ 18.1.6. Hand cleansing with a persistently active alcohol-based product followed by the donning of sterile gloves may occur within the ante or cleanroom.

☐ 18.1.7. Gloves are routinely disinfected with sterile 70 percent isopropyl alcohol before entering or re-entering the PEC and after contact with non-sterile objects.

☐ 18.1.8. Gloves are routinely inspected for holes, punctures, or tears and replaced immediately if such are detected.

☐ 18.1.9. Individuals experiencing exposed rashes, sunburn, weeping sores, conjunctivitis, active respiratory infections or other communicable disease, or those wearing cosmetics, nail polish, or artificial nails are excluded from the ISO Class 5 and ISO Class 7 compounding areas until their conditions are remedied.

☐ ☐ ☐ 18.2. When preparing hazardous agents, appropriate gowns and personal protective equipment are worn regardless of the PECs used (e.g., biological safety cabinet and compounding aseptic containment isolator). (CCR 1751.5[b])

CORRECTIVE ACTION OR ACTION PLAN: _____

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19. Sterile Compounding Consultation; Training of Sterile Compounding Staff. (CCR 1751.6)

Yes No N/A

☐ ☐ ☐ 19.1. Consultation is available to the patient and/or primary caregiver concerning proper use, storage, handling, and disposal of sterile drug preparations and related supplies furnished by the pharmacy. (CCR 1751.6[a])

☐ ☐ ☐ 19.2. The pharmacist-in-charge ensures all pharmacy personnel engaging in compounding sterile drug preparations have training and demonstrated competence in the safe handling and compounding of sterile drug preparations, including hazardous agents if the pharmacy compounds products with hazardous agents. (CCR 1751.6[b])

☐ ☐ ☐ 19.3. Records of training and demonstrated competence are available for each individual and shall be retained for three years beyond the period of employment (CCR 1751.6[c])

☐ ☐ ☐ 19.4. The pharmacist-in-charge is responsible to ensure the continuing competence of pharmacy personnel engaged in compounding sterile drug preparations (CCR 1751.6[d])

☐ ☐ ☐ 19.5. The pharmacy complies with at least the following training requirements: (CCR 1751.6[e])

☐ 19.5.1. The pharmacy establishes and follows a written program of training and performance evaluation designed to ensure each person working in the designated area has the knowledge and skills necessary to perform their

assigned tasks properly. This program of training and performance evaluation must address at least the following: (CCR 1751.6[e][1][A-J])

- ☐ 19.5.1.1. Aseptic technique.
- ☐ 19.5.1.2. Pharmaceutical calculations and terminology.
- ☐ 19.5.1.3. Sterile preparation compounding documentation.
- ☐ 19.5.1.4. Quality assurance procedures.
- ☐ 19.5.1.5. Aseptic preparation procedures.
- ☐ 19.5.1.6. Proper hand hygiene, gowning and gloving technique.
- ☐ 19.5.1.7. General conduct in the controlled area (aseptic area practices).
- ☐ 19.5.1.8. Cleaning, sanitizing, and maintaining of the equipment and the controlled area.
- ☐ 19.5.1.9. Sterilization techniques for compounding sterile drug preparations from one or more non-sterile ingredients.
- ☐ 19.5.1.10. Container, equipment, and closure system selection.

☐ 19.5.2. Each person engaged in sterile compounding has successfully completed practical skills training in aseptic technique and aseptic area practices using models that are comparable to the most complex manipulations to be performed by the individual. (CCR 1751.6[e][2])

- ☐ 19.5.2.1. Each pharmacist responsible for, or directly supervising and controlling, aseptic techniques or practices, must demonstrate the skills needed to ensure the sterility of compounded drug preparations.
- ☐ 19.5.2.2. Evaluation must include written testing and a written protocol of periodic routine performance checks involving adherence to aseptic area policies and procedures.
- ☐ 19.5.2.3. Each person's proficiency and continuing training needs must be reassessed at least every 12 months.
- ☐ 19.5.2.3. Results of these assessments must be documented and retained in the pharmacy for three years.

CORRECTIVE ACTION OR ACTION PLAN: _____

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20. Sterile Compounding Quality Assurance and Process Validation (CCR 1751.7)

Yes No N/A

☐ ☐ ☐ 20.1. There is a written, documented, ongoing quality assurance program maintained by the pharmacy that monitors personnel performance, equipment, and facilities, and the pharmacist-in-charge assures the end-product meets the required specifications by periodic sampling. (CCR 1751.7[a])

- ☐ 20.1.1. The quality assurance program shall include at least the following: (CCR 1751.7[a][1-3])
  - ☐ 20.1.1.1. Procedures for cleaning and sanitization of the sterile preparation area.
  - ☐ 20.1.1.2. Actions to be taken in the event of a drug recall.
  - ☐ 20.1.1.3. Documentation justifying the chosen BUDs for compounded sterile drug preparations.

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☐ ☐ ☐ 20.2. The pharmacy and each individual involved in the compounding of sterile drug preparations successfully demonstrate competency on aseptic technique and aseptic area practices before being allowed to prepare sterile drug preparations. (CCR 1751.7[b][1])

- ☐ 20.2.1. Each individual's competency is revalidated at least every twelve months for sterile to sterile compounding and at least every six months for individuals compounding sterile preparations from non-sterile ingredients. (CCR 1751.7[b][2])
- ☐ 20.2.2. The pharmacy's validation process on aseptic technique and aseptic area practices is to be revalidated whenever: (CCR 1751.7[b][3][A-B])
  - ☐ 20.2.2.1. The quality assurance program yields an unacceptable result.
  - ☐ 20.2.2.2. There is any change in the compounding process, the Primary Engineering Control (PEC), or the compounding environment. For purposes of this subsection, a change includes, but is not limited to, when the PEC is moved, repaired or replaced, when the facility is modified in a manner affecting airflow or traffic patterns, or when improper aseptic techniques are observed.
- ☐ 20.2.3. The pharmacy must document the validation and revalidation process (CCR 1751.7[b][4]).

Yes No N/A

☐ ☐ ☐ 20.3 All sterile compounding personnel have successfully completed an initial competency evaluation. In addition, immediately following the initial hand hygiene and garbing procedure, each individual who may be required to do so in practice has successfully completed a gloved fingertip (all fingers on both hands) sampling procedure (zero colony forming units for both hands) at least three times before initially being allowed to compound sterile drug preparations. (CCR 1751.7[c])

☐ ☐ ☐ 20.4 Re-evaluation of garbing and gloving competency occurs at least every 12 months for personnel compounding products made from sterile ingredients and at least every six months for personnel compounding products from non-sterile ingredients. (CCR 1751.7[d])

☐ ☐ ☐ 20.5 Batch-produced sterile drug preparations compounded from one or more non-sterile ingredients, except as provided in paragraph (2), are subject to documented end product testing for sterility and pyrogens and are quarantined until the end product testing confirms sterility and acceptable levels of pyrogens. Sterility testing is performed per USP chapter 71 and pyrogen testing confirms acceptable levels of pyrogen per USP chapter 85 limits before dispensing. This requirement of end product testing confirming sterility and acceptable levels of pyrogens prior to dispensing applies regardless of any sterility or pyrogen testing that may have been conducted on any ingredient or combination of ingredients which were previously non-sterile. Exempt from pyrogen testing are topical ophthalmic and inhalation preparation. (CCR 1751.7[e][1])

- ☐ 20.5.1. The following non-sterile-to-sterile batch drug preparations do not require end product testing for sterility and pyrogens: (CCR 1751.7[e][2][A-B)

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☐ 20.5.1.1. Preparations for self-administered ophthalmic drops in a quantity sufficient for administration to a single patient for 30 days or less pursuant to a prescription.

☐ 20.5.1.2. Preparations for self-administered inhalation in a quantity sufficient for administration to a single patient for 5 days or less pursuant to a prescription.

CORRECTIVE ACTION OR ACTION PLAN: _____

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21. Beyond Use Dating for Sterile Compounded Drug Preparations (CCR 1751.8)

Yes No N/A

☐ ☐ ☐ 21.1. Every sterile compounded drug preparation is given and labeled with a BUD in compliance with 1735.2 and does not exceed the shortest expiration date or beyond use date of any ingredient in the sterile compounded drug preparation, nor the chemical stability of any one ingredient in the sterile compounded drug preparation, nor the chemical stability of the combination of all ingredients in the sterile compounded drug preparation, and , in the absence of passing a sterility test in accordance with standards for sterility testing found in Chapter 797 of the United States Pharmacopeia would justify an extended BUD, conforms to the following limitations:

Yes No N/A

☐ ☐ ☐ 21.2. The BUD states storage and exposure periods cannot exceed 48 hours at controlled room temperature, 14 days at controlled cold temperature, and 45 days in solid frozen state, where the sterile compounded drug preparation is compounded solely with aseptic manipulations and all of the following apply: (CCR 1751.8[a])

- ☐ 21.2.1. The preparation is compounded entirely within an ISO Class 5 PEC located in an ISO Class 7 cleanroom with an ante-area or compounded entirely within a CAI which meets the requirements in 1751.4(f)(1)-(3), using only sterile ingredients, products, components, and devices; and
- ☐ 21.2.2. The compounding process involves transferring, measuring, and mixing manipulations using not more than three commercially manufactured packages of sterile preparations and not more than two entries into any one sterile container or package of sterile preparations or administration containers/devices to prepare the drug preparation; and
- ☐ 21.2.3. Compounding manipulations are limited to aseptically opening ampules, penetrating disinfected stoppers on vials with sterile needles and syringes or spiked transfer devices, and transferring sterile liquids in sterile syringes to sterile administration devices, package containers of other sterile preparations, and containers for storage dispensing.

☐ ☐ ☐ 21.3. The BUD states storage and exposure periods cannot exceed 30 hours at controlled room temperature, 9 days at controlled cold temperature, and 45 days

in solid frozen state, where the sterile compounded drug preparation is compounded solely with aseptic manipulations and all of the following apply: (CCR 1751.8[b])

☐ 21.3.1. The preparation is compounded entirely within an ISO Class 5 PEC located in an ISO Class 7 cleanroom with an ante-area or compounded entirely within a CAI which meets the requirements in 1751.4(f)(1)-(3), using multiple individual or small doses of sterile preparations combined or pooled to prepare a compounded sterile preparation that will be administered either to multiple patients or to one patient on multiple occasions; and

☐ 21.3.2. The compounding process involves complex aseptic manipulations other than the single-volume transfer; and

☐ 21.3.3. The compounding process requires unusually long duration such as that required to complete dissolution or homogenous mixing.

☐ ☐ ☐ 21.4. The BUD states storage and exposure periods cannot exceed 24 hours at controlled room temperature, 3 days at controlled cold temperature, and 45 days in solid frozen state, where the sterile compounded drug preparation is compounded solely with aseptic manipulations using non-sterile ingredients, regardless of intervening sterilization of that ingredient and the following applies: (CCR 1751.8[c])

☐ 21.4.1. The preparation is compounded entirely within an ISO Class 5 PEC located in an ISO Class 7 cleanroom with an ante-area or compounded entirely within a CAI which meets the requirements in 1751.4(f)(1)-(3).

Yes No N/A

☐ ☐ ☐ 21.5. The BUD states storage and exposure periods cannot exceed 12 hours where the sterile compounded drug preparation is compounded solely with aseptic manipulations and all of the following apply: (CCR 1751.8[d])

☐ 21.5.1. The preparation was compounded entirely within an ISO Class 5 PEC that is located in a segregated sterile compounding area and restricted to sterile compounding activities, using only sterile ingredients, components, and devices, by personnel properly cleansed and garbed; and

☐ 21.5.2. The compounding process involves simple transfer of not more than three commercially manufactured packages of sterile nonhazardous preparations or diagnostic radiopharmaceutical preparations from the manufacturer's original containers; and

☐ 21.5.3. The compounding process involves not more than two entries into any one container or package (e.g., bag, vial) of sterile infusion solution or administration container/device.

☐ ☐ ☐ 21.6. Any sterile compounded drug preparation which was compounded either outside of an ISO class 5 PEC or under conditions that do not meet all of the requirements for any of subdivisions (a) through (e), the sterile compounded drug preparation is to be labeled "for immediate use only" and administration shall begin no later than one hour following the start of the compounding process.

☐ 21.6.1. Unless the "immediate use" preparation is immediately and completely administered by the person who prepared it or immediate and complete

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administration is witnessed by the preparer, the preparation shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the compounded sterile preparation, and the exact one-hour BUD and time.

☐ 21.6.2. If administration has not begun within one hour following the start of the compounding process, the compounded sterile preparation shall be promptly, properly, entirely, and safely discarded.

☐ 21.6.3. "Immediate use" preparations are only compounded in those limited situations where there is a need for immediate administration of a sterile preparation compounded outside of an ISO Class 5 environment and where failure to administer could result in loss of life or intense suffering.

☐ 21.6.4. Any such compounding shall be only in such quantity as is necessary to meet the immediate need and the circumstance causing the immediate need shall be documented in accordance with policies and procedures. (CCR 1751.8[e])

Yes No N/A

☐ ☐ ☐ 21.7. The BUD for any compounded allergen extracts is the earliest manufacturer expiration date of the individual allergen extracts. (CCR 1751.8[f])

CORRECTIVE ACTION OR ACTION PLAN: _____

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22. Single-Dose and Multi-Dose Containers; Limitations on Use (CCR 1751.9)

Yes No N/A

☐ ☐ ☐ 22.1. Single-dose ampules are for immediate use only, and once opened are not stored for any time period. (CCR 1751.9[a])

☐ ☐ ☐ 22.2. Unless otherwise specified by the manufacturer, any single-dose container of a compounded sterile drug preparation other than an ampule, such as a bag, bottle, syringe or vial, is used in its entirety or its remaining contents are to be labeled with a BUD and discarded within the following time limit, depending on the environment: (CCR 1751.9[b])

- ☐ 22.2.1. When needle-punctured in an environment with air quality worse than ISO Class 5, within one (1) hour.
- ☐ 22.2.2. When needle-punctured in an environment with ISO Class 5 or better air quality, within six (6) hours. A container remains within the ISO Class 5 or better air quality to be used for the full six hours, unless otherwise specified by the manufacturer.
- ☐ 22.2.3. If the puncture time is not noted on the container, the container is immediately discarded.

☐ ☐ ☐ 22.3. Unless otherwise specified by the manufacturer, a multi-dose container stored according to the manufacturer's specifications is used in its entirety or its

remaining contents are to be labeled with a BUD and discarded within twenty-eight (28) days from initial opening or puncture. (CCR 1751.9[c])

☐ 22.3.1. Any multi-dose container not stored according to the manufacturer's specifications is discarded immediately upon identification of such storage circumstance.

☐ 22.3.2. If any open container is not labeled with a BUD or the BUD is not correct, the container is immediately be discarded.

CORRECTIVE ACTION OR ACTION PLAN: _____

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23. Sterile Compounding Reference Materials (CCR 1751.10)

Yes No N/A

☐ ☐ ☐ 23.1. The pharmacy has current and appropriate reference materials regarding the compounding of sterile drug preparations located in or immediately available to the pharmacy. (CCR 1751.10)

CORRECTIVE ACTION OR ACTION PLAN: _____

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24. Sterile Compounding License Renewal (BPC 4127.1, 4127.15, 4127.2)

A license to compound sterile drug preparation will not be renewed until the following is met: (BPC 4127.1, 4127.15 4127.2)

Yes No N/A

☐ ☐ ☐ 24.1. The pharmacy has been inspected by the board and is in compliance with applicable laws and regulations.

☐ ☐ ☐ 24.2. The board reviews a current copy of the pharmacy's policies and procedures for sterile compounding.

☐ ☐ ☐ 24.3. The board is provided with copies of all inspection reports conducted of the pharmacy's premises in the prior 12 months documenting the pharmacy's operation.

☐ ☐ ☐ 24.4. The board is provided with copies of any reports from a private accrediting agency conducted in the prior 12 months documenting the pharmacy's operation.

☐ ☐ ☐ 24.5. The board receives a list of all sterile medications compounded by the pharmacy since the last license renewal.

☐ ☐ ☐ 24.6. A nonresident pharmacy has reimbursed the board for all actual and necessary costs incurred by the board in conducting an inspection of the pharmacy at least once annually. (BPC 4127.2[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

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25. Hospital Satellite Compounding Pharmacy (BPC 4127.15)

Yes No N/A

☐ ☐ ☐ 25.1. A hospital satellite compounding pharmacy compounds sterile drug products for administration only to registered hospital patients who are on the premises of the same physical plant in which the hospital satellite compounding pharmacy is located.

☐ ☐ ☐ 25.2. The services provided shall be directly related to the services or treatment plan administered in the physical plant.

CORRECTIVE ACTION OR ACTION PLAN: _____

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26. Nonresident Pharmacy (BPC 4127.2)

Yes No N/A

☐ ☐ ☐ 26.1. Pharmacy notifies the board within 10 days of the suspension of any accreditation held by the pharmacy.

☐ ☐ ☐ 26.2. Pharmacy provides to the board, within 12 hours, any recall notice issued by the pharmacy for sterile drug products it has compounded that have been shipped into, or dispensed in, California.

☐ ☐ ☐ 26.3. Pharmacy advises the board of any complaint it receives from a provider, pharmacy, or patient in California.

CORRECTIVE ACTION OR ACTION PLAN: _____

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27. Duties of a Pharmacy Issuing a Sterile Compounded Drug Recall (BPC 4127.9)

Yes No N/A

☐ ☐ ☐ 27.1. The pharmacy contacts the recipient pharmacy, prescriber or patient of the recalled drug and the board as soon as possible within 12 hours of the recall notice if both (1) the use of or exposure to the recalled drug preparations may cause serious adverse health consequences or death; and (2) the recalled drug

was dispensed or is intended for use in California. (BPC 4127.9[a] BPC 4127.1 and 4127.2)

☐ ☐ ☐ 27.2. A recall notice is made to the patient if the recalled drug was dispensed directly to the patient. (BPC 4127.9[b][1])

☐ ☐ ☐ 27.3. A recall notice is made to the prescriber if the recalled drug was dispensed directly to the prescriber. (BPC 4127.9[b][2])

Yes No N/A

☐ ☐ ☐ 27.4. A recall notice is made to the recipient pharmacy who shall notify the prescriber or patient if the recalled drug was dispensed thereafter. (BPC 4127.9[b][3])

CORRECTIVE ACTION OR ACTION PLAN: _____

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

ACKNOWLEDGEMENT BY OWNER OR HOSPITAL ADMINISTRATOR:

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

Signature _____ _____
Date

_____
PIC Initials

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 underline for added language. In cases where the original text contains underlined text, the underline text has been double underlined for emphasis that the original text contains underline and is not being added.

Amendments to the proposed changes are shown by ~~double strikethrough~~ for deleted language and wave 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 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 ~~and~~ may be completed online, printed, initialed, signed, and readily available ~~and retained~~ in the pharmacy. Signatures and initials shall be an original handwritten signature or initial on the self-assessment form. Do not copy a previous assessment.

Notes: If dispensing prescriptions for outpatient use, a Community Pharmacy Self-Assessment/Hospital Outpatient Pharmacy Self-Assessment (17M-13, Rev. ~~10/14~~ ~~07/18~~ 12/21) must be completed also. A hospital that compounds drug products must also complete the Compounding Self-Assessment (17M-39 Rev. 02/12).~~

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

Pharmacy Name: _____

Address: _____ Phone: _____

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

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

Licensed Sterile Compounding ~~Permit~~ License #_____ Expiration: _____

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

Centralized Hospital Packaging#: _____ Exp. Date: _____

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Initials

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

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

PIC: _____ RPH # _____ Exp. Date: _____

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

1. _____	RPH # _____	Exp. Date: _____
	APP APH# _____	Exp. Date: _____
	DEA # _____	Exp. Date: _____
2. _____	RPH # _____	Exp. Date: _____
	APP APH# _____	Exp. Date: _____
	DEA # _____	Exp. Date: _____
3. _____	RPH # _____	Exp. Date: _____
	APP APH# _____	Exp. Date: _____
	DEA # _____	Exp. Date: _____
4. _____	RPH # _____	Exp. Date: _____
	APP APH# _____	Exp. Date: _____
	DEA # _____	Exp. Date: _____
5. _____	RPH # _____	Exp. Date: _____
	APP APH# _____	Exp. Date: _____
	DEA # _____	Exp. Date: _____
9. _____	INT # _____	Exp. Date: _____
10. _____	INT # _____	Exp. Date: _____
11. _____	INT # _____	Exp. Date: _____
12. _____	INT # _____	Exp. Date: _____
13. _____	TCH # _____	Exp. Date: _____
14. _____	TCH # _____	Exp. Date: _____
15. _____	TCH # _____	Exp. Date: _____
16. _____	TCH # _____	Exp. Date: _____

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PIC
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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. (B&PC 4116, 4117, CCR 1714)

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

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

☐☐☐ 1.5. The pharmacy maintains ~~"night stock"~~ 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)

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

PIC Initials

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

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

Yes No N/A

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

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

☐☐☐ 1.12. Does the pharmacy compound sterile drugs?
~~(If yes, complete section 27 – "Compounding")~~ (If yes, complete the Compounding Self-Assessment ~~Form 17M-39, Rev. 10/12~~ required by CCR 1735.2[k])

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

Date Last Notification Received: _____

E-mail address registered with the board: _____

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

Date Last Notification Received: _____

E-mail address registered with the board: _____

CORRECTIVE ACTION OR ACTION PLAN: _____

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2. 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. (B~~&~~PC 4119.7[c], 4115[j], 22 CCR 70263[q][10])

☐ 2.2.1. An intern pharmacist shall report any irregularities to the pharmacist. (B~~&~~PC 4119.7[c]);

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

CORRECTIVE ACTION OR ACTION PLAN: _____

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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. (B&PC 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. (B&PC 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 (B&PC 4059.5[f]):

☐ 3.3.1. The drugs are placed in a secure storage facility in the same building as the pharmacy (B&PC 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 (B&PC 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 (B&PC 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 (B&PC 4059.5[f][4]); and

☐ 3.3.5. The agent delivering dangerous drugs and dangerous devices pursuant to this subdivision leaves documents indicating the name and amount of each dangerous drug or dangerous device delivered in the secure storage facility. The pharmacy shall be responsible for the dangerous drugs and dangerous devices delivered to the secure storage facility. The pharmacy shall also be responsible for obtaining and maintaining records relating to the delivery of dangerous drugs and dangerous devices to a secure storage facility. (B&PC 4059.5[f][5])

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

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

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

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

CORRECTIVE ACTION OR ACTION PLAN: _____

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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, B&PC 4169[a][2-4], 4342, H&SC 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. (B&PC 4380, CCR 1710[a])

~~Yes No N/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. (B&PC 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. (B&PC 4119.7[b]

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

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

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

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

☐☐☐ 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. The hospital pharmacy donates medications to a county-approved drug repository and distribution program, and meets the following requirements: (H&SC 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** (H&SC 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. (H&SC 150202.5)

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

☐☐☐ 5.3. Drugs that are donated are unused, unexpired and meet the following requirements: (H&SC 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. (H&SC 150204[c][2])

☐ 5.3.2. Were received directly from a manufacturer or wholesaler. (H&SC 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. (H&SC 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. (H&SC 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. (H&SC 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. (H&SC 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. (B&PC 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. (B&PC 4101, 4330)

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PIC Initials

☐☐☐ 6.5. Is the PIC serving concurrently as the designated representative-in-charge for a wholesaler or veterinary food-animal retailer? (CCR 1709.1 [d])

If yes, name the wholesaler or veterinary food-animal retailer. _____

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

CORRECTIVE ACTION OR ACTION PLAN: _____

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7. Duties of a Pharmacist

Yes No N/A

☐☐☐ 7.1. Within the scope of the inpatient pharmacy service, the pharmacist receives a chart order for an inpatient; identifies, evaluates and interprets the chart order; reviews patient's drug regimen and interprets the clinical data in the patient's medication record; consults with any prescriber, nurse or health care professional; calculates drug doses; supervises the packaging of drugs and checks the packaging procedures and products upon completion; 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; 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. (B&PC 4052, 4052.2, CCR 1793.1) Only a pharmacist: (BPC 4019, BPC 4051, BPC 4052, BPC 4052.2, CCR 1717[c], CCR 1793.1, CCR 1793.7)

- ☐ 7.1.1. Receives a chart order for an inpatient; (BPC 4019, BPC 4051 [b], BPC 4052, BPC 4052.2, CCR 1717, CCR 1793.1[a])
- ☐ 7.1.2. Identifies, evaluates and interprets the chart order; (CCR 1717[c], CCR 1793.1[c])
- ☐ 7.1.3. Reviews patient's drug regimen and interprets the clinical data in the patient's medication record; (BPC 4052.1[a][4], BPC 4052.2[a][4], CCR 1793.1[d])
- ☐ 7.1.4. Consults with any prescriber, nurse or health care professional; (CCR 1793.1[e])
- ☐ 7.1.5. Calculates drug doses; (BPC 4052 [a][3], BPC 4052.2 [a][3], BPC 4052.2 [a][4])
- ☐ 7.1.6. Supervises the packaging of drugs and checks the packaging procedures and products upon completion; (CCR 1793.1[f])
- ☐ 7.1.7. Is responsible for all activities of pharmacy technicians, interns and clerks related to the furnishing of drugs to ensure that all such activities are

performed completely, safely and without risk of harm to patients; (CCR 1793.7[e])

- 7.1.8. Performs any other duty which federal or state law or regulation authorizes only a registered pharmacist to perform; and performs all functions which require professional judgment. (BPC 4052, BPC 4052.2, CCR 1793.1[g])

☐☐☐ 7.2 ~~Pharmacists in a licensed health care facility who are performing the following functions are doing so in accordance with the hospital's policies, procedures and protocols which have been developed by health professionals including physicians, pharmacists, and registered nurses, with the concurrence of the facility administrator; ordering or performing routine drug therapy-related patient assessment procedures; ordering drug therapy-related laboratory tests; administering drugs or biologicals by injection; initiating or adjusting the drug regimen of a patient, and/or 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 B&PC section 4052.2.~~

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~~[d]~~)
- 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 (USC Sec 263a) and the pharmacist completes the testing in a pharmacy laboratory that is licensed in California as a laboratory pursuant to 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 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)

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

☐☐☐ 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])

CORRECTIVE ACTION OR ACTION PLAN: _____

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8. Duties of an Advanced Practice Pharmacist

Yes No N/A

~~☐☐☐ 8.1. The pharmacist who is authorized to issue an order to initiate or adjust a controlled substance therapy is personally registered with the federal Drug Enforcement Administration. (B&PC 4052[b])~~

☐☐☐ ~~8.2~~.8.1 The advanced practice pharmacist has received an advanced practice pharmacist ~~recognition~~ license ~~by~~ from the board and may do the following: (B&PC 4016.5, 4210)

- ☐ ~~8.2.1~~ 8.1.1 Perform patient assessments, order and interpret drug therapy-related tests, and refer patients to other health care providers; (B&PC 4052.6[a])
- ☐ ~~8.2.1~~ 8.1.2 Participate in the evaluation and management of diseases and health conditions in collaboration with other health care providers; (B&PC 4052.6[a])
- ☐ ~~8.2.1~~ 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; (B&PC 4052.6[a][5],[b])

☐ ~~8.2.1~~ 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; (B~~&~~PC 4052.6[b])

☐ ~~8.2.1~~ 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; (B~~&~~PC 4052.6[d])

☐ ~~8.2.1~~ 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. (B~~&~~PC 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. (B~~&~~PC 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. (B~~&~~PC 4119.6)

☐ 9.1.2. Inspect the drugs maintained in the health care facility at least once per month. (B~~&~~PC 4119.7[c])

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

☐☐☐ 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. (B~~&~~PC 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

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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. (B&PC 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 ~~on duty~~ when filling prescriptions for an inpatient of a licensed health facility. (BPC 4115[f], CCR 1793.7[f])

☐☐☐ ~~10.2~~ 10.3. ~~The ratio for technicians performing the tasks above, related to the furnishing of drugs to inpatients, does not exceed one pharmacist on duty for two technicians on duty. However,~~ ~~w~~When prescriptions are dispensed to discharge patients with only one pharmacist, there is no more than one technician performing the tasks as defined in B&PC 4115(a). The ratio of pharmacy technicians performing those tasks for additional pharmacists does not exceed 2:1. (B&PC 4038, 4115[f], CCR 1793.7[f])

☐☐☐ ~~10.3~~ 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)

☐☐☐ ~~10.4~~ 10.5. A pharmacy technician or pharmacy technician trainee wears identification, in 18-point type that identifies ~~him or her self~~ herself them as a pharmacy technician or pharmacy technician trainee. (B&PC 680, B&PC 4115.5[e], CCR 1793.7[d])

☐☐☐ ~~10.5~~ 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)

~~☐☐☐ 10.6. The ratio is no less than one pharmacist to two technicians. (B&PC 4115[g], 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. (B&PC 4115[g], CCR 1714.1[c])

~~Yes No N/A~~

☐☐☐ 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.

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☐ 10.8.2. Compounded or repackaged products are previously checked by a pharmacist, then used by the technician to fill unit dose distribution and floor and ward stock.

☐ 10.8.3. The overall operations are the responsibility of the pharmacist-in-charge.

☐ 10.8.4. The pharmacy technician checking technician program is under the direct supervision of the Pharmacist as specified in the policies and procedures.

☐ 10.8.5. There is an ongoing evaluation of the program that uses specialized and advanced trained pharmacy technicians to check the work of other pharmacy technicians.

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

☐ 10.9.1. Package emergency supplies for use in the health care facility and the hospital's emergency medical system. (B&PC 4119, 4115[i])

☐ 10.9.2. Seal emergency containers for use in the health care facility. (B&PC 4115[i])

☐ 10.9.3. Perform monthly checks of the drug supplies stored throughout the health care facility and report any irregularities within 24 hours to the pharmacist-in-charge and to the director or chief executive officer. (B&PC 4115[i])

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

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. (B&PC 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

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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~~, CCR 1751, CCR 1751.8~~)

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. (B~~&~~PC 688, 4019, 4040, CCR 1717.4)

☐☐☐ 13.2. The chart or medical record of the patient contains all of the information required by B~~&~~PC 4040 and the chart order is signed by the practitioner authorized by law

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to prescribe drugs if present or, if not present, within a specified time frame not exceeding 48 hours. (B&PC 688, 4019, 4040, 22 CCR 70263[g])

~~Yes No N/A~~

☐☐☐ 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, B&PC 4081, 4105, 4333)

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

CORRECTIVE ACTION OR ACTION PLAN: _____

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14. Labeling and Distribution

Yes No N/A

☐☐☐ 14.1. Unit dose medication ~~and parenteral admixtures~~ are properly labeled and include the information as required by B&PC 4076, or the information is otherwise readily available at the time of drug administration. (B&PC 4076[b]~~,~~ ~~CCR 1751.2~~)

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

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

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. (B&PC 4040, CCR 1764, Civil Code 56 et seq.)

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

☐☐☐ 16.4. The pharmacy ensures electronically transmitted prescriptions (chart orders, discharge patient or employee prescriptions) are received, maintained and transmitted in a secure and confidential manner. (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 three business days. (BPC 4105, CCR 1707)

Date Waiver Approved _____ Waiver Number _____

Address of offsite storage location: _____

☐☐☐ 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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Initials

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. (B&PC 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])

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

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

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

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

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

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

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

CORRECTIVE ACTION OR ACTION PLAN: _____

18. Record Keeping Requirements

Yes No N/A

☐☐☐ 18.1. ~~A~~ All completed ~~biennial~~ pharmacy ~~self -assessment~~ self-assessments ~~is~~ are on file in the pharmacy and ~~is~~ 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 (B~~&~~PC 4081[a])
- ☐ 18.2.2. Purchase Invoices and sales records for all prescription drugs (B~~&~~PC 4081~~[b]~~)
- ☐ 18.2.3. Biennial controlled substances inventory (21 CFR 1304.11)
- ☐ 18.2.4. U.S. Official Order Forms (DEA Form~~-~~ 222) (21 CFR 1305.13, 21 CFR 1305.22)
- ☐ 18.2.5. Power of Attorney for completion of DEA 222 forms (21 CFR 1305.~~07~~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 (B~~&~~PC 4081)
- ☐ 18.2.8. Record documenting transfers or sales to other pharmacies, ~~and~~ prescribers, and reverse distributors. (B~~&~~PC 4059, 4081, 4105, 4332, CCR 1718)
- ☐ 18.2.9. Centrally stored unused medications donated to a drug repository and distribution program. (H~~&~~SC 150200, 150202[a][1], 150204~~([~~[k]~~)~~, B~~&~~PC 4105~~([~~[c]).

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

☐☐☐ 18.3. Transfers or sales to other pharmacies and prescribers do not exceed five percent of the pharmacy's total annual purchases of dangerous drugs or devices. If more than five percent, registration with the board as a wholesaler has been obtained. (21 CFR 1307.11, ~~Prescription Drug Marketing Act [PDMA] [Pub. L. 100-293, Apr. 11, 1988] 503~~ Drug Supply Chain Security Act (DSCSA), B~~&~~PC 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, ~~PDMA 503~~ DSCSA, B~~&~~PC 4160)

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

Date completed: _____ (21 CFR 1304.11)

PIC Initials

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

☐☐☐ ~~18.6~~ 18.7. Separate Schedule II records are maintained. This includes triplicate prescriptions, invoices, US official order forms and inventory records. (21 CFR 1304.04)

☐☐☐ ~~18.7~~ 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)

☐☐☐ ~~18.8~~ 18.9. DEA Forms 222 are properly executed. (21 CFR 1305.12)

☐☐☐ ~~18.9~~ 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)

☐☐☐ ~~18.10~~ 18.11. Any controlled substances drug loss is reported upon discovery to the DEA and to the Board of Pharmacy within 30 days. (21 CFR 1301.74[c], CCR 1715.6)

☐☐☐ ~~18.11~~ 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)

☐☐☐ ~~18.12~~ 18.13. Do pharmacy staff hand initial prescription records and prescription labels, OR

☐☐☐ ~~18.13~~ 18.14. ~~Does~~ 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])

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

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

- 19.3.1 A physical count, not an estimate, of all quantities of federal Schedule II controlled substances. The biennial inventory of controlled substances required by federal law may serve as one of the mandated inventories under this section in the year where the federal biennial inventory is performed, provided the biennial inventory was taken no more than three months from the last inventory required by this section; (CCR 1715.65[c][1])

- 19.3.2 A review of all acquisitions and dispositions of federal Schedule II controlled substances since the last inventory reconciliation report; (CCR 1715.65[c][2])

- 19.3.3 A comparison of the two above-mentioned items to determine if there are any variances; (CCR 1715.65[c][3])

- 19.3.4 All records used to compile each inventory reconciliation report shall be maintained in the pharmacy or clinic for at least three years in a readily retrievable form; and (CCR 1715.65[c][4])

- 19.3.5 Possible causes of overages shall be identified in writing and incorporated into the inventory reconciliation report. (CCR 1715.65[c][5])

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

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

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PIC Initials

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

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

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

CORRECTIVE ACTION OR ACTION PLAN: _____

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~~19~~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])

☐☐☐ ~~19~~20.~~1~~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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~~20~~21. Drug Supplies for Use in Medical Emergencies

Yes No N/A

☐☐☐ ~~20~~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])

☐☐☐ ~~20~~21.2. Written policies and procedures have been developed that establish the contents of the supply, procedures for use, restocking and sealing of the emergency drug supply. (22 CCR 70263[f][1], BPC 4115[i][3], 4119.6))

☐☐☐ ~~20~~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])

☐☐☐ ~~20~~21.4. The pharmacist is responsible for inspection of the drug supply at periodic intervals (no less frequently than every 30 days) specified in the writ-ten policies. Records of the inspection are kept for at least three years. The inspection can be done by a pharmacy technician or pharmacy intern as defined in the pharmacy's written inspection policies and procedures. (22 CCR 70263[f][3], BPC 4115[i][3], 4119.7[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

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~~21~~22. Schedule II-V Controlled Substances Floor Stock Distribution Records

Yes No N/A

☐☐☐ ~~21~~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. (B~~&~~PC 4081)

CORRECTIVE ACTION OR ACTION PLAN: _____

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~~22~~23. Emergency Room Dispensing

Yes No N/A

☐☐☐ ~~22~~23.1. A prescriber may dispense a dangerous drug, including a controlled substance, to an emergency room patient if all of the following apply: (B~~&~~PC 4068[a])

- ☐ ~~22~~23.1.1. The hospital pharmacy is closed and there is no pharmacist available in the hospital;
- ☐ ~~22~~23.1.2. The dangerous drug is acquired by the hospital pharmacy;

☐ ~~22~~23.1.3. The dispensing information is recorded and provided to the pharmacy when the pharmacy reopens;

☐ ~~22~~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, ~~reports~~ transmits the dispensing ~~information~~ data to the Department of Justice within one working day from the date the controlled substance is released to the patient. (HSC 11165[d]) ~~pursuant to Section 11165 of the Health and Safety Code;~~

☐ ~~22~~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

☐ ~~22~~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;

☐☐☐ ~~22~~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 4 required items in the required order. (BPC 4076, CCR 1707.5)~~The prescriber shall ensure that the label on the drug contains all the information required by Section 4076. (B&PC 4068[a][7])~~

☐☐☐ ~~22~~23.3. The prescriber shall be responsible for any error or omission related to the drugs dispensed. (B~~&~~PC 4068[b])

☐☐☐ ~~22~~23.4. The brand name or generic name and manufacturer of the prescription drug is accurately identified on the label and prescription record. (B~~&~~PC 4076, CCR 1717)

☐☐☐ ~~22~~23.5. Controlled substances are dispensed in prescription containers bearing a federal warning label prohibiting transfer of the drugs. (21 CFR 290.5)

☐☐☐ ~~22~~23.6. Prescriptions are dispensed in new, senior-adult ease –of-opening tested, and child-resistant containers or in a noncomplying package, only pursuant to the prescription or when requested by the purchaser. (15 USC 1473~~ section 4~~[b], 16 CFR 1700.15., CCR 1717)

☐☐☐ ~~22~~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 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])

CORRECTIVE ACTION OR ACTION PLAN: _____

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~~23~~24. Discharge Medication/Consultation Services

Yes No N/A

☐☐☐ ~~23~~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. (B&PC 4074, CCR 1707.2)

☐☐☐ ~~23~~24.2. Prescriptions are transmitted to another pharmacy as required by law. (B&PC 4072, CCR 1717[c],[f], 1717.4)

☐☐☐ ~~23~~24.3. The prescription label contains all the required information and is formatted in accordance with CCR 1707.5 including Patient Centered Labels in at least 12-point sans serif typeface for the 4 required items in the required order. (B&PC 4076, CCR 1707.5)

~~☐☐☐ 23.4. If requested by the patient, the prescription label is printed in 12-point typeface. (CCR 1707.5[a])~~

~~☐☐☐ 23.5. The pharmacy is exempt from the prescription label requirements in CCR 1707.5.~~

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

~~☐☐☐ 23~~24.6~~4~~. Appropriate drug warnings are provided orally or in writing. (B&PC 4074, ~~CCR 1744)~~

☐☐☐ 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])

☐☐☐ 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]).

☐☐☐ ~~23~~24.~~7~~5~~6~~. The trade name or generic name and manufacturer of the prescription drug is accurately identified ~~on the label and~~ in the prescription record. (~~B&PC 4076,~~ CCR 1717)

☐☐☐ ~~23~~24.~~8~~6~~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. (B~~&~~PC 4073)

☐☐☐ ~~23~~24.~~9~~7~~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. (~~B&PC 4115[f],~~ CCR 1712, 1793.7)

☐☐☐ ~~23~~24.~~10~~89. Controlled substances are dispensed in prescription containers bearing a federal warning label prohibiting transfer of the drugs. (21 CFR 290.5)

☐☐☐ ~~23~~24.~~11~~910. Prescriptions are dispensed in a new and child-resistant container, or senior-adult ease-of-opening tested container, or in a non-complying package only pursuant to the prescriber or when requested by the purchaser. (~~25~~ 15 USC 1473 ~~section 4[b]~~, 16 CFR 1700.15, CCR 1717)

☐☐☐ ~~23~~24.~~12~~~~10~~11. Patient package inserts are dispensed with all estrogen medications. (21 CFR 310.515)

☐☐☐ 24.~~11~~12. The pharmacy provides patients with required Black Box Warning. (21 CFR 201.57[c])

☐☐☐ 24.~~12~~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, the pharmacy has the capability to receive electronic data transmission prescriptions on behalf of patients. (BPC 688).

CORRECTIVE ACTION OR ACTION PLAN: _____

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~~24~~25. Central Filling of Patient Cassettes For Other Hospital Pharmacies

Yes No N/A

☐☐☐ ~~24~~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: _____

☐☐☐ ~~24~~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 ~~23.~~ 26.

☐☐☐ ~~24~~25.3. Prescription information is electronically transferred between the two pharmacies. (CCR 1710[b][6])

☐☐☐ ~~24~~25.4. Pharmacy has a contract with the ordering hospital pharmacy or has the same owner. (CCR 1710[b][1])

☐☐☐ ~~24~~25.5. Filled cassettes are delivered directly to the ordering hospital pharmacy. (CCR 1710[b][2])

☐☐☐ ~~24~~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])

☐☐☐ ~~24~~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])

~~25~~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: _____

☐☐☐ ~~25~~26.~~1~~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 ~~packages unit dose medication for inpatients of one or more hospitals under common ownership~~ within a 75-mile radius: (B~~&~~PC 4128)

Hospitals to which central packaged unit dose medications are provided:

- ☐ ~~25~~26.~~2~~1.1. _____ Distance (miles): _____
- ☐ ~~25~~26.~~2~~1.2. _____ Distance (miles): _____
- ☐ ~~25~~26.~~2~~1.3. _____ Distance (miles): _____
- ☐ ~~25~~26.~~2~~1.4. _____ Distance (miles): _____
- ☐ 26.~~2~~1.5 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~~1.6 Prepares sterile compounded unit dose drugs for administration to inpatients, if each unit dose drug is barcoded pursuant to BPC 4128.4.
- ☐ 26.~~2~~1.7 Prepares compounded unit dose drugs for administration to inpatients, if each unit dose package is barcoded pursuant to BPC 4128.4.

☐☐☐ ~~25~~26.3~~2~~. 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. (B~~&~~PC 4128.3)

☐☐☐ ~~25~~26.4~~3~~. ~~All~~ Any unit dose medications produced by a centralized hospital packaging pharmacy are barcoded ~~and readable~~ to be machine readable at the inpatient's bedside using barcode medication administrative software. ~~The barcode information contains:~~ (B~~&~~PC 4128.4)

☐ ~~25.3.1. The date the medication was prepared.~~ 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.

☐ ~~25.3.2. The components used in the drug product.~~ 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)]

~~☐ 25.3.3. The lot number or control number.~~

~~☐ 25.3.4. The expiration date.~~

~~☐ 25.3.5. The National Drug Code Directory number.~~

~~☐ 25.3.6. The name of the centralized hospital packaging pharmacy.~~

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

☐☐☐ ~~25~~26.5~~4~~. ~~The~~ Any label for each unit dose medication produced by a centralized hospital packaging pharmacy ~~contains the expiration date, the established name of the drug, the quantity of the active ingredient, and special storage or handling requirements~~ displays a human-readable label that contains the following: (B~~&~~PC 4128.5[a])

☐ 26.5~~4~~.1 The date the medication was prepared.

☐ 26.5~~4~~.2 The beyond-use date

☐ 26.5~~4~~.3 The established name of the drug.

☐ 26.5~~4~~.4 The quantity of each active ingredient.

☐ 26.5~~4~~.5 The lot number or control number assigned by the centralized hospital packaging pharmacy.

☐ 26.5~~4~~.6 Special storage or handling requirements.

☐ 26.5~~4~~.7 The name of the centralized hospital packaging pharmacy.

☐☐☐ 26.6~~5~~ The pharmacist is able to retrieve all of the following information using the lot number or control number: (BPC 4128.5[b])

☐ 26.6~~5~~.1. The components used in the drug product.

☐ 26.6~~5~~.2. The expiration date of each of the drug's components.

☐ 26.6~~5~~.3. The National Drug Code Directory number.

☐☐☐ ~~25~~26.~~5~~6~~6~~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. (B&PC 4128.7)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

~~26~~27. Policies and Procedures

Yes No N/A

☐☐☐ ~~26~~27.1. There are written policies and procedures in place for:

☐ ~~26~~27.1.1. Oral consultation for discharge medication to an inpatient of a health care facility licensed pursuant to HSC 1250. The assurance that each patient received information regarding each medication given at the time of discharge. (BPC 4074[e], CCR 1707.2[b][3])

☐ ~~26~~27.1.2. Action to be taken to protect the public when a licensed individual employed by or with the pharmacy is known to be chemically, mentally, or physically impaired to the extent that it effects his or her ability to practice the profession or occupation authorized by his or her license. (B&PC 4104[a])

☐ ~~26~~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. (B&PC 4104[b])

☐ ~~26~~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. (B&PC 4104[b])

☐ ~~26~~27.1.5. Reporting to the board within 14 days of the receipt or development of information as specified in B&PC 4104[c][1-6].

~~☐ 2627.1.6. Oral consultation for discharge medications to an inpatient of a health care facility licensed pursuant to H&SC 1250, or to an inmate of an adult correctional facility or juvenile detention facility. (B&PC 4074, CCR 1707.2[b][3])~~

☐ ~~26~~27.1.6~~7~~. 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])

☐ ~~26~~27.1.~~7~~8. 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])

☐ ~~26~~27.1.~~8~~9. Helping patients with limited or no English proficiency understand the information on the prescription container label in the patient's language, including the selected means to identify the patient's language and providing interpretive services in the patient's language. (CCR 1707.5)

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

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

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

☐ 27.1.12. Furnishing dangerous drug or dangerous device pursuant to preprinted or electronic standing orders, order sets, and protocol, if the order is dated, timed, and authenticated in the medical record of the patient to whom the dangerous drug or dangerous device is provided. (BPC 4119.7[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] Part 6)

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

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

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

CORRECTIVE ACTION OR ACTION PLAN: _____

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~~27~~28. Compounding

_____
PIC Initials

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

29. Automated Drug Delivery Systems

Yes No N/A

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

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

☐☐☐ 29.3. If the pharmacy operated an automated drug delivery systems, the pharmacist-in-charge has completed the annual 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: _____

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30. Prescription Drug Take-Back Services

Yes No N/A

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

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

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

☐☐☐ 30.2. Only prescription drugs that have been dispensed by any pharmacy or practitioner to a consumer are eligible for collection as part of drug take-back services maintained by the pharmacy. (CCR 1776.1[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) is not collected as part of the pharmacy's drug take-back service. (CCR 1776.1[f])

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

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

CORRECTIVE ACTION OR ACTION PLAN: _____

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

Yes No N/A

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

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

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

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

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

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

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

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

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

Yes No N/A

☐☐☐ 30.12. The pharmacy is registered with DEA as a collector for purposes of maintaining a prescription drug take-back collection receptacle. (21 CFR 1317.30, 1317.40, 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 inwriting within 14 days. (CCR 1776.1[i][3][4])
List the dates the board was notified of any tampering or theft from the collection receptacle and/or tampering, damage or theft of the removed liner:
Date reported: _____

☐☐☐ 30.16. The pharmacy is not on probation with the board. (CCR 1776.1[l])
If answered NO, meaning the pharmacy is on probation, the pharmacy cannot maintain a drug take back collection receptacle and must cease and notify the board in writing within 30 days and notify the DEA within 30 days.

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

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

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

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

□□□ 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[f][2]

□ 30.23.3 The liner bears a permanent, unique identification number established by the pharmacy or pre-entered onto the liner by the liner's manufacturer or distributor. (CCR 1776.3[f][2])

□ 30.23.4 The liner is removable as specified pursuant to CCR 1776.3.

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

□□□ 30.25. If the liner is not already itself rigid or already inside of a rigid container when it is removed from the collection receptacle, the liner is immediately, without interruption, placed in a rigid container for storage, handling and transport. (CCR 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 following records for each liner: (CCR 1776.3[k], 1776.6[a])

☐☐☐ 30.29. The pharmacy seals the inner liners and their contents are shipped to a 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])

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

CORRECTIVE ACTION OR ACTION PLAN: _____

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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 person lawfully entitled to dispose of resident decedent's property of unwanted or unused prescription drugs. (CCR 1776.4[a])

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

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

If no, answer N/A to the remaining questions in this section.
If yes, continue answering the questions in this section.
List the location(s) of the collection receptacle:

_____

_____

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

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

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

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

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PIC
Initials

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

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

☐☐☐ 30.39. The liner certified by the manufacturer to meet the American Society for Testing Materials(ASTM) D1709 standard test for impact resistance of 165 grams (drop dart test), the ASTM D1922standards for tear resistance of 480 grams in both parallel and perpendicular planes, waterproof, tamper evident, tear resistant, opaque to prevent viewing and discourage removal of any contents once the liner is removed from the collection receptacle, marked to display the maximum contents, and bear a permanent, unique identification number. (CCR 1776.4[h])

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

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

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

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

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

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

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

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

CORRECTIVE ACTION OR ACTION PLAN: _____

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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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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)

_____
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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.

California Code of Regulations (CCR), Title 16 and Title 24
Business and Professions Code (B&PC), Chapter 9, Division 2
Health and Safety Code (H&SC), Division 10, Uniform Controlled Substances Act
California Code of Regulations (CCR), Chapter 1, Division 5, Title 22
Code of Federal Regulations (CFR), Title 21, Chapter II, Drug Enforcement Administration (www.dea.gov)

California Board of Pharmacy
1625 N. Market Blvd., Suite N219
Sacramento, CA 95834
Phone: (916) 574-7900
Fax: (916) 574-8618
www.pharmacy.ca.gov

Pharmacy Law may be obtained by contacting:
Law Tech Publishing Co.
1060 Calle Cordillera, Suite 105
San Clements, CA 92673
Phone: (800) 498-0911 Ext. 5
www.lawtechpublishing.com

Pharmacist Recovery Program
(800) 522-9198 (24 hours a day)

Atlantic Associates, Inc. (CURES)
Prescription Collection
8030 S. Willow Street, Bldg 3 Unit 3
Manchester, NH 03103
Phone: (888) 492-7341
Fax: 877-508-6704

CURES
4949 Broadway
Sacramento, CA 95820
Phone: (916) 319-9062
Fax: (916) 319-9448
http://www.ag.ca.gov/bne

CURES Patient Activity Report Request Forms:
http://www.ag.ca.gov/bne/trips.php

PRESCRIBER BOARDS:

Medical Board of California
2005 Evergreen St., Suite 1200
Sacramento, CA 95815
Phone: (800) 633-2322
Phone: (916) 263-2382
Fax: (916) 263-2944
http://www.mbc.ca.gov

Dental Board of California
2005 Evergreen St., Suite 1550
Sacramento, CA 95815
Phone: (916) 263-2300
Fax: (916) 263-2140
http://www.dbc.ca.gov

Board of Registered Nursing
1625 N. Market Blvd., Suite N217
Sacramento, CA 95834
Phone: (916) 322-3350
Fax: (916) 574-7697
http://www.rn.ca.gov/

Board of Optometry
2420 Del Paso Road, Suite 255
Sacramento, CA 95834
Phone: (916) 575-7170
Fax: (916) 575-7292
http://www.optometry.ca.gov/

Osteopathic Medical Board of California
1300 National Drive, Suite 150
Sacramento, CA 95834
Phone: (916) 928-8390
Fax: (916) 928-8392
http://www.ombc.ca.gov

Physician Assistant Committee
2500 Evergreen St., Suite 1100
Sacramento, CA 95815
Phone: (916) 561-8780
Fax: (916) 263-2671
http://www.pac.ca.gov

Board of Podiatric Medicine
2005 Evergreen St., Suite 1300
Sacramento, CA 95815
Phone: (916) 263-2647
Fax: (916) 263-2651
http://www.bpm.ca.gov

Veterinary Medical Board
2005 Evergreen St., Suite 2250
Sacramento, CA 95815
Phone: (916) 263-2610
Fax: (916) 263-2621
http://www.vmb.ca.gov

FEDERAL AGENCIES:

Food and Drug Administration – Industry Compliance
http://www.fda.gov/oc/industry/centerlinks.htm l#drugs

The **Drug Enforcement Administration** may be contacted at:

DEA Website:
http://www.deadiversion.usdoj.gov

Online Registration – New Applicants:
http://www.deadiversion.usdoj.gov/drugreg/ reg_apps/onlineforms_new.htm

Online Registration - Renewal:
www.deadiversion.usdoj.gov/drugreg/reg_app s/ onlineforms.htm

Registration Changes (Forms):
http://www.deadiversion.usdoj.gov/drugreg/ change_requests/index.html

DEA Registration Support (all of CA):
(800) 882-9539

Online DEA 106 Theft/Loss Reporting:
https://www.deadiversion.usdoj.gov/webforms / app106Login.jsp

Online DEA 222 Controlled Substance Ordering System (CSOS): http://www.deaecom.gov/

DEA - Fresno
2444 Main Street, Suite 240
Fresno, CA 93721
Registration: (888) 304-3251 or (415) 436-7900
Diversion or Investigation: (559) 487-5406

DEA - Los Angeles
255 East Temple Street, 20th Floor
Los Angeles, CA 90012
Registration: (888) 415-9822 or (213) 621-6960
Diversion or Investigation: (213) 621-6942

DEA – Oakland
1301 Clay Street, Suite 460N
Oakland, CA 94612
Registration: (888) 304-3251
Diversion or Investigation: (510) 637-5600

DEA – Redding
310 Hensted Drive, Suite 310
Redding, CA 96002
Registration: (888) 304-3251 or (415) 436-7900
Diversion or Investigation: (530) 246-5043

DEA - Riverside
4470 Olivewood Avenue
Riverside, CA 92501-6210
Registration: (888) 415-9822 or (213) 621-6960
Diversion or Investigation: (951) 328-6200

DEA - Sacramento
4328 Watt Avenue
Sacramento, CA 95821
Registration: (888) 304-3251 or (415) 436-7900
Diversion or Investigation: (916) 480-7250

DEA – San Diego and Imperial Counties
4560 Viewridge Avenue
San Diego, CA 92123-1637
Registration: (800) 284-1152
Diversion or Investigation: (858) 616-4100

DEA – San Francisco
450 Golden Gate Avenue, 14th Floor
San Francisco, CA 94102
Registration: (888) 304-3251
Theft Reports or Diversion: (415) 436-7900

DEA – San Jose
One North First Street, Suite 405
San Jose, CA 95113
Registration: (888) 304-3251
Diversion or Investigation: (408) 291-2631

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)

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 underline for added language. Amendments to the proposed changes are shown by ~~double strikethrough~~ for deleted language and double underline for added language.

WHOLESALER/THIRD-PARTY LOGISTICS PROVIDER ~~DANGEROUS DRUGS & DANGEROUS DEVICES~~ SELF-ASSESSMENT

All legal references used throughout this self-assessment form are explained on page ~~21~~22.

All references to "drugs" throughout this self-assessment form refer to dangerous drugs and dangerous devices as defined in Business & Professions Code (B~~&~~PC) 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 = ~~includes~~ Designated Representative, Designated Representative-3PL, and Designated Representative Reverse Distributor

~~Wholesaler~~ Licensed Premises Name: _____

Address: _____

Phone: _____

~~Wholesaler~~ Licensed Premises E~~=~~mail address: _____

Ownership: Please mark one

○ sole owner ○ partnership ○ corporation ○ LLC

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

CA ~~Wholesaler Permit~~ License #_____ Expiration Date_____

Other ~~Permit~~ 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

~~Designated representative-in-charge (~~DRIC~~)~~ / RM ~~pharmacist (RPH)~~ _____

DR~~IC~~ License # / RPH License #_____ Expiration Date_____

Website Address (optional):__ _____

Other Licensed ~~Wholesaler~~ Staff (~~designated representative (~~DR~~),~~ pharmacist (RPH)):

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

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

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

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

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

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

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

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

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

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

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

1. Ownership/Location

Yes No N/A

☐ ☐ ☐ 1.1. Review the current ~~wholesaler permit~~ 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. (B~~&~~PC 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. (B~~&~~PC 4082)

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 ~~USP 1990 22nd Edition~~ the standards set forth in the latest edition of the USP) (CCR 1780[b])

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

Yes No N/A

☐ ☐ ☐ 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 and devices are stored limited to authorized personnel? (CCR 1780[c])

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

_____

_____

_____

~~Yes No N/A~~

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

2.6. The ~~wholesaler~~ 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.

_____

_____

~~Yes No N/A~~

☐ ☐ ☐ 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, ~~and~~ or others, by receiving, inventorying and managing the disposition of outdated or nonsaleable dangerous drugs or devices? (B~~&~~PC 4040.5)

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Yes No N/A

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

Date of approval from the board: _____

☐ ☐ ☐ 2.~~8~~9. The facility is subscribed to the board's email ~~e-mail~~ notifications. (B&PC 4013)

Date Last Notification Received: _____

Email ~~E-mail~~ address registered with the board: _____

CORRECTIVE ACTION OR ACTION PLAN _____

_____

~~Yes No N/A~~

☐ ☐ ☐ 2.~~9~~10. The facility receives the board's email ~~e-mail~~ notifications through the owner's electronic notice system. (B&PC 4013[c])

Date Last Notification Received: _____

Email ~~E-mail~~ address registered with the board: _____

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Note: There are specific requirements for wholesaling, storage, distribution, and disposal of controlled substances – these additional requirements are in Section ~~12~~ 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 ~~designated representative-in-charge~~ DRIC/RM are both equally responsible for maintenance of the records and inventory of the facility. (B&PC 4081[b])

☐ ☐ ☐ 3.2. Is the ~~designated representative-in-charge~~ DRIC/RM at least 18 years of age and ~~is~~ responsible for the ~~wholesaler's~~ compliance with all state and federal laws for

the ~~wholesale~~ distribution of drugs? The ~~designated representative-in-charge~~ DRIC may be a pharmacist. (B~~&~~PC 4160[d], 4053.1~~([~~[b]~~)~~, 4053.2)

☐ ☐ ☐ 3.3. The owner must notify the board within 30 days of termination of the ~~designated representative-in-charge~~ DRIC/RM ~~or pharmacist~~. (B~~&~~PC 4305.5[a])

~~Yes No N/A~~

☐ ☐ ☐ 3.4. The owner must identify and notify the board of ~~the appointment~~ a proposed ~~of a~~ new ~~designated representative-in-charge~~ DRIC/RM within 30 days of the termination of the former ~~designated representative-in-charge~~ DRIC/RM. (B~~&~~PC 4160[~~d~~f], 4160[g~~e~~], 4331[c]) The appropriate form for this notification is ~~a "Change of Designated Representative-in-Charge," which is~~ available on the board's website.

Yes No N/A

☐ ☐ ☐ 3.5. The ~~designated representative-in-charge~~ DRIC/RM who ends ~~his or her~~ their employment at a ~~wholesaler~~ licensed premises, must notify the board within 30 days. ~~-~~(B~~&~~PC 4305.5[c], 4101[b][c]). This notification is in addition to that required of the owner.

CORRECTIVE ACTION OR ACTION PLAN _____

_____

~~4. Designated Representative/Pharmacist~~

~~Yes No N/A~~

~~☐ ☐ ☐ If a designated representative or pharmacist changes his/her name or personal address of record, he/she must notify the board in writing within 30 days. (B&PC 4100, CCR 1704)~~

~~CORRECTIVE ACTION OR ACTION PLAN _____~~

~~_____~~

_____

4~~5~~. Ordering Drugs by this Business for Future Sale/Transfer or Trade

Yes No N/A

☐ ☐ ☐ ~~5~~4.1. Are drugs ordered only from a business licensed by this board or from a licensed manufacturer? (B~~&~~PC 4163[b], 4169)

☐ ☐ ☐ ~~5~~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? (B~~&~~PC 4081, 4332)

☐ ☐ ☐ ~~5~~4.3. For license verification, the ~~wholesaler~~ licensed premises may use the licensing information displayed on the board's Internet web site. (B~~&~~PC 4106)

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Note: There are specific requirements for wholesaling, storage, distribution, and disposal of controlled substances – these additional requirements are in Section ~~12~~ 11 of this document.

~~6~~5. Receipt of Drugs by this Business

Yes No N/A

☐ ☐ ☐ ~~6~~5.1. When drugs are received by your business, are they delivered to the licensed ~~wholesale~~ premises, and received by and signed for only by a ~~designated representative~~ DR or a pharmacist? (~~B & P~~ BPC 4059.5[a])

☐ ☐ ☐ ~~6~~5.2. When drugs are received by your business, are the outside containers visibly inspected to identify the drugs and prevent acceptance of contaminated drugs by detecting container damage? (CCR 1780[d][1])

CORRECTIVE ACTION OR ACTION PLAN _____

_____

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

~~7~~6. Drug Stock

Yes No N/A

☐ ☐ ☐ ~~7~~6.1. Is all drug stock open for inspection during regular business hours? (B~~&~~PC 4080)

☐ ☐ ☐ ~~7~~6.2. Are all drugs you order maintained in a secure manner at your licensed ~~wholesale~~ premises? You cannot order, obtain or purchase drugs that you are not able to store on your licensed premises. (B~~&~~PC 4167)

☐ ☐ ☐ ~~7~~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? (B~~&~~PC 4342[a])

☐ ☐ ☐ ~~7~~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)

☐ ☐ ☐ ~~7~~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]~~, CFR 1307.21~~)

☐ ☐ ☐ ~~7~~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]~~, CFR 1307.21~~)

Yes No N/A

☐ ☐ ☐ ~~7~~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]~~, CFR 1307.21~~)

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section ~~12~~ 11 of this document.

~~8~~7. Sale or Transfer of Drugs by this Business

Yes No N/A

☐ ☐ ☐ ~~8~~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?

~~8~~7.2. Describe how you verify a business or person is appropriately licensed. (B~~&~~PC 4059.5[a], [b],[d],[g], B~~&~~PC 4169)

_____

_____

~~8~~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~~

☐ ☐ ☐ ~~8~~7.4. Are drugs only furnished by your business to an authorized person? (B&PC 4163[a]) Note: An authorized person can be a business or natural person.

~~8~~7.5. Does your business only receive drugs from a pharmacy if:

☐ ☐ ☐ ~~8~~7.5.1. the pharmacy originally purchased the drugs from you?

☐ ☐ ☐ ~~8~~7.5.2. your business is a "reverse distributor"?

☐ ☐ ☐ ~~8~~7.5.3. the drugs are needed to alleviate a shortage? (and only a quantity sufficient to alleviate a specific shortage). (B~~&~~PC 4126.5[a])

Yes No N/A

☐ ☐ ☐ ~~8~~7.6 Are all drugs that are purchased from another business or that are sold, traded or transferred by your business:

☐ ☐ ☐ ~~8~~7.6.1. transacted with a business licensed with this board as a ~~wholesaler~~ WLS/3PL or pharmacy?

☐ ☐ ☐ ~~8~~7.6.2. free of adulteration as defined by the CA Health & Safety Code section 111250?

☐ ☐ ☐ ~~8~~7.6.3. free of misbranding as defined by CA Health & Safety Code section 111335?

☐ ☐ ☐ ~~8~~7.6.4. **confirmed** to not be beyond their use date (expired drugs)? (B~~&~~PC 4169)

~~8~~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.

_____

_____

~~8~~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

☐ ☐ ☐ ~~8~~7.8.1. comply with all CA pharmacy laws related to the distribution of drugs?

☐ ☐ ☐ ~~8~~7.8.2. comply with the pharmacy law of the receiving state within the United States?

☐ ☐ ☐ ~~8~~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?

☐ ☐ ☐ ~~8~~7.8.4. comply with all laws of the receiving foreign country related to the wholesale distribution of drugs?

☐ ☐ ☐ ~~8~~7.8.5. comply with all applicable federal regulations regarding the exportation of dangerous drugs?

~~8~~7.9. Describe how you determine a business in a foreign country is authorized to receive dangerous drugs or dangerous devices. (B~~&~~PC 4059.5[e])

_____

_____

~~Yes No N/A~~

☐ ☐ ☐ ~~8.10. When you are not an authorized distributor for a drug, a pedigree must accompany the product when sold, traded, or transferred (Prescription Drug Marketing Act of 1987).~~

~~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])

Yes No N/A

☐ ☐ ☐ ~~8~~7.11. If preferentially priced drugs are sold by your business, that sale complies with ~~the Prescription Drug Marketing Act of 1987 and~~ CA Pharmacy Law. (B~~&~~PC 4380)

~~Yes No N/A~~

☐ ☐ ☐ ~~8~~7.12. Does your business' advertisements for dangerous drugs or devices contain false, fraudulent, misleading or deceptive claims? (B~~&~~PC 4341, B&PC 651, CCR 1766)

☐ ☐ ☐ ~~8~~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. (B~~&~~PC 650)

_____

_____

☐ ☐ ☐ ~~8~~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. (B~~&~~PC 4066, CFR 1301.25)

_____

_____

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section ~~12~~ 11 of this document.

~~9~~8. Donations of Medication to Voluntary Drug Repository and Distribution Programs (H~~&~~SC 150200, 150203, 150204)

Yes No N/A

☐☐☐ ~~9~~8.1. The wholesaler donates medications to a county-approved drug repository and distribution program, provided the following requirements are met: (H~~&~~SC 150203, 150204)

☐☐☐ ~~9~~8.2. No controlled substances shall be donated. (H~~&~~SC 150204[c][1])

Yes No N/A

☐☐☐ ~~9~~8.3. Drugs that are donated are unused, unexpired and meet the following requirements: (H~~&~~SC 150204[c])

- ☐ ~~9~~8.3.1. Have not been adulterated, misbranded, or stored under conditions contrary to standards set by the USP or the product manufacturer. (H~~&~~SC 150204[c][2])
- ☐ ~~9~~8.3.2. Have never been in the possession of a patient or individual member of the public. (H~~&~~SC 150204[c][3])
- ☐ ~~9~~8.3.3. Are in unopened, tamper-evident packaging or modified unit dose containers with lot numbers and expiration dates affixed. (H~~&~~SC 105204[d])
- ☐ ~~9~~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. (H~~&~~SC 150204[m])

~~10~~9. Outgoing Shipments of Drugs

Yes No N/A

☐ ☐ ☐ ~~10~~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])

☐ ☐ ☐ ~~10~~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? (B~~&~~PC 4166[a])

~~10~~9.3. List the common carriers (shipping or delivery companies) you use.

_____

_____

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section ~~12~~ 11 of this document.

~~11~~10. Delivery of Drugs

Yes No N/A

☐ ☐ ☐ ~~11~~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? (B~~&~~PC 4059.5[a])

~~Yes No N/A~~

☐ ☐ ☐ ~~11~~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? (B~~&~~PC 4059.5[d])

☐ ☐ ☐ ~~11~~10.3. All drugs delivered to a hospital are delivered either to the pharmacy premises or to a central receiving area within the hospital. (B~~&~~PC 4059.5[c])

☐ ☐ ☐ ~~11~~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. (B~~&~~PC 4059.5[f])

CORRECTIVE ACTION OR ACTION PLAN _____

_____

~~12~~11. Controlled Substances

Yes No N/A

☐ ☐ ☐ ~~12~~11.1. Are there effective controls to prevent theft or diversion of controlled substances? (CFR 1301.71)

☐ ☐ ☐ ~~12~~11.2. Are DEA requirements for storage of Schedule II controlled substances being met? (specific requirements are listed in CFR 1301.72[a])

☐ ☐ ☐ ~~12~~11.3. Are DEA requirements for storage of Schedule III, IV and V controlled substances being met? (~~s~~ Specific requirements are listed in CFR 1301.72[b])

☐ ☐ ☐ ~~12~~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])

☐ ☐ ☐ ~~12~~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])

☐ ☐ ☐ ~~12~~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)

Yes No N/A

☐ ☐ ☐ ~~12~~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)

~~12~~11.7.1. List the individuals at this location authorized by power of attorney to order controlled substances.

_____

_____

~~Yes No N/A~~

☐ ☐ ☐ ~~12~~11.8. Does your business follow employee-screening procedures required by DEA to assure the security of controlled substances? (CFR 1301.90)

☐ ☐ ☐ ~~12~~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)

☐ ☐ ☐ ~~12~~11.10. Are all controlled substances purchased, sold or transferred by your business, done so for legitimate medical purposes? (~~H & S~~ HSC 11153.5[a],[b],[c])

☐ ☐ ☐ ~~12~~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])

☐ ☐ ☐ ~~12~~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])

~~12~~11.13. Explain how your business determines an unknown business or individual is appropriately licensed to purchase controlled substances

_____

_____

☐ ☐ ☐ ~~12~~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])

☐ ☐ ☐ ~~12~~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])

Yes No N/A

☐ ☐ ☐ ~~12~~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)

~~Yes No N/A~~

☐ ☐ ☐ ~~12~~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])

☐ ☐ ☐ ~~12~~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)

☐ ☐ ☐ ~~12~~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])

☐ ☐ ☐ ~~12~~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])

☐ ☐ ☐ ~~12~~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)

☐ ☐ ☐ ~~12~~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))

☐ ☐ ☐ ~~12~~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? (B~~&~~PC 4081, CCR 1718, CFR 1304.03, 1305.17[c], 1305.17[a], [b], and H~~&~~SC 11252, 11253~~, 1304.03~~)

☐ ☐ ☐ ~~12~~11.24. Are records of Schedule II controlled substances stored separate from all others? (CFR 1304.04 [f][1])

☐ ☐ ☐ ~~12~~11.25. Are records for Schedule III-V controlled substances stored so that they are easily retrievable? (CFR 1304.04 [f][2])

☐ ☐ ☐ ~~12~~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.~~75~~74[g]~~, 1305.16[b]~~)

☐ ☐ ☐ ~~12~~11.27. Do you separate records for the sale of carfentanil etorphine hydrochloride and or diprenorphine from all other records? (CFR 1305.17[d])

~~Yes No N/A~~

☐ ☐ ☐ ~~12~~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])

☐ ☐ ☐ ~~12~~11.29. Does the owner of your business notify the board of any loss of controlled substances within 30 days of discovering the loss? (CCR 1715.6)

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

CORRECTIVE ACTION OR ACTION PLAN _____

_____

~~13~~12. Policies and Procedures

~~13~~12.1. Does this business maintain and adhere to policies and procedures for the following: (CCR 1780[f])

Yes No N/A

☐ ☐ ☐ ~~13~~12.1.1. Receipt of drugs

☐ ☐ ☐ ~~13~~12.1.2. Security of drugs

☐ ☐ ☐ ~~13~~12.1.3. Storage of drugs (including maintaining records to document proper storage)

☐ ☐ ☐ ~~13~~12.1.4. Inventory of drug (including correcting inaccuracies in inventories)

☐ ☐ ☐ ~~13~~12.1.5. Distributing drugs

☐ ☐ ☐ ~~13~~12.1.6. Identifying, recording and reporting theft or losses

☐ ☐ ☐ ~~13~~12.1.7. Correcting errors and inaccuracies in inventories

Physically quarantining and separating:

☐ ☐ ☐ ~~13~~12.1.8. returned, damaged, outdated, deteriorated, misbranded or adulterated drugs

☐ ☐ ☐ ~~13~~12.1.9. drugs that have been partially used~~?~~

☐ ☐ ☐ ~~13~~12.1.10. drugs where the outer or secondary seals on the container have been broken

☐ ☐ ☐ ~~13~~12.1.11. drugs returned to your business, when there is doubt about the safety, identity, strength, quality, or purity of the drug

☐ ☐ ☐ ~~13~~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 _____

_____

~~14~~13. Training

Yes No N/A

☐ ☐ ☐ ~~14~~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 _____

_____

~~15~~14. Dialysis Drugs

Yes No N/A

☐ ☐ ☐ ~~15~~14.1. Does your business provide dialysis drugs directly to patients, pursuant to a prescription? (B~~&~~PC 4054~~,~~) ~~(~~4059[c]) If so, please complete the next 4 questions, if not proceed to Section ~~16~~15.

☐ ☐ ☐ ~~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. (B~~&~~PC 4059[d])

☐ ☐ ☐ ~~15~~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])

☐ ☐ ☐ ~~15~~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

☐ ☐ ☐ ~~15~~14.5. Is each case or full shelf package of the dialysis drugs dispensed labeled with the patient name and the shipment? Note that additional information as required is provided with each shipment. (CCR 1791)

CORRECTIVE ACTION OR ACTION PLAN _____

_____

~~16~~15. Record Keeping Requirements

Yes No N/A

☐ ☐ ☐ ~~16~~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? (B~~&~~PC 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])

☐ ☐ ☐ ~~16~~15.3.~~2.~~ Are purchase and sales records for all transactions retained on your licensed premises for 3 years from the date of making? (B~~&~~PC ~~4059.5 [a],~~ 4081~~[a]~~, 4105[c], ~~4081,~~ 4332~~, 4059.5~~[a]) ~~Note: A drug pedigree is considered to be a part of the records of purchase and sale and must be retained for three years from the making.~~

☐ ☐ ☐ ~~16~~15.4.~~3.~~ Are all purchase and sales records retained in a readily retrievable form? (B~~&~~PC 4105[a])

☐ ☐ ☐ ~~16~~15.5.~~4.~~ Is a current accurate inventory maintained for all dangerous drugs? (B~~&~~PC 4081, 4332, CCR 1718)

☐ ☐ ☐ ~~16~~15.6.~~5.~~ 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? (B~~&~~PC 4105[b])

☐ ☐ ☐ ~~16~~15.7.~~6.~~ Are required records stored off-site only if a board issued written waiver has been granted?

~~16~~15.8.~~7.~~ 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_____

☐ ☐ ☐ ~~16~~15.9.~~8.~~ Is an off-site written waiver in place and is the storage area secure from unauthorized access? (CCR 1707[b][1])

Yes No N/A

☐ ☐ ☐ ~~16~~15.10.~~9.~~ If an off-site written waiver is in place, are the records stored off-site retrievable within 2 business days? (CCR 1707[b][2])

☐ ☐ ☐ ~~16~~15.11.~~10.~~ 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? (B~~ &~~ PC 4105[d][2])

☐ ☐ ☐ ~~16~~15.12.~~11.~~ Are records of training provided to employees to assure compliance with licensing requirements, retained for 3 years? (CCR 1780[f][4])

~~Yes No N/A~~

☐ ☐ ☐ ~~16~~15.13.~~12.~~ Has this licensed premises, or the designated representative-in-charge/responsible manager ~~or pharmacist~~, 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 (B~~&~~PC 4162[a][~~4~~5]):

_____

_____

☐ ☐ ☐ ~~16~~15.14.~~13.~~ 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. (B~~&~~PC 4083)

☐ ☐ ☐ ~~16~~15.15.~~14.~~ Has this ~~business~~ 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. (B~~&~~PC 4315[~~e~~ f])

☐ ☐ ☐ ~~16~~15.16.~~15.~~ If this ~~business~~ licensed premises dispenses dialysis drugs directly to patients, are the prescription records retained for 3 years, including refill authorizations and expanded invoices for dialysis patients? (CCR 1787[c], 1790)

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section ~~12~~ 11 of this document.

~~17~~16. Reporting Requirements to the Board

Yes No N/A

☐ ☐ ☐ ~~17~~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 (B~~&~~PC 4101[b], 4305.5[c].

☐ ☐ ☐ ~~17~~16.2. The owner must report to the board within 30 days the termination of the designated representative-in-charge or responsible manager ~~or pharmacist~~ (B~~&~~PC 4305.5[a])

☐ ☐ ☐ ~~17~~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)

☐ ☐ ☐ ~~17~~16.4. The owner must notify the DEA, on a DEA form 106, any theft or significant loss of controlled substances upon discovery. (CFR 1301.74[c])

~~Yes No N/A~~

☐ ☐ ☐ ~~17~~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)

☐ ☐ ☐ ~~17~~16.6. The owner must notify the board within 30 days of any change in the beneficial ownership of this business. (B~~&~~PC 4201[~~i~~j], CCR 1709[b])

☐ ☐ ☐ ~~17~~16.7. When called upon by the board, your business can report all sales of dangerous drugs or controlled substances subject to abuse. (B~~&~~PC 4164[a])

☐ ☐ ☐ ~~17~~16.8. ~~Effective January 1, 2006 your~~ The wholesaler ~~business will develop and~~ 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:

- ☐ ~~17~~16.8.1. identify pharmacies that primarily or solely dispense prescription drugs to patients of long term care facilities
- ☐ ~~17~~16.8.2. identify purchases of any dangerous drugs at preferential or contract prices
- ☐ ~~17~~16.8.3. identify current purchases that exceed prior purchases by 20 percent over the previous 12 calendar months. (B~~&~~PC 4164[b])

☐ ☐ ☐ ~~17~~16.9. I understand that this ~~wholesaler~~ 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 (B~~&~~PC 4201[g])

Yes No N/A

☐ ☐ ☐ ~~17~~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)

☐ ☐ ☐ ~~17~~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.

CORRECTIVE ACTION OR ACTION PLAN _____

_____

~~18~~17. Additional Licenses/Permits Required

~~18~~17.1. List all licenses and permits required to conduct this business, including local business licenses, ~~wholesale~~ licenses held in other states, permits or licenses required by foreign countries or other entities (B~~&~~PC 4059.5[e], 4107, CFR 1305.11[a]) ~~-~~Use additional sheets if necessary.

_____

_____

DESIGNATED REPRESENTATIVE-IN-CHARGE / RESPONSIBLE MANAGER ~~PHARMACIST~~ CERTIFICATION:

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

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

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 ~~pharmacy's~~ 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 ~~(see *Laws and Regulations*)~~, at the California State Law Library, or at other libraries or Internet ~~Web sites~~ 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)

~~California Code of Regulations (CCR), Title 16, unless otherwise noted~~

~~Business and Professions Code (B&PC), Chapter 9, Division 2, unless otherwise noted~~

~~Health and Safety Code (H&SC), Division 10, Uniform Controlled Substances Act~~

~~Health and Safety Code (H&SC), Division 104, Part 5, Sherman Food, Drug and Cosmetic Laws~~

~~United States Code of Federal Regulations (CFR), Title 21, Chapter II, Part 1300, Drug Enforcement Administration, Food and Drugs and Codified Controlled Substances Act (CSA)~~

~~**California Board of Pharmacy**~~
~~1625 N. Market Blvd., Suite N219~~
~~Sacramento, CA 95834~~
~~Phone: (916) 574-7900~~
~~Fax: (916) 574-8618~~
~~www.pharmacy.ca.gov~~

~~***Pharmacy Law*** may be obtained by contacting:~~
~~LawTech Publishing Co.~~
~~1060 Calle Cordillera, Suite 105~~
~~San Clements, CA 92673~~
~~Phone: (800) 498-0911 Ext. 5~~
~~www.lawtechpublishing.com~~

~~**Pharmacist Recovery Program**~~
~~Phone: (800) 522-9198 (24 hours a day)~~

~~***Prescriber Boards:***~~

~~**Medical Board of California**~~
~~2005 Evergreen St., Suite 1200~~
~~Sacramento, CA 95815~~
~~Phone: (800) 633-2322~~
~~Phone: (916) 263-2382~~
~~Fax: (916) 263-2944~~
~~http://www.mbc.ca.gov~~

~~**Dental Board of California**~~
~~2005 Evergreen St., Suite 1550~~
~~Sacramento, CA 95815~~
~~Phone: (916) 263-2300~~

Fax: (916) 263-2140
http://www.dbc.ca.gov

Board of Registered Nursing
1625 N. Market Blvd., Suite N217
Sacramento, CA 95834
Phone: (916) 322-7697
Fax: (916) 574-8637
http://www.rn.ca.gov/

Board of Optometry
2420 Del Paso Road, Suite 255
Sacramento, CA 95834
Phone: (916) 575-7170
Fax: (916) 575-7292
http://www.optometry.ca.gov/

Osteopathic Medical Board of California
1300 National Drive, Suite 150
Veterinary Medical Board
2005 Evergreen St., Suite 2250
Sacramento, CA 95815
Phone: (916) 263-2610
Fax: (916) 263-2621
http://www.vmb.ca.gov

Federal Agencies:

Food and Drug Administration – Industry Compliance
http://www.fda.gov/oc/industry/centerlinks.html#drugs

The **Drug Enforcement Administration** may be contacted at:

DEA Website:
http://www.deadiversion.usdoj.gov
Online Registration – New Applicants:
http://www.deadiversion.usdoj.gov/drugreg/reg_apps/onlineforms_new.htm
Online Registration – Renewal:
www.deadiversion.usdoj.gov/drugreg/reg_apps/onlineforms.htm
Registration Changes (Forms):
http://www.deadiversion.usdoj.gov/drugreg/change_requests/index.html
Sacramento, CA 95834

Phone: (916) 928-8390
Fax: (916) 928-8392
http://www.ombc.ca.gov

Physician Assistant Committee
2005 Evergreen St., Suite 1100
Sacramento, CA 95815
Phone: (916) 561-8780
Fax: (916) 263-2671
http://www.pac.ca.gov

Board of Podiatric Medicine
2005 Evergreen St., Suite 1300
Sacramento, CA 95815
Phone: (916) 263-2647
Fax: (916) 263-2651
http://www.bpm.ca.gov
Online DEA 106 Theft/Loss Reporting:
https://www.deadiversion.usdoj.gov/webforms/app106Login.jsp
Controlled Substance Ordering System (CSOS):
http://www.deaecom.gov/

DEA Registration Support (all of CA):
(800) 882-9539

DEA - Los Angeles
255 East Temple Street, 20th Floor
Los Angeles, CA 90012
Registration: (888) 415-9822 or (213) 621-6960
Diversion or Investigation: (213) 621-6942

DEA – San Francisco
450 Golden Gate Avenue, 14th Floor
San Francisco, CA 94102
Registration: (888) 304-3251
Theft Reports or Diversion: (415) 436-7900

~~**DEA – Sacramento**~~
~~4328 Watt Avenue~~
~~Sacramento, CA 95821~~
~~Registration: (888) 304-3251 or (415) 436-7900~~
~~Diversion or Investigation: (916) 480-7250~~

~~**DEA – Riverside**~~
~~4470 Olivewood Avenue~~
~~Riverside, CA 92501-6210~~
~~Registration: (888) 415-9822 or (213) 621-6960~~
~~Diversion or Investigation: (951) 328-6200~~

~~**DEA – Fresno**~~
~~2444 Main Street, Suite 240~~
~~Fresno, CA 93721~~
~~Registration: (888) 304-3251 or (415) 436-7900~~
~~Diversion or Investigation: (559) 487-5406~~

~~**DEA – San Diego and Imperial Counties**~~
~~4560 Viewridge Avenue~~
~~San Diego, CA 92123-1637~~
~~Registration: (800) 284-1152~~
~~Diversion or Investigation: (858) 616-4100~~

~~**DEA – Oakland**~~
~~1301 Clay Street, Suite 460N~~
~~Oakland, CA 94612~~
~~Registration: (888) 304-3251~~
~~Diversion or Investigation: (510) 637-5600~~

~~**DEA – San Jose**~~
~~One North First Street, Suite 405~~
~~San Jose, CA 95113~~
~~Registration: (888) 304-3251~~
~~Diversion or Investigation: (408) 291-2631~~

~~**DEA – Redding**~~
~~310 Hensted Drive, Suite 310~~
~~Redding, CA 96002~~
~~Registration: (888) 304-3251 or (415) 436-7900~~
~~Diversion or Investigation: (530) 246-5043~~

California State Board of Pharmacy
2720 Gateway Oaks Drive, Ste. 100
Sacramento, CA 95833
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www.pharmacy.ca.gov

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

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

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 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 **annually before July 1 of every 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, the signed original readily available and retained in the pharmacy for three (3) years after performed.

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: _____
Phone: _____
Fax number: _____
Website: _____
Pharmacy License #: _____
Expiration Date: _____
DEA Registration #: _____
DEA Expiration Date: _____

DEA Inventory Date: _____
Last ~~C2~~ CS Inventory Reconciliation Date (CCR 1715.65(c)): _____
Pharmacy Hours: M-F: _____Saturday_____ Sunday_____
PIC: _____RPH#_____
ADDS License #: _____
ADDS Expiration Date:_____
ADDS Address: _____
City: _____
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 annually before July 1 of every year. [BPC 4427.7, CCR 1715.1(a)]**
☐ **Completing a self-assessment within 30 days when a new ADDS license was issued. [BPC 4427.7, CCR 1715.1(b)(1)]**
☐ **Completing a self-assessment within 30 days when there was a change in PIC. [BPC 4427.7, CCR 1715.1(b)(2)]**
☐ **Completing a self-assessment within 30 days when there was a change in the licensed location of an ADDS to a new address. [BPC 4427.7, CCR 1715.1(b)(3)]**

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

SECTION 1: DEFINITIONS/TYPE OF ADDS DEVICE USED

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

IDENTIFY THE TYPE OF ADDS DEVICE USED

Yes No N/A

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

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

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

SECTION 2: LOCATION OF DEVICES

Yes No N/A

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

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

Yes No N/A

☐☐☐ 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(a), HSC 1261.6]

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

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

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

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

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

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

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

Note: Licensure of AUDS operated under these provisions is required. Please refer to FAQs for additional information.

Yes No N/A

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

Type of Facility:_____

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

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

Type of Facility:_____

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

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

SECTION 3: GENERAL REQUIREMENTS FOR ALL TYPES OF ADDS

(Answer N/A if licensure not required)

Yes No N/A

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

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

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

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

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

Yes No N/A

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

_____

_____

_____

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

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

☐☐☐ 3.8 The pharmacy is aware the ADDS license will be canceled by operation of law if the underlying pharmacy license is not current, valid, and active. Upon reissuance or reinstatement

of the underlying pharmacy license, a new application for an ADDS license is submitted to the board. [BPC 4427.2(f)]

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

Yes No N/A

☐☐☐ 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)]

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

☐☐☐ 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~~ Business and Professions Code section 4008.
[BPC 4427.4(c)]

☐☐☐ 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), BPC 4427.65(c)(5)(D), HSC 1261.6(f)(4)]

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

☐☐☐ 3.19 Are drugs or devices not immediately transferred into an ADDS upon arrival at the ADDS location, stored for no longer than 48 hours in a secured room within the ADDS location approved by the board under section 4427.3 of the Business and Professions Code, and, upon retrieval of the dangerous drugs and devices from the secured storage, is an inventory taken to detect any losses or overages? [BPC 4427.4(f)]

Yes No N/A

☐☐☐ 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 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(f)]

☐☐☐ 3.24 The Pharmacist-in-Charge 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)]:

- Annually, before July 1 of every 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 Pharmacist-in-Charge of an ADDS assesses the system's compliance with current laws and regulations by using the components of Form 17M-112 (Rev 12/21) 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 regulation 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)]

Yes No N/A

☐☐☐ 3.29 The PIC has certified 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)]

☐☐☐ 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)]

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

☐☐☐ 3.34 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_____

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

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

- ☐ SECTION 4: ~~–~~APDS used to provide pharmacy service to covered entities and medical professionals contracted with a covered entity.
- ☐ SECTION 5: ~~– ADDS~~
  - APDS adjacent to the secured pharmacy area (or)
  - APDS located in a Medical Office~~s~~ (or)
  - APDS located where patients are regularly seen for purposes of diagnosis and treatment to only be used for patients of the practice (or)
  - APDS located at a clinic pursuant to HSC 1204, HSC 1204.1, BPC 4180, or BPC 4190.
- ☐ SECTION 6: ~~–~~ADDS in a health facility pursuant to HSC 1250(a) through (n) that complies with HSC 1261.6.
- ~~☐ SECTION 7 – APDS through a clinic pursuant to HSC 1204 or 1204.1 or BPC 4180 or 4190.~~
- ☐ SECTION ~~8~~7:– ADDS operated by a correctional clinic pursuant to BPC 4187.1, 4427.3(b)(6), or 4427.65(a)(2).
- ☐ SECTION ~~9~~8:
  - Hospital Pharmacy: AUDS used for dispensing pursuant to BPC 4068 ~~(~~when the hospital pharmacy is closed and no pharmacist is available~~)~~.
  - Drug Room: AUDS used for dispensing pursuant to BPC 4056.
- ☐ SECTION 9:
  - AUDS through a facility licensed in California with statutory authority to provide pharmaceutical services (or)
  - AUDS through a jail, youth detention facility, or other correctional facility where drugs are administered within the facility under the authority of the medical director pursuant to BPC 4187.1, 4427.3(b)(6), or BPC 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)]

Yes No N/A

☐☐☐ 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_____

_____

_____

_____

_____

B. UNDERLYING OPERATING PHARMACY

Yes No N/A

☐☐☐ 4.7 The operating pharmacy has obtained a license from the Board to operate the APDS which includes the address of the APDS location and the identity of the covered entity or affiliated site. [BPC 4119.11(a)(1)]

☐☐☐ 4.8 A separate license was obtained for each APDS location and has been renewed annually concurrent with the pharmacy license. (Note: The Board may issue a license for operation of an APDS at an address for which the Board has issued another site license.) [BPC 4119.11(a)(1), 4119.11(a)(8), 4107]

☐☐☐ 4.9 A prelicensure inspection of the proposed APDS location was conducted by the Board within 30 days after Board receipt of the APDS application before Board approval. [BPC 4119.11(a)(9)]

Date of Inspection: _____

Yes No N/A

☐☐☐ 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 The pharmacy does not have more than 15 APDS licenses for one underlying operating pharmacy under this section. [BPC 4119.11(d)(10), 4427.6(k)] List of current APDS licenses:

1._____ 2. _____

3._____ 4. _____

5._____6. _____

7._____8. _____

9._____10._____

11. _____ 12._____

13._____14. _____

15. _____

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

☐☐☐ 4.14 The operating pharmacy will maintain the written APDS policies and procedures for 3 years after the last date of use for that APDS. [BPC 4119.11(d)(11), CCR 1713(f)]

☐☐☐ 4.15 The operating pharmacy of an APDS has completed an annual Self-Assessment pursuant to CCR 1715 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: ☐ Annual; ☐ New ADDS; ☐ Change in PIC; ☐ Change in location of ADDS

☐ ☐ ☐ ~~4.16 The operating pharmacy has complied with all recordkeeping and quality assurance requirements pursuant to BPC 4119.11 and those records will be maintain within the pharmacy holding the APDS and separately from the other pharmacy records. [BPC 4119.11(j)]~~

☐ ☐ ☐ ~~4.17 The pharmacy is aware that the drugs stored in an APDS are a part of the operating pharmacy's drug inventory and the drugs dispensed by the APDS shall be considered to have been dispensed by that pharmacy. [BPC 4119.11(a)(3)]~~

☐ ☐ ☐ 4.1~~8~~6 The underlying operating pharmacy is solely responsible for the security, operation, maintenance and training for both the pharmacy and covered entity personnel using the system.~~:~~ [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: _____
_____
_____
_____
_____
_____
_____

C. PHARMACIST RESPONSIBILITIES

Yes No N/A

☐ ☐ ☐ 4.1~~9~~7 The operation of the APDS is under the supervision of a licensed pharmacist acting on behalf of the operating pharmacy. [BPC 4119.11(a)(7)]. Note: The pharmacist need not be physically present at the site of the APDS and may supervise the system electronically.

☐ ☐ ☐ 4.~~20~~18 The pharmacist performs the stocking of the APDS or if the APDS utilizes removable pockets, cards, drawers, similar technology, or unit of use or single dose containers are used, the stocking of the APDS may be done outside of the facility if the following conditions are met: [BPC 4119.11(g)]

- ☐ 4.~~20~~18.1 A pharmacist, intern pharmacist or pharmacy technician working under the supervision of the pharmacist may place drugs into the removeable pockets, cards, drawers, similar technology, or unit of use or single dose containers. [BPC 4119.11(g)(1)]
- ☐ 4.~~20~~18.2 Transportation of removeable pockets, cards, drawers or similar technology o~~O~~r unit of use or single dose container between the pharmacy and the facility are in a tamper-evident container. [BPC 4119.11(g)(2]

☐ 4.~~20~~18.3 There are policies and procedures to ensure the removeable pockets, cards, drawers, similar technology, or unit of use or single dose containers are properly placed into the APDS. [BPC 4119.11(g)(3)]

Yes No N/A

☐☐☐ 4.~~21~~19 ~~The~~ A pharmacist conducts a monthly review of the APDS including a physical inspection of the drugs contained within, operation, maintenance, and cleanliness of the APDS, and a review of all transaction records in order to verify the security and accountability of the APDS. [BPC 4119.11(h)]

Date of Last Review: _____

☐☐☐ 4.~~22~~20 The Pharmacist-in-charge of the offsite ADDS/APDS has ensured the following: [CCR 1715.65(h)]

☐ 4.20.1 All controlled substances added to the ADDS/APDS are accounted for;
☐ 4.20.2 Access to ADDS/APDS is limited to authorized facility personnel;
☐ 4.20.3 An ongoing evaluation of discrepancies or unusual access associated with controlled substance is performed; and
☐ 4.20.4 Confirmed losses of controlled substances are reported to the Board.

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE:

_____
_____
_____
_____
_____

D. DEVICE REQUIREMENTS

Yes No N/A

☐☐☐ 4.2~~3~~1 Access to the APDS is controlled and tracked using an identification or password system or biosensor. Systems tracked via password shall include a camera that records a picture of the individual accessing the APDS and the picture must be maintained for a minimum of 180 days. [BPC 4119.11(~~c~~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)]~~

Yes No N/A

☐☐☐ 4.2~~5~~2 The APDS will collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of APDS. [BPC 4119.11(c)(1)]

☐☐☐ 4.2~~6~~3 The APDS will maintain transaction information in a readily available in downloadable format for review and inspection by authorized individuals for a minimum of 3 years. [BPC 4119.11(c)(2)]

☐☐☐ 4.2~~7~~4 The 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)]

- Maintaining the security of the APDS and dangerous drug and devices within the APDS.
- 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.
- Ensuring patients are aware that consultation with a pharmacist is available for any prescription medication, including those delivered via APDS.
- 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.
- Orienting patients on the use of APDS and notifying patients when expected medications are not available in the APDS. The pharmacy must ensure the use of the APDS does not interfere with the delivery of drugs and devices.
- 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)]

☐ 4.2~~7~~4.3 The ~~device~~ APDS shall have a means to identify each patient and only release the identified patient's drugs and devices to the patient or the patient's agent. [BPC 4119.11(d)(3), CCR 1713(d)(3)]

☐ 4.2~~7~~4.4 The pharmacist has performed all clinical services as part of the dispensing process, including, but not limited to, drug utilization review and consultation. [BPC 4119.11(d)(4)]

☐ 4.2~~7~~4.5 Drugs are dispensed from the APDS only upon authorization from the pharmacist after the pharmacist has reviewed the prescription and the patient's profile for potential~~s~~ contraindications and adverse drug reactions. [BPC 4119.11(d)(5)]

☐ 4.2~~7~~4.6 The pharmacist shall consult patients for the first time on all prescribed drugs and devices dispensed from the APDS. The consultation shall be provided by a Board-licensed pharmacist via telecommunication link that has two-way audio and video capabilities. [BPC 4119.11(d)(6)]

☐ 4.2~~7~~4.7 The APDS shall prominently post a notice that provides the name, address and telephone number of the pharmacy [BPC 4119.11(d)(7)]

☐ 4.2~~7~~4.8 The prescription labels on all drugs dispensed via APDS shall comply with BPC 4076 and CCR 1707.5. [BPC 4119.11(d)(8)]

~~☐☐☐ 4.27.9 Any complaint, error or omission involving the APDS shall be reviewed as a part of the pharmacy's quality assurance program pursuant to BPC 4125. [BPC 4119.11(d)(9)]~~

Yes No N/A

☐☐☐ 4.2~~8~~5 The federal warning label prohibiting transfer of controlled substances is on the prescription container. [21 CFR 290.5]

☐☐☐ 4.2~~9~~6 Prescriptions are dispensed in a new and child-resistant container, or senior-adult ease-of-opening tested container, or in a non-complying package only pursuant to the prescriber or when requested by the purchaser. [15 USC 1473(b), 16 CFR 1700.15, CCR 1717]

☐☐☐ 4.~~30~~27 Patient package inserts are dispensed with all estrogen medications. [21 CFR 310.515]

☐☐☐ 4.~~31~~28 The pharmacy provides patients with Black Box Warning Information in conformance with 21 CFR 201.57(c).

☐☐☐ 4.~~32~~29Medication guides are provided on required medications. [~~(~~21 CFR 208.1]~~)~~

☐☐☐ 4.30 The pharmacy uses the APDS to deliver prescription medications to patients as provided: [CCR 1713(d)]

☐ 4.30.1 The pharmacist has determined that each patient using the APDS met the inclusion criteria for use of the APDS established by the pharmacy prior to the delivery of the prescription medication to the patient.

☐ 4.30.2 The APDS has a means to identify each patient and only release the patient's prescription medications to the patient or patient's agent.

☐ 4.30.3 The pharmacy provides an immediate consultation with a pharmacist, either in-person or via telephone, upon the request of a patient.

☐ 4.30.4 Any incident involving the APDS where a complaint, deliver error, or omission has occurred shall be reviewed as part of the pharmacy's quality assurance program mandated by Business and Professions Code section 4125.

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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E. RECORD KEEPING REQUIREMENTS

Yes No N/A

☐☐☐ ~~4.33 The operating pharmacy has complied with all recordkeeping and quality assurance requirements pursuant to BPC 4119.11 and those records shall be maintain within the pharmacy holding the APDS and separately from the other pharmacy records. [BPC 4119.11(j)]~~

☐☐☐ ~~4.34 The operating pharmacy will maintain records of acquisition and disposition of dangerous drugs stored in the APDS separate from other pharmacy records. [BPC 4119.11(a)(4)]~~

☐☐☐ 4.3~~5~~1 Any records maintained electronically must be maintained so that the pharmacist-in-charge, or the pharmacist on duty if the pharmacist-in-charge is not on duty, must, at all times during which the licensed premises are open for business, be able to produce a hardcopy and electronic copy of all records of acquisition and disposition or other drug or dispensing-related records maintained electronically. [BPC 4105(d)(1)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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F. POLICIES AND PROCEDURES

Yes No N/A

☐☐☐ 4.3~~6~~2 The pharmacy has developed and implemented written policies and procedures with respect to all the following and the policies are reviewed annually [BPC 4119.11(d)(1), CCR 1713(e)]:

☐ 4.32.1 Maintaining the security of the APDS and dangerous drugs ~~and devices~~ within the APDS.

☐ 4.32.2 Determine and apply inclusion criteria regarding which drugs, devices are appropriate for placement in the APDS and for which patients, including when consultation is needed.

☐ 4.32.3 Ensuring patients are aware that consultation with a pharmacist is available for any prescription medication including those delivered via APDS.

☐ 4.32.4 Describing assignment of responsibilities and training of pharmacy personnel and other personnel using the APDS at that location regarding maintenance and filling procedures for the APDS.

☐ 4.32.5 Orienting patients on use of the APDS and notifying patients when expected

medications are not available in the APDS. The pharmacy must ensure the use of the APDS does not interfere with the delivery of drugs and devices.

☐ 4.32.6 Ensuring the delivery of drugs and devices to patients expecting medications from the APDS ~~in the event~~ if the APDS is disabled or malfunctions.

Date of Last Policy Review: _____

Yes No N/A

☐☐☐ 4.3~~7~~3 The pharmacy has policies and procedures for security measures and monitoring of the inventory to prevent theft and diversion. [BPC 4427.2(a)(3)~~4105.5(c)(2)~~]

☐☐☐ 4.3~~8~~4 The pharmacy reports drug losses as required by law. [BPC 4104, 4427.2(a)(4)~~4105.5(c)~~, CCR 1715.6, 21 CFR 1301.76]

Last Reported Drug Loss: _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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SECTION 5: ~~ADDS~~

- ☐ **APDS ADJACENT TO THE SECURED PHARMACY AREA ~~OR~~**
- ☐ **APDS LOCATED IN MEDICAL OFFICES ~~(OR)~~**
- ☐ **APDS A LOCATION WHERE PATIENTS ARE REGULARLY SEEN FOR PURPOSES OF DIAGNOSIS AND TREATMENT TO ONLY BE USED FOR PATIENTS OF THE PRACTICE~~(OR).~~**
- ☐ **APDS THROUGH A CLINIC PURSUANT TO HSC 1204 OR 1204.1 OR BPC 4180 OR 4190.**

A. GENERAL REQUIREMENTS

Yes No N/A

☐☐☐ 5.1 The pharmacy maintains the APDS policies and procedures for 3 years after the last date of use for that APDS. [BPC 4427.6(l), CCR 1713(f)]

~~☐☐☐ 5.2 The pharmacy developed and implemented, and reviewed annually the APDS policy and procedures pertaining to the APDS, including: [BPC 4427.6(a)]~~

- ~~Maintaining the security of the APDS and the dangerous drugs and devices within the APDS.~~
- ~~Determining and applying inclusion criteria regarding which drugs and devices are appropriate for placement in the APDS and for which patients.~~
- ~~Ensuring patients are aware consultation with a pharmacist is available for any prescription medications, including those delivered via the APDS.~~

- ~~Describing assignment of responsibilities to, and training of, pharmacy personnel and other personnel using the APDS at the location where the APDS is placed, regarding maintenance and filing procedures for the APDS.~~
- ~~Orienting participating patients on the use of the APDS, notifying patients when expected prescription medications are not available in the APDS, and ensuring patient use of the APDS does not interfere with delivery of drugs and devices.~~
- ~~Ensuring delivery of drugs and devices to patients expecting to receive them from the APDS in the event the APDS is disabled or malfunctions.~~

☐☐☐ 5.2 The pharmacy uses the APDS to deliver prescription medications to patients provided: [CCR 1713(d)]

- ☐ 5.2.1 A pharmacist has determined that each patient using the APDS meets inclusion criteria for use of the APDS established by the pharmacy prior to deliver of prescription medication to the patient.
- ☐ 5.2.2 The APDS has a means of identifying each patient and only release that patient's prescription medication to the patient or patient's agent.
- ☐ 5.2.3 The pharmacy provides an immediate consultation with a pharmacist, either in-person or via telephone, upon the request of a patient.
- ☐ 5.2.4 Any incident involving the APDS where a complaint, delivery error, or omission has occurred shall be reviewed as part of the pharmacy's quality assurance program mandated by Business and Professions Code section 4125.

Yes No N/A

☐☐☐ 5.3 The pharmacy does not have more than 15 APDS licenses for one underlying operating pharmacy under this section. [BPC 4427.6(k)] List of current APDS licenses:

1._____ 2. _____

3._____ 4. _____

5._____ 6. _____

7._____ 8. _____

9._____ 10._____

11. _____ 12._____

13._____ 14. _____

15. _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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)]

Yes No N/A

☐☐☐ 5.7 The ~~P~~pharmacist-in-charge of the offsite ADDS/APDS has ensured the following: [CCR 1715.65(h)]

- ☐ 5.7.1 All controlled substances added to the ADDS/APDS are accounted for;
- ☐ 5.7.2 Access to ADDS/APDS is limited to authorized facility personnel;
- ☐ 5.7.3 An ongoing evaluation of discrepancies or unusual access associated with controlled substance is performed; and
- ☐ 5.7.4 Confirmed losses of controlled substances are reported to the Board.

~~☐☐☐ 5.8. The pharmacy operating the APDS has completed an annual Self-Assessment pursuant to CCR 1715 evaluating the pharmacy's compliance with pharmacy law relating to the use of the APDS. [BPC 4427.7(a)]~~

~~Date of Last Self-Assessment: _____~~

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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.~~20~~22 The pharmacy reports drug losses as required by law. [BPC 4104, 4427.2(a)(4)~~4105.5(c)~~, CCR 1715.6, 21 CFR 1301.76]

Last Reported Drug Loss: _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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SECTION 6: ADDS IN A HEALTH FACILITY PURSUANT TO HSC 1250 ~~– LONG TERM CARE FACILITIES~~ THAT COMPLIES WITH HSC 1261.6

A. GENERAL REQUIREMENTS

For purposes of this section, "FACILITY" means any health facility licensed pursuant to subdivisions ~~(c), (d), or (k)~~ (a) through (n) 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: [HSC 1261.6(g)]

- ☐ 6.~~5~~3.1 The task of placing drugs into the removeable pockets, cards, drawers, or unit or use or single dose containers is performed by a pharmacist, or by an intern pharmacist or a pharmacy technician under the direct supervision of a pharmacist. [HSC 1261.6(g)(1)]
- ☐ 6.~~5~~3.2 The removable pockets, cards, drawers, or unit of use or single dose containers are transported between the pharmacy and the facility in a secure tamper-evident container. [HSC 1261.6(g)(2)]
- ☐ 6.~~5~~3.3 The facility, in conjunction with the pharmacy, has developed policies and procedures to ensure that the removable pockets, cards, drawers, or unit of use or single dose containers are properly placed into the ADDS. [HSC 1261.6(g)(3)]

☐☐☐ 6.~~6~~4 Individualized and specific access to the ADDS is limited to facility and contract personnel authorized by law to administer drugs. [HSC 1261.6(c)]

☐☐☐ 6.~~7~~5 A pharmacist reviews and approves all orders prior to a drug being removed from the ADDS for administration to a patient. The pharmacist reviews the prescriber's orders and the patient's profile for potential contraindications and adverse drug reactions. [HSC 1261.6(f)(2)]

☐☐☐ 6.6 A Schedule II controlled substance for a patient in a licensed skilled nursing facility or licensed intermediate care facility is dispensed only after the pharmacist has received:

- ☐ 6.6.1 An **orally transmitted** prescription for a Schedule II controlled substance from the prescriber and only after the pharmacist reduced the prescription to writing in ink in the handwriting of the pharmacist on a form developed by the pharmacy. The prescription must contain: [HSC 11167.5(a)]
  - ☐ The date the prescription was orally transmitted by the prescriber.
  - ☐ The name of the person for whom the prescription was authorized.
  - ☐ The name and address of the licensed skilled nursing facility or licensed intermediate care facility in which the person is the patient.
  - ☐ The name and quantity of the controlled substance prescribed.
  - ☐ The directions for use, and the name, address, category of the professional licensure, license number, and federal controlled substance registration number of the prescriber.
  - ☐ The prescription is endorsed by the pharmacist with the pharmacy's name, license number, and address.

- ☐ 6.6.2 Prior to filling a prescription for a Schedule II controlled substance that has been **electronically transmitted,** the pharmacist has produced, signed, and dated a hard copy prescription. The prescription contains the date the prescription was electronically transmitted by the prescriber, the name of the person for whom the prescription was authorized, the name and address of the licensed skilled nursing facility or licensed intermediate care facility in which the person is the patient, the name and quantity of the controlled substance prescribed, the directions for use, and the name, address, category of the professional licensure, license number, and federal controlled substance registration number of the prescriber. [HSC 11167.5(a)]
  - ☐ The prescription is endorsed by the pharmacist with the pharmacy's name, license and address.
  - ☐ The prescription contains the signature of the person who received the controlled substance for the licensed skilled nursing facility or licensed intermediate care facility.

- ☐ 6.6.3 An original Schedule II prescription is written on a form that complies with Health and Safety Code section 11162.1. [HSC 11164(a)]

- ☐ 6.6.4 An original Schedule II prescription is written with the "11159.2 exemption" for the terminally ill. [HSC 11159.2]

☐ 6.6.5 In an emergency where failure to issue the prescription may result in loss of life or intense suffering, a Schedule II controlled substance may be dispensed from a prescription transmitted orally or electronically by a prescriber or written on a form not as specified in HSC 11162.1, subject to the following: [HSC 11167(a)-(c)]

- ☐ The order contains all information required by subdivision (a) of Section 11164.
- ☐ 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.

☐ 6.6.6 An electronic prescription (e-scripts) for controlled substances that is received from the prescriber and meets federal requirements. [21 CFR 1306.08, 21 CFR 1311]

Yes No N/A

☐☐☐ 6.~~8~~7 The review of the drugs contained within the ADDS and the operation and maintenance of the ADDS is conducted, on a monthly basis, by a pharmacist. The review includes a physical inspection of the ADDS for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system. [HSC 1261.6(h)]

Date of Last Review: _____

☐☐☐ 6.~~9~~8 The p~~P~~harmacist-in-charge of the offsite ADDS has ensured the following: [CCR 1715.65(h)]

- ☐ 6.8.1 All controlled substances added to the ADDS are accounted for;
- ☐ 6.8.2 Access to ADDS is limited to authorized facility personnel;
- ☐ 6.8.3 An ongoing evaluation of discrepancies or unusual access associated with controlled substance is performed; and
- ☐ 6.8.4 Confirmed losses of controlled substances are reported to the Board.

☐☐☐ 6.~~10~~9 The pharmacy operating the ADDS has completed an annual Self-Assessment pursuant to BPC 4427.7(a) evaluating the pharmacy's compliance with pharmacy law relating to the use of the APDS. ~~(~~[BPC 4427.7(a)]~~)~~

Date of Last Self-Assessment: _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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C. DEVICE REQUIREMENTS:

Yes No N/A

☐☐☐ 6.~~11~~10 The stocking and restocking of the ADDS is performed in compliance with section 1261.6 of the Health and Safety Code. [BPC 4427.4(e)(1), HSC 1261(c), (g)]

~~☐☐☐ 6.12 Drugs and devices not immediately transferred into an ADDS upon arrival at the ADDS location are stored for no longer than 48 hours in a secured room within the ADDS location. Upon retrieval of these drugs and devices from secured storage, an inventory is taken to detect any losses or overages. [BPC 4427.4(f)]~~

☐☐☐ 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)]~~

☐☐☐ 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 allow~~s~~ licensed personnel to have access to multiple drugs and ~~are~~ is not patient specific in their design, the ADDS has electronic and mechanical safeguards in place to ensure that the drugs delivered to the patient are specific to that patient. ~~(~~[HSC 1261.6(f)(7)]~~)~~.

Please Note: A skilled nursing facility or intermediate care facility using an ADDS that allows licensed personnel to have access to multiple drugs is required to contact the California Department of Public Health, Licensing, and Certification in writing prior to utilizing this type of ADDS. [HSC1261.6(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.~~28~~23 Records of inspections completed by the pharmacist are kept for at least three years. [HSC 1261.6(h), 22 CCR 70263(f)(3)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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E. POLICIES AND PROCEDURES

Yes No N/A

☐☐☐ 6.~~28~~24 The facility and the pharmacy has developed and implemented written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the ADDS as well as quality, potency, and purity of the stored drugs and devices. [BPC 4427.3(c), HSC 1261.6(d)(1)]

☐☐☐ 6.~~29~~25 The ADDS policies and procedures define access to the ADDS and limits to access to equipment and drugs. [HSC 1261.6(d)(1)]

☐☐☐ 6.~~30~~26 All ADDS policies and procedures are maintained at the pharmacy and the location where the ADDS is being used. [HSC 1261.6(d)(2), BPC 4427.3(c)]

☐☐☐ 6.~~31~~27 The facility, in conjunction with the pharmacy, has developed policies and procedures to ensure that the removable pockets, cards, drawers, or unit of use or single dose containers are properly placed into the ADDS. [HSC 1261.6(g)(3)]

~~☐☐☐ 6.32 The pharmacy has policies and procedures that include appropriate security measures and monitoring of the inventory to prevent theft and diversion. [BPC 4427.2(d)(3)]~~

☐☐☐ 6.~~33~~28 The pharmacy's policies and procedures include provisions for reporting to the board drug losses from the ADDS inventory, as required by law. [BPC 4104, 4427.2(d)(4), CCR 1715.6, 21 CFR 1301.76]

Last Reported Drug Loss: _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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~~**SECTION 7: APDS THROUGH A CLINIC PURSUANT TO HSC 1204 OR 1204.1 OR BPC 4180 OR 4190**~~

~~**A. GENERAL REQUIREMENTS**~~

~~Yes No N/A~~

~~☐-☐-☐ 7.1 The ADDS is located inside an enclosed building with a premises address, at a location approved by the Board [BPC 4427.3 (a)]. The clinic has a current Board of Pharmacy Clinic license pursuant to BPC 4180 or BPC 4190? or the clinic is licensed pursuant to HSC 1204 or 1204.1. [BPC 4427.3(b)(3)]~~

~~License number: _____ Expiration Date: _____~~

~~☐-☐-☐ 7.2 The clinic has developed and implemented written policies and procedures that ensure the safety, accuracy, accountability, security and patient confidentiality. Additionally, the policies and procedures shall ensure the maintenance of the quality, potency and purity of the drugs.~~ ~~**The policies and procedures shall be maintained at the location where the ADDS is being used.**~~ ~~[BPC 4186(a)]~~

~~☐-☐-☐ 7.3 Drugs removed from the ADDS shall be provided to the patient by a health professional licensed pursuant to BPC 4186(b).~~

~~☐-☐-☐ 7.4 The clinic is responsible for the review of the drugs contained within, and the operation and maintenance of, the ADDS. [BPC 4186(d)]~~

~~☐-☐-☐ 7.5 Drugs dispensed from the clinic ADDS shall comply with labeling requirements in BPC 4076 with CCR 1707.5. [BPC 4186(g), 4426.7(h)]~~

~~☐-☐-☐ 7.6 The clinic shall keep records of the kind and amounts of drugs purchased, administered, and dispensed and the records shall be available and maintained for a minimum of three years for inspection by all authorized personnel. [BPC 4180(a)(2)]~~

☐-☐-☐ 7.7 The proposed ADDS installation location meets the requirement of BPC 4427.3 and the ADDS is secure from access and removal by unauthorized individuals. [BPC 4427.2(d)(2)]

☐-☐-☐ 7.8 The clinics licensed under BPC 4180 or BPC 4190 perform periodic inventory and inventory reconciliation functions to detect and prevent the loss of controlled substances. [CCR 1715.65(a)]

☐-☐-☐ 7.9 The clinic shall compile an inventory reconciliation report of all **federal Schedule II controlled substance** at least every three months. [CCR 1715.65(c)] The compilation requires:

- A physical count (not estimate) of all quantities of all **federal Schedule II controlled substances.**
- A review of all acquisition and disposition records of **federal Schedule II controlled substances** since that last inventory reconciliation report.

Date of last inventory_____

- A comparison of (1) and (2) to determine if there are any variances.
- All records used to compile each inventory reconciliation report shall be maintained at clinic for 3 years in a readily retrievable form.
- Possible causes of overages shall be identified in writing and incorporated into the inventory reconciliation report.

Yes No N/A

☐-☐-☐ 7.10 The clinic shall report in writing identified drug losses and known cause to the Board within 30 days of discovery. Cases of the loss is due to theft, diversion or self-use shall be reported to the Board within 14 days of discovery. If the clinic is unable to identify the cause of loss, further investigation shall be undertaken to identify the cause and actions necessary to prevent additional losses of controlled substances. [CCR 1715.65(d)]

☐-☐-☐ 7.11 The individuals performing the inventory AND the clinic professional director shall date and sign the inventory reconciliation reports. The reports shall be readily retrievable at the clinic for 3 years. [CCR 1715.65(e)]

☐-☐-☐ 7.12 Any incident involving the APDS where a complaint, error, or omission has occurred is reviewed as part of the pharmacy's quality assurance program pursuant to BPC 4125. [BPC 4427.6(i)]

☐-☐-☐ 7.13 The federal warning label prohibiting transfer of controlled substances is on the prescription container. [21 CFR 290.5]

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

☐-☐-☐ 7.15 Patient package inserts are dispensed with all estrogen medications. [21 CFR 310.515]

☐-☐-☐ 7.16 The pharmacy provides patients with Black Box Warning Information in conformance with 21 CFR 201.57(c).

☐-☐-☐ 7.17 Medication guides are provided on required medications. [21 CFR 208.1]

☐-☐-☐ 7.18 Is the APDS located and operated only used to dispense dangerous drugs and dangerous devices to patients of the clinic? [BPC 4427.6j)]

☐-☐-☐ 7.19 Does the pharmacy have no more than 15 ADDS licensed as APDS units? [BPC 4427.6(k)]
List of current APDS licenses:

1. _____ 2. _____

3. _____ 4. _____

5. _____ 6. _____

7. _____ 8. _____

9. _____ 10. _____

11. _____ 12. _____

13. _____ 14. _____

15. _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE _____

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B. PHARMACIST RESPONSIBILITY

Yes No N/A

☐-☐-☐ 7.20 The pharmacist performs the stocking of the ADDS. [BPC 4186(c)]

☐-☐-☐ 7.21 Drugs are removed from the ADDS system only upon the authorization of the pharmacist after the pharmacist has reviewed the prescription and patient profile for potential contraindications and adverse drug reactions. [BPC 4186(b)]

☐-☐-☐ 7.22 The pharmacist shall conduct a review on a monthly basis including a physical inspection of the drugs in the ADDS for cleanliness and a review of all transaction records in order to verify the security and accountability of the ADDS. [BPC 4186(d)]

Date of Last Review: _____

☐-☐-☐ 7.23 The pharmacist licensed by the board performs all clinical services conducted as part of the dispensing process, including, but not limited to, drug utilization review and consultation. [BPC 4427.6(d)]

Yes No N/A

☐-☐-☐ 7.24 Drugs are dispensed from the APDS after the pharmacist has reviewed the prescription and the patient's profile for potential contraindications and adverse drug reactions. [BPC 4427.6(e)]

☐-☐-☐ 7.25 All prescribed drugs and devices dispensed to the patient from an APDS for the first time shall be accompanied by a consultation conducted by a pharmacist licensed by the board via telecommunication link with a two-way audio and video. [BPC 4427.6(f)]

☐-☐-☐ 7.26 The APDS has a notice, prominently posted on the APDS, with the name, address, and phone number of the pharmacy holding the ADDS license for the APDS. [BPC 4427.6(g)]

☐-☐-☐ 7.27 The pharmacist shall provide patient consultation pursuant to CCR 1707.2 via a two-way audio and video telecommunication link for drugs dispensed by the clinic ADDS. [BPC 4186(e)]

☐-☐-☐ 7.28 The pharmacist operating the ADDS shall be located in California. [BPC 4186(f)]

☐-☐-☐ 7.29 The clinic consultant pharmacist shall review all inventory and inventory reconciliation reports taken and establish and maintain secure methods to prevent losses of controlled substances. The clinic shall develop written policies and procedures for performing the inventory reconciliation reports. (CCR 1715.65(b))

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE _____

C. POLICIES AND PROCEDURES

Yes No N/A

☐-☐-☐ 7.32 The pharmacy has developed and implemented, and reviewed annually, written policies and procedures pertaining to the APDS, including all the following: [BPC 4427.6(a)]

- Maintaining the security of the APDS and dangerous drugs and dangerous devices within the APDS.
- Determining and applying inclusion criteria regarding which drugs and devices are appropriate for placement in the APDS and for which patients.

- ~~Ensuring patients are aware consultation with a pharmacist is available for any prescription medication, including those delivered via the APDS.~~
- ~~Describing assignments of responsibilities to, and training of, pharmacy personnel, and other personnel using the APDS at the location where the APDS is placed pursuant to subdivision (b) of section 4427.3, regarding maintenance and filing procedures for the APDS.~~
- ~~Orienting participating patients on the use of the APDS, notifying patient when expected prescription medications are not available in the APDS, and ensuring the patient use of the APDS does not interfere with delivery of drugs and devices.~~
- ~~Ensuring delivery of drugs and devices to patients expecting to receive them from the APDS in the event the APDS is disabled or malfunctions.~~

~~Date of Last Policy Review: _____~~

~~Yes No N/A~~

☐-☐-☐ ~~7.33 Is the APDS only used for patients who have signed a written consent form demonstrating their informed consent to receive prescribed drugs and devices from an APDS, and whose use of the APDS meets inclusion criteria established by policies and procedures. [BPC 4427.6(b)]~~

☐-☐-☐ ~~7.34 The APDS shall have a means of identifying each patient and only release the identified patient's drugs and devices to the patient or patient's agent. [BPC 4427.6(c)]~~

☐-☐-☐ ~~7.35 The pharmacy holding the ADDS license for an APDS maintains its policies and procedures for three (3) years after the last date of use of an APDS. [BPC 4427.6(l)]~~

☐-☐-☐ ~~7.36 Does the pharmacy maintain all recordkeeping and quality assurance requirements established in pharmacy law and regulations, and maintain these records within the licensed pharmacy holding the ADDS license and separate from other pharmacy records. [BPC 4427.7(b)]~~

SECTION ~~8~~7: ADDS OPERATED BY A CORRECTIONAL CLINIC

A. GENERAL REQUIREMENTS

Yes No N/A

☐☐☐ 7~~8~~.1 The pharmacy uses an "automated drug delivery system" used in a correctional clinic, meaning a mechanical system controlled remotely by a pharmacist that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of prepackaged dangerous drugs or dangerous devices. An automated drug delivery system shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability. [BPC 4187.5(h)]

☐☐☐ 7~~8~~.2 The ADDS is located in a "correctional clinic," a primary care clinic, as referred to in subdivision (b) of section 1206 of the Health and Safety Co~~n~~de, conducted, maintained, or

operated by the state to provide health care eligible patients of the Department of Corrections and Rehabilitation. ~~(~~[BPC 4187(a)].

~~Yes No N/A~~

☐☐☐ 7~~8~~.3 The correctional clinic licensed by the board obtains the drugs from a licensed correctional pharmacy, the Department of Correction and Rehabilitation's Central Fill Pharmacy, or from another correctional clinic licensed by the board within the same institution for the administration or dispensing of drugs or devices to patients eligible for care at the correctional facility if under either: [BPC 4187.1(a)]

- 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]

~~Yes No N/A~~

☐☐☐ 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]

☐☐☐ 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)]

☐☐☐ 7~~8~~.1~~4~~3 The chief executive officer is responsible for the safe, orderly and lawful provision of pharmacy services. [BPC 4187.2(b)(1)]

☐☐☐ 7~~8~~.1~~5~~4 The pharmacist-in-charge of the correctional facility shall implement the policies and procedures developed and approved by the statewide Correctional Pharmacy and Therapeutics Committee referenced in section 5042.2 of the Penal Code and the ~~statewide Inmate Medical Services~~ California Correctional Health Care Services ~~Policies and Procedures~~ Health Care Department Operations Manual in conjunction with the chief executive officer, the chief medical executive, the supervising dentist, and the chief nurse executive. [BPC 4187.2(b)(1)]

☐☐☐ 7~~8~~.1~~6~~5 The licensed correctional clinic will notify the board within 30 days of any change in the chief executive officer on a form furnished by the board. [BPC 4187.2(b)(2)]

☐☐☐ 7~~8~~.1~~7~~6 Schedule II, III, IV or V controlled substances may be administered by health care staff of the licensed correctional clinic lawfully authorized to administer pursuant to a chart order, as defined in section 4019, a valid prescription consistent with chapter 9 division 2 of the Business and Professions Code, or pursuant to an approved protocol as identified within the ~~statewide Inmate Medical Services Policies and Procedures~~ California Correctional Health Care Services Health Care Department Operations Manual. [BPC 4187.2, 4187.3]

☐☐☐ 7~~8~~.1~~8~~7 The ADDS located in a licensed correctional clinic has implemented the statewide Correctional Pharmacy and Therapeutics Committee's policies and procedures and the ~~statewide Inmate Medical Services~~ California Correctional Health Care Services Health Care Department Operations Manual ~~Policies and Procedures~~ to ensure safety, accuracy,

accountability, security, patient confidentiality, and maintenance of the quality, potency, and purity of drugs. [BPC 4187.5(a)]

☐☐☐ 7~~8~~.1~~9~~8 All policies and procedures are maintained either in an electronic form or paper form at the location where the ~~automated drug system~~ ADDS is being used. [BPC 4187.5(a)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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C. PHARMACIST RESPONSIBILITIES

Yes No N/A

☐☐☐ 7~~8~~.~~20~~19 A correctional facility pharmacist inspects the clinic at least quarterly. [BPC 4187.2(c)]

☐☐☐ 7~~8~~.~~21~~20 Drugs removed from the ~~automated drug system~~ ADDS ~~is~~ are removed upon authorization by a pharmacist after the pharmacist has reviewed the prescription and the patient profile for potential contraindications and adverse drug reactions. ~~If the correctional pharmacy is closed,~~ Where administration of the drug is necessary before a pharmacist has reviewed the prescription and if, in the prescriber's professional judgment, a delay in therapy may cause patient harm, the medication may be removed from the ~~automated drug delivery system~~ ADDS and administered or furnished to the patient under the direction of the prescriber. Where the drug is otherwise unavailable, a medication may be removed and administered or furnished to the patient pursuant to an approved protocol as identified within the ~~statewide Inmate Medical Services Policies and Procedures~~ California Correctional Health Care Services Health Care Department Operations Manual. Any removal of the medication from an ~~automated drug delivery~~ ADDS ~~system~~ is documented and provided to the correctional pharmacy when it reopens. [BPC 4187.5(b)]

Yes No N/A

☐☐☐ 7~~8~~.~~22~~21 The review is conducted on a monthly basis by a pharmacist and shall include a physical inspection of the drugs in the ~~automated drug delivery system~~ ADDS, an inspection of the ~~automated drug delivery system~~ ADDS machine for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system. [BPC 4187.5(e)]

Date of Last Review: _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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D. DEVICE REQUIREMENT

Yes No N/A

☐☐☐ 7~~8~~.~~23~~22 Drugs removed from the ADDS ~~is~~ are provided to the patient by a health professional licensed pursuant to division 2 of the Business and Professions Code who is lawfully authorized to perform the task. [BPC 4187.5(c)]

☐☐☐ 7~~8~~.~~24~~23 The review of the drugs contained within, and the operation and maintenance of, the ADDS shall be the responsibility of the correctional clinic. [BPC 4187.5(e)]

☐☐☐ 7~~8~~.~~25~~24 The ADDS is operated by a licensed correctional pharmacy. Any drugs within the ADDS are considered owned by the licensed correctional pharmacy until they are dispensed from the ADDS. [BPC 4187.5(f)]

☐☐☐ 7~~8~~.~~26~~25 Drugs from the ADDS in the correctional clinic are removed by a person authorized to stock the ADDS, or by a person lawfully authorized to administer or dispense the drugs. [BPC 4187.5(g)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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E. RECORD KEEPING REQUIREMENTS

Yes No N/A

☐☐☐ 7~~8~~.~~27~~26 All records of manufacture and of sale, acquisition, receipt, shipment, or disposition of dangerous drugs or dangerous devices, at all times during business hours, are open for inspection by authorized officer of the law and ~~is~~ are preserved for at least three years from the date of making. A current inventory is kept by the licensed correctional clinic. [BPC 4081(a)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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SECTION ~~9~~8:

- ☐ **DRUG ROOM: AUDS ~~used for dispensing pursuant to BPC 4056 (Drug Room) or BPC 4068 (Hospital Pharmacy is closed and no pharmacist is available)~~ USED FOR DISPENSING PURSUANT TO BPC 4056 (DRUG ROOM) OR**
- ☐ **HOSPITAL PHARMACY: AUDS USED FOR DISPENSING PURSUANT TO BPC 4068**

Please Note: Hospital pharmacies and drug rooms must also complete Section 6 for ADDS used for administration. This section addresses additional requirements for hospital pharmacies and drug rooms operating an ADDS used 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 section 4076.

☐☐☐ 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~~

☐☐☐ ~~9.34~~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)]~~

☐☐☐ 8.10 Medication guides are provided on required medications. [21 CFR 208.1]

☐☐☐ 8.11 Black box warning information is in conformance with 21 CFR 201.57(c).

☐☐☐ 8.12 Whenever an opioid prescription drug is dispensed to a patient for outpatient use, the pharmacy or practitioner dispensing the drug prominently displays on the label or container, by means of a flag or other notification mechanism attached to the container, a notice that states, "Caution: Opioid. Risk of overdose and addiction." [BPC 4076.7]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____
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SECTION 9 – AUDS THROUGH A FACILITY LICENSED IN CALIFORNIA WITH STATUTORY AUTHORITY TO PROVIDE PHARMACEUTICAL SERVICES (OR) AUDS THROUGH A JAIL, YOUTH DETENTION FACILITY, OR OTHER CORRECTIONAL FACILITY WHERE DRUGS ARE ADMINISTERED WITH THE FACILITY UNDER THE AUTHORITY OF THE MEDICAL DIRECTOR.

A. GENERAL REQUIREMENTS

Yes No N/A

☐☐☐ 9.1 Review of the drugs contained within, and the operation and maintenance of, the ADDS is done in accordance with law and is the responsibility of the pharmacy. A pharmacist conducts the review on a monthly basis, which includes a physical inspection of the drugs in the ADDS, an inspection of the ADDS for cleanliness, and a review of all transaction records in order to verify the security and accountability of the ADDS. [BPC 4427.65(c)(7)]

Date of Last Review: _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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B. PHARMACIST RESPONSIBILITIES:

Yes No N/A

☐☐☐ 9.2 The stocking of an ADDS is performed by a pharmacist. If the ADDS utilizes removable pockets, cards, drawers, similar technology, or unit of use or single dose containers, as defined by the United States Pharmacopoeia, the stocking system may be done outside of the facility and be delivered to the facility, if all the following conditions are met: [BPC 4427.65(c)(6)]

- ☐ 9.2.1 The task of placing drugs into the removable pockets, cards, drawers, or unit of use or single dose containers is performed by a pharmacist, or by an intern pharmacist or a pharmacy technician working under the direct supervision of a pharmacist.
- ☐ 9.2.2 The removable pockets, cards, drawers, or unit of use or single dose containers are transported between the pharmacy and the facility in a secure tamper-evident container.
- ☐ 9.2.3 The facility, in conjunction with the pharmacy, has developed policies and procedures to ensure that the removable pockets, cards, drawers, or unit of use or single dose containers are properly placed into the ADDS.

☐☐☐ 9.3 The pharmacist-in-charge of a pharmacy servicing an onsite or offsite ADDS ensures the following: [CCR 1715.65(h)]

- ☐ 9.3.1 All controlled substances added to an ADDS are accounted for.

☐ 9.3.2 Access to the ADDS is limited to authorized facility personnel.

☐ 9.3.3 An ongoing evaluation of discrepancies or unusual access associated with controlled substances is performed.

☐ 9.3.4 Confirmed losses of controlled substances are reported to the board.

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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C. DEVICE REQUIREMENTS:

Yes No N/A

☐☐☐ 9.4 Individualized and specific access to the ADDS is limited to facility and contract personnel authorized by law to administer drugs. [BPC 4427.65(c)(2)]

When the ADDS is used as an emergency pharmaceutical supplies container, drugs removed from the ADDS are limited to the following [BPC 4427.65(c)(4)]:

☐☐☐ 9.5 A new drug order given by a prescriber for a patient of the facility for administration prior to the next scheduled delivery from the pharmacy, or 72 hours, whichever is less. The drugs are retrieved only upon authorization by a pharmacist and after the pharmacist has reviewed the prescriber's order and the patient's profile for potential contraindications and adverse drug reactions. [BPC 4427.65(c)(4)(A)]

☐☐☐ 9.6 Drugs that a prescriber has ordered for the patient on an as-needed basis, if the utilization and retrieval of the drugs are subject to ongoing review by the pharmacist. [BPC 4427.65(c)(4)(B)]

☐☐☐ 9.7 Drugs designed by the patient care policy committee or pharmaceutical service committee of the facility as emergency drugs or acute onset drugs. These drugs may be retrieved from the ADDS pursuant to the order of the prescriber for emergency or immediate administration to the patient of the facility. Within 48 hours after retrieval, the case is reviewed by the pharmacist. [BPC 4427.65(c)(4)(C)]

When the ADDS is used to provide pharmacy services pursuant to BPC 4017.3, the ADDS is subject to the following requirements [BPC 4427.65(c)(5)]:

☐☐☐ 9.8 The drugs removed from the ADDS for administration to a patient are in properly labeled units of administration containers or packages. [BPC 4427.65(c)(5)(A)]

☐☐☐ 9.9 The pharmacist reviewed and approved all orders prior to a drug being removed from the ADDS for administration to the patient. The pharmacist reviewed the prescriber's order and the

patient's profile for potential contraindications and adverse drug reactions. [BPC 4427.65(c)(5)(B)]

☐☐☐ 9.10 The pharmacy providing services to the facility controls the access to the drugs stored in the ADDS. [BPC 4427.65(c)(5)(C)]

☐☐☐ 9.11 After the pharmacist reviews the prescriber's order, access by licensed personnel to the ADDS is limited only to drugs ordered by the prescriber and reviewed by the pharmacist and that are specific to the patient. When the prescriber's order requires a dosage variation of the same drug, licensed personnel has access to the drug ordered for that scheduled time of administration. [BPC 4427.65(c)(5)(F)]

☐☐☐ 9.12 ADDS that allow licensed personnel to have access to multiple drugs and are not patient specific in their design, shall be allowed if the ADDS has electronic and mechanical safeguards in place to ensure the drugs delivered to the patient are specific to the patient. [BPC 4427.65(c)(5)(G)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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D. RECORD KEEPING REQUIREMENTS

Yes No N/A

☐☐☐ 9.13 Transaction information shall be made readily available in a written format for review and inspection by individuals authorized by law and are maintained in the facility for a minimum of three years. [BPC 4427.65(c)(1)]

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E. POLICIES AND PROCEDURES

Yes No N/A

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

☐☐☐ 9.15 The facility and the pharmacy has developed and implemented written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and

maintenance of the quality, potency, and purity of stored drugs. The policies and procedures define access to the ADDS and limits to access to equipment and drugs. [BPC 4427.5(c)(3)(A)

☐☐☐ 9.16 All policies and procedures are maintained at the pharmacy operating the ADDS and the location where the ADDS is being used. [BPC 4427.5(c)(3)(B)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

_____

_____

_____

_____

CERTIFICATION ACKNOWLEDGMENT

PHARMACIST-IN-CHARGE CERTIFICATION:

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

Signature _____Date _____
(Pharmacist-in-Charge)

ACKNOWLEDGEMENT BY OWNER OF ADDS:

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

Signature _____Date _____

CERTIFICATION OF COMPLETED ACTION PLAN

PHARMACIST-IN-CHARGE CERTIFICATION:

I, (please print)_____, RPH #_____ hereby certify that I have completed 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)

ACKNOWLEDGEMENT BY OWNER OF ADDS:

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

Signature _____Date _____

Attachment 6

Board of Pharmacy

Enforcement Workload Statistics FY 2021/22

Complaint Investigations	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Received	661	718	0	0	1,379
Closed	755	740	0	0	1,495
Pending	1,308	1,294	0	0	1,308
Average Days for Investigation	246	194	0	0	246

Cases Under Investigation (By Team)	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Quarter Ending
Compliance / Routine	484	541	0	0	484
Drug Diversion / Fraud	144	178	0	0	144
Prescription Drug Abuse	107	92	0	0	107
Compounding	38	43	0	0	38
Outsourcing	15	15	0	0	15
Probation / PRP	19	25	0	0	19
Enforcement	235	93	0	0	235
Criminal Conviction	266	307	0	0	266

Application Investigations	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Received	54	42	0	0	96
Closed					
Approved	36	44	0	0	80
Denied	16	11	0	0	27
Total Closed (includes withdrawn)	***54***	***61***	***0***	***0***	***115***
Pending	74	53	0	0	74

Complaint Closure Outcomes Not Resulting in Further Action	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Insufficient Evidence	189	149	0	0	338
Non-Jurisdictional	119	122	0	0	241
No Violation	92	108	0	0	200
No Further Action	59	68	0	0	127
Other - Non-Substantiated	7	4	0	0	11
Subject Educated	20	17	0	0	37

Letter of Admonishment / Citations	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
LOA Issued	92	73	0	0	165
Citations Issued	359	332	0	0	691
Proof of Abatement Requested	89	84	0	0	173
Appeals Received	27	22	0	0	49
Dismissed	5	14	0	0	19
Total Fines Collected	***$205,461***	***$237,224***	***$0***	***$0***	***$442,685***

Administrative Cases	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Referred to the AG's Office	44	21	0	0	65
Pleadings Filed	51	50	0	0	101
Pending					Quarter Ending
Pre-Accusation	85	58	0	0	85
Post-Accusation	153	167	0	0	153

Total Pending	**242**	**225**	**0**	**0**	**242**
Total Closed	50	45	0	0	50

Administrative Case Outcome	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Revocation					
Pharmacist	2	1	0	0	3
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	5	1	0	0	6
Designated Representative	1	0	0	0	1
Wholesaler	0	0	0	0	0
Pharmacy	10	1	0	0	11
Sterile Compounding	1	0	0	0	1
Outsourcing	0	0	0	0	0
Total	***19***	***3***	***0***	***0***	***22***

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
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 Outcome	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Revocation; stayed; probation					
Pharmacist	10	16	0	0	26
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	1	2	0	0	3
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Pharmacy	6	6	0	0	12
Sterile Compounding	2	1	0	0	3
Outsourcing	0	1	0	0	1
Total	***19***	***26***	***0***	***0***	***45***

Administrative Case Outcome	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Surrender / Voluntary Surrender					
Pharmacist	4	7	0	0	11
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	3	3	0	0	6
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Pharmacy	11	9	0	0	20
Sterile Compounding	0	0	0	0	0
Outsourcing	0	0	0	0	0
Total	***18***	***19***	***0***	***0***	***37***

Administrative Case Outcome	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total

Public Reproval / Reprimand					
Pharmacist	3	3	0	0	6
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	1	0	0	0	1
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Pharmacy	5	9	0	0	14
Sterile Compounding	1	0	0	0	1
Outsourcing	0	0	0	0	0
Total	***10***	***12***	***0***	***0***	***22***

Administrative Case Outcome	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Licenses Granted					
Pharmacist	1	0	0	0	1
Intern Pharmacist	1	0	0	0	1
Pharmacy Technician	0	0	0	0	0
Designated Representative	0	0	0	0	0
Wholesaler	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	***2***	***1***	***0***	***0***	***3***

Administrative Case Outcome	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Licenses Denied					
Pharmacist	0	0	0	0	0
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	1	0	0	0	1
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Pharmacy	0	3	0	0	3
Sterile Compounding	0	0	0	0	0
Outsourcing	0	0	0	0	0
Total	***1***	***3***	***0***	***0***	***4***

Administrative Case Cost Recovery Efforts	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Cost Recovery Requested	***$348,542***	***$1,126,539***	***$0***	***$0***	***$1,475,081***
Cost Recovery Collected	***$262,261***	***$1,082,219***	***$0***	***$0***	***$1,344,480***

Immediate Public Protection Sanctions	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Interim Suspension Orders	0	1	0	0	1
Automatic Suspension Orders	1	0	0	0	1
Penal Code 23 Restrictions	0	0	0	0	0
Cease and Desist - Outsourcing	1	0	0	0	1
Cease and Desist - Unlicensed Activity	0	1	0	0	1
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	223	226	0	0	223
Intern Pharmacist	3	3	0	0	3

Pharmacy Technician	29	27	0	0	29
Designated Representative	2	2	0	0	2
Wholesaler	3	3	0	0	3
Pharmacy	68	65	0	0	68
Sterile Compounding	10	11	0	0	10
Total	***338***	***337***	***0***	***0***	***338***

Probation Statistics	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Probation Office Conferences	18	23	0	0	41
Probation Site Inspections	127	96	0	0	223
Probation Terminated / Completed	30	24	0	0	54
Referred to AG for Non-Compliance	6	1	0	0	7

As of 12/31/2021

Board of Pharmacy

Citation and Fine Statistics FY 2021/22

Citation Outcomes	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Pharmacist with Fine	88	75	0	0	163
Pharmacist no Fine	61	48	0	0	109
Pharmacy with Fine	74	75	0	0	149
Pharmacy no Fine	66	56	0	0	122
Pharmacist-in-Charge with Fine*	44	53	0	0	97
Pharmacist-in-Charge no Fine	70	52	0	0	122
Pharmacy Technician with Fine	20	32	0	0	52
Pharmacy Technician no Fine	0	0	0	0	0
Wholesalers	2	4	0	0	6
Designated Representative	4	1	0	0	5
Clinics	0	1	0	0	1
Drug Room	0	0	0	0	0
Exempt Hospital	2	0	0	0	2
Hospital Pharmacy	4	7	0	0	11
Miscellaneous**	36	30	0	0	66
Unlicensed Premises	2	5	0	0	7
Unlicensed Person	1	0	0	0	1

*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

Top Ten Violations by License Type

Pharmacists	%	Pharmacies	%	Pharmacists In Charge	%
1716 - Variation from prescription	46%	1716 - Variation from prescription	37%	1716 - Variation from prescription	29%
1764/56.10 - Unauthorized disclosure of prescription and medical information	11%	4113(d) - Every pharmacy shall notify the board in writing within 30 days of the date of a change in pharmacist-in-charge	17%	4301(l) - Unprofessional Conduct - Conviction of a crime substantially related to the practice of pharmacy	20%
1707.2(a)(3) - A pharmacist shall provide oral consultation to his or her patient or the patient's agent in all care settings whenever the prescription drug has not previously been dispensed to a patient	8%	4113(a) - Pharmacist-in-Charge: Notification to Board; Responsibilities; Every pharmacy shall designate a pharmacist-in-charge within 30 days in writing of the identity and license number of that pharmacy	14%	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	16%
1714(b) - Operational Standards and Security; pharmacy responsible for pharmacy security	7%	1764/56.10 - Unauthorized disclosure of prescription and medical information	11%	1764/56.10 - Unauthorized disclosure of prescription and medical information	10%
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	5%	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	6%	4301(f) - Unprofessional Conduct - Acts of moral turpitude, dishonesty, fraud, deceit or corruption	7%
4301(c) - Unprofessional Conduct - Gross negligence	5%	1714(b) - Operational Standards and Security; pharmacy responsible for pharmacy security	5%	1714(b) - Operational Standards and Security; pharmacy responsible for pharmacy security	6%
4051(a)/1735(a) - Except as otherwise provided in this chapter, it is unlawful for any person to manufacture, compound, furnish, sell, or dispense... unless he or she is a pharmacist under this chapter	5%	1711(d) - Quality assurance program finding shall be used to develop systems to prevent medication errors…	3%	1707.2(a)(3) - A pharmacist shall provide oral consultation to his or her patient or the patient's agent in all care settings whenever the prescription drug has not previously been dispensed to a patient	3%
4301(l) - Unprofessional Conduct - Conviction of a crime substantially related to the practice of pharmacy	4%	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	2%	1711(d) - Quality assurance program finding shall be used to develop systems to prevent medication errors…	3%
4306.5(a) - Acts or omissions that involve, in whole or in part, the inappropriate exercise of his or her education, training, or experience as a pharmacist	4%	11153(a)/1306.03(a)(1) - Responsibility for legitimacy of prescription; a prescription for a controlled substance shall only be issued for a legitimate medical purpose.../Persons entitled to issue pre	2%	1714(C) - Operational Standards and Security; pharmacy, fixtures and equipment shall be maintained in a sanitary and orderly condition	2%
4063 - Refill of Prescription for Dangerous Drug or Device Requires Prescriber Authorization	3%	4301(c) - Unprofessional Conduct - Gross negligence	2%	1714(d) - Operational Standards and Security; Pharmacist responsible for pharmacy security	2%

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.

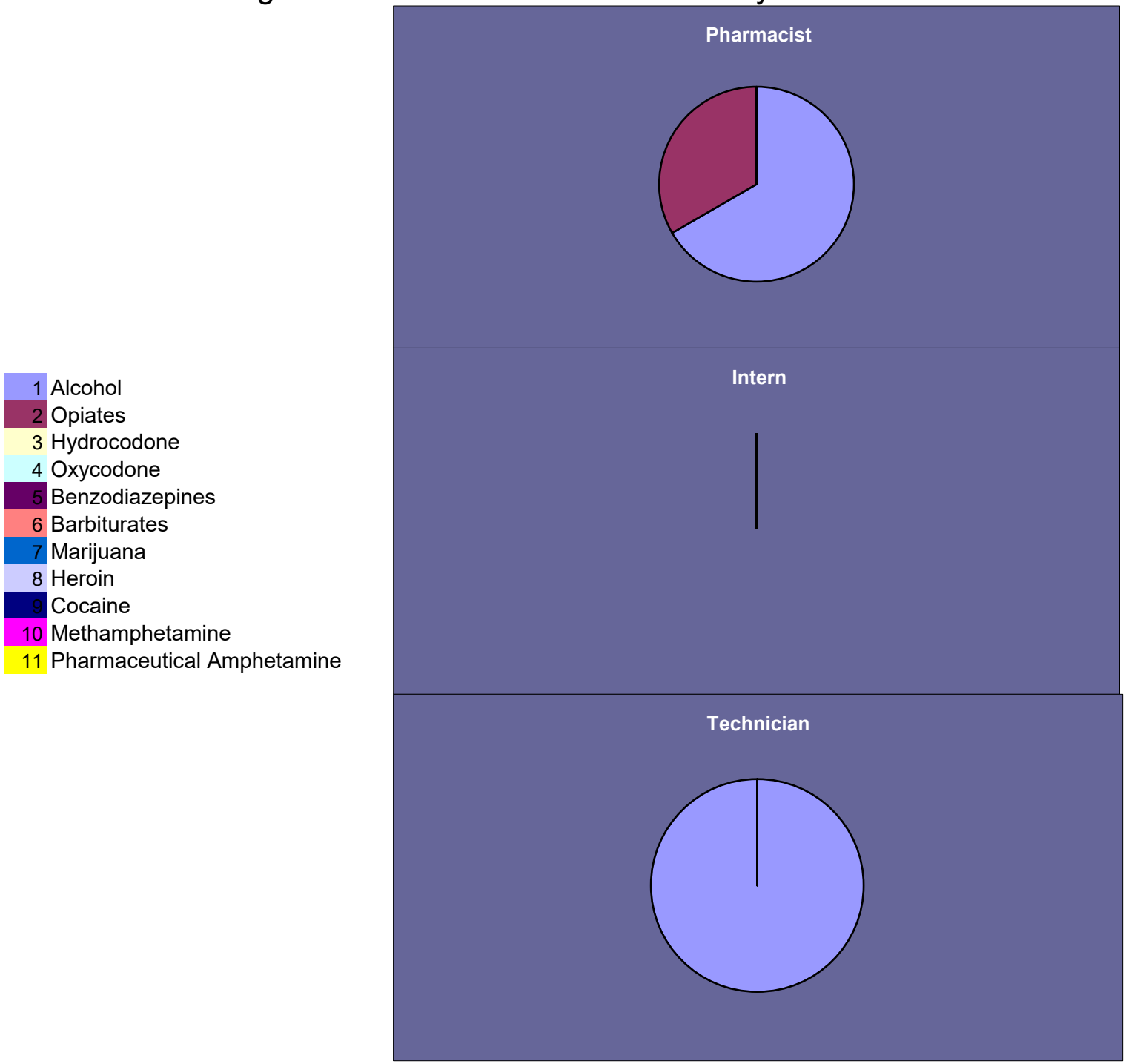
Board of Pharmacy	July Sep	Oct Dec	Jan-Mar	Apr-Jun	Total 21/22
PRP Intakes					
PRP Self-Referrals					
PRP Probation Referrals					
PRP Under Investigation	1				1
PRP In Lieu Of (investigation conducted)					
Total Number of PRP Intakes	1				1
New Probationers					
Pharmacists	1	1			2
Intern Pharmacists					
Pharmacy Technicians	1	1			2
Total New Probationers	2	2			4
PRP Participants and Recovery Agreements					
Total PRP Participants	52	47			N/A
Recovery Agreements Reviewed	40	43			83
Probationers and Inspections					
Total Probationers	70	69			N/A
Inspections Completed	44	41			85
Referrals to Treatment					
Referrals to Treatment (PRP and Probationers)	1				1
Drug Tests					
Drug Test Ordered (PRP and Probationers)	694	689			1383
Drug Tests Conducted (PRP and Probationers)	661	663			1324
Relapses (Break in Sobriety)					
Relapsed (PRP and Probationers)		2			2
Major Violation Actions					
Cease Practice/Suspension (PRP and Probationers)	3	3			6
Termination from PRP	1				1
Probationers Referred for Discipline	3				3
Closure					
Successful Completion (PRP and Probationers)	3	6			9
Termination (Probation)					
Voluntary Surrender (Probation)	2	2			4
Surrender as a result of PTR (Probation)					
Closed Public Risk (PRP)					
Non-compliance (PRP and Probationers)	51	38			89
Other (PRP)					
Patients Harmed					
Number of Patients Harmed (PRP and Probationers)					Zero
Drug of Choice at PRP Intake or Probation					
Pharmacists	**July-Sep**	**Oct-Dec**	**Jan-Mar**	**Apr-Jun**	**Total 20/21**
Alcohol	1	1			2
Ambien	1				1
Opiates					
Hydrocodone					
Oxycodone					
Morphine					
Benzodiazepines					
Barbiturates					
Marijuana					
Heroin					
Cocaine					
Methamphetamine					
Pharmaceutical Amphetamine					

SB 1441 Uniform Standards

The data includes licensees participating in the Pharmacist Recovery Program (PRP) and licensees on probation with substance use disorders.

Board of Pharmacy	July Sep	Oct Dec	Jan-Mar	Apr-Jun	Total 21/22
Phentermine					
Methadone					
Zolpidem Tartrate					
Hydromorphone					
Clonazepam					
Tramadol					
Carisprodol					
Phendimetrazine					
Promethazine w/Codeine					
Intern Pharmacists	**July-Sep**	**Oct-Dec**	**Jan-Mar**	**Apr-Jun**	**Total 20/21**
Alcohol					
Opiates					
Hydrocodone					
Oxycodone					
Benzodiazepines					
Barbiturates					
Marijuana					
Heroin					
Cocaine					
Methamphetamine					
Pharmaceutical Amphetamine					
Phentermine					
Methadone					
Zolpidem Tartrate					
Hydromorphone					
Clonazepam					
Tramadol					
Carisprodol					
Phendimetrazine					
Promethazine w/Codeine					
Pharmacy Technicians	**July-Sep**	**Oct-Dec**	**Jan-Mar**	**Apr-Jun**	**Total 20/21**
Alcohol	1	1			2
Opiates					
Hydrocodone					
Oxycodone					
Benzodiazepines					
Barbiturates					
Marijuana					
Heroin					
Cocaine					
Methamphetamine					
Pharmaceutical Amphetamine					
Phentermine					
Methadone					
Zolpidem Tartrate					
Hydromorphone					
Clonazepam					
Tramadol					
Carisprodol					
Phendimetrazine					
Promethazine w/Codeine					

Drug Of Choice - Data entered from July 2021 to December 2021



Printed on 1/11/2022