Attachment IV. Approval of Board Meeting Minutes

a. February 6-7, 2023, Board Meeting

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
DRAFT 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~~23~~)~~) 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.

Attachment IV. Approval of Board Meeting Minutes

b. March 15, 2023, Board Meeting

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

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

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

Date: March 15, 2023

Location: Note: Pursuant to the provisions of Government Code section 11133, neither a public location nor teleconference locations are provided

Board Members Present:
Seung Oh, Licensee Member, President
Maria Serpa, Licensee Member, Vice President
Indira Cameron-Banks, Public Member
Trevor Chandler, Public Member
Jessica Crowley, Licensee Member
Jose De La Paz, Public Member
Kartikeya "KK" Jha, Licensee Member
Kula Koenig, Public Member
Jason Weisz, Public Member

Board Members Not Present:
Jignesh Patel, Licensee Member, Treasurer
Renee Barker, Licensee Member
Ricardo Sanchez, Public Member
Nicole Thibeau, Licensee Member

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

March 15, 2023

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

President Oh called the Board Meeting to order at approximately 9:04 a.m.

President 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.

President Oh advised all individuals the meeting was being conducted via WebEx. Dr. Oh advised participants watching the webcast they could only observe the meeting. Dr. Oh 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.

Roll call was taken. Board Members present included: Maria Serpa, Licensee Member; Trevor Chandler, Public Member; Jessi Crowley, Licensee Member; Jose De La Paz, Public Member; KK Jha, Licensee Member; Jason Weisz, Public Member; and Seung Oh, Licensee Member. A quorum was established.

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

Members of the public were provided with an opportunity to provide comment for items not on the agenda or agenda items for a future meeting.

The Board heard a comment from a representative of Shaw Yoder Antwih Schmelzer & Lange (SYASL) on behalf of the California State Association of Psychiatrists. The representative advised there were problems with dispensing medication around the country as a result of large opioid settlements. The representative added specifically large retail chains were making it difficult for patients to get medications needed for mental illness. The representative advised protocols were put into place to required psychiatrists and patients to jump through hoops to get medications. The representative requested the Board add to a future agenda an item to discuss and collaboration between the Board, pharmacies, pharmacists, psychiatrists, advocates for the mentally ill and other groups.

The Board heard comments about licensing processing times and pending legislation. Counsel Smiley advised the comments were not appropriate for the agenda item. Ms. Smiley advised to contact the Executive Officer.

Member were asked if they would like to add any items to future agendas. Member Serpa requested to get additional information about the issue raised by the SYASL representative to understand the scope of the issue. President Oh noted it could be discussed and added to a future agenda if needed after being discussed.

Member Cameron-Banks joined the meeting at 9:22 a.m.

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

President Oh reminded members several years ago, 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 were 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. Discussion, Consideration and Possible Action to Sponsor Legislation to Amend Business and Professions Code section 4427.8 Related to Legislative Report on the Regulation of Automated Drug Delivery Systems

President Oh reported the Board was required to report to the Legislature on the regulation of automated drug delivery systems. Dr. Oh noted as included Business and Professions Code (BPC) section 4427.8, the report was due on or before January 1, 2024, as part of the Board's sunset review evaluation. Dr. Oh added in response to the COVID-19 health emergency, the Board's sunset date was changed; however, a conforming change to align the ADDS legislative report was not made.

President Oh advised staff were recommending sponsorship of a technical change to the language in BPC section 4427.8 to update the due date for submission of the legislative report, to align with the Board's sunset process. Dr. Oh understood that such a change could potentially be facilitated as an omnibus change that could be done through a Legislative Committee sponsored measure. Dr. Oh added being comfortable with the staff recommendation and noted the meeting materials include a possible motion.

Members were provided the opportunity to comment. Member Crowley requested clarification for the report due date being one year before the sunset date. Executive Officer Sodergren clarified the report was typically due one year before the sunset date to allow time for the review during the legislative process.

Motion: Pursue an amendment to Business and Professions Code section 4427.8(b) as follows:

4427.8. … (b) On or before January 1, ~~2024~~ 2025, as part of the board's sunset evaluation process, and notwithstanding Sections 9795 and 10231.5

of the Government Code, the board shall report to the appropriate committees of the Legislature on the regulation of ADDS units as provided in this article. At a minimum, this report shall require all of the following: …

M/S: Crowley/Chandler

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

Support: 7 Oppose: 0 Abstain: 1 Not Present: 5

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

VIII. Petitions for Reinstatement of Licensure, Early Termination or Other Modification of Penalty.

Administrative Law Judge Jessica Wall presided over the hearings. Petitions heard by members as a committee included:

a. Radford K. Henriquez, RPH 61884

The Board took a break from 10:00 a.m. to 10:10 a.m. Roll call was taken. Board Members present included: Maria Serpa, Licensee Member; Trevor Chandler, Public Member; Jessi Crowley, Licensee Member; Jose De La Paz, Public Member; KK Jha, Licensee Member; Jason Weisz, Public Member; and Seung Oh, Licensee Member. A quorum was established.

b. Henry Nguyen, RPH 52399

Member Cameron-Banks returned to the meeting at approximately 10:21 a.m.

c. So Hyung Kim, INT 47051
d. Apothecary Pharmacy, PHY 46250
e. Ronald Clinton, RPH 46778

The Board took a break from 12:00 p.m. to 12:45 p.m. Roll call was taken. Board Members present included: Maria Serpa, Licensee Member; Indira Cameron-Banks, Public Member; Trevor Chandler, Public Member; Jessi Crowley, Licensee Member; Jose De La Paz, Public Member; KK Jha, Licensee Member; Kula Koenig, Public Member; Jason Weisz, Public Member; and Seung Oh, Licensee Member. A quorum was established.

f. Afshin Yoram Shamooni, RPH 57014

Counsel Smiley announced pursuant to Government Code section 11126.3 subdivision (a) in addition to the closed session items listed on the agenda, the Board would also be meeting to discuss a recent case entitled Absolute Pharmacy LLC doing business as Absolute Pharmacy and Andreas Dieter Dettlaff versus the California State Board of Pharmacy and Anne Sodergren filed in Los Angeles Superior Court Case Number 22 STCP 04253. Ms. Smiley advised the Board would also be discussing in closed session entitled Joel Abergel and The Druggist Inc. vs. California State Board of Pharmacy, in the Los Angeles Superior Court, case number 21STCP01008.

IX. Closed Session

Open session concluded at approximately 1:40 p.m. The Board entered closed session at approximately 1:50 p.m. and ended closed session at 3:43 p.m. The Board Meeting concluded at approximately 3:43 p.m.