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

California State Board of Pharmacy
Department of Consumer Affairs
Public Board Meeting Minutes

Date: February 6-7, 2023

Location: Public participation provided via WebEx

Board Members Present:
Seung Oh, Licensee Member, President
Maria Serpa, Licensee Member, Vice President
Jignesh Patel, Licensee Member, Treasurer
Renee Barker, Licensee Member
Indira Cameron-Banks, Public Member
Trevor Chandler, Public Member (2/7/23)
Jessi Crowley, Licensee Member
Jose De La Paz, Public Member
Kartikeya "KK" Jha, Licensee Member (2/7/23)
Ricardo Sanchez, Public Member
Jason Weisz, Public Member (2/6/23)

Board Members Not Present:
Kula Koenig, Public Member
Nicole Thibeau, Licensee Member

Staff Present:
Anne Sodergren, Executive Officer
Eileen Smiley, DCA Staff Counsel
Debbie Damoth, Executive Manager Specialist

February 6, 2023

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

President Oh called the Board Meeting to order at 1:00 p.m. Dr. Oh reminded all individuals present that the Board is a consumer protection agency charged with administering and enforcing Pharmacy Law. Where protection of the public is inconsistent with other interests sought to be promoted, the protection of the public

shall be paramount. Dr. Oh advised all individuals the meeting was being conducted via WebEx. Dr. Oh advised participants watching the webcast that they could only observe the meeting. He noted anyone interested in participating in the meeting must join the WebEx meeting using the instructions posted on the Board's website.

Department of Consumer Affairs' staff provided general instructions for the WebEx Board Meeting for members of the public participating in the meeting.

President Oh confirmed Members received comments sent to them today about agenda items. Dr. Oh respectfully reminded and requested members of the public to submit materials two business days prior to the meeting to allow for dissemination and posting.

Roll call was taken. Board Members present included: Maria Serpa, Licensee Member; Jig Patel, Licensee Member; Renee Barker, Licensee Member; Jessi Crowley, Licensee Member; Jose De La Paz, Public Member; Ricardo Sanchez, Public Member; Jason Weisz, Public Member; and Seung Oh, Licensee Member. A quorum was established.

Member Cameron-Banks arrived at 1:08 p.m.

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

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

The Board heard public comment from a regional call center manager interested in staff working remotely.

President Oh inquired if Members wanted to add any future agenda item; however, no items were recommended.

III. Recognition and Celebration of Pharmacists Licensed in California for 40 Years and other Recognition

President Oh reminded the Board changed its recognition program for pharmacists and currently recognizes pharmacists that have been licensed for 40 or more years. Dr. Oh noted the information was posted on the Board's website and pharmacists are provided with a certificate.

President Oh noted prior to transitioning to remote meetings, the Board routinely provided an opportunity for pharmacists licensed for 40 years to attend a Board meeting and be recognized by the Board. Dr. Oh continued although the Board has

returned to remote meetings, the Board would like to provide an opportunity for the Board to recognize pharmacists that have been licensed in California for 40 years. There were no pharmacists identifying themselves to be recognized for 40 years of service as a pharmacist. President Oh thanked and congratulated pharmacists who had been licensed as a pharmacist for over 40-years. Dr. Oh thanked all pharmacy staff who worked in pharmacy serving the consumers of California.

IV. Approval of Board Meeting Minutes

a. President Oh referenced the draft minutes from the October 25-26, 2022, meeting.

Members were provided with an opportunity to comment. Member Serpa requested the last statement in page 33 should be changed to indicate that the Members inquired about amending the motion but were advised that the Committee recommendation could not be amended. Dr. Serpa wanted to add that another motion could be made should the Committee's motion be voted down.

Motion: Approve the October 25-26, 2022, minutes as presented in the meeting materials with proposed changes.

M/S: Serpa/Patel

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

Support: 9 Oppose: 0 Abstain: 0 Not Present: 4

Board Member	Vote
Barker	Support
Cameron-Banks	Support
Chandler	Not Present
Crowley	Support
De La Paz	Support
Jha	Not Present
Koenig	Not Present
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Thibeau	Not Present
Weisz	Support

b. President Oh referenced the draft minutes from the December 14, 2022, meeting.

Members were provided with an opportunity to provide comments. Member Serpa requested a change on page 5 that stated "Dr. Serpa advised ISMP works with national guidelines and recommendations" should be changed to "Dr. Serpa advised health care organizations work with national guidelines and recommendations."

Motion: Approve the December 14, 2022, minutes as presented in the meeting materials with proposed changes.

M/S: Serpa/Patel

Members of the public were provided with an opportunity to provide comments; however, no comments were made.

Support: 9 Oppose: 0 Abstain: 0 Not Present: 4

Board Member	Vote
Barker	Support
Cameron-Banks	Support
Chandler	Not Present
Crowley	Support
De La Paz	Support
Jha	Not Present
Koenig	Not Present
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Thibeau	Not Present
Weisz	Support

V. Standard of Care Ad Hoc Committee Report

President Oh provided an update and thanked fellow committee members Maria Serpa, Renee Barker, Indira Cameron-Banks, Jessica Crowley, and Nicole Thibeau. Dr. Oh reported the Committee covered a lot of ground with stakeholders. Dr. Oh provided a brief update on the activities from the meetings on November 16, 2022, and February 1, 2023.

a. Continuation of Discussion and Consideration of Policy Questions Related to Standard of Care Enforcement Model in the Practice of Pharmacy

President Oh advised during the November 16, 2022, meeting, the Committee continued the discussion on policy questions intended to assist the Committee in evaluating if a transition to a standard of care enforcement model was feasible and appropriate for the regulation of pharmacy. Dr. Oh referenced background included in the meeting materials reminding the Board was required to evaluate this issue with interested stakeholders and was required to make a recommendation to the Legislature.

President Oh provided the Board already used the standard of care as part of its enforcement model. Dr. Oh noted consistent with the legislative mandate the Board must see if there were opportunities to use such a model more robustly in enforcement. Dr. Oh advised meeting materials contained two examples of how the standard of care enforcement model was currently applied in investigations in enforcement. Dr. Oh noted the information from the November

16, 2022, meeting was included in the draft report. Dr. Oh added the Committee enjoyed significant participation from stakeholders.

Committee Members were provided the opportunity to comment; however, no comments were made. Member Serpa commented the Committee did a great job and changes to the draft have been submitted.

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

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

b. Discussion and Consideration of Draft Legislative Report Regarding Assessment of Standard of Care Enforcement Model in the Practice of Pharmacy

President Oh advised the Committee reviewed the first draft of the legislative report and will review it again in May 2023. Dr. Oh noted the draft appeared appropriate to members and stakeholders alike. Staff will be making some formatting changes, such as numbering the policy questions, adding page numbers, and correcting some typographical errors. In addition, the Committee received written comment to clarify portions of their presentation that will be incorporated into the next draft as well.

President Oh provided the majority of the discussion during the meeting centered around two of the policy questions included in the report, questions 3 and 4. Specifically related to question 3, it was determined appropriate to further refine the response to clarify that the need of pharmacist autonomy was necessary to treat patients within their clinical care consistent with their expertise and judgement.

President Oh advised there was significant discussion surrounding question 4 regarding the Board's belief if there should be a prohibition on the corporate practice of pharmacy. Dr. Oh noted the discussion included many different aspects including, perhaps the need to clarify that the intent is not to prohibit corporations from ownership of pharmacies, but more related to corporations driving the practice or interfering in a pharmacist's practice. It was determined that this issue must be expanded upon in the Board's response to the question. Dr. Oh noted comments from stakeholders supported the further expansion of the answer to clarify the intent. There appeared to be consensus that caution was necessary.

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

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

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

President Oh noted during the discussion of the recommendations, members noted agreement with content. Members suggested that the Board provide definitions of standard of care enforcement model and a standard of care patient care model. Members also noted that the recommendation did not sufficiently reflect that the recommendations were consistent with the Board's consumer protection mandate. Dr. Oh added public comment agreed with the need for definitions and also suggested that the report should include some next steps.

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

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

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

President Oh advised staff will be working on updating the report consistent with the discussion. The updated draft will be reviewed during the May 2023 meeting.

c. Discussion and Consideration of Legislative Proposal Related to Pharmacist Scope of Practice

President Oh reported the Committee transitioned to discussing opportunities to realize some of the recommendations included in the report. The Committee with stakeholders, considered several policy questions. Because of the timing of the Committee meeting and the release of the meeting materials, Dr. Oh provided a summary of the discussion was not included in the meeting materials. Dr. Oh provided a brief summary.

1. Under current law, the scope of practice varies based in part on the practice setting, i.e., pharmacists working in a health care setting may perform

functions under BPC 4052.1 and 4052.2. Is it appropriate to include the authorities for all pharmacists?

President Oh advised Members agreed that the authorities should not be limited to just some practice settings. Public comment was in support and also highlighted some related sections of law that would also require amendment to allow all pharmacists to have the same authorities. Public comment also suggested that the Board should no longer require compounding regulations above USP compounding chapters; however, Members did not agree with the comment. Members also noted that a pharmacist must have the ability to decline to perform a clinical service if they believe they do not have the requisite knowledge, skills, and abilities.

2. Under current law there are specified functions that pharmacists are authorized to perform, but only pursuant to state protocols developed and/or approved by other boards or authorities. Could a transition to more of a standard of care practice model to provide these services remove a barrier to access to care while ensure patient safety?

   President Oh reported Members all spoke in support of removing such protocols. Public comment also spoke in support of the change, with some public comments suggesting that the Board's protocols could become guidelines as opposed to requirements. Public comments indicated that with this transition, there was going to be a higher need for record keeping requirements. Public comments suggested that the Board should consider including a provision in the law that explicitly states that no other agency may define or interpret the practice of pharmacy. Commenters suggested that the scope of practice of pharmacy technicians must also change and that changes to payor reimbursement models must be made to ensure new pharmacist services provided will be reimbursed. Members noted that working conditions in some environments must be addressed to support the expanded patient care services.

3. Are there opportunities to simplify pharmacists' authority related to dispensing functions? Should pharmacist have authority to complete missing information on a prescription?

   President Oh provided Members generally spoke in support but noted the issue could be nuanced. Members indicated that a pharmacist should have the authority to complete missing information if they believe they have sufficient information to do so and it was in the best interest of the patient.

Other Members indicated that there is a need for more discussion. Public comment indicated that there were opportunities to simplify the law, but that such changes could have a negative impact on provisions for reimbursement that are relied upon for authority.

4. Should pharmacists have the authority to furnish medications that do not require diagnosis or are preventative in nature?

   President Oh advised Members noted that when considering health equity and access to care, such authority generally seems appropriate; however, it could be complicated. Members also indicated that clarification to the question may be helpful to specify if it is limited to new diagnosis versus no diagnosis. Public comment indicated that there were times when a medication was missing from a drug order that would be included as part of a standardized treatment protocol such as an anti-nausea medication along with the chemotherapy medication. Allowing a pharmacist to provide the missing complimentary medication appeared appropriate. Public comment suggested that the PIC at a location would determine which services would be provided.

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

5. Should pharmacist have the authority to furnish medications for minor, non-chronic health conditions, such as pink eye, lice, ringworm, etc.?

   President Oh noted during the meeting, the Committee discussed some of the authorities' pharmacists enjoy in Ontario, Canada including prescribing for common medical ailments like rashes, pink eye, insect bites and urinary tract infections. Dr. Oh added the Committee generally agreed pharmacists should have such authority but noted that without insurance reimbursement issues being addressed, it may not be implemented. Members considered if this authority should be limited to adult patients. Public comment spoke in support of the expansion and noted the need for pharmacists to have access to information.

6. Should pharmacist have the authority to furnish medications for which a CLIA waived test provides diagnosis, and the treatment is limited in duration, e.g., flu, COVID, strep throat?

   President Oh provided Members agreed that a test to treat model was in the best interest of patients, especially for conditions with a narrow therapeutic

window such as for treatment of COVID or flu. Dr. Oh reported public comment noted that the authority should not be limited to CLIA waived tests indicating that it should also include tests performed by patients. Comments also noted that the Board may need to either develop regulation or develop expectations about the records a pharmacist must maintain documenting their process and clinical thinking in providing these patient care services.

7. Should pharmacists have the authority to order and interpret drug therapy related tests as opposed to current authority limited to only ordering an interpreting test for purposes of monitoring and managing the efficacy and toxicity of drug therapy?

   President Oh shared some Members spoke in support of the expansion while others were concerned it may not be appropriate in all settings. Public comments suggested that the Board needs to look to the future and the needs to maximize access. Other comments spoke in support of the expansion.

8. Where a pharmacist is practicing outside of a pharmacy, what requirements are necessary for records and the Board's ability to inspect such practice?

   President Oh provided Members noted agreement with the concept and discussed the importance of pharmacists sharing information with other health care providers.

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

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

Members of the public were provided the opportunity to comment.

The Board heard a comment from a representative of CSHP requesting to have the PIC responsible for determining whether pharmacists can perform different furnishing functions. The representative noted the practice of pharmacy also happens outside of the pharmacy where there is no PIC and warned about requiring a PIC approval where there was no requirement for a PIC.

VI. Closed Session Matters

Following completion of the open session at 1:36 p.m. the Board convened in closed session at 1:50 p.m. for the stated purposes indicated on the agenda. Closed session ended at 2:44 p.m.

VII. Reconvene Open Session, to Adjourn for the Day

Due to technological limitations, adjournment for the day was not broadcast. The meeting adjourned at 2:44 p.m.

February 7, 2027

President Oh called the Board Meeting to order at 9:00 a.m. Dr. Oh reminded all individuals present that the Board is a consumer protection agency charged with administering and enforcing Pharmacy Law. Where protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount. Dr. Oh advised all individuals the meeting was being conducted via WebEx. Dr. Oh advised participants watching the webcast they could only observe the meeting. He noted anyone interested in participating in the meeting must join the WebEx meeting using the instructions posted on the Board's website. Department of Consumer Affairs' (DCA) staff provided general instructions for the WebEx Board Meeting for members of the public participating in the meeting.

Roll call was taken. Board Members present included: Jignesh Patel, Licensee Member; Renee Barker, Licensee Member; Trevor Chandler, Public Member; Jessi Crowley, Licensee Member; Jose De La Paz, Public Member; Kartikeya "KK" Jha, Licensee Member; Ricardo Sanchez, Public Member; and Seung Oh, Licensee Member. A quorum was established.

Due to technological issues Member Serpa and Member Cameron-Banks joined at 9:07 a.m.

VIII. Communication and Public Education Committee Report

Chairperson Sanchez provided a summary of the Committee's Meeting on February 6, 2023. Mr. Sanchez thanked fellow Committee Members Vice-Chair Jason Weisz, Jose De La Paz, KK Jha, Kula Koenig, and Nicole Thibeau.

a. Discussion and Consideration of FAQs about Mobile Units

Chairperson Sanchez referenced meeting materials that contained information on Senate Bill 872 that allows a county, a city and county, or two special hospital authorities to operate a mobile unit as an extension of the pharmacy license held. Mr. Sanchez continued the law authorizes the mobile unit to dispense prescription medications (except controlled substances) under specified conditions. The measure also requires notification to the Board 30 days before beginning or discontinuing use of a mobile unit.

Chairperson Sanchez reported at the Committee Meeting, members discussed the FAQ draft standardized notification form intended to facilitate the notification process for the use of the mobile unit. Mr. Sanchez noted the Committee reviewed the draft FAQs developed to assist licensees in complying

with the new law included in the meeting materials. Mr. Sanchez noted that during the discussion, the Committee requested modification to the notification form to also include collection of the municipality under which the mobile unit was operating. The Committee otherwise spoke in support of the notification form and draft FAQs.

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

Committee Recommendation (Motion): Approve the notification form with modification requested and approve the FAQs as presented. (Note: A copy of the approved notification form and approved FAQs are appended to the minutes.)

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

Support: 10 Oppose: 0 Abstain: 0 Not Present: 3

Board Member	Vote
Barker	Support
Cameron-Banks	Support
Chandler	Support
Crowley	Support
De La Paz	Support
Jha	Support
Koenig	Not Present
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Thibeau	Not Present
Weisz	Not Present

Chairperson Sanchez thanked the Board for their consideration of the FAQs and noted the Board's licensees benefit when the Board develops FAQs providing guidance on implementation issues such as this.

b. Update on Communication and Public Education Activities by Staff

Executive Officer Anne Sodergren provided an update on communication and public activities by staff.

Ms. Sodergren advised the January 2023 issue of The Script was published and available on the Board's website. The newsletter included articles about news pharmacy laws for 2022, the end of the COVID-19 state of emergency, sharps waste programs, revised USP chapters, and other topics.

Ms. Sodergren reported Board staff conducted a day long training on drug abuse prevention via WebEx in November 2022. The Committee reviewed messaging that occurred in September 2022 as part of the opioid heroin, fentanyl, and prescription drug awareness month. Meeting materials contained some of the messages including consumer and licensee facing messages partnering with DCA and CA Medical Board who both shared Board messaging on their platforms as well.

Ms. Sodergren reported areas of outreach under development include naloxone educational materials; public awareness campaign on treating pharmacy staff with courtesy; and educational campaign regarding the Institute for Safe Medication Practices (ISMP). Additional information would be provided at the July 2023 Committee Meetings as well as an update on an alternative process by which licensees can complete self-assessment forms.

Ms. Sodergren referred to meeting materials that included media inquiries received during the third and fourth quarters of 2022.

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

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

Chairperson Sanchez acknowledged Public Information Officer Bob Dávila for his work with the Board and Committee. Mr. Sanchez advised Mr. Dávila retired from the Board noting he will be missed.

Chairperson Sanchez thanked the Committee Members as it was his last Committee Member as Chairperson of the Communication and Public Education Committee noting he was serving his year of grace as a Board Member not eligible for reappointment. Mr. Sanchez noted it was an honor to work and serve with the Committee and Board.

Chairperson Sanchez advised the next meeting was set for July 19, 2023.

IX. Medication Error Reduction and Workforce Ad Hoc Committee Report

President Oh advised Chairperson Thibeau was unable to attend the meeting and Dr. Oh would be providing the update on behalf of the Committee. Dr. Oh recalled that during the December 2022 Board Meeting, the Committee considered a few of the items from the Medication Error Reduction and Workforce Committee.

a. Summary of Presentation and Discussion on Just Culture

President Oh advised Committee continues its education on Just Culture and received a presentation on Just Culture at the November 2022 meeting. Dr. Oh referenced the meeting materials summarizing the presentation received highlighting that Just Culture is about shared accountability for individuals, organizations, and others. Dr. Oh encouraged interested parties review the livestream of the presentation.

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

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

b. Discussion and Consideration of Medication Errors and Possible Future Development of Medication Error Reporting Requirements, Including Use of Required Standardized Report

President Oh referenced meeting materials containing draft changes to CCR section 1711 establishing the requirements for a quality assurance program. Dr. Oh noted the Committee considered the Board's current requirements and ultimately concluded that the current requirements were insufficient. Dr. Oh added meeting materials indicate the current requirements were fairly general. Over the course of two meetings, the Committee considered the policy questions detailed in the meeting materials and through this discussion determined changes to the Board's regulation was appropriate. Dr. Oh referenced meeting materials that included a copy of the proposed language for the Board's consideration. Dr. Oh provided the proposed language was intended to ensure a more robust review of the circumstances surrounding the error and identification of possible contributing factors, including workload.

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

Committee Recommendation (Motion): Recommend to the Board approval of the proposed regulatory text for Section 1711 as presented, direct staff to submit the text to the Director of the Department of Consumer Affairs and the Business, Consumer Services, and Housing Agency for review and if no adverse comments are received, authorize the Executive Officer to take all steps necessary to initiate the rulemaking process, make any nonsubstantive changes to the package, and set the matter for 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 necessary steps to complete the rulemaking and adopt the proposed regulations at section 1711 as noticed.

Proposal to Amend 16 CCR § 1711 as follows:

§ 1711. Quality Assurance Programs.

(a) Each pharmacy shall establish or participate in an established quality assurance program that documents and assesses medication errors to determine cause and an appropriate response as part of a mission to improve the quality of pharmacy service and prevent errors.
(b) For purposes of this section, "medication error" means any variation from a prescription or drug order not authorized by the prescriber, as described in Section 1716. Medication error, as defined in the section, does not include any variation that is corrected prior to furnishing the drug to the patient or patient's agent or any variation allowed by law.
(c)(1) Each quality assurance program shall be managed in accordance with written policies and procedures maintained in the pharmacy in an immediately retrievable form.
(2) When a pharmacist determines that a medication error has occurred, a pharmacist shall as soon as possible:
(A) Communicate to the patient or the patient's agent the fact that a medication error has occurred and the steps required to avoid injury or mitigate the error.
(B) Communicate to the prescriber the fact that a medication error has occurred.
(3) The communication requirement in paragraph (2) of this subdivision shall only apply to medication errors if the drug was administered to or by the patient, or if the medication error resulted in a clinically significant delay in therapy.

(4) If a pharmacist is notified of a prescription error by the patient, the patient's agent, or a prescriber, the pharmacist is not required to communicate with that individual as required in paragraph (2) of this subdivision.
(d) Each pharmacy shall use the findings of its quality assurance program to develop pharmacy systems and workflow processes designed to prevent medication errors. An investigation of each medication error shall commence as soon as is reasonably possible, but no later than 2 business days from the date the medication error is discovered. All medication errors discovered shall be subject to a quality assurance review.
(e) The primary purpose of the quality assurance review shall be to advance error prevention by analyzing, individually and collectively, investigative and other pertinent data collected in response to a medication error to assess the cause and any contributing factors such as system or process failures. A record of the quality assurance review shall be immediately retrievable in the pharmacy. The record shall contain at least the following:
(1) The date, location, and participants in the quality assurance review;
(2) The pertinent data and other information relating to the medication error(s) reviewed and documentation of any patient contact required by subdivision (c)~~;~~, including:
(A) The date and approximate time or date range when the error occurred if known or can be determined. If it cannot be determined, the pharmacy shall note "unknown" in the record.
(B) The names of staff involved in the error.
(C) The use of automation, if any, in the dispensing process.
(D) The type of error that occurred. To ensure standardization of error reporting, the pharmacies' policies and procedures shall include the category the pharmacy uses for identifying the types of errors.
(E) The volume of workload completed by the pharmacy staff on the date of the error including clinical functions. If the date of the error is unknown, the average volume of workload completed daily shall be documented. For errors that occur in a community pharmacy, at a minimum the volume of workload records shall include the number of new prescriptions dispensed, the number of refill prescriptions dispensed, the number of vaccines administered, number of patient consultations given, and any other mandatory activities required by the pharmacy employer. Prescriptions filled at a central fill location and dispensed at the pharmacy must be documented separately from other prescriptions filled at the pharmacy.
(3) The findings and determinations generated by the quality assurance review; and,
(4) Recommend changes to pharmacy policy, procedure, systems, or processes, if any.

The pharmacy shall inform pharmacy personnel of changes to pharmacy policy, procedure, systems, or processes made as a result of recommendations generated in the quality assurance program. Documentation of the steps taken to prevent future errors shall be maintained as part quality assurance report.
(f) The record of the quality assurance review, as provided in subdivision (e) shall be immediately retrievable in the pharmacy for at least ~~one~~ three years from the date the record was created. Any quality assurance record related to the use of a licensed automated drug delivery system must also be submitted to the board within 30 days of completion of the quality assurance review and any facility with an unlicensed automated drug delivery system must report the quality assurance review to the Board at the time of annual renewal of the facility license.
(g) The pharmacy's compliance with this section will be considered by the board as a mitigating factor in the investigation and evaluation of a medication error.
(h) Nothing in this section shall be construed to prevent a pharmacy from contracting or otherwise arranging for the provision of personnel or other resources, by a third party or administrative offices, with such skill or expertise as the pharmacy believes to be necessary to satisfy the requirements of this section.

NOTE: Authority cited: Section 4005, Business and Professions Code; and Section 2 of Chapter 677, Statutes of 2000. Reference: Sections 4125 and 4427.7, Business and Professions Code.

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

Support: 10 Oppose: 0 Abstain: 0 Not Present: 3

Board Member	Vote
Barker	Support
Cameron-Banks	Support
Chandler	Support
Crowley	Support
De La Paz	Support
Jha	Support
Koenig	Not Present
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Thibeau	Not Present
Weisz	Not Present

c. Discussion and Review of Enforcement Actions Taken and Enforcement Authority Exercised by Other Jurisdictions Related to Workplace Conditions.

President Oh reported the Committee reviewed the findings of the October 2022 Pharmacist Well-being index which showed a slight increase in the distress percent for California respondents. The Committee also reviewed the National Academy of Medicine's National Plan of Health Workforce Well-being. The Committee did not act on these items and will continue to monitor the results of the well-being index.

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

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

President Oh advised as part of the Committee's next meeting a presentation would be provided by a Patient Safety Organization (PSO).

X. Enforcement and Compounding Committee Report

Chairperson Serpa thanked fellow members Vice-Chair Jignesh Patel, Renee Barker, Indira Cameron-Banks, Seung Oh, and Ricardo Sanchez for their work on the Committee. Dr. Serpa advised the Committee met twice since the July 2022 Board Meeting.

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

i. Community Pharmacy/Hospital Outpatient Self-Assessment (17M-13)
ii. Hospital Pharmacy Self-Assessment (17M-14)
iii. Wholesaler/Third Party Logistics Provider Self-Assessment (17M-26)
iv. Automated Drug Delivery System Self-Assessment (17M-112)

Chairperson Serpa reported the dynamic nature of the pharmacy law generally results in the need to update the self-assessment forms on an annual basis to incorporate law changes made at either the state or federal level. Dr. Serpa advised the Committee reviewed proposed changes to several self-assessment forms which were included and detailed in the meeting materials. Dr. Serpa provided an overview of the streamlined section 100 regulation process noting Members were comfortable with the process.

Chairperson Serpa provided the Committee also considered the proposed changes to the self-assessment form related to automated drug delivery systems reflected in the meeting materials. Dr. Serpa highlighted that procedurally the self-assessment was reviewed in a different manner than the other three because the regulation section, CCR section 1715.1 that incorporated by reference the ADDS self-assessment, and the form itself are currently going through the rulemaking process. Dr. Serpa provided the comment period closed on December 27, 2022, and comments received during the comment period will be considered after the Enforcement and Compounding Committee Report.

Chairperson Serpa noted the Committee's review and discussion was limited to only the new changes being recommended in response to changes in the law. Dr. Serpa reviewed the formatting of the proposed text and noted because the Board would be considering the comments received during the comment period, to ensure compliance with the Government Code, it was very important that comments were limited to only the new changes. Dr. Serpa advised the Committee was offering a recommendation; however, no action would be taken on the Committee's recommendation until later in the meeting because of the need to consider the comments received in response to the public comment period.

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

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

b. Discussion and Consideration of Barriers to Timely Case Resolutions

Chairperson Serpa advised one of the Committee's strategic objectives was to determine and reduce barriers to timely case resolutions to improve consumer protections. Dr. Serpa noted there were many steps involved in an investigation and the egregiousness of the violations, if any, would in large part determine the outcome of the matter. Dr. Serpa highlighted about 7 percent of the Board's investigations result in referral to the Office of the Attorney General for discipline. Dr. Serpa noted this because there appeared to be a perception that the formal discipline taken by the Board constitutes a significant portion of its investigations while the data tells otherwise. Dr. Serpa added the Committee considered aggregated data for investigations noting investigation timeframes were currently the longest step.

Chairperson Serpa referenced the meeting materials that included recommendations that were offered by staff to remove some barriers experienced by inspector staff. During the Committee meeting, Members spoke in support of the recommendations and requested that staff prepare proposed statutory language for consideration at a future meeting.

Members were provided the opportunity to comment. Member Crowley inquired about discussion on the proposal having timeframes the items should be provided to investigators. Dr. Serpa advised the first step was to establish the authority to request it and then it could be determined through statutory or regulatory language.

Members of the public were provided the opportunity to comment. The Board heard a comment about how to make professional directors and professional administrators of clinics accountable for following policies and procedures but was not clear what the ramifications are if not followed. DCA Counsel Smiley advised the comment period was only for the item that has been offered for comment.

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

Chairperson Serpa reported DCA Counsel Eileen Smiley provided an excellent overview of the requirements for authorized individuals to qualify for some exemptions to federal law under provisions of section 503A. The overview served as a great reminder to all licensees to be mindful of the larger picture as the Committee contemplates areas of drug handling, processing, and compounding triggered by actions of the USP.

Members were provided the opportunity to comment. Member Barker commented the presentation was excellent and encouraged reviewing materials and webinar.

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

d. Presentation on USP General Chapter 825, Regarding Radiopharmaceuticals

Chairperson Serpa reported the Committee received a presentation from Supervising Inspector Christine Acosta on the new USP Chapter 825 related to Radiopharmaceuticals. Dr. Serpa advised USP Chapter 825 provides standards for the preparation, compounding, dispensing, and repackaging of radiopharmaceuticals, including all sterile radioactive material that must maintain sterility through manipulations prior to administrations. Dr. Serpa added provisions of this chapter become effective November 1, 2023, and encouraged Members to review the livestream of the presentation to learn more about the requirements of the Chapter.

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

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

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

Chairperson Serpa reported following the overview from Ms. Smiley and presentation by Dr. Acosta, the Committee undertook a review of proposed regulations that may be necessary to implement, clarify, or make more specific requirements necessary to protect the public. Dr. Serpa advised one of the goals was to have the regulation mirror the USP chapter to clarify but not duplicate information in the USP Chapter. Dr. Serpa advised consideration of the Board's compounding regulations was a dynamic process and individuals would have opportunities to participate throughout the development and rulemaking process. Dr. Serpa reported members of the public were provided with numerous opportunities to participate in public comment including following the Committee's discussion of each proposed section.

Chairperson Serpa reported the proposed regulations for radiopharmaceuticals included new sections 1738 through 1738.14 and covered a range of areas related to radiopharmaceuticals. These proposed regulations will build upon the requirements included in federal law and those included in USP Chapter 825.

Chairperson Serpa advised Members after the Committee completes its work on development of all of the compounding chapters, it intends to present the Board with all of the proposed regulations together for consideration and action. Dr. Serpa anticipated this could occur by the April 2023 Board Meeting noting it was an aggressive schedule but the Committee was working hard to complete its work to ensure licensees have a clear understanding of the Board's expectations related to compounding to coincide with the November 1, 2023, compendial effective date if possible.

Members were provided an opportunity to comment. Member Chandler inquired if there were any concerns with the proposed language. Dr. Serpa advised radiopharmaceuticals were very a narrow area and expected more comments for other chapters.

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

Chairperson Serpa reported the next Committee Meeting was scheduled for February 15, 2023, where the Committee would be considering proposed changes to regulations related to pharmaceutical compounding of nonsterile preparations. Dr. Serpa welcomed all interested parties to attend the meeting either in person or via WebEx adding meeting materials were posted on the website.

f. Review and Discussion of Enforcement Statistics

Chairperson Serpa reported meeting materials include enforcement statistics reflecting enforcement related activities between July 1 and December 31, 2022. Dr. Serpa continued the Board received 1,839 complaints during this period and closed 1,459 investigations. The Board secured 3 interim suspensions orders, 2 automatic suspension orders and has been granted 4 penal code 23 restrictions.

Chairperson Serpa added as of January 1, the Board had 1,450 field investigations pending. The average days for various stages of the investigation process were included in the meeting materials. Dr. Serpa reported there had been a large increase in the supervisor review time and second level review

time believed to be due in part to a vacancy at the supervising inspector level. Dr. Serpa advised the Committee will monitor the progress.

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

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

XI. Discussion and Consideration and Possible Action Related to Proposed Regulations to Amend title 16, California Code of Regulations Section 1715.1 and Automated Drug Delivery System Self-Assessment (Form 17M-112), Including Comments Received During Public Comment Period

President Oh referenced meeting materials where in January 2022 the Board approved proposed regulation text to amend CCR Section 1715.1 related to the Automated Drug Delivery System Self-Assessment and the form incorporated by reference. Dr. Oh reported the Board was to consider comments received during the 45-day comment period that concluded December 27, 2022. Dr. Oh referenced meeting materials included the language, comments received, staff recommendations based on the comments received. Dr. Oh advised the discussion also needed to include the recommendation from the Enforcement and Compounding Committee.

President Oh reviewed the information and agreed with the changes offered by staff and the recommended responses. Dr. Oh agreed with the changes offered by the Enforcement and Compounding Committee. Dr. Oh introduced Assistant Deputy Director Grace Arupo Rodriguez who was present to assist with the regulation process and any questions.

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

M/S: Chandler/Serpa

Motion: Accept the Board staff recommended comment response, approve the staff recommended modified self-assessment form, and initiate a 15-day public comment period. Additionally, 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 and adopt the proposed regulation at Section 1715.1. Further, delegate to the executive officer the authority to make technical or non-substantive

changes as may be required by the Control agencies to complete the rulemaking file.

Title 16. Board of Pharmacy
Modified Regulation Text

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

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

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

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

(a) The pharmacist-in-charge of each automated drug delivery system as defined under section 4119.11, 4187.5 or section 4427.3 of the Business and Professions Code (BPC) shall complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. The assessment shall be performed ~~annually~~ before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.
(b) In addition to the self-assessment required in subdivision (a) of this section, the pharmacist-in-charge shall complete a self-assessment within 30 days whenever:
  (1) A new automated drug delivery system license has been issued.
  (2) There is a change in the pharmacist-in-charge~~, and he or she becomes the new pharmacist-in-charge of an automated drug delivery system~~.
  (3) There is a change in the licensed location of an automated drug delivery system to a new address.
(c) A pharmacist-in-charge of an automated drug delivery system shall assess the system's compliance with current laws and regulations by using the components of Form 17M-112 (Rev 1~~2~~/18~~2~~2~~3~~) entitled “Automated Drug Delivery System Self-Assessment”. Form 17M-112 shall be used for all automated drug delivery systems and is hereby incorporated by reference.
  (1) The pharmacist-in-charge shall provide identifying information about the underlying operating pharmacy including:
    (A) Name and any license number(s) of the underlying pharmacy and their expiration date(s);
    (B) Address, phone number, and website address, if applicable, of the underlying pharmacy;

(C) DEA registration number, expiration date, and date of most recent DEA inventory;
(D) Hours of operation of the pharmacy; and
(E) ADDS license number, address, and hours of operation.

(2) The pharmacist-in-charge shall respond “yes”, “no”, or “not applicable” (N/A) about whether the automated drug delivery system is, at the time of the self-assessment, in compliance with laws and regulations that apply to that pharmacy setting.

(3) For each “no” response, the pharmacist-in-charge shall provide a written corrective action or action plan to come into compliance with the law.

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

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

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

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

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

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

(1) The mechanical devices used as part of the automated drug delivery system to store, dispense or distribute dangerous drugs are of the same manufacturer and controlled by the same software system on a single server; and
(2) The same policies and procedures required by Section 4427.2 of BPC are used.

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

[Note: A copy of the staff recommended modified self-assessment form is included as an attachment to the minutes.]

Executive Officer Sodergren invited DCA Counsel Grace Arupo Rodriguez to assist the Board in navigating with the Enforcement and Compounding Committee recommendation with the Board for consideration. Counsel advised the Board could table or reject the Committee recommendation with the recommendation to vote down the Committee recommendation and move forward with the current motion.

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

Members of the public were provided the opportunity to comment.

A pharmacist representative of Kaiser referenced comments submitted explaining why the pharmacist believed establishing a requirement for PICs to complete the ADDS Self-Assessment for Hospital AUDS that are exempt from licensure was inconsistent with the underlying statute specifically BPC section 4427.7 (a) and was inconsistent with the legislature's intent. The pharmacist provided an example of why the pharmacist thought it was to be logical and inconsistent with the underlying statute.

President Oh inquired about advice based on the comment. Counsel advised it would need to be researched further. Member Serpa provided Counsel in the past have disagreed with the interpretation provided by Kaiser. Member Jha commented

believe that 3.31 was not required as most of the time the devices are located in a locked medication room.

Support: 10 Oppose: 0 Abstain: 0 Not Present: 3

Board Member	Vote
Barker	No
Cameron-Banks	No
Chandler	No
Crowley	No
De La Paz	No
Jha	No
Koenig	Not present
Oh	No
Patel	No
Sanchez	No
Serpa	No
Thibeau	Not present
Weisz	Not Present

M/S: Chandler/Serpa

Motion: Accept the Board staff recommended modified text in response to the public comment received during the 15-day period as well as approve the recommended changes to incorporate new changes in the law as identified by the Enforcement and Compounding Committee, approve the staff recommended modified self-assessment form, and initiate a 15-day public comment period. Additionally, 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 and adopt the proposed regulation at Section 1715.1. Further, delegate to the executive officer the authority to make technical or non-substantive changes as may be required by the Control agencies to complete the rulemaking file.

Title 16. Board of Pharmacy
Modified Regulation Text

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

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

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

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

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

(4) The pharmacist-in-charge shall initial each page of the self-assessment with original handwritten initials in ink or digitally signed in compliance with Civil Code Section 1633.2(h) on the self-assessment form.
(5) The pharmacist-in-charge shall certify on the last page of the self-assessment that ~~he or she has~~ they have completed the self-assessment of the automated drug delivery system of which ~~he or she is~~ they are the pharmacist-in-charge. The pharmacist-in-charge shall also certify a timeframe within which any deficiency identified within the self-assessment will be corrected and acknowledge that all responses are subject to verification by the Board of Pharmacy. The certification shall be made under penalty of perjury of the laws of the State of California that the information provided in the self-assessment form is true and correct with an original handwritten signature in ink or digitally signed in compliance with Civil Code Section 1633.2(h) on the self-assessment form.
(6) The automated drug delivery system owner shall certify on the final page of the self-assessment that ~~he or she~~ they have ~~has~~ read and reviewed the completed self-assessment and acknowledges that failure to correct any deficiency identified in the self-assessment could result in the revocation of the automated ~~dispensing~~ drug delivery system's license issued by the board. This certification shall be made under penalty of perjury of the laws of the State of California with an original handwritten signature in ink or digitally signed in compliance Civil Code Section 1633.2(h) on the self-assessment form.

(d) Each self-assessment shall be completed in its entirety and kept on file in the underlying pharmacy for three years after it is performed. The completed, initialed, and signed original must be readily available for review during any inspection by the board.
(e) Any identified areas of noncompliance shall be corrected as specified in the assessment.
(f) The pharmacist-in-charge of a hospital using more than one unlicensed automated drug delivery system as authorized in BPC section 4427.2(i) may complete a single self-assessment of the hospital's compliance with federal and state pharmacy law for all automated drug delivery systems under the following conditions:
(1) The mechanical devices used as part of the automated drug delivery system to store, dispense or distribute dangerous drugs are of the same manufacturer and controlled by the same software system on a single server; and
(2) The same policies and procedures required by Section 4427.2 of BPC are used.

Note: Authority cited: Sections 4119.11 and 4427.7, Business and Professions Code. Reference: Sections 4001.1, 4008, 4017.3, 4021, 4022, 4036, 4037, 4038, 4040, 4050, 4051, 4052, 4059, 4070, 4076, 4081, 4101, 4105, 4107, 4113,

4117.3, 4119.1, 4119.11, 4125, 4126, 4180, 4186, 4305, 4330, 4332, 4333, 4400, 4427, 4427.1, 4427.2, 4427.3, 4427.4, 4427.5, 4427.6, and 4427.7, Business and Professions Code; and Section 16.5, Government Code.

[Note: A copy of the staff recommended modified self-assessment form is included as an attachment to the minutes.]

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

Support: 10 Oppose: 0 Abstain: 0 Not Present: 3

Board Member	Vote
Barker	Support
Cameron-Banks	Support
Chandler	Support
Crowley	Support
De La Paz	Support
Jha	Support
Koenig	Not present
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Thibeau	Not present
Weisz	Not Present

The Board took a break from 10:00 a.m. to 10:10 a.m. After break, roll call was taken. Members present included Maria Serpa, Licensee Member; Jig Patel, Licensee Member; Renee Barker, Licensee Member; Trevor Chandler, Public Member; Jessi Crowley, Licensee Member; KK Jha, Licensee Member; Ricardo Sanchez, Public Member; and Seung Oh, Licensee Member.

Member Patel left the meeting at 10:57 a.m.

XII. Licensing Committee Report

President Oh reported on the actions of the Licensing Committee and thanked fellow Committee Members: Jig Patel, Indira Cameron-Banks, Jessica Crowley and Jason Weisz.

a. Discussion, Consideration and Possible Action on State Protocol Consistent with Provisions of Business and Professions Code section 4052.01 as amended in Senate Bill 1259 (Chapter 245, Statutes of 2022) Including Proposed Amendment to Title 16, California Code of Regulations Section 1746.3

President Oh recalled the Board previously considered and established a support position on Senate Bill 1259 which sought to amendment BPC section 4052.01 to provide the authority for a pharmacist to furnish federal Food Drug and Administration approved opioid antagonist in accordance with standardized procedures or protocols developed under specified conditions. The Governor signed this measure which would become effective January 1, 2023. Dr. Oh advised as required in the statute, the Board and the Medical Board of California must approve the regulation with consultation with the California Society of Addiction Medicine, the California Pharmacists Association, and other appropriate entities. The statute also specifies areas that must be included in the standardized procedures.

President Oh advised the required protocol for pharmacists was included in California Code of Regulations (CCR) section 1746.3 and established the requirements of the standardized procedures established for a pharmacist to furnish naloxone hydrochloride pursuant to BPC section 4052.01. Dr. Oh recalled as products were approved by the FDA it was appropriate to evaluate the Board's current regulation to establish flexibility in the regulation for the furnishing of additional opioid antagonists approved by the FDA. Dr. Oh reported Board staff worked an expert in the field Dr. James Gasper to develop language and secured feedback as required by the statute.

President Oh reported as required by the statute, the draft proposed language was provided to the California Society of Addiction Medicine, who was offering one comment for consideration, which was moving a portion of the language to earlier in the section. Dr. Oh reported no comments or concerns were identified by the Medical Board of California. Dr. Oh provided the proposed language was included in the meeting materials with a summary of the changes being proposed and the recommendation being offered by the Committee. Dr. Oh added as required by statute, the proposed change must be approved by the Medical Board as well. If approved at the meeting, the Executive Officer will present before the Medical Board later the same week seeking their approval.

Member Cameron-Banks returned to the meeting at approximately 10:14 a.m.

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

Committee Recommendation (Motion): Recommend initiation of a rulemaking to amend CCR section 1746.3 as proposed to be amended. Authorize the executive officer to further refine the language consistent with the policy discussions, including those of the Medical Board of California, and as may be required by control agencies (DCA or Agency) and to make any nonsubstantive 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 1746.3 as noticed for public comment.

16 CCR § 1746.3

§ 1746.3. Protocol for Pharmacists Furnishing Opioid Antagonists ~~Naloxone Hydrochloride~~.

A pharmacist furnishing an opioid antagonist ~~naloxone hydrochloride~~ pursuant to section 4052.01 of the Business and Professions Code shall satisfy the requirements of this section.

(a) As used in this section:

(1) "Opioid" means naturally derived opiates as well as synthetic and semi-synthetic opioids.

(2) "Recipient" means the person to whom ~~naloxone hydrochloride~~ an opioid antagonist is furnished.

(b) Training. Prior to furnishing ~~naloxone hydrochloride~~ an opioid antagonist, pharmacists who use this protocol must have successfully completed a minimum of one hour of an approved continuing education program or equivalent-based training program completed in a board recognized school of pharmacy specific to the use of opioid antagonists for overdose reversal. ~~naloxone hydrochloride such products including in all routes of administration recognized in subsection (c)(4) of this protocol, or an equivalent curriculum-based training program completed in a board recognized school of pharmacy.~~

(c) Protocol for Pharmacists Furnishing Opioid Antagonists ~~Naloxone Hydrochloride~~.

Before providing an opioid antagonist ~~naloxone hydrochloride~~, the pharmacist shall:

~~(1) Screen the potential recipient by asking the following questions: Make a reasonable inquiry to determine:~~

~~(A) Whether the potential recipient currently uses or has a history of using illicit or prescription opioids. (If the recipient answers yes, the pharmacist may skip screening question B.);~~
~~(B) Whether the potential recipient is in contact with anyone who uses or has a history of using illicit or prescription opioids. (If the recipient answers yes, the pharmacist may continue.);~~
~~(C) Whether the person to whom the naloxone hydrochloride would be administered has a known hypersensitivity to naloxone. (If the recipient answers yes, the pharmacist may not provide naloxone. If the recipient responds no, the pharmacist may continue.)~~
~~The screening questions shall be made available on the Board of Pharmacy's website in alternate languages for patients whose primary language is not English.~~
(~~2~~1) Provide the recipient training in opioid overdose prevention, recognition, response, and administration of the opioid antagonist ~~antidote naloxone~~.
(~~3~~2) When an opioid antagonist ~~naloxone hydrochloride~~ is furnished:
(A) The pharmacist shall provide the recipient with appropriate counseling and information on the product furnished, including dosing, effectiveness, adverse effects, storage conditions, shelf-life, and safety. The recipient is not permitted to waive the required consultation.
(B) The pharmacist shall provide the recipient with any informational resources on hand and/or referrals to appropriate resources if the recipient indicates interest in addiction treatment, recovery services, or medication disposal resources at this time.
(C) The pharmacist shall answer any questions the recipient may have regarding ~~naloxone hydrochloride~~ the opioid antagonist.
(~~4~~3) Product Selection: A pharmacist shall advise the recipient on how to choose the route of administration based on the formulation available, how well it can likely be administered, the setting, and local context. ~~A pharmacist may supply naloxone hydrochloride as an intramuscular injection, intranasal spray, auto-injector or in another FDA-approved product form.~~ A pharmacist may also recommend optional items when appropriate, including alcohol pads, rescue breathing masks, and rubber gloves.
(~~5~~4) Labeling: A pharmacist shall label the ~~naloxone hydrochloride~~ product consistent with law and regulations. The patient shall also receive the FDA approved medication guide. ~~Labels shall include an expiration date for the naloxone hydrochloride furnished. An example of appropriate labeling is available on the Board of Pharmacy's website~~.
~~(6) Fact Sheet: The pharmacist shall provide the recipient a copy of the current naloxone fact sheet approved by the Board of Pharmacy or a fact sheet approved by the executive officer. The executive officer may only approve a fact sheet that has all the elements and information that are contained in the~~

~~current board-approved fact sheet. The board-approved fact sheet shall be made available on the Board of Pharmacy's website in alternate languages for patients whose primary language is not English. Fact sheets in alternate languages must be the current naloxone fact sheet approved by the Board of Pharmacy.~~

(~~7~~5) Notifications: ~~If the recipient of the naloxone hydrochloride is also the person to whom the naloxone hydrochloride would be administered, then the naloxone recipient is considered a patient for purposes of this protocol and notification may be required under this section.~~

~~If the patient gives verbal or written consent, then the pharmacist shall notify the patient's primary care provider of any drug(s) and/or device(s) furnished, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by the patient and that primary care provider.~~

~~If the patient does not have a primary care provider, or chooses not to give notification consent, then the pharmacist shall provide a written record of the drug(s) and/or device(s) furnished and advise the patient to consult an appropriate health care provider of the patient's choice.~~ At the request of the patient, a pharmacist shall notify to the identified primary care provider of the product furnished or enter appropriate information in a shared patient record system as permitted by the primary care provider. If the patient does not have or does not identify a primary care provider, the pharmacist shall provide the recipient a written record of the drug furnished along with a recommendation to consult with an appropriate health care provider of the patient's choice.

~~(8) Documentation: Each naloxone hydrochloride~~ A ~~product furnished by a pharmacist pursuant to this protocol shall be documented in~~ the pharmacy's ~~a medication record for the naloxone recipient, and securely stored within the originating pharmacy or health care facility for a period of at least three years from the date of dispense in compliance with . The medication record shall be maintained in an automated data or manual record mode such that the required information under title 16, sections 1707.1 and 1717 of the California Code of Regulations is readily retrievable during the pharmacy or facility's normal operating hours.~~

~~(9) Privacy: All pharmacists furnishing naloxone hydrochloride in a pharmacy or health care facility shall operate under the pharmacy or facility's policies and procedures to ensure that recipient confidentiality and privacy are maintained.~~

Credits

NOTE: Authority cited: Section 4052.01, Business and Professions Code. Reference: Section 4052.01, Business and Professions Code.

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

A representative from CSHP commented as a policy CSHP always advocated for drug class versus a single drug entity noting at the time, naloxone was the only drug. CSHP supported the change to class.

A retired pharmacist commented there had been lack of clarity if the proposed language and was not clear that the statute and regulation overruled what a pharmacist can do in a collaborative practice agreement and requested clarification. The retired pharmacist stated it would be a good idea to open to all opioid antagonist but noted naloxone might become over the counter (OTC) and inquired if the opioid antagonist was OTCC would the regulation and requirements apply.

Member Chandler spoke in favor of this motion and looked forward to hearing staff clarifying questions. Mr. Chandler understood that this would allow pharmacists to approve OTC or prescription for opioid antagonist.

Support: 10 Oppose: 0 Abstain: 0 Not Present: 3

Board Member	Vote
Barker	Support
Cameron-Banks	Support
Chandler	Support
Crowley	Support
De La Paz	Support
Jha	Support
Koenig	Not Present
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Thibeau	Not Present
Weisz	Not Present

b. Discussion, Consideration and Possible Action on State Protocol to Facilitate Pharmacist Provided Medication-Assisted Treatment Pursuant to Business and Professions Code section 4052(a)(14), Including Proposed Addition of Title 16, California Code of Regulations Section 1746.6

President Oh advised as included in the meeting materials, BPC 4052(a)(14) provides authority for pharmacists to provide medication-assisted treatment

(MAT) pursuant to a state protocol. Dr. Oh added during the meeting, the Committee considered proposed regulations establishing such a protocol. Dr. Oh referenced background meeting materials and provided an overview of MAT as a way used to treat substance use disorders as well as to sustain recovery and prevent overdose.

President Oh reported recently federal law was changed to expand access to MAT including removal of the x-waiver requirement. With this change in the federal law and the Board's proposed regulation, Dr. Oh believed pharmacists that choose to provide MAT will be well positioned to serve as an important access point for patients in need of MAT. Dr. Oh provided the proposed regulation language considered by the Committee was included in the meeting materials noting experts in the field assisted staff with the development of the draft proposal.

President Oh reported during the meeting Members spoke in support of the draft proposal and received public comment also in support. The Committee was offering a recommendation. Dr. Oh sought input from Members if they thought specifically about a private patient care area versus confidential patient care should be required.

Members were provided with the opportunity to comment.

Member Chandler noted as someone in active recovery was very excited about this as another approach to assist in recovery in the opioid epidemic.

Member Crowley provided context that there were reports in retail and chain settings where pharmacists do not believe they have a designated area for a private discussion. Dr. Crowley was also interested in hearing discussion on private versus confidential.

President Oh was not certain of the legal difference between private versus confidential.

Committee Recommendation (Motion): Recommend initiation of a rulemaking to add CCR section 1746.6 as proposed. Authorize the executive officer to further refine the language consistent with the policy discussions and as may be required by control agencies (DCA or Agency) and 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 1746.6 as noticed for public comment.

Proposal to Add CCR Section 1746.6 Pharmacist Provided Medication-Assisted Treatment

(a) A pharmacist may initiate, modify, administer, or discontinue medication-assisted treatment pursuant to Section 4052(a)(14) consistent with all relevant provisions of federal law and shall satisfy the requirements of this section.
   a. The pharmacist possesses appropriate education and training to provide such treatment consistent with the established standard of care used by other health care practitioners providing medication-assisted treatment including nationally accepted guidelines.
   b. The pharmacist must ensure a private patient care area is used to provide the services. The patient may not waive consultation.
   c. Assessment of the substance use disorder is performed including physical and laboratory examinations for signs and symptoms of substance use disorder. Initial assessment may be waived if the patient is referred to the pharmacist for treatment following diagnosis by another health care provider.
   d. Development of a treatment plan for substance use disorder including referral to medical services, case management, psychosocial services, substance use counseling, and residential treatment is provided as indicated.
   e. Documentation of the pharmacist's assessment, clinical findings, plan of care, and medications dispensed and administered will be documented in a patient record system and shared with a patient's primary care provider or other prescriber, if one is identified.
   f. A pharmacist performing the functions authorized in this section shall do so in collaboration with other health care providers.

(b) For purposes of this section medication assisted treatment includes any medication used to treat a substance use disorder.

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

A representative from CSHP commented that originally CSHP requested an amendment that was accepted because the original language was for non-opiate MAT when the standard was buprenorphine which was a Schedule III controlled substance. The commenter requested in developing the protocol and regulation request reminding the pharmacist that they must obtain their personal DEA registration and not use the DEA registration of the pharmacy.

A retired pharmacist commented that the pharmacist needs their personal DEA registration. The retired pharmacist commented it was not clear on the impact under current collaborative practice agreements and needed to be clarified. The retired pharmacist commented pharmacists have been dealing with confidential issues for over 30 years that find a way to do it that satisfy the patient. If the Board required strict limits, it would be denying MAT access with privacy that the pharmacy offers. The retired pharmacist encouraged not requiring a strict specification noting confidentiality can be provided without a separate room.

Support: 10 Oppose: 0 Abstain: 0 Not Present: 3

Board Member	Vote
Barker	Support
Cameron-Banks	Support
Chandler	Support
Crowley	Support
De La Paz	Support
Jha	Support
Koenig	Not Present
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Thibeau	Not Present
Weisz	Not Present

c. Discussion and Consideration of Pharmacist Provided HIV Preexposure and Postexposure Prophylaxis, including presentations

President Oh recalled during the October 2022 Board Meeting the Committee received a presentation on research underway on pharmacist-furnished HIV prevention. Dr. Oh noted the results of the research were not yet available; however, when available the Board would receive a presentation on the outcome.

President Oh reported the Committee received presentations on pharmacist-driven models currently used to expand access to HIV PrEP and PEP. Dr. Oh reported as part of presentations, Members learned about the models used to provide HIV PrEP and PEP services and about barriers to care. Common themes

arose around barriers including reimbursement challenges and the 60-day limit on furnishing PrEP.

President Oh reported given the barriers identified, the Committee believed it may be appropriate to dedicate a meeting to learn more from stakeholders about these issues. Dr. Oh believed there were actions the Board could take to remove barriers to care, but believed actions must also be taken by others, including payors to fully actualize this expanded access to care. Dr. Oh requested Board staff work with the Office of AIDS to expand education on funding sources available for pharmacists.

Members were provided with the opportunity to comment.

Member Chandler commented the presentations by Dr. Lopez and Dr. Hopkins were excellent. Mr. Chandler noted the barrier appears to be the lack of insurance reimbursement for the HIV tests necessary to prescribe PrEP and PEP and there needed to be a legislative fix to the issue. Mr. Chandler appreciated the Board working to resolve it.

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

d. Discussion, Consideration and Possible Action on Discontinuance of Business by a Pharmacy and Potential Changes to Title 16, California Code of Regulations Section 1708.2

President Oh reported the Committee continued its discussion on potential changes to the Board's requirements for a discontinuance of business. Dr. Oh referenced relevant provisions of pharmacy law noted in the meeting materials. Dr. Oh added in prior discussions the Committee discussed general areas of complaints received related to this issue including scenarios where a pharmacy has closed, and a patient cannot receive a refill because they are unable to contact the pharmacy to request a prescription transfer or where a pharmacy has closed and transferred patient prescription refills to another pharmacy not of the patient's choosing.

President Oh advised the Committee considered a number of policy questions which were detailed in the meeting materials and determined changes to current regulation requirements were appropriate. The Committee requested staff develop proposed language for consideration.

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

Committee Recommendation (Motion): Recommend initiation of a rulemaking to amend CCR section 1708.2 as proposed and further refined by the Committee. Authorize the executive officer to further refine the language consistent with the policy discussions and as may be required by control agencies (DCA or Agency) and 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 1708.2 as noticed for public comment.

16 CCR § 1708.2

Proposal to Amend § 1708.2. Discontinuance of Business as follows:

(a) Any permit holder shall contact the board prior to transferring or selling any dangerous drugs, devices or hypodermics inventory as a result of termination of business or bankruptcy proceedings (collectively referred to as a "closure") and shall follow official instructions given by the board applicable to the transaction.

(b)In addition to the requirements in (a), a pharmacy that shall cease operations due to a closure shall complete the following:

(1) Provide written notice to its patients that have received a prescription within the last year, at least 30 days in advance of the closure. At a minimum this notice shall include:

(A) the name of the patient and/or legal representative of the patient, if known,

(B) the name and physical address of the pharmacy closure,

(C) the name of pharmacy where patient records will be transferred or maintained, and

(D) information on how to request a prescription transfer prior to closure of the pharmacy.

(2) Reverse all prescriptions for which reimbursement was sought that are not picked up by patients,

(3) Provide the board with a copy of the notice specified in subsection (b)(1),

(4) The pharmacist-in-charge shall certify compliance with the requirements in this section. In the event the pharmacist-in-charge is no longer available, the owner must certify the compliance along with a pharmacist retained to perform these functions.

NOTE: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4080, 4081, 4113, 4332 and 4333, Business and Professions Code; and Section 11205, Health and Safety Code.

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

A retired pharmacist commented on items that should be considered with an FAQ including the required notice for closure noting that it was not clear what the Board will do with the notice. The commenter noted it would be good to have the notices posted on the Board's website. The commenter noted if the information won't be posted on the Board's website then it should be posted on the pharmacy's website.

Support: 10 Oppose: 0 Abstain: 0 Not Present: 3

Board Member	Vote
Barker	Support
Cameron-Banks	Support
Chandler	Support
Crowley	Support
De La Paz	Support
Jha	Support
Koenig	Not Present
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Thibeau	Not Present
Weisz	Not Present

e. Discussion and Consideration of Legal Requirements for Nonresident Pharmacies Including Possible Statutory Change to Require Licensure by the Pharmacist-in-Charge (PIC)

President Oh reported the Committee continued the discussion on potential changes to licensure requirements for the PIC working in a nonresident pharmacy. Dr. Oh referenced meeting materials that included the definition of a "pharmacist-in-charge" as a pharmacist proposed by a pharmacy and approved by the Board as the supervisor or manager responsible for ensuring the pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy.

President Oh advised as required by law every pharmacy must designate a PIC who was responsible for the pharmacy's compliance with state and federal laws. Dr. Oh reported California law requires that any pharmacy located outside California that provides services into California shall be considered a nonresident pharmacy. Dr. Oh continued this section requires licensure as a nonresident pharmacy noting there were no current requirements for pharmacists working in these pharmacies to be licensed in California even when providing care to California patients. Dr. Oh advised there was no requirement for the PIC of the nonresident pharmacy to be licensed in California; however, California law currently establishes a prohibition for a pharmacist to provide services to California patients if the pharmacist's license was revoked in California.

President Oh reported in previous discussions, the Committee reviewed the model rules provided by the National Association of Board of Pharmacy provided for Boards to consider as part of its regulation of the practice of pharmacy which includes a requirement for a pharmacist to be licensing in the state in which it is providing services to patients. The Committee reviewed the range of requirements in other states required for licensure of staff working out of state but providing care to their residents. Dr. Oh provided during the meeting, the Committee discussed draft statutory language which was included in meeting materials. Dr. Oh noted the Committee received comments both in support of the proposal as well as in opposition. Dr. Oh advised the Committee was offering a recommendation to sponsor legislation related to legal requirements for nonresident pharmacies.

Members were provided with the opportunity to comment.

Member Jha provided the long-term care (LTC) pharmacies serve the communities with old, sick, and frail patients. Mr. Jha noted LTC pharmacies do not have the portability as retail pharmacies; for example, in the event of a natural disaster, there was no way another pharmacy can take of 2,000-6,000 patients of an LTC pharmacy overnight. Mr. Jha noted LTC pharmacies rely on other pharmacies in other states to assist with workload in the case of emergencies. Mr. Jha stated it was already a struggle trying to get other pharmacies licensed in California and adding another layer of licensure for the PIC will add more complexity. Mr. Jha requested this be reconsidered.

Member Crowley stated there needed to be accountability for every pharmacy. Dr. Crowley added without having a PIC licensed in California, there was no way to assure California law was operating under California standards.

Member Barker commented in concern if there was not someone at the pharmacies that were aware of California law and added this would be a safeguard to patients. Dr. Barker noted it wasn't over burdensome to have one of the many pharmacists to be in charge and licensed in California.

Committee Recommendation (Motion): Recommend sponsorship of changes to Business and Professions Code section 4112 related to legal requirements for nonresident pharmacies to require licensure by the pharmacist-in-charge consistent with the language presented.

ARTICLE 7. Pharmacies [4110 - 4126.10]
(Article 7 added by Stats. 1996, Ch. 890, Sec. 3.)

4112.
(a) Any pharmacy located outside this state that ships, mails, or delivers, in any manner, controlled substances, dangerous drugs, or dangerous devices into this state shall be considered a nonresident pharmacy.

(b) A person may not act as a nonresident pharmacy unless he or she has obtained a license from the board. The board may register a nonresident pharmacy that is organized as a limited liability company in the state in which it is licensed.

(c) A nonresident pharmacy shall disclose to the board the location, names, and titles of (1) its agent for service of process in this state, (2) all principal corporate officers, if any, (3) all general partners, if any, ~~and~~ (4) the name of a California licensed pharmacist designated as the pharmacist-in-charge, and (5) all pharmacists who are dispensing controlled substances, dangerous drugs, or dangerous devices to residents of this state. A report containing this information shall be made on an annual basis and within 30 days after any change of office, corporate officer, partner, pharmacist-in-charge, or pharmacist.

(d) All nonresident pharmacies shall comply with all lawful directions and requests for information from the regulatory or licensing agency of the state in which it is licensed as well as with all requests for information made by the board pursuant to this section. The nonresident pharmacy shall maintain, at all times, a valid unexpired license, permit, or registration to conduct the pharmacy in compliance with the laws of the state in which it is a resident. As a prerequisite to registering with the board, the nonresident pharmacy shall identify a California licensed pharmacist employed and working at the nonresident pharmacy to be proposed to serve as the pharmacist-in-charge, and shall

submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the state in which it is located.

(e) All nonresident pharmacies shall maintain records of controlled substances, dangerous drugs, or dangerous devices dispensed to patients in this state so that the records are readily retrievable from the records of other drugs dispensed.

(f) Any pharmacy subject to this section shall, during its regular hours of operation, but not less than six days per week, and for a minimum of 40 hours per week, provide a toll-free telephone service to facilitate communication between patients in this state and a pharmacist at the pharmacy who has access to the patient's records. This toll-free telephone number shall be disclosed on a label affixed to each container of drugs dispensed to patients in this state.

(g) A nonresident pharmacy shall not permit a pharmacist whose license has been revoked by the board to manufacture, compound, furnish, sell, dispense, or initiate the prescription of a dangerous drug or dangerous device, or to provide any pharmacy-related service, to a person residing in California.

(h) The board shall adopt regulations that apply the same requirements or standards for oral consultation to a nonresident pharmacy that operates pursuant to this section and ships, mails, or delivers any controlled substances, dangerous drugs, or dangerous devices to residents of this state, as are applied to an in-state pharmacy that operates pursuant to Section 4037 when the pharmacy ships, mails, or delivers any controlled substances, dangerous drugs, or dangerous devices to residents of this state. The board shall not adopt any regulations that require face-to-face consultation for a prescription that is shipped, mailed, or delivered to the patient. The regulations adopted pursuant to this subdivision shall not result in any unnecessary delay in patients receiving their medication.

(i) The registration fee shall be the fee specified in subdivision (a) of Section 4400.

(j) The registration requirements of this section shall apply only to a nonresident pharmacy that ships, mails, or delivers controlled substances, dangerous drugs, and dangerous devices into this state pursuant to a prescription.

(k) Nothing in this section shall be construed to authorize the dispensing of contact lenses by nonresident pharmacists except as provided by Section 4124.

(m) Effective date July 1, 2024.

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

The Board heard comments in opposition from CVS Health, CRA, Kaiser, Walgreens, CCAP, and a retired pharmacist recommending options other than licensure be explored.

Member Serpa commented other states do what the Board was proposing and understood a concern about taking a test but believed patient safety was above the difficult nature of passing the test.

Member Patel commented about concern of barriers to pass the test and access if PICs aren't licensed in time.

Member Chandler commented with California being the 4th largest economy in the world, California set the standards for the country and wanted to make sure the standards aren't being lowered.

Member Jha recommended reconsidering noting safety standards are important but need to consider for contingency planning. Mr. Jha's concern was adding another barrier to licensure.

Member Crowley appreciated different perspectives and noted there needed to be responsibility for the people operating the pharmacy to understand California standards particularly due to high-risk medications and populations. Dr. Crowley added usually there was a grace period for implementation. Dr. Crowley noted there was a comment at the Licensing Committee by someone who had licensure in 17 states and noted it was not an issue.

Member Patel added concern about the number of graduates and people who will need to take the CPJE impacting access. Mr. Patel recommended reevaluating the issue.

Member Barker noted the mandate for consumer protection was being pitted against a challenging test for a PIC which was a concern for her. Dr. Barker added it seemed like the Board didn't have a choice but to require the examination and licensure for the PIC to ensure protection of the most vulnerable populations.

President Oh added the Board was interested in making sure the PIC has the autonomy needed which has been a focus for the last few years. Dr. Oh noted it was important for the PIC to understand the laws of California and it had to be brought up because of past enforcement cases where the PIC was not aware of the laws and regulations. Dr. Oh commented understanding about access but added there were waivers available.

Executive Officer Sodergren provided in the event of a declared disaster or emergency, the Board has the authority to waive provisions of pharmacy law to ensure continuity of patient care pursuant to BPC 4062. Ms. Sodergren added provisions of pharmacy law allow for interim PICs and transition periods. Ms. Sodergren clarified if a pharmacist is licensed in another state, the pharmacist doesn't have to retake the NAPLEX.

Support: 7 Oppose: 2 Abstain: 0 Not Present: 4

Board Member	Vote
Barker	Support
Cameron-Banks	Support
Chandler	Support
Crowley	Support
De La Paz	Not Present
Jha	Oppose
Koenig	Not Present
Oh	Support
Patel	Oppose
Sanchez	Support
Serpa	Support
Thibeau	Not Present
Weisz	Not Present

f. Discussion, Consideration and Possible Action on Continuing Education Requirements for Pharmacists and Pharmacy Technicians, Including Development of Regulation Language to Facilitate Implementation of Recently Enacted Legislation, Including Possible Amendment to Title 16, California Code of Regulations Section 1732.5 and Possible Addition of Section 1732.8

President Oh referred to meeting materials that included the relevant sections of law and background and draft regulation language to establish the continuing education requirements for cultural competency as required by the legislation. Dr. Oh highlighted the provisions related to pharmacists also include consolidation of various CE requirements for pharmacists that are currently included in various provisions of statute and regulation. Dr. Oh added the proposed language establishes new regulations defining the continuing education requirements for pharmacy technicians that mirror the process used for pharmacist renewal.

President Oh reported during the meeting, the Committee requested that staff confirm the language was sufficiently specific to ensure the required course content was included. Dr. Oh advised subsequent to the meeting, staff confirmed with counsel the language was appropriate and offered additional language to further cross reference the statute.

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

Committee Recommendation (Motion): Recommend initiation of a rulemaking to amend CCR section 1732.5 and add section 1732.8 as proposed and further refined by the Committee. Authorize the executive officer to further refine the language consistent with the policy discussions and as may be required by control agencies (DCA or Agency) and to make any nonsubstantive 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 sections 1732.5 and 1732.8 as noticed for public comment.

Proposal to Amend § 1732.5. Renewal Requirements for Pharmacists.
(a) Except as provided in Section 4234 of the Business and Professions Code and Section 1732.6 of this Division, each applicant for renewal of a pharmacist license shall submit proof satisfactory to the board, that the applicant has completed 30 hours of continuing education (CE) in the prior 24 months.
(b) At least two (2) of the thirty (30) hours required for pharmacist license renewal ("required CE hours") shall be completed by participation in a Board provided CE course in Law and Ethics. Further, beginning January 1, 2024, at least one (1) hour of the required CE hours shall be completed by participation in a cultural competency course from an accreditation agency approved by the board pursuant to Section 1732.05, covering the specified content areas as required by Section 4231 of the Business and Professions Code. ~~Pharmacists renewing their licenses which expire on or after July 1, 2019, shall be subject to the requirements of this subdivision~~.
(c) Pharmacists providing specified patient-care services must complete continuing education as specified below.
(1) At least one (1) hour of approved CE specific to smoking cessation therapy, as required by Section 4052.9 of the Business and Professions Code, if applicable.

(2) At least two (2) hours of approved CE specific to travel medicine, as required by Section 1746.5, if applicable.

(3) At least one (1) hour of approved CE specific to emergency contraception drug therapy as required by Business and Professions section 4052.3, if applicable.

(4) At least one (1) hour of approved CE specific to vaccinations as required by Section 1746.4, if applicable.

(d) For a pharmacist who prescribes a Schedule II controlled substance (as defined in Health and Safety Code section 11055), at least one (1) hour of the required CE hours shall be completed by participation in a Board approved CE course once every four (4) years on the risks of additional associated with the use of Schedule II drugs, as required by Section 4232.5 of the Business and Professions Code.

(e) All pharmacists shall retain their certificates of completion for four (4) years following completion of a continuing education course demonstrating compliance with the provisions of this section.

(e) "Board approved CE course" shall mean coursework from a provider meeting the requirements of Section 1732.1.

NOTE: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4052.3, 4052.8, 4052.9, 4231 ~~and~~ 4232, and 4232.5, Business and Professions Code.

Proposal to Add § 1732.8. Renewal Requirements for Pharmacy Technicians

(a) Beginning January 1, 2024, as a condition of renewal, a pharmacy technician licensee shall submit proof satisfactory to the board that the applicant has completed at least one (1) hour of continuing education in a cultural competency course covering the specified content areas from an accreditation agency approved by the board pursuant to Section 1732.05 during the two years preceding the application for renewal, as required by Section 4202 of the Business and Professions Code. All pharmacy technicians shall retain their certificate of completion for four (4) years from the date of completion of the cultural competency course demonstrating compliance with the provisions of this section.

(b) If an applicant for renewal of a pharmacy technician license submits the renewal application and payment of the renewal fee but does not submit proof satisfactory to the board that the licensee has completed the cultural competency course as required, the board shall not renew the license and shall issue the applicant an inactive pharmacy technician license.

(c) If, as part of an investigation or audit conducted by the board, a pharmacy technician fails to provide documentation substantiating the

completion of continuing education as required in subdivision (a), the board shall cancel the active pharmacy technician license and issue an inactive pharmacy technician license in its place. A licensee with an inactive pharmacy technician license issued pursuant to this section may obtain an active pharmacy technician license by submitting renewal fees due and submitting proof to the board that the pharmacy technician has completed the required continuing education.

NOTE: Authority cited: Section 462 and 4005, Business and Professions Code. Reference: Sections 462 and 4202, Business and Professions Code.

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

Support: 9 Oppose: 0 Abstain: 0 Not Present: 4

Board Member	Vote
Barker	Support
Cameron-Banks	Support
Chandler	Support
Crowley	Support
De La Paz	Not Present
Jha	Support
Koenig	Not Present
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Thibeau	Not Present
Weisz	Not Present

g. Discussion and Consideration of Business and Professions Code section 4111 Including Possible Changes Related to Ownership Prohibitions

President Oh recalled at the July 2022 meeting, the Committee considered the issue of ownership prohibitions specifically related to prescriber ownership including a prohibition by a person who shares a community or other financial interest with the prescriber. Dr. Oh noted at the time, the Committee considered proposed language that could be used to create flexibility for such ownership while maintaining the legislative intent of the prohibition. Dr. Oh referenced meeting materials that provided background on the issue and highlighted at

the time of the initial discussion, in response to public comment, the Committee determined that additional consideration of other forms of ownership prohibitions should be considered related to pharmacist ownership. Meeting materials contained the language considered by the Committee that could be used to expand provisions to allow a pharmacist that is authorized to issue a drug order under specified conditions to also own a pharmacy. Dr. Oh noted the Committee was offering a recommendation to sponsor legislation.

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

Committee Recommendation (Motion): Recommend sponsorship of changes to Business and Professions Code section 4111 related to ownership prohibitions consistent with the language presented.

Possible amendment to BPC Section 4111

(a) Except as otherwise provided in subdivision (b), (d), or (e), the board shall not issue or renew a license to conduct a pharmacy to any of the following:

(1) A person or persons authorized to prescribe or write a prescription, as specified in Section 4040, in the State of California.

(2) A person or persons with whom a person or persons specified in paragraph

(1) shares a community or other financial interest in the permit sought unless both the person or persons specified in paragraph (1) and the person seeking a license to conduct pharmacy provide statements disavowing any community or financial interest on behalf of the person or persons specified in paragraph (1) and transmute any such community property under the Family Law Codes of the State of California into the separate property of the person seeking a license to conduct pharmacy. In addition, the pharmacy seeking a license with an owner specified in paragraph (1) if such license is granted, shall be prohibited from filling any prescriptions, emergency or otherwise issued or prescribed by the person or persons specified in paragraph (1) or another prescriber at the same place of business as the person specified in paragraph (1) if the prescriber owns a greater than 10% interest in the practice issuing the prescription.

(3) Any corporation that is controlled by, or in which 10 percent or more of the stock is owned by a person or persons prohibited from pharmacy ownership by paragraph (1) or (2).

(b) Subdivision (a) shall not preclude the issuance of a permit for an inpatient hospital pharmacy to the owner of the hospital in which it is located.

(c) The board may require any information the board deems is reasonably necessary for the enforcement of this section.

(d) Subdivision (a) shall not preclude the issuance of a new or renewal license for a pharmacy to be owned or owned and operated by a person licensed on or before August 1, 1981, under the Knox-Keene Health Care Service Plan Act of 1975 (Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code) and qualified on or before August 1, 1981, under subsection (d) of Section 1310 of Title XIII of the federal Public Health Service Act, as amended, whose ownership includes persons defined pursuant to paragraphs (1) and (2) of subdivision (a).

(e) Subdivision (a) shall not preclude the issuance of a new or renewal license for a pharmacy to be owned or owned and operated by a pharmacist authorized to issue a drug order ~~pursuant to Section 4052.1, 4052.2, or 4052.6~~ under the following conditions:

1. The pharmacist issuing the drug order offers to provide a prescription to the patient that the patient may elect to have filled by a pharmacy of the patient's choice unless prohibited by the collaborative practice agreement.

2. The pharmacist issuing the drug order must provide a full patient consultation prior to issuing the drug order.

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

Support: 9 Oppose: 0 Abstain: 0 Not Present: 4

Board Member	Vote
Barker	Support
Cameron-Banks	Support
Chandler	Support
Crowley	Support
De La Paz	Not Present
Jha	Support
Koenig	Not Present
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Thibeau	Not Present
Weisz	Not Present

h. Discussion and Consideration of Provisions for Remote Processing

President Oh recalled to facilitate physical distancing early in the COVID-19 pandemic, the Board approved a waiver to extend the provisions for remote processing based on the in BPC section 4062. The waiver was limited in duration and set to expire May 28, 2023. Dr. Oh referenced meeting materials containing extensive information on remote processing and the remote processing waiver that have been in effect for a majority of the pandemic.

President Oh recalled through the years it appeared that some may have overstated the provisions and flexibilities provided in California law where the approval and release of the waiver then appeared to cause a stir among some that may have implemented practices that exceed what the law provides in California. Dr. Oh clarified this was not the point of the discussion. Dr. Oh advised current law provides that under BPC section 4071.1, a pharmacist may electronically enter a prescription, or an order as defined in Section 4019, into a pharmacy's or hospital's computer system from any location outside of the pharmacy or hospital with the permission of the pharmacy or hospital. Controlled substances are explicitly exempt from these provisions.

President Oh advised under the conditions of the waiver, however, the Board expanded authority for pharmacists to receive, interpret, evaluate, clarify and approve mediation orders and prescriptions, including such orders for controlled medications. The waiver allowed for order entry, other data entry, performing prospective drug utilization review, interpreting clinical data, insurance processing, performing therapeutic interventions, providing drug information

services, and authorizing release of medications for administration. The waiver did not permit dispensing of a drug or final product verification by remote processing. Dr. Oh continued although the waiver has been in place for a significant period of time, it was limited in duration and unless legislation was passed, at the end of the waiver, provisions of the law will return to those currently included in BPC section 4071.1.

President Oh advised during the meeting, the Committee spent a significant amount of time discussing the policy questions included in the meeting materials. Dr. Oh noted there appeared to be consensus that changes were necessary for inpatient provisions; however, a solution on possible expansion for outpatient had not yet been identified.

With Committee Member agreement, President Oh sought feedback on three questions included in the meeting materials. Dr. Oh believed these questions would provide guidance to the Committee in continued evaluation of the issue.

1. Does the Board believe permanent changes to the Board's current remote processing provisions are appropriate?

   President Oh stated in general yes but limitations and guardrails were needed as well as being mindful of unintended consequences.

   Member Patel commented remote processing helps to save on cost as well as provide additional avenues for people with disabilities to work from home. Mr. Patel added it allows the pharmacist to assist the patient in front of them while allowing work to be done remotely. Mr. Patel felt it should be extended to pharmacists and pharmacy technicians with guardrails (e.g., security, etc.) in place.

   President Oh added the Board tried to sponsor legislation last year but there was significant resistance and it didn't move.

   Member Crowley noted significant differences depending on setting. In an acute setting where there was a need for an overnight pharmacist to approve urgent or emergency medication, it seemed essential. Dr. Crowley expressed concern about guardrails, impact on working conditions long term in community chain settings, final tactile verification, and record keeping.

   Member Jha added the pandemic underlined importance of doing the work. Mr. Jha noted from a longer-term care pharmacy perspective, it

reduces barrier to entry and increases the availability of pharmacists. Mr. Jha recommended defining what a pharmacist and pharmacy technician can do as a remote worker as well as working more uniformly for data access and security standards. Mr. Jha noted the pandemic allowed remote working to be tested and determine it is useful, efficacy is not an issue but data and HIPAA safety needs to be improved. Mr. Jha noted the pandemic allowed for the utility's case to be proven. Mr. Jha wanted to see definition of actions that can be done remotely and uniform data security measures.

Member Serpa commented more discussion, testimony and thought on remote processing for the various personnel and locations. Dr. Serpa encouraged the dialogue to continue.

Member Chandler's takeaways from previous testimony was that there needs to be confidence that the data was protected and the labor wasn't impacted. Mr. Chandler wanted to make sure that the guardrails were significant enough in the event they are abused or broken there are significant penalties to prevent misuse or insufficient data handling. Mr. Chandler suggested possibly tying the pharmacy license to the working conditions so that if working conditions were found to be purposefully inadequate or inadequate this would have an impact on the revocation of the pharmacist's license. Mr. Chandler provided this would require a legislative remedy.

Members of the public were provided the opportunity to comment.

A representative from UFCW WSC commented in opposition as waiver was for emergency. The representative expressed concerns about chain pharmacies being able to conduct remote pharmacies as the owners are not licensed professionals; liability of the PIC; enforcement of labor and pharmacy laws; concern with HIPAA issues; lack of security and data protections. The representative recommended the following amendment to the proposal as excluding chain pharmacies; limit remote processing during business hours; allow pharmacist the authority to expressly refuse remote processing; prohibit pharmacy technicians and unlicensed pharmacy staff from remote processing; and requiring remote processing pharmacies and licensees to register with the Board for enforcement purposes.

A pharmacist representative from Kaiser commented the proposed language doesn't go as far as Kaiser would like to see in authorizing

remote work for pharmacy personnel. The representative noted after three years, pharmacists, interns, and pharmacy technicians in all practice setting and have provided evidence that the practice is safe and provides flexibility.

A full-time remote pharmacist for a mail order pharmacy commented she lived six hours away from her workplace and will lose her job. The commenter noted remote working was inclusive for many people, demonstrated need and safe using VPN password protection in place.

A pharmacist for 20 years commented remote processing in specialty pharmacy was safe and effective meeting the need of pharmacists and patients. The commenter added many pharmacies are closed door pharmacies and provide consultation via phone noting current technology provides safeguards. Remote processing allowed for more clinical review for specialty drugs that are needed to understand therapy.

Member De La Paz returned at 11:50 a.m.

A commenter inquired about response time from the Board. Counsel advised this was outside the agenda item and directed the commenter to contact the Executive Officer.

A representative of CRA/NACDS commented about submitting a letter to the Board regarding this agenda item and spoke in support of the Board taking action to move forward for all pharmacy settings. The representative stated in inability for retail pharmacies to utilize remote processing for non-dispensing functions result in significant job loss and increased pressure on the community pharmacy workforce. Many states allow remote processing for pharmacists and pharmacy technicians and pharmacies have processes have systems set up for remote processing.

A specialty pharmacist commented remote processing allows her to take time with each patient and supported remote work.

Member Chandler left the meeting at 12:00 p.m.

A specialty pharmacist commented in support of remote processing for better care of patients and staff.

A pharmacist of 20 years commented remote processing was safe and the technology allows for it. It also kept him safe as he has allergies.

A representative of CVS Health commented at least 45 states allow for remote processing noting the proposal didn't address the cognitive practice of pharmacy. The waiver focused on a pharmacist being electronically connected to a pharmacy but pharmacists practice outside of a pharmacy. The representative stated the proposal would not allow pharmacists working in physicians' offices and advanced practice pharmacists working independently. Remote work improves working conditions and public safety.

A specialty pharmacist commented in favor of remote processing that allows for reduced medication errors, improved staff attendance and improved safety for employees.

A representative of Walgreens spoke in support of expanding permanent use for all practice settings believing it allows for expansion of opportunities for pharmacists and support local community stores.

The Board took a break from 12:12 p.m. – 1:00 p.m. Roll call was taken. Members present included Maria Serpa, Licensee Member; Jig Patel, Licensee Member; Renee Barker, Licensee Member; Jessi Crowley, Licensee Member; Jose De La Paz, Public Member; KK Jha, Licensee Member; Indira Cameron-Banks, Public Member; Trevor Chandler, Public Member; and Seung Oh, Licensee Member. A quorum was established.

President Oh sought feedback on the remaining questions included in the meeting materials.

2. Given the federal requirements for hospital pharmacy patient care, should the Board prioritize a legislative solution for inpatients and request that the Licensing Committee continue its policy discussion on possible expansion for outpatient prescriptions. Last date to introduce a bill 2/17/23.

   Member Serpa commented for more than 20 years hospitals that are not open 24 hours have a remote verification of chart orders and verified by pharmacist at the hospital or remotely to meet federal guidelines and standards. Pharmacists are required to review all orders prior to administration in an acute care hospital. Dr. Serpa noted it was a shock to the community that this wasn't clear in the law and noted a sense of urgency in acute care facilities because the system for remote order verification allows for hospitals to comply with federal standards and provides for patient safety. Dr. Serpa added it has been well documented

that patient lives are saved and medication errors are reduced with a pharmacist is part of the process and was the standard of care across the country. Dr. Serpa stated it needed to be prioritized and not held back with the ongoing discussion with other practice settings. If the Board waits, a gap would be created and patient harm could result.

Member Chandler added the Board will need to pursue through the legislative process and will take time.

Member Serpa added if everything was done at once, it will take longer and patients will be harmed. Dr. Serpa suggested a step-by-step approach.

President Oh clarified the Committee didn't have a motion and the motion would need to come from the Board if pursued.

Member Crowley requested clarification that this wouldn't change current law but clarify it. Counsel Smiley added hospitals have special authority for pharmacists operating in a hospital. Dr. Crowley thought the language provided would apply to any licensed facility. Ms. Sodergren noted BPC section 4052.1 specifies functions performed in a licensed health care facility where the pharmacist was located and licensed in California may on behalf of the licensed health care facility pursuant to section 1250.

Ms. Sodergren provided power was lost where the moderator and co-moderator were located. A break was taken from 1:15 p.m. to 1:30 p.m. Roll call was taken. Members present included Maria Serpa, Licensee Member; Jig Patel, Licensee Member; Renee Barker, Licensee Member; Trevor Chandler, Public Member; Jessi Crowley, Licensee Member; Jose De La Paz, Public Member; KK Jha, Licensee Member; Ricardo Sanchez, Public Member; and Seung Oh, Licensee Member. A quorum was established.

Members were provided the opportunity to comment.

A specialty pharmacist commented specialty pharmacy has patients that need immediate care as well or be hospitalized without pharmacist intervention. The commenter implored the Board to regard specialty pharmacists not only as an outpatient setting but as an important role in pharmacy to prevent patients from having to be admitted to the hospital.

A pharmacist representative of Kaiser that operates dozens of hospitals served by dedicated inpatient pharmacies in California. Kaiser would not

prefer a stepwise approach but rather than no proposal would like to see the hospital proposal advance now. The representative indicated there might be important words missing in proposed language to change BPC section 4071.1 and should read, "A pharmacist license located and licensed in California may on behalf of a health care facility licensed pursuant to Health and Safety Code section 1250 verify medication chart orders for appropriateness prior to administration from any location outside of the facility consistent with federal requirements and as established in the health care facilities policies and procedures." specifically adding "any location outside the facility."

Member Cameron-Banks rejoined the meeting at approximately 1:35 p.m.

A retired pharmacist commented BPC section 4071.1 was about entering a prescription or order into a pharmacy system from outside the facility where enter means ready for administration. The commenter stated there was no need to have (d) added. The commenter stated if this was going into effect and the Board didn't use its discretion for discipline, it would mean at the federal level, all hospitals would have to stop admitting Medicare and Medicaid because of the conditions of participation.

3. Does the board wish to provide policy direction to the Committee on specific elements it believes must be included in any proposal related to expanding current remote processing provisions for outpatient prescription process?

   Members were provided the opportunity to comment.

   Member Crowley stated the biggest concern was with regard to chain pharmacy. Dr. Crowley added after hearing public comment that those who work remotely had to take a pay cut to get to remote work, was more concerned about a long-term about chain pharmacies choosing to do that than staffing pharmacies appropriately. As a pharmacist who works in person at the pharmacy, Dr. Crowley needed help with registers, answering phone calls, and physically filling the prescription. Dr. Crowley noted while it was helpful to have assistance with verification and entering from time to time, Dr. Crowley wanted to ensure the actual tactile help in the pharmacy was not lost long-term. Dr. Crowley also wanted to ensure the issue of PIC liability was delt with head on in terms of who will be liable for a specific pharmacy. Dr. Crowley noted as a pharmacist who was verifying there were times where a DUR, drug interaction, or note in a

patient's profile that results in making a note to discuss during consultation which would be lost during remote verification.

Members of the public were provided the opportunity to comment.

A pharmacist representative from Kaiser commented looking forward to further discussion to guardrails that need to be in place for remote work to be authorized in other facility types (e.g., inpatient hospital, etc.) and other pharmacy personal. The representative recommended if the Board needs to run a bill this year to include a provision that gives the Board authority to allow remote processing in the outpatient setting via the regulatory pathway.

A pharmacist who worked in retail for eight years commented that sometimes different pharmacists do the data verification, product verification, and counseling due to different shifts. It also applied to specialty pharmacy.

A pharmacist commented about the pay cut for remote working noting that remote working allows for pharmacists who can't work in the retail or hospital setting to work as a pharmacist. The pharmacist commented rather than be afraid of moving forward to add guardrails.

A pharmacist who worked at specialty home infusion pharmacy commented that the pharmacist had been taking calls after hours for over 20 years to communicate with patients and was concerned this would limit how the pharmacist could communicate, assist, and evaluate patients. The pharmacist noted there was a template of telemedicine with the California Department of Corrections.

President Oh clarified BPC section 4052 details functions that a pharmacist may do regardless of a location.

Member Serpa added there was a difference between remote order entry versus remote processing. Remote order entry was processing a request for prescription or order while remote processing was reviewing and potentially approving the product. Dr. Serpa was comfortable with remote order entry but not remote processing.

Member Jha stated the disconnect was limited to permitting the current set of activities that are already happening and have happened previous to COVID related to remote processing, which was mostly order entry,

pharmacist verification, drug interaction and taking verbals. Mr. Jha understood the Board was continuing the definition of what is or was permissible and exploring the idea of how to allow it to happen after the restrictions are lifted and make it safer with data security regulations.

President Oh noted the Committee didn't have a quorum to put forth a recommendation but had a discussion. Based on the discussion at the Committee and Board level seeing where there might be a consensus in terms of inpatient per the discussion and meeting materials.

Member Serpa added it needed to be clearer about being outside of the facility. Member Crowley stated the first sentence was clear that it didn't have to be in a licensed facility. Counsel Smiley agreed with Member Crowley and the intent could be conveyed in the legislative proposal.

Motion: Sponsor legislation to amend Business and Professions Code section 4071.1 as presented

M/S: Serpa/Sanchez

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

A representative of Walgreens requested considering opening this for all practice settings.

A pharmacist representative of Kaiser encouraged adding language to (d) to clarify "outside of the facility" as there was ambiguity about definition of "enter" and encouraged the Board to attempt to eliminate ambiguity.

Members were provided the opportunity to comment.

Member Chandler commented there was a lot of policy and logistical information up in the error and cautioned on getting legislation sponsored without the policy and logistical requirements being clarified. Mr. Chandler added the recommended language did not have the guardrails of tying licensure to ensure the remote locations are being held to the same standards.

Member Crowley commented it sounded like existing statute was being clarified or inquired if the proposal was necessary.

Member Serpa was concerned when practice was going beyond the scope of the law and recommended it being very clear as the intent was not in the words and the words need to show the intent.

Member Crowley inquired if Dr. Serpa would consider clarifying the language to add to (d) that the facility is outside of the licensed facility. Dr. Serpa thought that was a helpful commented to support the intent and to clarify the language.

Amended Motion: Sponsor legislation to amend BPC section 4071.1 as presented and to delegate to the Executive Officer, Board President and Counsel the ability to amend to make clear outside of a facility in BPC section 4071.1

M/S: Serpa/Sanchez

Members of the public were provided the opportunity to comment.

A retired pharmacist recommended the Board discuss the option of exercising its enforcement discretion until this issue was resolved. The commenter noted hospitals under 100 beds do not have a pharmacist and other hospitals use this to meet federal requirements. The commenter recommended discussing with CDPH, other entities, and CHA.

Member Chandler made a point of the clarification that the motion was the original motion with the amendment to allow the Board's Executive Officer, President and Counsel to clarify the language so that was clear to be outside of facility in BPC section 4071.1. President Oh confirmed it was the original motion with the amendment to make it clear to be outside of facility in BPC section 4071.1.

Support: 8 Oppose: 2 Abstain: 0 Not Present: 3

Board Member	Vote
Barker	Support
Cameron-Banks	Support
Chandler	Oppose
Crowley	Support
De La Paz	Oppose
Jha	Support
Koenig	Not Present
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Thibeau	Not Present
Weisz	Not Present

President Oh noted the Board was aware of this and will hopefully provide next steps on what needs to be done. Dr. Oh confirmed the Board was aware of the realities.

XIII. Organizational Development Committee Report

President Oh provided an update on several items under the purview of the Organizational Development Committee.

a. Budget Update and Report

Budget Update FY 2022/23
President Oh advised the new fiscal year began July 1, 2022. Dr. Oh reported the Board's spending authorization for the new fiscal year was about $31.3 Million which was 2.5 percent increase from the prior year.

Fund Condition
President Oh provided a review of the fund condition prepared by the Department indicates that at the end of the fiscal year 2021/22, the Board has 5.1 months in reserve. Dr. Oh referenced meeting materials noting under provisions of Pharmacy Law, the Board shall seek to maintain a reserve equal to approximately one year's operating expenditures. Dr. Oh continued the fund condition projects a continued depletion of the Board's fund. Dr. Oh reminded members the Board was attempting to sponsor a fee bill this year.

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

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

b. Board Member Attendance and Mail Vote Information

President Oh reported Board Member attendance and mail vote records were included in the meeting materials.

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

Members of the public were provided the opportunity to comment.

The Board heard a comment from a pharmacist Chief Pharmacy Officer at UCSD who wanted to confirm written comments submitted regarding mandatory reporting errors were received.

c. Personnel Update

President Oh referenced meeting materials the Board has a number of vacancies including a key leadership position noting the vacancy count was higher as the Board received new positions July 1. Dr. Oh's understanding was several of the inspector and licensing position have active recruitments underway. Dr. Oh looked forward to monitoring the progress of these recruitments as filling vacancies would help to reduce processing times and was working with the Executive Officer on recruitment challenges.

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

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

d. Future Meeting Dates

President Oh advised meeting materials contained the meeting calendar for the remainder of the year noting the April Meeting was changed to April 19-20, 2023. Dr. Oh noted the remote meetings will be in place until June 30, 2023, where there may be a possibility that meeting in person will resume.

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

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

XIV. Executive Officer Report

a. Discussion of Board's Response to COVID-19 Pandemic Pending Termination of the State's Declared Emergency

Executive Officer Sodergren advised the Board was continuing wind down activities following the governor's termination of the COVID emergency effective 2/28/23. Ms. Sodergren noted meeting materials highlight waivers and related expiration dates which was May 28, 2023. Ms. Sodergren highlighted the Board's waivers have a different expiration date than the DCA Director. The Board has been doing outreach to clarify misunderstandings with the licensees using the Board's subscriber alert system.

Ms. Sodergren highlighted specific to the use of mobile pharmacies and mobile clinics allowed under BPC section 4062. Ms. Sodergren advised through COVID a number of entities requested the use of mobile pharmacies. The Board issued and approved almost 3,300 mobile pharmacies which must stop being used within 48 hours of the declared emergency which was 2/28/23. The Board has done outreach to those entities but wanted Members to be aware of the different time frames. The was also information in the recent newsletter to understand winding down from COVID and respect to pharmacy law.

b. Discussion on Federal PREP Act and the COVID-19 Federal State of Emergency

Ms. Sodergren reported there had been discussion about the PREP Act referenced meeting materials on the PREP Act and encouraged people to read the information.

Members were provided the opportunity to comment.

Member Chandler noted mobile vaccination sites used in underserved communities were extremely helpful and anticipated it being helpful for future pandemics or future breakouts (e.g., MPX). Mr. Chandler asked if the Board should be discussing a legislative remedy now rather than wait for another emergency.

Ms. Sodergren advised the mobile pharmacies were used for vaccinations because it allowed pharmacy technicians to participate in the process. Ms. Sodergren noted this was something the Licensing Committee may want to consider. Ms. Sodergren noted the mass vaccination sites assisted with the logistics of drug distribution.

Members of the public were provided the opportunity to comment.

A pharmacist representative of Kaiser commented in favor of future discussions for statute and regulation changes for pharmacy technicians to help pharmacists outside of the pharmacy setting.

A representative of CRA inquired about the PREP Act and pharmacy technicians performing vaccinations. With the end of the COVID state of emergency in California being 2/28/23 and all DCA waivers end on that date as well including the DCA waiver that allows pharmacy technicians to perform COVID vaccinations and testing on 2/28/23, the representative stated the federal PREP Act does allow pharmacy technicians to perform both of these tasks as well as flu vaccines the PREP Act won't expire until the fall of 2024. The representative was looking for confirmation as to whether the pharmacy technicians can continue vaccinations and testing through the PREP Act. The representative noted the Board was pursuing legislation that if enacted would go into effect in 2024.

A representative from Walgreens clarified in the discussion related to mobile pharmacies that it was permissible for pharmacists to provide vaccines outside of the pharmacy noting the waiver was to add the pharmacy technicians the ability to provide vaccinations. The representative stated related to the PREP Act that the current statutory provisions for pharmacists related to scope of practice only allow a pharmacist to order CLIA waived tests adding throughout the pandemic, pharmacists have ordered through the PREP Act and DCA waiver clinical labs (e.g., PCR testing for COVID). The representative had concerns with the way the current statute was written that outside of a collaborative practice agreement or physician's order, the pharmacist couldn't order PCR testing for COVID. The representative stated the Board needs to consider and provide guidance.

DCA Counsel Eileen Smiley addressed a few items. Ms. Smiley noted the US Attorney General and the General Counsel of the federal Health and Human Services Agency have concluded that the Secretary's declarations under the PREP Act with respect to pharmacy technicians and pharmacists' ability to perform certain testing and vaccination functions preempt state licensing laws

that would otherwise prevent them from carrying out those functions. Ms. Smiley stated that consequently pharmacists and pharmacy technicians that strictly adhere to this Secretary's PREP Act authorizations including any incorporated EUA or other condition would have an argument that any conflicting state law that would otherwise prohibit them from engaging in the authorized activities is preempted, and a defense to any claim that their actions would be unauthorized under state law. Ms. Smiley continued; however, that Section 3.5 of Article 3 of the California Constitution generally prohibits an administrative agency, including the Board, from declaring that any state statute is unconstitutional or unenforceable unless there is unless an appellate court opinion has declared a state statute unconstitutional or unenforceable. Ms. Smiley added since there hadn't been any specific litigation on how far the PREP Act declarations extends in the disciplinary context and no appellate court opinion on point, the Board is precluded from opining that the PREP Act preempts all state licensing and disciplinary laws. Additionally, Ms. Smiley noted for PREP Act protections to potentially apply as a defense, the person would need to comply precisely with all conditions set out in the Secretary's declaration including any other documents incorporated by reference (e.g., EUA, etc.). Ms. Smiley added a failure to comply with the conditions would place the person outside of the PREP Act protection. Ms. Smiley also stated that e this would require a case-by-case evaluation of each scenario, it would not be prudent or possible for the Board to suggest that the PREP Act preempts state licensing and disciplinary laws. Therefore, Ms. Smiley stated that the Board doesn't have the ability to give legal guidance and opinions to the industry that are being requested. Finally, Ms. Smiley concluded that the we recommend that licensees interested in fully understanding the applicability of the PREP ACT can review the information put out by the federal government and consult with their own counsel.

President Oh thanked Ms. Smiley for the extensive summary and stakeholder participation.

XV. Closed Session Matters

Open session concluded at approximately 2:36 p.m. The Board entered closed session at approximately 2:47 p.m. and ended closed session at 4:07 p.m. The Board Meeting concluded at approximately 4:07 p.m.

Appended to the Minutes for the February 2023 Board Meeting Regarding:

Agenda Item VIII. Communication and Public Education Committee Report

The Communication and Public Education Committee Recommendation (Motion) presented during Agenda Item VIII. Communication and Public Education Committee Report

Committee Recommendation (Motion): Approve the notification form with modification requested and approve the FAQs as presented.

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

NOTIFICATION TO OPERATE OR DISCONTINUE OPERATING A MOBILE UNIT

BPC 4110.5

This form is intended to assist in the notification to operate or discontinue operation of a mobile unit to provide prescription medication within its jurisdiction to those individuals without fixed addresses, individuals living in county-owned or city-and-county-owned housing facilities, and those enrolled in Medi-Cal plans operated by the county or a city and county, a health district, or a joint powers authority.

The mobile unit shall be operated as an extension of a pharmacy license held by the county, city and county, or special hospital authority as provided in Business and Professions Code section 4110.5.

As required, notification to the Board is required at least 30 days prior to commencing operation of a mobile unit. Notice is also required at least 30 days prior to discontinuing operation of a mobile unit.

1. **Enter the Date:** Operation Date: _____ Discontinuance Date: _____

2. **Pharmacy Information**

_____ _____
Pharmacy Name License Prefix & Number

_____ _____
Address Pharmacy: Street City State Zip Code Name of Municipality

_____ _____ _____
Name of Pharmacist-in-Charge (PIC) License # PIC Email Address

3. **The person(s) signing below must be identified on the pharmacy license and have the authority to bind the license.** I certify under penalty of perjury under the laws of the State of California to the truth and accuracy of all statements, answers and representations made on this form including all supplementary statements.

_____ _____ _____
Signature of Authorized Government Authority Listed on the License Name (please print) Date

I certify under penalty of perjury under the laws of the State of California to the truth and accuracy of all statements, answers and representation made on this form including all supplementary statements.

_____ _____ _____
Signature of Pharmacist-in-Charge Name (please print) Date

For Office Use Only
Date Processed: _____ Processed by: _____

Mobile Units – Frequently Asked Questions

1. **Q: What is the difference between a mobile unit and a mobile pharmacy?**

   A: A mobile unit is an extension of a pharmacy license held by the county, city and county, or special hospital authority that provides prescription medication within its jurisdiction to individuals without fixed addresses, individuals living in county-owned or city-and-county-owned housing facilities, and those enrolled in Medi-Cal plans operated by the county or a city and county, a health district, or a joint powers authority pursuant to Chapter 7 (commencing with Section 14000) or Chapter 8 (commencing with Section 14200) of Part 3 of Division 0 of the Welfare and Institutions Code.

   Whereas a mobile pharmacy is used temporarily when a pharmacy is destroyed or damaged, and the mobile pharmacy is necessary to protect the health and safety of the public under specified conditions. The Board must be contacted to approve the use of a mobile pharmacy and the pharmacy must provide the Board with records of the destruction of, or damage to, the pharmacy with an expected restoration date prior to operating a mobile pharmacy.

   A mobile pharmacy can also be employed during a declared federal, state, or local emergency in impacted areas in order to ensure the continuity of patient care under specified conditions, including being located within the declared emergency or affected areas. An approved waiver from the Board is required to operate a mobile pharmacy during a declared emergency.

   (BPC 4062(c), BPC 4110(c), BPC 4110.5)

   Q: How many mobile units may a county, city and county, or special hospital authority pharmacy operate?

   A: A county, city and county, or special hospital authority may only operate one mobile unit.

   (BPC 4110.5)

2. **Q: What "special hospital authority" can operate a mobile unit?**

   A: The special hospital authority that may operate a mobile unit is limited to the Alameda Health System described in Chapter 5 (commencing with Section 101850) and the Kern County Hospital Authority Act describe in Chapter 5.5 (commencing with Section 101852 of Part 4 of Division 101 of the Health and Safety Code.

(BPC 4110.5, HSC 101850, HSC 101852, BPC 4380(a)(3), CCR 1710)

3. **Q: How can a county, city and county, or special hospital authority notify the Board of their intent to operate a mobile unit?**

   A: At least 30 days prior to commencing operations of a mobile unit, the county, city or county, or special hospital authority must notify the board of its intention to operate a mobile unit. To assist with notification requirements, the Board has developed a form that can be accessed here.

   (BPC 4110.5(f)

4. **Q: I am an independent retail pharmacy and would like to service my community by helping the homeless by providing better access in obtaining their medications. Can I operate a mobile unit?**

   A: No, only a county, city and county, or special hospital authority described in Chapter 5 commencing with HSC 101850 or Chapter 5.5 commencing with HSC 101852 may operate a mobile unit to provide prescription medications.

   (BPC 4110.5)

5. **Q: Can a clinic licensed by the Board pursuant to BPC 4180 qualify to operate a mobile unit?**

   A: No, a mobile unit can only be operated as an extension of a pharmacy license.

   (BPC 4110.5)

6. **Q: Our county operates a mobile unit. At the end of the day, can we park the mobile unit in a secured garage located where the pharmacy operating the mobile unit is located? Can we leave the drugs in the mobile unit if the garage has a security gate only accessible with a key fob by authorized personnel, the garage is well lit and there is a security guard that patrols the area?**

   A: No, dangerous drugs must not be left in the mobile unit during the hours the mobile unit is not in operation. Mobile units are extensions of the pharmacy when they are open for business and when not in use the stock of dangerous drugs and devices must be stored in the pharmacy.

   (BP 4110.5(e))

7. **Q: At the end of the day, where can the mobile unit be parked?**

   A: Pharmacy law does not specify where the mobile unit is required to be parked. However, when the mobile unit is not operating, the drugs cannot be left in the mobile unit. Therefore, the Board recommends the mobile unit be parked at or close to the address of the licensed pharmacy since the drugs are required to be stored and secured at the licensed pharmacy operating the mobile unit.

   (BPC 4110.5, CCR 1714(b)(d))

8. **Q: If a county, city and county, or special hospital authority are planning to discontinue the use of a mobile unit, how should the Board be notified?**

   A: Notice must be given to the Board at least 30 days prior to discontinuing the operation of a mobile unit. To assist with notification requirements, the Board has development a form that can be accessed here.

   (BPC 4110.5(f))

9. **Q: Does the mobile unit require the Notice to Consumer poster to be posted in public view?**

   A: Yes, the mobile unit operates as an extension of a pharmacy license. Pharmacy law requires every pharmacy to prominently post in a place that is conspicuous and readable by a prescription drug consumer. The mobile unit must use the standardized poster available by the Board unless the pharmacy has received prior approval of another format or display methodology from the board. The mobile unit can also display the notice on a video screen. In addition to the English version required to be posted, the Notice to Consumer poster is also available in other languages from the board and may be printed from the board's website.

   (BPC 4110.5, CCR 1707.6)

10. **Q: Is the mobile unit required to have hot and cold running water?**

    A: Yes, the mobile unit operates as an extension of a pharmacy license. Therefore, the mobile unit is required to have a sink with hot and cold running water for pharmaceutical purposes.

    (BPC 4110.5, CCR 1714(c))

11. **Q: Who can possess the keys to the mobile unit:**

    A: The mobile unit operates as an extension of a pharmacy license. When drugs are stored in the mobile unit, the key to the mobile unit is restricted to a pharmacist. The pharmacy owner (the county, city and county, or the special

hospital authority) may possess a key to the mobile unit that is maintained in a tamper evident container for the purposes of 1) delivering the key to a pharmacist or 2) providing access in case of emergency that would include fire, flood or earthquake. The signature of the pharmacist-in-charge must be present in such a way that the pharmacist may readily determine whether the key was removed from the container.

(BPC 4110.5, CCR 1714(d)(e))

12. **Q: Can the County pharmacy operate a mobile unit to assist the County's methadone program to dispense methadone to better serve the homeless population?**

    A: No, methadone is classified as a Schedule II controlled substance and a mobile unit cannot carry or dispense controlled substances.

    (BPC 4110.5(d))

13. **Q: What are the staffing limitations for a mobile unit?**

    A: A mobile unit operates as an extension of a pharmacy. Therefore, if the pharmacy operating the mobile unit has a community pharmacy license (PHY or PHE), then the pharmacy with only one pharmacist must have no more than one pharmacy technician performing the tasks specified in BPC 4115(a). Any additional pharmacist, the ratio of pharmacy technicians to pharmacist shall not exceed 2:1.

    (BPC 4110.5, BPC 4115(f)(1))

14. **Q: Can a pharmacist working on a mobile unit provide vaccine administration?**

    A: Yes, the pharmacist may provide vaccine administration. In addition to dispensing prescriptions, the pharmacist may perform activities consistent with pharmacy law listed in Article 3 commencing with BPC 4050.

    (BPC 4110.5(b), BPC 4050-4068)

15. **Q: During the temporary absence of a pharmacist for their 30-minute meal break, can the pharmacist leave the mobile unit leaving the pharmacy technicians and clerks in the mobile unit and continue to fill prescriptions?**

    A: The decision to keep the mobile unit open resides with the pharmacist working in the mobile unit. As part of the decision making, the pharmacy must reasonably believe that the security of the dangerous drugs and devised will be maintained in the pharmacist's absence.

    If the mobile unit remains open during any temporary absence of the pharmacist no prescription medications may be provided to the patient or

patient's agent unless the prescription medication is a refill medication that the pharmacist checked and released for furnishing to the patient and the pharmacist determined that a consultation was not required. The ancillary staff may continue to perform the non-discretionary duties authorized by pharmacy law.

During the temporary absence of the pharmacist, an intern pharmacist may not perform any discretionary duties nor otherwise act as a pharmacist. However, the intern pharmacist may perform non-discretionary tasks such as removing the drugs from stock, counting, pouring, or mixing pharmaceuticals, placing the product into a container, packaging and repackaging.

Note: To operate a mobile unit, a licensed pharmacist must be on the premises and the mobile unit must be under the control and management of a pharmacist except during the pharmacist duty free breaks and 30-minute meal break. Medications should not be dispensed while a pharmacist is on break except for refills released by the pharmacist that do not require a patient consultation.

(BPC 4110.5(a), CCR 1714.1(a)(b)(c)(d)), CCR 1793.2

16. **Q: Our mobile unit has very limited storage space. Where can a mobile unit store its records?**

A: All records required by BPC 4081 and 4105 may be temporarily stored in the mobile unit while in operations. At the end of the day, when the mobile unit is not in operation, all records required by BPC 4081 and 4105 must be transferred and maintained on the licensed pharmacy premises that is operating the mobile unit. All required records must be preserved for at least three years from the date of making. If the licensed pharmacy has an approved waiver for storing records offsite from the board, the records from the mobile unit for non-controlled substances are required to be stored on the licensed pharmacy premise for a period of one year from the date of making. The records beyond one year from the date of making may be stored at the approved offsite storage location.

Note: A mobile unit cannot carry or dispense controlled substances. Therefore, the mobile unit should not have any records for controlled substances.

(BPC 4110.5, BPC 4081, BPC 4105)

17. **Q: Are the prescription labels dispensed by the mobile unit required to have patient centered labeling?**

    A: Yes, all prescription medication dispensed by the mobile unit must comply with all labeling requirements applicable to a California licensed pharmacy, including all the requirements for patient centered labeling. Also, upon request of the patient or patient's representative, the mobile unit must provide translated directions for use printed on the prescription container, label, or on a supplemental document.

    (BPC 4076, BPC 4076.5, CCR 1707.5)

18. **Q: Are pharmacists required to provide consultation for new prescriptions dispensed from the mobile unit?**

    A: Yes, the mobile unit is an extension of the licensed pharmacy. Therefore, the same requirements for consultation pursuant to CCR 1707.2 applies for patient consultation.

    (BPC 4110.5 CCR 1714)

19. **Q: If a physician is practicing in the mobile unit, writes a new prescription for the patient and consults the patient on how to take the new medication, is the pharmacist also required to provide consultation to the patient when the mobile unit dispenses the new prescription to the patient?**

    A: Yes, the pharmacist is still responsible to provide patient consultation pursuant to CCR 1707.2.

    (BPC 4110.5, CCR 1711)

20. **Q: Does a board inspector have the authority to inspect a mobile unit?**
    A: Yes. Inspectors employed by the board may inspect during business hours all pharmacies or places where drugs or devices are compounded, prepared, furnished, dispensed, or stored.
    (BPC 4008)

21. **Q: When the mobile unit is in use, what security and maintenance measures are required for the drugs stocked and patient confidential records in the mobile unit?**
    A: The mobile unit is an extension of the pharmacy. Therefore, the mobile unit is required to maintain its facility, fixtures, and equipment so that drugs are safely and properly prepared, maintained, secured and distributed. The mobile unit, fixtures and equipment must be maintained in a clean and orderly condition. The mobile unit must be dry, well-ventilated, free from rodents and insects, and properly lighted. Each pharmacist while on duty is responsible for the security of

the prescription drugs on the mobile unit, including provisions for effective control against theft or diversion of dangerous drugs and devices, and records. When the mobile unit is not in use, the dangerous drugs and patient confidential records must be safely removed from the mobile unit to the licensed pharmacy.

To ensure security of the drug stock and patient confidential records, the board recommends the mobile unit to consider the following:

- When the mobile unit is in operation, the drugs are secured to prevent drugs from being displaced while the mobile unit is in motion.
- Use of a secured and lockable storage unit for the dangerous drugs and devices, and patient confidential records that is easily transferrable to the licensed pharmacy at the end of the day.
- Coordinating breaks and meal breaks if the pharmacist leaves the mobile unit and the pharmacy technician(s) remain in the mobile unit.
- Relocating the mobile unit to a safe area during meal breaks.

(CCR 1714(b)(c)(d))

Appended to the Minutes for the February 2023 Board Meeting Regarding:

Agenda Item X. Enforcement and Compounding Committee
Agenda Item XI. Discussion and Consideration and Possible Action Related to Proposed Regulations to Amend title 16, CCR section 1715.1 and ADDS Self-Assessment Form

Enforcement and Committee Recommendation (Motion) presented during the February 2023 Board Meeting Agenda Item – X. Enforcement and Compounding Committee Report and tabled until February 2023 Board Meeting Agenda Item XI. – Discussion and Consideration and Possible Action Related to Proposed Regulations to Amend title 16, CCR section 1715.1 and ADDS Self-Assessment Form

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

During Agenda Item XI. Discussion and Consideration and Possible Action Related to Proposed Regulations to Amend title 16, CCR section 1715.1 and ADDS Self-Assessment Form, the Enforcement and Compounding Committee Recommendation was Rejected at the February 7, 2023, Board Meeting.

California State Board of Pharmacy
2720 Gateway Oaks Drive, Ste. 100
Sacramento, CA 95833
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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

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

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

AUTOMATED DRUG DELIVERY SYSTEM SELF-ASSESSMENT

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

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

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

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

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

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

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

Reason for completing self-assessment:

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

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

SECTION 1: DEFINITIONS/TYPE OF ADDS DEVICE USED

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

IDENTIFY THE TYPE OF ADDS DEVICE USED

Yes No N/A

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

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

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

SECTION 2: LOCATION OF DEVICES

Yes No N/A

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

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

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

~~Yes No N/A~~

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

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

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

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

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

Yes No N/A

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

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

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

☐☐☐ 2.10 **A facility licensed in CA with the statutory authority to provide pharmaceutical services**. [BPC 4427.65(a)(1)]
Type of Facility: _____
Statutory authority to provide pharmaceutical services (List code section): _____

☐☐☐ 2.11 **Jail, youth detention facility, or other correctional facility where drugs are administered within the facility under the authority of the medical director**. [BPC 4427.3(b)(6), BPC 4427.65(a)(2)]
Type of Facility: _____
Statutory authority for type of Facility (List code section): _____

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

SECTION 3: GENERAL REQUIREMENTS FOR ALL TYPES OF ADDS

(Answer N/A if licensure not required)

Yes No N/A

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

Yes No N/A

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

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

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

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

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

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

_____

_____

_____

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

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

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

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

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

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

Yes No N/A

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

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

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

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

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

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

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

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

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

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

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

Yes No N/A

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

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

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

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

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

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

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

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

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

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

~~Yes No N/A~~

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

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

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

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

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

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

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

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

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

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

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

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

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

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

_____

_____

_____

_____

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

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

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

☐ SECTION 5: ~~ADDS~~

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

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

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

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

☐ SECTION ~~9~~8:

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

☐ SECTION 9:

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

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

A. GENERAL REQUIREMENTS

Yes No N/A

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

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

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

Yes No N/A

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

☐☐☐ 4.5 The drugs shall be returned to the distributor from which the drugs were obtained if drugs to be dispensed to patient of a covered entity pursuant to section 256b of Title 42 USC cannot be distributed because of a change in circumstances of the covered entity or the pharmacy. [BPC 4126(c)]

☐☐☐ 4.6 A licensee that participates in a contract to dispense preferentially priced drugs pursuant to this section shall not have both a pharmacy and a wholesaler license. [BPC 4126(d)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

_____

_____

_____

_____

B. UNDERLYING OPERATING PHARMACY

Yes No N/A

☐☐☐ 4.7 The operating pharmacy has obtained a license from the Board to operate the APDS which includes the address of the APDS location and the identity of the covered entity or affiliated site. [BPC 4119.11(a)(1)]

☐☐☐ 4.8 A separate license was obtained for each APDS location and has been renewed annually concurrent with the pharmacy license. (Note: The Board may issue a license for operation of an APDS at an address for which the Board has issued another site license.) [BPC 4119.11(a)(1), 4119.11(a)(8), 4107]

☐☐☐ 4.9 A prelicensure inspection of the proposed APDS location was conducted by the Board within 30 days after Board receipt of the APDS application before Board approval. [BPC 4119.11(a)(9)]

Date of Inspection: _____

☐☐☐ 4.10 The pharmacy will submit a new APDS licensure application for Board approval if the current APDS is relocated. [BPC 4119.11(a)(9)]

☐☐☐ 4.11 The pharmacy will notify the Board within 30 days of replacement of an APDS or discontinuing an APDS. [BPC 4119.11(a)(9), 4119.11(a)(11)]

☐☐☐ 4.12 A new APDS licensure application will be submitted if original APDS is cancelled due to the underlying operating pharmacy's permit being cancelled, not current, not valid, or inactive. (Once cancelled, a new APDS license can only be issued if the underlying pharmacy's permit is reissued or reinstated.) [BPC 4119.11(a)(10)]

Yes No N/A

☐☐☐ 4.13 The pharmacy does not have more than 15 APDS licenses for one underlying operating pharmacy under this section. [BPC 4119.11(d)(10), 4427.6(k)] List of current APDS licenses:

1._____ 2. _____

3._____ 4. _____

5._____6. _____

7._____8. _____

9._____10._____

11. _____ 12._____

13._____14. _____

15. _____

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

☐☐☐ 4.14 The operating pharmacy will maintain the written APDS policies and procedures for 3 years after the last date of use for that APDS. [BPC 4119.11(d)(11), CCR 1713(f)]

☐☐☐ 4.15 The operating pharmacy of an APDS has completed a~~n annual~~ biennial Self-Assessment pursuant to CCR 1715.1 or BPC 4427.7(a) evaluating the pharmacy's compliance with pharmacy law relating to the use of the APDS. [BPC 4119.11(i)]

Date of Last Self-Assessment: _____
Reason: ☐ Biennial; ☐ New ADDS; ☐ Change in PIC; ☐ Change in location of ADDS

~~☐-☐-☐ 4.16 The operating pharmacy has complied with all recordkeeping and quality assurance requirements pursuant to BPC 4119.11 and those records will be maintain within the pharmacy holding the APDS and separately from the other pharmacy records. [BPC 4119.11(j)]~~

~~☐-☐-☐ 4.17 The pharmacy is aware that the drugs stored in an APDS are a part of the operating pharmacy's drug inventory and the drugs dispensed by the APDS shall be considered to have been dispensed by that pharmacy. [BPC 4119.11(a)(3)]~~

☐☐☐ 4.1~~8~~6 The underlying operating pharmacy is solely responsible for: [BPC 4119.11(a)(5), (6)]

- ☐ 4.16.1 The security of the APDS. [BPC 4119.11(a)(5)]
- ☐ 4.16.2 The operation of the APDS. [BPC 4119.11(a)(5)]
- ☐ 4.16.3 The maintenance of the APDS. [BPC 4119.11(a)(5)]
- ☐ 4.16.4 The training regarding the operation and use of the APDS for both the pharmacy and covered entity personnel using system. [BPC 4119.11(a)(6)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE: _____
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C. PHARMACIST RESPONSIBILITIES

Yes No N/A

☐☐☐ 4.1~~9~~7 The operation of the APDS is under the supervision of a licensed pharmacist acting on behalf of the operating pharmacy. [BPC 4119.11(a)(7)]. Note: The pharmacist need not be physically present at the site of the APDS and may supervise the system electronically.

☐☐☐ 4.~~20~~18 The pharmacist performs the stocking of the APDS or if the APDS utilizes removable pockets, cards, drawers, similar technology, or unit of use or single dose containers are used, the stocking of the APDS may be done outside of the facility if the following conditions are met: [BPC 4119.11(g)]

- ☐ 4.~~20~~18.1 A pharmacist, intern pharmacist or pharmacy technician working under the supervision of the pharmacist may place drugs into the removeable pockets, cards, drawers, similar technology, or unit of use or single dose containers. [BPC 4119.11(g)(1)]
- ☐ 4.~~20~~18.2 Transportation of removeable pockets, cards, drawers or similar technology o~~O~~r unit of use or single dose container between the pharmacy and the facility are in a tamper-evident container. [BPC 4119.11(g)(2]
- ☐ 4.~~20~~18.3 There are policies and procedures to ensure the removeable pockets, cards, drawers, similar technology, or unit of use or single dose containers are properly placed into the APDS. [BPC 4119.11(g)(3)]

☐☐☐ 4.~~21~~19 ~~The~~ A pharmacist conducts a monthly review of the APDS including a physical inspection of the drugs contained within, operation, maintenance, and cleanliness of the APDS, and a review of all transaction records in order to verify the security and accountability of the APDS. [BPC 4119.11(h)]

Date of Last Review: _____

☐☐☐ 4.~~22~~20 The Pharmacist-in-charge of the offsite ADDS/APDS has ensured the following: [CCR 1715.65(h)]

☐ 4.20.1 All controlled substances added to the ADDS/APDS are accounted for;
☐ 4.20.2 Access to ADDS/APDS is limited to authorized facility personnel;
☐ 4.20.3 An ongoing evaluation of discrepancies or unusual access associated with controlled substance is performed; and
☐ 4.20.4 Confirmed losses of controlled substances are reported to the Board.

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE:

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D. DEVICE REQUIREMENTS

Yes No N/A

☐☐☐ 4.2~~3~~1 Access to the APDS is controlled and tracked using an identification or password system or biosensor. Systems tracked via password shall include a camera that records a picture of the individual accessing the APDS and the picture must be maintained for a minimum of 180 days. [BPC 4119.11(e)]

~~☐☐☐ 4.24 The APDS makes complete and accurate records of all transactions including users accessing system and drugs added and removed from the APDS. [BPC 4119.11(f)]~~

☐☐☐ 4.2~~5~~2 The APDS will collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of APDS. [BPC 4119.11(c)(1)]

☐☐☐ 4.2~~6~~3 The APDS will maintain transaction information in a readily available in downloadable format for review and inspection by authorized individuals for a minimum of 3 years. [BPC 4119.11(c)(2)]

☐☐☐ 4.2~~7~~4The APDS may dispense medications **DIRECTLY** to the patient if **all** the following are met: [BPC 4119.11(d)]

☐ 4.2~~7~~4.1 The pharmacy has developed, ~~and~~ implemented, and maintained~~s~~ written policies and procedures with respect to all the following and the policies are reviewed annually: [BPC 4119.11(d)(1)~~(d)(1)(F)~~, CCR 1713(e)]

☐ 4.24.1.1 Maintaining the security of the APDS and dangerous drug and devices within the APDS.

☐ 4.24.1.2 Determining ~~e~~ and applying inclusion criteria regarding which drugs~~,~~ and devices are appropriate for placement in the APDS and for which patients, including when consultation is needed.

☐ 4.24.1.3 Ensuring patients are aware that consultation with a pharmacist is available for any prescription medication, including those delivered via APDS.

☐ 4.24.1.4 Describing assignment of responsibilities and training of pharmacy personnel, and other personnel using the APDS at that location, regarding maintenance and filling procedures for the APDS.

☐ 4.24.1.5 Orienting patients on the use of APDS and notifying patients when expected medications are not available in the APDS. The pharmacy must ensure the use of the APDS does not interfere with the delivery of drugs and devices.

☐ 4.24.1.6 Ensuring the delivery of drugs and devices to patients expecting medications from the APDS in the event that the APDS is disabled or malfunctions.

Date of Last Policy Review: _____

☐ 4.2~~7~~4.2 The APDS may only be used for patients who have signed a written consent demonstrating their informed consent to receive prescribed drugs and devices from the APDS. Attach a copy of the consent form to the back of the self-assessment. [BPC 4119.11(d)(2), CCR 1713(d)(1)]

~~Yes No N/A~~

☐ 4.2~~7~~4.3 The ~~device~~ APDS shall have a means to identify each patient and only release the identified patient's drugs and devices to the patient or the patient's agent. [BPC 4119.11(d)(3), CCR 1713(d)(3)]

☐ 4.2~~7~~4.4 The pharmacist has performed all clinical services as part of the dispensing process, including, but not limited to, drug utilization review and consultation. [BPC 4119.11(d)(4)]

☐ 4.2~~7~~4.5 Drugs are dispensed from the APDS only upon authorization from the pharmacist after the pharmacist has reviewed the prescription and the patient's profile for potential~~s~~ contraindications and adverse drug reactions. [BPC 4119.11(d)(5)]

☐ 4.2~~7~~4.6 The pharmacist shall consult patients for the first time on all prescribed drugs and devices dispensed from the APDS. The consultation shall be provided by a Board-licensed pharmacist via telecommunication link that has two-way audio and video capabilities. [BPC 4119.11(d)(6)]

☐ 4.2~~7~~4.7 The APDS shall prominently post a notice that provides the name, address and telephone number of the pharmacy [BPC 4119.11(d)(7)]

☐ 4.2~~7~~4.8 The prescription labels on all drugs dispensed via APDS shall comply with BPC 4076 and CCR 1707.5. [BPC 4119.11(d)(8)]

☐☐☐ ~~4.27.9 Any complaint, error or omission involving the APDS shall be reviewed as a part of the pharmacy's quality assurance program pursuant to BPC 4125. [BPC 4119.11(d)(9)]~~

☐☐☐ 4.2~~8~~5 The federal warning label prohibiting transfer of controlled substances is on the prescription container. [21 CFR 290.5]

Yes No N/A

☐☐☐ 4.2~~9~~6 Prescriptions are dispensed in a new and child-resistant container, or senior-adult ease-of-opening tested container, or in a non-complying package only pursuant to the prescriber or when requested by the purchaser. [15 USC 1473(b), 16 CFR 1700.15, CCR 1717]

☐☐☐ 4.~~30~~27 Patient package inserts are dispensed with all estrogen medications. [21 CFR 310.515]

☐☐☐ 4.~~31~~28 The pharmacy provides patients with Black Box Warning Information in conformance with 21 CFR 201.57(c).

☐☐☐ 4.~~32~~29Medication guides are provided on required medications. [~~(~~21 CFR 208.1]~~)~~

☐☐☐ 4.30 The pharmacy uses the APDS to deliver prescription medications to patients as provided: [CCR 1713(d)]

- ☐ 4.30.1 The pharmacist has determined that each patient using the APDS met the inclusion criteria for use of the APDS established by the pharmacy prior to the delivery of the prescription medication to the patient.
- ☐ 4.30.2 The APDS has a means to identify each patient and only release the patient's prescription medications to the patient or patient's agent.
- ☐ 4.30.3 The pharmacy provides an immediate consultation with a pharmacist, either in-person or via telephone, upon the request of a patient.
- ☐ 4.30.4 Any incident involving the APDS where a complaint, deliver error, or omission has occurred shall be reviewed as part of the pharmacy's quality assurance program mandated by Business and Professions Code section 4125.

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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E. RECORD KEEPING REQUIREMENTS

Yes No N/A

☐☐☐ ~~4.33 The operating pharmacy has complied with all recordkeeping and quality assurance requirements pursuant to BPC 4119.11 and those records shall be maintain within the pharmacy holding the APDS and separately from the other pharmacy records. [BPC 4119.11(j)]~~

☐☐☐ ~~4.34 The operating pharmacy will maintain records of acquisition and disposition of dangerous drugs stored in the APDS separate from other pharmacy records. [BPC 4119.11(a)(4)]~~

☐☐☐ 4.3~~5~~1 Any records maintained electronically must be maintained so that the pharmacist-in-charge, or the pharmacist on duty if the pharmacist-in-charge is not on duty, must, at all times during which the licensed premises are open for business, be able to produce a hardcopy and electronic copy of all records of acquisition and disposition or other drug or dispensing-related records maintained electronically. [BPC 4105(d)(1)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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F. POLICIES AND PROCEDURES

Yes No N/A

☐☐☐ 4.3~~6~~2 The pharmacy has developed and implemented written policies and procedures with respect to all the following and the policies are reviewed annually [BPC 4119.11(d)(1), CCR 1713(e)]:

- ☐ 4.32.1 Maintaining the security of the APDS and dangerous drugs and devices within the APDS.
- ☐ 4.32.2 Determine and apply inclusion criteria regarding which drugs, devices are appropriate for placement in the APDS and for which patients, including when consultation is needed.
- ☐ 4.32.3 Ensuring patients are aware that consultation with a pharmacist is available for any prescription medication including those delivered via APDS.
- ☐ 4.32.4 Describing assignment of responsibilities and training of pharmacy personnel and other personnel using the APDS at that location regarding maintenance and filling procedures for the APDS.
- ☐ 4.32.5 Orienting patients on use of the APDS and notifying patients when expected medications are not available in the APDS. The pharmacy must ensure the use of the APDS does not interfere with the delivery of drugs and devices.
- ☐ 4.32.6 Ensuring the delivery of drugs and devices to patients expecting medications from the APDS ~~in the event~~ if the APDS is disabled or malfunctions.

Date of Last Policy Review: _____

☐☐☐ 4.3~~7~~3 The pharmacy has policies and procedures for security measures and monitoring of the inventory to prevent theft and diversion. [BPC 4427.2(d)(3)~~4105.5(c)(2)~~]

☐☐☐ 4.3~~8~~4 The pharmacy reports drug losses as required by law. [BPC 4104, 4427.2(d)(4)~~4105.5(c)~~, CCR 1715.6, 21 CFR 1301.76]

Last Reported Drug Loss: _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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SECTION 5: ~~ADDS~~

- ☐ **APDS ADJACENT TO THE SECURED PHARMACY AREA ~~OR~~**
- ☐ **APDS LOCATED IN MEDICAL OFFICES ~~(OR)~~**
- ☐ **APDS A LOCATION WHERE PATIENTS ARE REGULARLY SEEN FOR PURPOSES OF DIAGNOSIS AND TREATMENT TO ONLY BE USED FOR PATIENTS OF THE PRACTICE~~(OR).~~**
- ☐ **APDS THROUGH A CLINIC PURSUANT TO HSC 1204 OR 1204.1 OR BPC 4180 OR 4190.**

A. GENERAL REQUIREMENTS

Yes No N/A

☐☐☐ 5.1 The pharmacy maintains the APDS policies and procedures for 3 years after the last date of use for that APDS. [BPC 4427.6(l), CCR 1713(f)]

☐☐☐ ~~5.2 The pharmacy developed and implemented, and reviewed annually the APDS policy and procedures pertaining to the APDS, including: [BPC 4427.6(a)]~~

- ~~Maintaining the security of the APDS and the dangerous drugs and devices within the APDS.~~
- ~~Determining and applying inclusion criteria regarding which drugs and devices are appropriate for placement in the APDS and for which patients.~~
- ~~Ensuring patients are aware consultation with a pharmacist is available for any prescription medications, including those delivered via the APDS.~~
- ~~Describing assignment of responsibilities to, and training of, pharmacy personnel and other personnel using the APDS at the location where the APDS is placed, regarding maintenance and filing procedures for the APDS.~~
- ~~Orienting participating patients on the use of the APDS, notifying patients when expected prescription medications are not available in the APDS, and ensuring patient use of the APDS does not interfere with delivery of drugs and devices.~~
- ~~Ensuring delivery of drugs and devices to patients expecting to receive them from the APDS in the event the APDS is disabled or malfunctions.~~

☐☐☐ 5.2 The pharmacy uses the APDS to deliver prescription medications to patients provided: [CCR 1713(d)]

☐ 5.2.1 A pharmacist has determined that each patient using the APDS meets inclusion

criteria for use of the APDS established by the pharmacy prior to deliver of prescription medication to the patient.

☐ 5.2.2 The APDS has a means of identifying each patient and only release that patient's prescription medication to the patient or patient's agent.

☐ 5.2.3 The pharmacy provides an immediate consultation with a pharmacist, either in-person or via telephone, upon the request of a patient.

☐ 5.2.4 Any incident involving the APDS where a complaint, delivery error, or omission has occurred shall be reviewed as part of the pharmacy's quality assurance program mandated by Business and Professions Code section 4125.

Yes No N/A

☐☐☐ 5.3 The pharmacy does not have more than 15 APDS licenses for one underlying operating pharmacy under this section. [BPC 4427.6(k)] List of current APDS licenses:

1._____ 2. _____

3._____ 4. _____

5._____ 6. _____

7._____ 8. _____

9._____ 10._____

11. _____ 12._____

13._____ 14. _____

15. _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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B. PHARMACIST RESPONSIBILITIES:

Yes No N/A

☐☐☐ 5.4 A pharmacist licensed by the board performs all clinical services conducted as part of the dispensing process, including, but not limited to, drug utilization review and consultation. [BPC 4427.6(d)]

☐☐☐ 5.5 Drugs are dispensed from the APDS only upon authorization from the pharmacist after the pharmacist has reviewed the prescription and the patient's profile for potential contraindications and adverse drug reactions. [BPC 4427.6(e)]

Yes No N/A

☐☐☐ 5.6 ~~The pharmacist shall consult patients for the first time on all prescribed drugs and devices dispensed from the APDS.~~ All prescribed drugs and devices dispensed to the patient from the APDS for the first time are accompanied by a consultation conducted by a California licensed pharmacist. The consultation shall be provided by a Board licensed pharmacist via telecommunication link that has two-way audio and video capabilities. [BPC 4427.6(f)]

~~Yes No N/A~~

☐☐☐ 5.7 The ~~P~~pharmacist-in-charge of the offsite ADDS/APDS has ensured the following: [CCR 1715.65(h)]

- ☐ 5.7.1 All controlled substances added to the ADDS/APDS are accounted for;
- ☐ 5.7.2 Access to ADDS/APDS is limited to authorized facility personnel;
- ☐ 5.7.3 An ongoing evaluation of discrepancies or unusual access associated with controlled substance is performed; and
- ☐ 5.7.4 Confirmed losses of controlled substances are reported to the Board.

~~☐-☐-☐ 5.8. The pharmacy operating the APDS has completed an annual Self-Assessment pursuant to CCR 1715 evaluating the pharmacy's compliance with pharmacy law relating to the use of the APDS. [BPC 4427.7(a)]~~

~~Date of Last Self-Assessment: _____~~

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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C. DEVICE REQUIREMENTS:

~~Yes No N/A~~

~~☐-☐-☐ 5.9 The stocking of the APDS is performed by a pharmacist, or by a pharmacy technician or intern pharmacist under the supervision of a pharmacist, except for an APDS located in a health facility pursuant to HSC 1250, where the stocking and restocking of the APDS may be performed in compliance with HSC 1261.6. [BPC 4427.4(e)(1)]~~

~~☐-☐-☐ 5.10 Access to the APDS is controlled and tracked using an identification or password system or biosensor. [BPC 4427.4(e)(2)]~~

~~☐ ☐ ☐ 5.11 The ADDS makes a complete and accurate record of all transactions including all users accessing the system and all drugs added to, or removed from, the system. [BPC 4427.4(e)(3)]~~

~~☐ ☐ ☐ 5.12 Drugs and devices not immediately transferred into an APDS upon arrival at the APDS location are stored for no longer than 48 hours in a secured room within the APDS location. Upon retrieval of these drugs and devices from secured storage, an inventory is taken to detect any losses or overages. [BPC 4427.4(f)]~~

~~☐ ☐ ☐ 5.13 Drugs stored in the APDS are part of the inventory of the operating pharmacy and drugs dispensed by the APDS shall be considered to have been dispensed by the pharmacy. [BPC 4427.4(d)]~~

Yes No N/A

☐☐☐ 5.~~14~~8 The APDS may only be used for patients who have signed a written consent demonstrating their informed consent to receive prescribed drug and devices from the APDS. Attach a copy of the consent form to the back of the self-assessment. [BPC 4427.6(b)]

☐☐☐ 5.~~15~~9 The APDS has a means to identify each patient and only release the identified patient's drugs and devices to the patient or the patient's agent. [BPC 4427.6(c)]

☐☐☐ 5.~~16~~10 The APDS has a notice, prominently posted on the APDS, which provides the name, address, and phone number of the pharmacy. [BPC 4427.6(g)]

☐☐☐ 5.~~17~~11 Any incident involving the APDS where a complaint, error, or omission occurred is reviewed as part of the pharmacy's quality assurance program pursuant to BPC 4125. [BPC 4427.6(i)]

☐☐☐ 5.~~18~~12 If the APDS is located and operated in a medical office or other location where patients are regularly seen for purposes of diagnosis and treatment, the APDS is only used to dispense dangerous drugs and dangerous devices to patients of the practice. [BPC 4427.6(j)]

☐☐☐ 5.~~19~~13 The labels on all drugs and devices dispensed by the APDS comply with section 4076 and with section 1707.5 of Title 16 of the California Code of Regulations. [BPC 4427.6(h)]

☐☐☐ 5.~~20~~14 The federal warning label prohibiting transfer of controlled substances is on the prescription container. [21 CFR 290.5]

☐☐☐ 5.~~21~~15 Prescriptions are dispensed in a new and child-resistant container, or senior-adult ease-of-opening tested container, or in a non-complying package only pursuant to the prescriber or when requested by the purchaser. [15 USC 1473[b], 16 CFR 1700.15, CCR 1717]

☐☐☐ 5.~~22~~16 Patient package inserts are dispensed with all estrogen medications. [21 CFR 310.515]

☐☐☐ 5.~~23~~17 The pharmacy provides patients with Black Box Warning Information in conformance with 21 CFR 201.57(c).

☐☐☐ 5.~~24~~18 Medication guides are provided on required medications. [21 CFR 208.1]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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D. RECORD KEEPING REQUIREMENTS

Yes No N/A

~~☐☐☐ 5.25 The operating pharmacy has complied with all recordkeeping and quality assurance requirements pursuant to BPC 4427.6 and those records shall be maintain within the pharmacy holding the APDS and separately from the other pharmacy records. [BPC 4427.7(b)]~~

☐☐☐ 5.~~26~~19 The operating pharmacy will maintain records of acquisition and disposition of dangerous drugs stored in the APDS separate from other pharmacy records. [BPC 4119.11(a)(4)]

☐☐☐ 5.~~27~~20 Any records maintained electronically must be maintained so that the pharmacist-in-charge, or the pharmacist on duty if the pharmacist-in-charge is not on duty, must, at all times during which the licensed premises are open for business, be able to produce a hardcopy and electronic copy of all records of acquisition and disposition or other drug or dispensing-related records maintained electronically. [BPC 4105(d)(1)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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E. POLICIES AND PROCEDURES

Yes No N/A

☐☐☐ 5.~~28~~21 The pharmacy has developed and implemented written policies and procedures with respect to all the following and the policies are maintained and reviewed annually: [BPC 4427.6(a)~~, 4427.6(a)(6)~~, CCR 1713(e)]

- ☐ 5.21.1 Maintaining the security of the APDS and dangerous drug and devices within the APDS.
- ☐ 5.21.2 Determining~~e~~ and applying inclusion criteria regarding which drugs and~~,~~ devices are appropriate for placement in the APDS and for which patients.
- ☐ 5.21.3 Ensuring patients are aware that consultation with a pharmacist is available for any prescription medication including those delivered via APDS.
- ☐ 5.21.4 Describing assignment of responsibilities and training of pharmacy personnel

and other personnel using the APDS at that location regarding maintenance and filling procedures for the APDS.

☐ 5.21.5 Orienting patients on use of APDS and notifying patients when expected medications are not available in the APDS. The pharmacy must ensure the use of the APDS does not interfere with the delivery of drugs and devices.

☐ 5.21.6 Ensuring the delivery of drugs and devices to patients expecting medications from the APDS in the event the APDS is disabled or malfunctions.

Date of Last Policy Review: _____

Yes No N/A

☐☐☐ 5.~~29~~22 The pharmacy reports drug losses as required by law. [BPC 4104, 4427.2(d)(4)~~4105.5(c)~~, CCR 1715.6, 21 CFR 1301.76]

Last Reported Drug Loss: _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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SECTION 6: ADDS IN A HEALTH FACILITY PURSUANT TO HSC 1250 ~~– LONG TERM CARE FACILITIES~~ THAT COMPLIES WITH HSC 1261.6

A. GENERAL REQUIREMENTS

For purposes of this section, "FACILITY" means any health facility licensed pursuant to ~~subdivision (c), (d), or (k) of~~ section 1250 of the Health and Safety Code that has an ADDS provided by a pharmacy. [HSC ~~1261.6(a)(2)~~ 1250]

For purposes of this section, "PHARMACY SERVICES" means the provision of both routine and emergency drugs and biologicals to meet the needs of the patient, as prescribed by a physician. [HSC 1261.6(a)(3)]

Yes No N/A

~~☐-☐-☐ 6.1 The facility and the pharmacy has developed and implemented written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the ADDS as well as quality, potency, and purity of the stored drugs and devices. [BPC 4427.3(c), HSC 1261.6 (d)(1)]~~

☐☐☐ 6.~~2~~1The ADDS policies and procedures define access to the ADDS and limits to access to equipment and drugs. [HSC 1261.6(d)(1)]

~~☐-☐-☐ 6.3 All ADDS policies and procedures are maintained at the pharmacy and the location where the ADDS is being used. [HSC 1261.6(d)(2), BPC 4427.3(c)]~~

☐☐☐ 6.~~4~~2 The pharmacy is responsible for review of drugs contained within the ADDS and the operation and maintenance of the ADDS. [HSC 1261.6(h)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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B. PHARMACIST RESPONSIBILITIES:

Yes No N/A

☐☐☐ 6.~~5~~3 The stocking of the ADDS is performed by a pharmacist, or, if the ADDS utilizes removable pockets, cards, drawers, similar technology, or unit of use or single dose containers ~~are used~~, the stocking system may be done outside the facility and be delivered to the facility if the following conditions are met: [*BPC 4427.4(e)(1),* 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. [*BPC 4427.4(e)(1),* HSC 1261.6(g)(1)]
- ☐ 6.~~5~~3.2 The removable pockets, cards, drawers, or unit of use or single dose containers are transported between the pharmacy and the facility in a secure tamper-evident container. [HSC 1261.6(g)(2)]
- ☐ 6.~~5~~3.3 The facility, in conjunction with the pharmacy, has developed policies and procedures to ensure that the removable pockets, cards, drawers, or unit of use or single dose containers are properly placed into the ADDS. [HSC 1261.6(g)(3)]

Yes No N/A

☐☐☐ 6.~~6~~4 Individualized and specific access to the ADDS is limited to facility and contract personnel authorized by law to administer drugs. [HSC 1261.6(c)]

☐☐☐ 6.~~7~~5 A pharmacist reviews and approves all orders prior to a drug being removed from the ADDS for administration to a patient. The pharmacist reviews the prescriber's orders and the patient's profile for potential contraindications and adverse drug reactions. [HSC 1261.6(f)(2)]

☐☐☐ 6.6 A Schedule II controlled substance for a patient in a licensed skilled nursing facility or licensed intermediate care facility is dispensed only after the pharmacist has received:

- ☐ 6.6.1 An **orally transmitted** prescription for a Schedule II controlled substance from the prescriber and only after the pharmacist reduced the prescription to writing in ink in the handwriting of the pharmacist on a form developed by the pharmacy. The prescription must contain: [HSC 11167.5(a)]
  - ☐ 6.6.1.1 The date the prescription was orally transmitted by the prescriber.
  - ☐ 6.6.1.2 The name of the person for whom the prescription was authorized.

- ☐ 6.6.1.3 The name and address of the licensed skilled nursing facility or licensed intermediate care facility in which the person is the patient.
- ☐ 6.6.1.4 The name and quantity of the controlled substance prescribed.
- ☐ 6.6.1.5 The directions for use, and the name, address, category of the professional licensure, license number, and federal controlled substance registration number of the prescriber.
- ☐ 6.6.1.6 The prescription is endorsed by the pharmacist with the pharmacy's name, license number, and address.

☐ 6.6.2 Prior to filling a prescription for a Schedule II controlled substance that has been **electronically transmitted,** the pharmacist has produced, signed, and dated a hard copy prescription. The prescription must contain: [HSC 11167.5(a)]

- ☐ 6.6.2.1 The date the prescription was electronically transmitted by the prescriber;
- ☐ 6.6.2.2 The name of the person for whom the prescription was authorized;
- ☐ 6.6.2.3 The name and address of the licensed skilled nursing facility or licensed intermediate care facility in which the person is the patient;
- ☐ 6.6.2.4 The name and quantity of the controlled substance prescribed;
- ☐ 6.6.2.5 The directions for use, and the name, address, category of the professional licensure, license number, and federal controlled substance registration number of the prescriber.
- ☐ 6.6.2.6 The prescription is endorsed by the pharmacist with the pharmacy's name, license number, and address.
- ☐ 6.6.2.7 The prescription contains the signature of the person who received the controlled substance for the licensed skilled nursing facility or licensed intermediate care facility.

☐ 6.6.3 An original Schedule II prescription is written on a form that complies with Health and Safety Code section 11162.1. [HSC 11164(a)]

☐ 6.6.4 An original Schedule II prescription is written with the "11159.2 exemption" for the terminally ill. [HSC 11159.2]

☐ 6.6.5 In an emergency where failure to issue the prescription may result in loss of life or intense suffering, a Schedule II controlled substance may be dispensed from a prescription transmitted orally or electronically by a prescriber or written on a form not as specified in HSC 11162.1, subject to the following: [HSC 11167(a)-(c)]

- ☐ 6.6.5.1 The order contains all information required by subdivision (a) of Section 11164.

☐ 6.6.5.2 If the order is written by the prescriber, the prescription is in ink, signed, and dated by the prescriber.

☐ 6.6.5.3 If the prescription is orally or electronically transmitted, it must be reduced to hard copy.

☐ 6.6.5.4 The prescriber provides a written prescription on a controlled substance form that meets the requirements of HSC 11162.1 by the seventh day following the transmission of the initial order.

☐ 6.6.6 An electronic prescription (e-script) for controlled substances that is received from the prescriber and meets federal requirements. [21 CFR 1306.08, 21 CFR 1311]

Yes No N/A

☐☐☐ 6.~~8~~7 The review of the drugs contained within the ADDS and the operation and maintenance of the ADDS is conducted, on a monthly basis, by a pharmacist. The review includes a physical inspection of the ADDS for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system. [HSC 1261.6(h)]

Date of Last Review: _____

☐☐☐ 6.~~9~~8 The p~~P~~harmacist-in-charge of the offsite ADDS has ensured the following: [CCR 1715.65(h)]

- ☐ 6.8.1 All controlled substances added to the ADDS are accounted for;
- ☐ 6.8.2 Access to ADDS is limited to authorized facility personnel;
- ☐ 6.8.3 An ongoing evaluation of discrepancies or unusual access associated with controlled substance is performed; and
- ☐ 6.8.4 Confirmed losses of controlled substances are reported to the Board.

☐☐☐ 6.~~10~~9 The pharmacy operating the ADDS has completed a~~n~~ biennial Self-Assessment pursuant to BPC 4427.7(a) evaluating the pharmacy's compliance with pharmacy law relating to the use of the APDS. ~~(~~[BPC 4427.7(a)]~~)~~

Date of Last Self-Assessment: _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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C. DEVICE REQUIREMENTS:

Yes No N/A

☐☐☐ 6.~~11~~10 The stocking and restocking of the ADDS is performed in compliance with section 1261.6 of the Health and Safety Code. [BPC 4427.4(e)(1), HSC 1261(c), (g)]

~~☐☐☐ 6.12 Drugs and devices not immediately transferred into an ADDS upon arrival at the ADDS location are stored for no longer than 48 hours in a secured room within the ADDS location. Upon retrieval of these drugs and devices from secured storage, an inventory is taken to detect any losses or overages. [BPC 4427.4(f)]~~

~~Yes No N/A~~

☐☐☐ 6.~~13~~11 Transaction information from the ADDS will be made readily available in a written format for review and inspection by individuals authorized by law and maintained in the facility for a minimum of three years. [HSC 1261.6(b)]

☐☐☐ 6.~~14~~12 The information required by BPC section 4076 and HSC 111480 is readily available at the time of drug administration if unit dose packaging or unit of use packaging is used. Unit dose packaging, for purposes of this section, includes blister pack cards. [HSC 1261.6(i)]

When the ADDS is used as an emergency pharmaceutical supplies container, drugs removed from the ADDS are limited to the following [HSC 1261.6(e)]:

~~Yes No N/A~~

☐☐☐ 6.~~15~~13 A new drug order given by a prescriber for a patient of the facility for administration prior to the next scheduled delivery from the pharmacy, or 72 hours, whichever is less. The drug is retrieved only upon the authorization of a pharmacist and after the pharmacist has reviewed the prescriber's order and the patient's profile for potential contraindications and adverse drug reactions. [HSC 1261.6(e)(1)]

☐☐☐ 6.~~16~~14 Drugs that a prescriber has ordered for a patient on an as-needed basis, if the utilization and retrieval of those drugs are subject to ongoing review by a pharmacist. [HSC 1261.6(e)(2)]

☐☐☐ 6.~~17~~15 Drugs designed by the patient care policy committee or pharmaceutical service committee of the facility as emergency drugs or acute onset drugs. These drugs are retrieved from the ADDS pursuant to the order of a prescriber for emergency or immediate administration to a patient of the facility and reviewed by a pharmacist within 48 hours. [HSC 1261.6(e)(3)]

When the ADDS is used to provide pharmacy services pursuant to BPC 4017.3, the ADDS is subject to the following requirements [HSC 1261.6(f)]:

~~Yes No N/A~~

☐☐☐ 6.~~18~~16 Drugs removed from the ADDS for administration to a patient are in properly labeled units of administration containers or packages. [HSC 1261.6(f)(1)]

☐☐☐ 6.~~19~~17 A pharmacist reviews and approves all orders prior to a drug being removed from the ADDS for administration to a patient. The pharmacist reviews the prescriber's orders and the patient's profile for potential contraindications and adverse drug reactions. [HSC 1261.6(f)(2)]

☐☐☐ 6.~~20~~18 The pharmacy controls access to the drugs stored in the ADDS. [HSC 1261.6(f)(3)]

~~☐☐☐ 6.21 Access to the ADDS is controlled and tracked using an identification or password system or biosensor. [BPC 4427.4(e)(2), HSC 1261.6(f)(4)]~~

~~☐☐☐ 6.22 The ADDS makes a complete and accurate record of all transactions that includes all users accessing the system and all drugs added to, or removed from, the system. [BPC 4427.4(e)(3), HSC 1261.6(f)(5)]~~

Yes No N/A

☐☐☐ 6.~~23~~19 After the pharmacist reviews the prescriber's order, access by licensed personnel to the ADDS is limited only to drugs ordered by the prescriber and reviewed by the pharmacist and that are specific to the patient. [HSC 1261.6(f)(6)]

☐☐☐ 6.~~24~~20 When the prescriber's order requires a dosage variation of the same drug, licensed personnel only have access to the drug ordered for that scheduled time of administration. [HSC 1261.6 (f)(6)]

☐☐☐ 6.~~25~~21 If the ADDS allows licensed personnel to have access to multiple drugs and ~~are~~ is not patient specific in its~~their~~ design, the ADDS has electronic and mechanical safeguards in place to ensure that the drugs delivered to the patient are specific to that patient. ~~(~~[HSC 1261.6(f)(7)]~~)~~.

Please Note: A skilled nursing facility or intermediate care facility using an ADDS that allows licensed personnel to have access to multiple drugs is required to contact the California Department of Public Health, Licensing, and Certification in writing prior to utilizing this type of ADDS. [HSC 1261.6(f)(7)(A)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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D. RECORD KEEPING REQUIREMENTS

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

~~☐☐☐ 6.26 The pharmacy complies with all recordkeeping and quality assurance requirements, established in pharmacy law and regulation, and maintains those records within the licensed pharmacy holding the ADDS license and separate from the other pharmacy records. [BPC 4427.7(b)]~~

Yes No N/A

☐☐☐ 6.~~27~~22 Transaction information from the ADDS will be made readily available in a written format for review and inspection by individuals authorized by law and maintained in the facility for a minimum of three years. [HSC 1261.6(b)]

☐☐☐ 6.23 Records of inspections completed by the pharmacist are kept for at least three years. [HSC 1261.6(b), 22 CCR 70263(f)(3)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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E. POLICIES AND PROCEDURES

Yes No N/A

☐☐☐ 6.~~28~~24 The facility and the pharmacy has developed and implemented written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the ADDS as well as quality, potency, and purity of the stored drugs and devices. [BPC 4427.3(c), HSC 1261.6(d)(1)]

☐☐☐ 6.~~29~~25 The ADDS policies and procedures define access to the ADDS and limits to access to equipment and drugs. [HSC 1261.6(d)(1)]

☐☐☐ 6.~~30~~26 All ADDS policies and procedures are maintained at the pharmacy and the location where the ADDS is being used. [HSC 1261.6(d)(2), BPC 4427.3(c)]

☐☐☐ 6.~~31~~27 The facility, in conjunction with the pharmacy, has developed policies and procedures to ensure that the removable pockets, cards, drawers, or unit of use or single dose containers are properly placed into the ADDS. [HSC 1261.6(g)(3)]

~~☐☐☐ 6.32 The pharmacy has policies and procedures that include appropriate security measures and monitoring of the inventory to prevent theft and diversion. [BPC 4427.2(d)(3)]~~

☐☐☐ 6.~~33~~28 The pharmacy's policies and procedures include provisions for reporting to the board drug losses from the ADDS inventory, as required by law. [BPC 4104, 4427.2(d)(4), CCR 1715.6, 21 CFR 1301.76]

Last Reported Drug Loss: _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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~~**SECTION 7: APDS THROUGH A CLINIC PURSUANT TO HSC 1204 OR 1204.1 OR BPC 4180 OR 4190**~~

A. GENERAL REQUIREMENTS

Yes No N/A

☐☐☐ 7.1 The ADDS is located inside an enclosed building with a premises address, at a location approved by the Board [BPC 4427.3 (a)]. The clinic has a current Board of Pharmacy Clinic license pursuant to BPC 4180 or BPC 4190? or the clinic is licensed pursuant to HSC 1204 or 1204.1. [BPC 4427.3(b)(3)]

License number: _____ Expiration Date: _____

☐☐☐ 7.2 The clinic has developed and implemented written policies and procedures that ensure the safety, accuracy, accountability, security and patient confidentiality. Additionally, the policies and procedures shall ensure the maintenance of the quality, potency and purity of the drugs. **The policies and procedures shall be maintained at the location where the ADDS is being used.** [BPC 4186(a)]

☐☐☐ 7.3 Drugs removed from the ADDS shall be provided to the patient by a health professional licensed pursuant to BPC 4186(b).

☐☐☐ 7.4 The clinic is responsible for the review of the drugs contained within, and the operation and maintenance of, the ADDS. [BPC 4186(d)]

☐☐☐ 7.5 Drugs dispensed from the clinic ADDS shall comply with labeling requirements in BPC 4076 with CCR 1707.5. [BPC 4186(g), 4426.7(h)]

☐☐☐ 7.6 The clinic shall keep records of the kind and amounts of drugs purchased, administered, and dispensed and the records shall be available and maintained for a minimum of three years for inspection by all authorized personnel. [BPC 4180(a)(2)]

☐☐☐ 7.7 The proposed ADDS installation location meets the requirement of BPC 4427.3 and the ADDS is secure from access and removal by unauthorized individuals. [BPC 4427.2(d)(2)]

☐☐☐ 7.8 The clinics licensed under BPC 4180 or BPC 4190 perform periodic inventory and inventory reconciliation functions to detect and prevent the loss of controlled substances. [CCR 1715.65(a)]

☐☐☐ 7.9 The clinic shall compile an inventory reconciliation report of all **federal Schedule II controlled substance** at least every three months. [CCR 1715.65(c)] The compilation requires:

- A physical count (not estimate) of all quantities of all **federal Schedule II controlled substances.**
- A review of all acquisition and disposition records of **federal Schedule II controlled substances** since that last inventory reconciliation report:

Date of last inventory_____

- A comparison of (1) and (2) to determine if there are any variances.
- All records used to compile each inventory reconciliation report shall be maintained at clinic for 3 years in a readily retrievable form.
- Possible causes of overages shall be identified in writing and incorporated into the inventory reconciliation report.

Yes No N/A

☐☐☐ 7.10 The clinic shall report in writing identified drug losses and known cause to the Board within 30 days of discovery. Cases of the loss is due to theft, diversion or self-use shall be reported to the Board within 14 days of discovery. If the clinic is unable to identify the cause of loss, further investigation shall be undertaken to identify the cause and actions necessary to prevent additional losses of controlled substances. [CCR 1715.65(d)]

☐☐☐ 7.11 The individuals performing the inventory AND the clinic professional director shall date and sign the inventory reconciliation reports. The reports shall be readily retrievable at the clinic for 3 years. [CCR 1715.65(e)]

☐☐☐ 7.12 Any incident involving the APDS where a complaint, error, or omission has occurred is reviewed as part of the pharmacy's quality assurance program pursuant to BPC 4125. [BPC 4427.6(i)]

☐☐☐ 7.13 The federal warning label prohibiting transfer of controlled substances is on the prescription container. [21 CFR 290.5]

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

☐☐☐ 7.15 Patient package inserts are dispensed with all estrogen medications. [21 CFR 310.515]

☐☐☐ 7.16 The pharmacy provides patients with Black Box Warning Information in conformance with 21 CFR 201.57(c).

☐☐☐ 7.17 Medication guides are provided on required medications. [21 CFR 208.1]

☐☐☐ 7.18 Is the APDS located and operated only used to dispense dangerous drugs and dangerous devices to patients of the clinic? [BPC 4427.6j)]

☐☐☐ 7.19 Does the pharmacy have no more than 15 ADDS licensed as APDS units? [BPC 4427.6(k)]
List of current APDS licenses:

1. _____ 2. _____

3. _____ 4. _____

5. _____ 6. _____

7. _____ 8. _____

9. _____ 10. _____

11. _____ 12. _____

13. _____ 14. _____

15. _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE _____

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B. PHARMACIST RESPONSIBILITY

Yes No N/A

☐☐☐ 7.20 The pharmacist performs the stocking of the ADDS. [BPC 4186(c)]

☐☐☐ 7.21 Drugs are removed from the ADDS system only upon the authorization of the pharmacist after the pharmacist has reviewed the prescription and patient profile for potential contraindications and adverse drug reactions. [BPC 4186(b)]

☐☐☐ 7.22 The pharmacist shall conduct a review on a monthly basis including a physical inspection of the drugs in the ADDS for cleanliness and a review of all transaction records in order to verify the security and accountability of the ADDS. [BPC 4186(d)]

Date of Last Review: _____

☐☐☐ 7.23 The pharmacist licensed by the board performs all clinical services conducted as part of the dispensing process, including, but not limited to, drug utilization review and consultation. [BPC 4427.6(d)]

Yes No N/A

☐☐☐ 7.24 Drugs are dispensed from the APDS after the pharmacist has reviewed the prescription and the patient's profile for potential contraindications and adverse drug reactions. [BPC 4427.6(e)]

☐☐☐ 7.25 All prescribed drugs and devices dispensed to the patient from an APDS for the first time shall be accompanied by a consultation conducted by a pharmacist licensed by the board via telecommunication link with a two-way audio and video. [BPC 4427.6(f)]

☐☐☐ 7.26 The APDS has a notice, prominently posted on the APDS, with the name, address, and phone number of the pharmacy holding the ADDS license for the APDS. [BPC 4427.6(g)]

☐☐☐ 7.27 The pharmacist shall provide patient consultation pursuant to CCR 1707.2 via a two-way audio and video telecommunication link for drugs dispensed by the clinic ADDS. [BPC 4186(e)]

☐☐☐ 7.28 The pharmacist operating the ADDS shall be located in California. [BPC 4186(f)]

☐☐☐ 7.29 The clinic consultant pharmacist shall review all inventory and inventory reconciliation reports taken and establish and maintain secure methods to prevent losses of controlled substances. The clinic shall develop written policies and procedures for performing the inventory reconciliation reports. (CCR 1715.65(b))

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

C. POLICIES AND PROCEDURES

Yes No N/A

☐☐☐ 7.32 The pharmacy has developed and implemented, and reviewed annually, written policies and procedures pertaining to the APDS, including all the following: [BPC 4427.6(a)]

- Maintaining the security of the APDS and dangerous drugs and dangerous devices within the APDS.
- Determining and applying inclusion criteria regarding which drugs and devices are appropriate for placement in the APDS and for which patients.
- Ensuring patients are aware consultation with a pharmacist is available for any prescription medication, including those delivered via the APDS.
- Describing assignments of responsibilities to, and training of, pharmacy personnel, and other personnel using the APDS at the location where the APDS is placed pursuant to subdivision (b) of section 4427.3, regarding maintenance and filing procedures for the APDS.
- Orienting participating patients on the use of the APDS, notifying patient when expected prescription medications are not available in the APDS, and ensuring the patient use of the APDS does not interfere with delivery of drugs and devices.
- Ensuring delivery of drugs and devices to patients expecting to receive them from the APDS in the event the APDS is disabled or malfunctions.

Date of Last Policy Review: _____

Yes No N/A

~~☐☐☐ 7.33 Is the APDS only used for patients who have signed a written consent form demonstrating their informed consent to receive prescribed drugs and devices from an APDS, and whose use of the APDS meets inclusion criteria established by policies and procedures. [BPC 4427.6(b)]~~

~~☐☐☐ 7.34 The APDS shall have a means of identifying each patient and only release the identified patient's drugs and devices to the patient or patient's agent. [BPC 4427.6(c)]~~

~~☐☐☐ 7.35 The pharmacy holding the ADDS license for an APDS maintains its policies and procedures for three (3) years after the last date of use of an APDS. [BPC 4427.6(l)]~~

~~☐☐☐ 7.36 Does the pharmacy maintain all recordkeeping and quality assurance requirements established in pharmacy law and regulations, and maintain these records within the licensed pharmacy holding the ADDS license and separate from other pharmacy records. [BPC 4427.7(b)]~~

SECTION ~~8~~7: ADDS OPERATED BY A CORRECTIONAL CLINIC

A. GENERAL REQUIREMENTS

Yes No N/A

☐☐☐ 7~~8~~.1 The pharmacy uses an "automated drug delivery system" used in a correctional clinic, meaning a mechanical system controlled remotely by a pharmacist that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of prepackaged dangerous drugs or dangerous devices. An automated drug delivery system shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability. [BPC 4187.5(h)]

☐☐☐ 7~~8~~.2 The ADDS is located in a "correctional clinic," a primary care clinic, as referred to in subdivision (b) of section 1206 of the Health and Safety Co~~n~~de, conducted, maintained, or operated by the state to provide health care eligible patients of the Department of Corrections and Rehabilitation. ~~(~~[BPC 4187(a)].

~~Yes No N/A~~

☐☐☐ 7~~8~~.3 The correctional clinic licensed by the board obtains the drugs from a licensed correctional pharmacy, the Department of Correction and Rehabilitation's Central Fill Pharmacy, or from another correctional clinic licensed by the board within the same institution for the administration or dispensing of drugs or devices to patients eligible for care at the correctional facility if under either: [BPC 4187.1(a), 4187.2]

- The direction~~s~~ of a physician and surgeon, dentist, or other person lawfully authorized to prescribe.
- An approved protocol as identified within the ~~statewide Inmate Medical Services Policies and Procedures.~~ California Correctional Health Care Services Health Care Department Operations Manual. [BPC 4187.2]

☐☐☐ 7~~8~~.4 The dispensing or administering of drugs in the correctional clinic is performed pursuant to a chart order, as defined in section 4019, a valid prescription consistent with chapter 9 division 2 of the Business and Professions Code, or pursuant to an approved protocol as identified within the ~~statewide Inmate Medical Services Policies and Procedures.~~ California Correctional Health Care Services Health Care Department Operations Manual. [BPC 4187.1(b), 4187.2]

Yes No N/A

☐☐☐ 7~~8~~.5 Medications dispensed to patients that are kept on the patient's person for use shall meet the labeling requirements of section 4076 and all record~~-~~keeping requirements of chapter 9 division 2 of the Business and Professions Code. [BPC 4187.1(b)]

☐☐☐ 7~~8~~.6 The correctional clinic keeps records of the kind and amounts of drugs acquired, administered, transferred, and dispensed. The records must be readily available and maintained for a minimum of three years for inspection by all properly authorized personnel. [BPC 4187.1(c)]

☐☐☐ 7~~8~~.7 The correctional clinic has obtained a license from the board. [BPC 4187.1(d)(1)]

☐☐☐ 7~~8~~.8 A separate license was obtained for each correctional clinic location where an APDS is located and is not to be transferrable. [BPC 4187.1(d)(2)]

☐☐☐ 7~~8~~.9 The correctional clinic's location and address is identified by the correctional institution and building within the correctional institution. [BPC 4187.1(d)(3)]

☐☐☐ 7~~8~~.10 The correctional clinic will notify the board in advance of any change in the clinic's address on a form furnished by the board. [BPC 4187.1(d)(4)]

~~☐☐☐ 8.11 The ADDS is secured from access and removal by unauthorized individuals. [BPC 4427.2(d)(2)]~~

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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B. POLICIES AND PROCEDURES

Yes No N/A

☐☐☐ 7~~8~~.1~~2~~1 The policies and procedures to implement the laws and regulations of this article within the correctional clinic was developed and approved by the statewide Correctional Pharmacy and Therapeutics Committee referenced in section 5024.2 of the Penal Code. [BPC 4187.2(a)]

☐☐☐ 7~~8~~.1~~3~~2 Prior to the issuance of the correctional clinic license by the board, an acknowledgment of the policies and procedures was signed by the correctional facility pharmacist-in-charge

servicing the institution, the pharmacist-in-charge for the California Department of Correction and Rehabilitation's Central Fill Pharmacy, and the correctional clinic's chief medical executive, supervising dentist, chief nurse executive, and chief executive officer. [BPC 4187.2(a)]

Yes No N/A

☐☐☐ 7~~8~~.1~~4~~3 The chief executive officer is responsible for the safe, orderly and lawful provision of pharmacy services. [BPC 4187.2(b)(1)]

☐☐☐ 7~~8~~.1~~5~~4 The pharmacist-in-charge of the correctional facility shall implement the policies and procedures developed and approved by the statewide Correctional Pharmacy and Therapeutics Committee referenced in section 5042.2 of the Penal Code and the ~~statewide Inmate Medical Services~~ California Correctional Health Care Services ~~Policies and Procedures~~ Health Care Department Operations Manual in conjunction with the chief executive officer, the chief medical executive, the supervising dentist, and the chief nurse executive. [BPC 4187.2(b)(1)]

☐☐☐ 7~~8~~.1~~6~~5 The licensed correctional clinic will notify the board within 30 days of any change in the chief executive officer on a form furnished by the board. [BPC 4187.2(b)(2)]

☐☐☐ 7~~8~~.1~~7~~6 Schedule II, III, IV or V controlled substances may be administered by health care staff of the licensed correctional clinic lawfully authorized to administer pursuant to a chart order, as defined in section 4019, a valid prescription consistent with chapter 9 division 2 of the Business and Professions Code, or pursuant to an approved protocol as identified within the ~~statewide Inmate Medical Services Policies and Procedures~~ California Correctional Health Care Services Health Care Department Operations Manual. [BPC 4187.2, 4187.3]

☐☐☐ 7~~8~~.1~~8~~7 The ADDS located in a licensed correctional clinic has implemented the statewide Correctional Pharmacy and Therapeutics Committee's policies and procedures and the ~~statewide Inmate Medical Services~~ California Correctional Health Care Services Health Care Department Operations Manual ~~Policies and Procedures~~ to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the quality, potency, and purity of drugs. [BPC 4187.5(a)]

☐☐☐ 7~~8~~.1~~9~~8 All policies and procedures are maintained either in an electronic form or paper form at the location where the ~~automated drug system~~ ADDS is being used. [BPC 4187.5(a)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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C. PHARMACIST RESPONSIBILITIES

Yes No N/A

☐☐☐ 7~~8~~.~~20~~19 A correctional facility pharmacist inspects the clinic at least quarterly. [BPC 4187.2(c)]

☐☐☐ 7~~8~~.~~21~~20 Drugs removed from the ~~automated drug system.~~ADDS ~~is~~ are removed upon authorization by a pharmacist after the pharmacist has reviewed the prescription and the patient profile for potential contraindications and adverse drug reactions. ~~If the correctional pharmacy is closed,~~ Where administration of the drug is necessary before a pharmacist has reviewed the prescription and if, in the prescriber's professional judgment, a delay in therapy may cause patient harm, the medication may be removed from the ~~automated drug delivery system.~~ADDS and administered or furnished to the patient under the direction of the prescriber. Where the drug is otherwise unavailable, a medication may be removed and administered or furnished to the patient pursuant to an approved protocol as identified within the ~~statewide Inmate Medical Services Policies and Procedures.~~California Correctional Health Care Services Health Care Department Operations Manual. Any removal of the medication from an ~~automated drug delivery~~ ADDS ~~system~~ is documented and provided to the correctional pharmacy when it reopens. [BPC 4187.5(b)]

Yes No N/A

☐☐☐ 7~~8~~.~~22~~21 The review is conducted on a monthly basis by a pharmacist and shall include a physical inspection of the drugs in the ~~automated drug delivery system.~~ADDS, an inspection of the ~~automated drug delivery system.~~ADDS machine for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system. [BPC 4187.5(e)]

Date of Last Review: _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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D. DEVICE REQUIREMENT

Yes No N/A

☐☐☐ 7~~8~~.~~23~~22 Drugs removed from the ADDS ~~is~~ are provided to the patient by a health professional licensed pursuant to division 2 of the Business and Professions Code who is lawfully authorized to perform the task. [BPC 4187.5(c)]

☐☐☐ 7~~8~~.~~24~~23 The review of the drugs contained within, and the operation and maintenance of, the ADDS shall be the responsibility of the correctional clinic. [BPC 4187.5(e)]

☐☐☐ 7~~8~~.~~25~~24 The ADDS is operated by a licensed correctional pharmacy. Any drugs within the ADDS are considered owned by the licensed correctional pharmacy until they are dispensed from the ADDS. [BPC 4187.5(f)]

☐☐☐ 7~~8~~.~~26~~25 Drugs from the ADDS in the correctional clinic are removed by a person authorized to stock the ADDS, or by a person lawfully authorized to administer or dispense the drugs. [BPC 4187.5(g)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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E. RECORD KEEPING REQUIREMENTS

Yes No N/A

☐☐☐ 7~~8~~.~~27~~26 All records of manufacture and of sale, acquisition, receipt, shipment, or disposition of dangerous drugs or dangerous devices, at all times during business hours, are open for inspection by authorized officer of the law and ~~is~~are preserved for at least three years from the date of making. A current inventory is kept by the licensed correctional clinic. [BPC 4081(a)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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SECTION ~~9~~8:

☐ **DRUG ROOM: AUDS ~~used for dispensing pursuant to BPC 4056 (Drug Room) or BPC 4068 (Hospital Pharmacy is closed and no pharmacist is available)~~ USED FOR DISPENSING PURSUANT TO BPC 4056 (DRUG ROOM) OR**

☐ **HOSPITAL PHARMACY: AUDS USED FOR DISPENSING PURSUANT TO BPC 4068**

Please Note: Hospital pharmacies and drug rooms must also complete Section 6 for ADDS used for administration. This section addresses additional requirements for hospital pharmacies and drug rooms operating an ADDS uses for dispensing.

A. GENERAL REQUIREMENTS

Yes No N/A

☐☐☐ 8~~9~~.1 The licensed drug room does not employ a full-time pharmacist and the AUDS is used for administration and dispensation by a physician to persons registered as inpatients of the hospital, to emergency cases under treatment in the hospital, or to outpatients if the physician determines that it is in the best interest of the patient that a particular drug regimen be immediately commenced or continued, and the physician reasonably believes that a pharmacy located outside the hospital is not available and accessible at the time of dispensation to the patient within 30 minutes of the hospital pharmaceutical services or within a 30-mile radius by means of the method of transportation the patient states they ~~he/she~~ intend to use. The quantity dispensed is limited to the amount necessary to maintain uninterrupted therapy, but shall not exceed a 72-hour supply. [BPC 4056(a), (f)]

☐☐☐ 8~~9~~.2 ~~The~~ Where the prescriber in a hospital emergency room dispenses a dangerous drug, including a controlled substance, from the AUDS to an emergency room patient, the following conditions apply [BPC 4068(a)]:

- ☐ 8.2.1 ~~when t~~ The hospital pharmacy is closed and there is no pharmacist available in the hospital.
- ☐ 8.2.2 The drugs ~~is~~ are acquired by the hospital pharmacy.
- ☐ 8.2.3 The dispensing information is recorded and provided to the pharmacy when the pharmacy reopens.
- ☐ 8.2.4 The hospital pharmacy retains the dispensing information and, if the drug is a schedule II, schedule III, or schedule IV controlled substance, reports the dispensing information to the Department of Justice pursuant to Section 11165 of the Health and Safety Code.
- ☐ 8.2.5 The prescriber determines it is in the best interest of the patient that a particular drug regimen be immediately commenced or continued, and the prescriber reasonable believes that a pharmacy located outside the hospital is not available and accessible at the time of dispensing to the patients.
- ☐ 8.2.6 The quantity dispensed is limited to the amount necessary to maintain uninterrupted therapy when pharmacy services outside the hospital are not readily available or accessible, and shall not exceed a 72-hour supply. ~~[BPC 4068(a)(1-6)]~~
- ☐ 8.2.7 The prescriber ensures that the label on the drug contains all the information required by BPC section 4076.

Yes No N/A

☐☐☐ 8.3 The operating pharmacy has obtained a license from the Board to operate the AUDS that is used for administration and dispensing which includes the address of the AUDS location. [BPC 4427.2(i)]

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

☐☐☐ ~~9.3~~8.4 The prescriber ensures the label on the drug contains all the information required by BPC 4076 and~~,~~ CCR 1707.5.

☐☐☐ ~~9.4~~8.5 The federal warning label~~s~~ prohibiting transfer of controlled substances is on the prescription container. [21 CFR 290.5]

☐☐☐ ~~9.5~~8.6 The prescription drug is dispensed in a new and child-resistant container, or senior-adult ease-of-opening tested container, or in a non-complying package only pursuant to the request of the prescriber or patient. [15 USC 1473(b), 16 CFR 1700.15, CCR 1717]

☐☐☐ ~~9.6~~8.7 The hospital pharmacy or drug room reports the dispensing information of a Schedule II, III or IV controlled substance to the Dept of Justice pursuant to HSC 11165 as soon as

reasonably possible, but not more than seven days after the date a controlled substance is dispensed. [BPC 4068(a)(4), HSC 11165(d)]

☐☐☐ ~~9.7~~8.8 Patient package inserts are dispensed with all estrogen medications. [21 CFR 310.515]

Yes No N/A

☐☐☐ ~~9.8~~8.9 The hospital has written policies and procedures to ensure each patient receives information regarding each drug given at the time of discharge or dispensed from a prescriber from a drug room, including the use and storage of each drug, the precautions and relevant warnings, and the importance of compliance with directions. [BPC 4074(e)]

~~☐☐☐ 9.9 The operating pharmacy has obtained a license from the Board to operate the AUDS that is used for administration and dispensing which includes the address of the AUDS location. [BPC 4427.2(i)]~~

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

☐☐☐ 8.10 Medication guides are provided on required medications. [21 CFR 208.1]

☐☐☐ 8.11 Black box warning information is in conformance with 21 CFR 201.57(c).

☐☐☐ 8.12 Whenever an opioid prescription drug is dispensed to a patient for outpatient use, the pharmacy or practitioner dispensing the drug prominently displays on the label or container, by means of a flag or other notification mechanism attached to the container, a notice that states, "Caution: Opioid. Risk of overdose and addiction." [BPC 4076.7]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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SECTION 9 – AUDS THROUGH A FACILITY LICENSED IN CALIFORNIA WITH STATUTORY AUTHORITY TO PROVIDE PHARMACEUTICAL SERVICES (OR) AUDS THROUGH A JAIL, YOUTH DETENTION FACILITY, OR OTHER CORRECTIONAL FACILITY WHERE DRUGS ARE ADMINISTERED WITH THE FACILITY UNDER THE AUTHORITY OF THE MEDICAL DIRECTOR.

A. GENERAL REQUIREMENTS

Yes No N/A

☐☐☐ 9.1 Review of the drugs contained within, and the operation and maintenance of, the ADDS is done in accordance with law and is the responsibility of the pharmacy. A pharmacist conducts the review on a monthly basis, which includes a physical inspection of the drugs in the ADDS, an inspection of the ADDS for cleanliness, and a review of all transaction records in order to verify the security and accountability of the ADDS. [BPC 4427.65(c)(7)]

Date of Last Review: _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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B. PHARMACIST RESPONSIBILITIES:

Yes No N/A

☐☐☐ 9.2 The stocking of an ADDS is performed by a pharmacist. If the ADDS utilizes removable pockets, cards, drawers, similar technology, or unit of use or single dose containers, as defined by the United States Pharmacopoeia, the stocking system may be done outside of the facility and be delivered to the facility, if all the following conditions are met: [BPC 4427.65(c)(6)]

☐ 9.2.1 The task of placing drugs into the removable pockets, cards, drawers, or unit of use or single dose containers is performed by a pharmacist, or by an intern pharmacist or a pharmacy technician working under the direct supervision of a pharmacist.

☐ 9.2.2 The removable pockets, cards, drawers, or unit of use or single dose containers are transported between the pharmacy and the facility in a secure tamper-evident container.

☐ 9.2.3 The facility, in conjunction with the pharmacy, has developed policies and procedures to ensure that the removable pockets, cards, drawers, or unit of use or single dose containers are properly placed into the ADDS.

☐☐☐ 9.3 The pharmacist-in-charge of a pharmacy servicing an onsite or offsite ADDS ensures the following: [CCR 1715.65(h)]

☐ 9.3.1 All controlled substances added to an ADDS are accounted for.

☐ 9.3.2 Access to the ADDS is limited to authorized facility personnel.

☐ 9.3.3 An ongoing evaluation of discrepancies or unusual access associated with controlled substances is performed.

☐ 9.3.4 Confirmed losses of controlled substances are reported to the board.

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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C. DEVICE REQUIREMENTS:

Yes No N/A

☐☐☐ 9.4 Individualized and specific access to the ADDS is limited to facility and contract personnel authorized by law to administer drugs. [BPC 4427.65(c)(2)]

When the ADDS is used as an emergency pharmaceutical supplies container, drugs removed from the ADDS are limited to the following [BPC 4427.65(c)(4)]:

Yes No N/A

☐☐☐ 9.5 A new drug order given by a prescriber for a patient of the facility for administration prior to the next scheduled delivery from the pharmacy, or 72 hours, whichever is less. The drugs are retrieved only upon authorization by a pharmacist and after the pharmacist has reviewed the prescriber's order and the patient's profile for potential contraindications and adverse drug reactions. [BPC 4427.65(c)(4)(A)]

☐☐☐ 9.6 Drugs that a prescriber has ordered for the patient on an as-needed basis, if the utilization and retrieval of the drugs are subject to ongoing review by the pharmacist. [BPC 4427.65(c)(4)(B)]

☐☐☐ 9.7 Drugs designed by the patient care policy committee or pharmaceutical service committee of the facility as emergency drugs or acute onset drugs. These drugs may be retrieved from the ADDS pursuant to the order of the prescriber for emergency or immediate administration to the patient of the facility. Within 48 hours after retrieval, the case is reviewed by the pharmacist. [BPC 4427.65(c)(4)(C)]

When the ADDS is used to provide pharmacy services pursuant to BPC 4017.3, the ADDS is subject to the following requirements [BPC 4427.65(c)(5)]:

☐☐☐ 9.8 The drugs removed from the ADDS for administration to a patient are in properly labeled units of administration containers or packages. [BPC 4427.65(c)(5)(A)]

☐☐☐ 9.9 The pharmacist reviewed and approved all orders prior to a drug being removed from the ADDS for administration to the patient. The pharmacist reviewed the prescriber's order and the patient's profile for potential contraindications and adverse drug reactions. [BPC 4427.65(c)(5)(B)]

☐☐☐ 9.10 The pharmacy providing services to the facility controls the access to the drugs stored in the ADDS. [BPC 4427.65(c)(5)(C)]

☐☐☐ 9.11 After the pharmacist reviews the prescriber's order, access by licensed personnel to the ADDS is limited only to drugs ordered by the prescriber and reviewed by the pharmacist and that are specific to the patient. When the prescriber's order requires a dosage variation of the same drug, licensed personnel has access to the drug ordered for that scheduled time of administration. [BPC 4427.65(c)(5)(F)]

☐☐☐ 9.12 ADDS that allow licensed personnel to have access to multiple drugs and are not patient specific in their design, shall be allowed if the ADDS has electronic and mechanical safeguards in place to ensure the drugs delivered to the patient are specific to the patient. [BPC 4427.65(c)(5)(G)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

D. RECORD KEEPING REQUIREMENTS

Yes No N/A

☐☐☐ 9.13 Transaction information shall be made readily available in a written format for review and inspection by individuals authorized by law and are maintained in the facility for a minimum of three years. [BPC 4427.65(c)(1)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

E. POLICIES AND PROCEDURES

Yes No N/A

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

☐☐☐ 9.15 The facility and the pharmacy has developed and implemented written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the quality, potency, and purity of stored drugs. The policies and procedures define access to the ADDS and limits to access to equipment and drugs. [BPC 4427.5(c)(3)(A)

☐☐☐ 9.16 All policies and procedures are maintained at the pharmacy operating the ADDS and the location where the ADDS is being used. [BPC 4427.5(c)(3)(B)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

CERTIFICATION ACKNOWLEDGMENT

PHARMACIST-IN-CHARGE CERTIFICATION:

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

Signature _____ Date _____
(Pharmacist-in-Charge)

ACKNOWLEDGMENT BY OWNER *OF THE PHARMACY OR HOSPITAL ADMINISTRATOR OPERATING THE ~~OF~~* ADDS:

I, ~~*(please print)*~~ _____ *[insert name and title]*, hereby certify under penalty of perjury *under ~~of~~* the laws of the State of California that I have *full authority, without any limitations to provide this certification, that I am the Owner of the Pharmacy or the Hospital Administrator Operating the ADDS and that I have reviewed this form, and acknowledge that all facts and information stated herein is true, correct and complete.* ~~*read and reviewed this completed self-assessment.*~~ *Further,* I understand that failure to correct any deficiency identified in this self-assessment could result in the revocation of the automated drug delivery system's license issued by the California State Board of Pharmacy.

Signature _____ Date _____

CERTIFICATION OF COMPLETED ACTION PLAN

PHARMACIST-IN-CHARGE CERTIFICATION:

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

Signature _____Date _____
(Pharmacist-in-Charge)

ACKNOWLEDGMENT BY *OF THE PHARMACY OR HOSPITAL ADMINISTRATOR OPERATING THE ~~OF~~* ADDS:

I, ~~*(please print)*~~ _____ *[insert name and title]*, hereby certify under penalty of perjury *under* ~~*of*~~ the laws of the State of California that I have *full authority, without any limitations to provide this certification, that I am the Owner of the Pharmacy or the Hospital Administrator Operating the ADDS and that I have reviewed this form, and acknowledge that all facts and information stated herein is true, correct and complete.* ~~*read and reviewed this completed self-assessment.*~~ *Further,* I understand that failure to correct any deficiency identified in this self-assessment could result in the revocation of the automated drug delivery system's license issued by the California State Board of Pharmacy.

Signature _____Date _____