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
Enforcement and Compounding Committee Meeting Minutes

Date: June 11, 2025

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

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

PUBLIC PARTICIPATION AND COMMENT FROM REMOTE LOCATIONS VIA WEBEX

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

Board Members Not Present:
Jeff Hughes, Public Member
Ricardo Sanchez, Public Member

Staff Present:
Anne Sodergren, Executive Officer (Webex)
Julie Ansel, Deputy Executive Officer
Lori Martinez, Chief of Legislation, Policy and Public Affairs
Corinne Gartner, DCA Counsel
Jennifer Robbins, DCA Regulations Counsel
Debbie Damoth, Senior Administration Manager

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

Chairperson Serpa called the meeting to order at approximately 9:08 a.m. Dr. Serpa reminded everyone that the Board is a consumer protection agency charged with administering and enforcing Pharmacy Law. Department of Consumer Affairs' staff provided instructions for participating in the meeting.

Roll call was taken. The following members were present via Webex: Renee Barker, Licensee Member; Seung Oh, Licensee Member; Nicole Thibeau, Licensee Member; and Maria Serpa, Licensee Member. A quorum was established.

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

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

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

Members of the public participating via Webex were provided the opportunity to comment.

A member of the public requested the Board become more transparent regarding how settlements are reached for community pharmacies. DCA Counsel noted the Committee could not discuss open citations.

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

III. Approval of Draft Minutes from the March 27, 2025 Enforcement and Compounding Committee Meeting

The draft minutes of the March 27, 2025 Enforcement and Compounding Committee meeting were presented for review and approval. Members were provided the opportunity to comment; however, no comments were made.

Motion: Approve March 27, 2025 Enforcement and Compounding Committee meeting minutes as presented.

M/S: Oh/Barker

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

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

Board Member	Vote
Barker	Support
Hughes	Not Present
Oh	Support
Sanchez	Not Present
Serpa	Support
Thibeau	Support

IV. Annual Presentation on the Board's Inspection Program

Chairperson Serpa advised strategic objective 2.3 of the Board's strategic plan calls for completion of routine inspections of all licensed pharmacies at least every four years to proactively assess pharmacy operations and educate licensees. Annually, the Committee receives a presentation providing summary information detailing accomplishments towards this objective. Dr. Serpa commended Board staff on their significant efforts to meet the Board's strategic goal.

Dr. Serpa welcomed Deputy Executive Officer Julie Ansel to provide the annual inspection presentation. Ms. Ansel provided an overview of the Board's inspection process including observations, items reviewed, what's inspected, and education of licensees. Ms. Ansel reviewed historical trends of inspections completed, types of inspections, routine inspections including outcomes, top violations, and top corrections.

Dr. Serpa recalled comments from members of the public at previous Board meetings regarding hospital pharmacies' request to provide inspection data divided by pharmacy license type. Dr. Serpa requested next year's inspection data be broken down by license type as it may be more informative to licensees.

Following the presentation, members were provided the opportunity to comment. Members thanked Board staff for their efforts in this accomplishment. Members discussed creating a fact sheet or *Script* article on orders of corrections, notice of violations, and possible outcomes.

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

V. Annual Presentation on the Board's Citation Program – Anne Sodergren, Executive Officer

Chairperson Serpa advised consistent with strategic objective 2.2, on an annual basis the Committee receives a presentation on the citation and fine program that includes information on common violations. The information shared during the annual presentation generally is also provided in the Board's newsletter, providing education to licensees about the most common violations for which citations are issued.

Dr. Serpa welcomed Executive Officer Anne Sodergren to provide the annual citation program. Ms. Sodergren reminded members and participants depending on the nature and severity of the violations, the Board has various tools to use ranging from education, issuance of a letter of admonishment, or issuance of a citation (with or without a fine). Ms. Sodergren reviewed the complaint and citation process; and relevant law including fine authority. Ms. Sodergren provided an overview of factors considered in assessing administrative fines and reviewed citation statistics. Ms. Sodergren reviewed top violations by license type as well as related to duty to consult. Ms. Sodergren provided an overview of orders of abatement and abatement statistics. Ms. Sodergren highlighted the appeal process and appeal outcomes.

Following the presentation, members were provided the opportunity to comment. A member requested additional information on what qualifies as "unlicensed activity." Ms. Sodergren explained it encompasses a wide range of factors and provided an example. A member requested clarification on the average days to complete a citation. Ms. Sodergren explained the data reflected the entire timelines from the receipt of the complaint and the initiation of the investigation, through the norming and review stages, culminating in the issuance of the citation.

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

VI. Presentation on Quality Assurance Reports Received Pursuant to California Code of Regulations, Title 16, Section 1711(f) Related to the Use of Automated Drug Delivery Systems

Chairperson Serpa advised that Business and Professions Code (BPC) section 4427.8 required the Board, on or before January 1, 2025, to report to the Legislature on the regulation of automated drug delivery system (ADDS) units as part of the sunset evaluation process. This report was submitted to the Legislature in January of 2025. In addition, Title 16 CCR Section 1711(f) established an ongoing reporting requirement for any quality assurance record related to the use of an ADDS.

Dr. Serpa noted the Committee received presentations related to the findings of the Quality Assurance (QA) reports which revealed what appeared to be a lack of compliance with reporting requirements. Staff continues to educate licensees on the reporting requirements. Dr. Serpa thanked everyone for submitting reports and the staff for performing additional education about the mandatory reporting.

Dr. Serpa welcomed Supervising Inspector Janice Dang, PharmD, to provide the presentation on the data received through these reports. Dr. Dang provided an overview of the ADDS system and provided ADDS licensing statics from July 2024 to April 2025. Dr. Dang provided information about the ADDS medication error reporting requirements and ADDS Quality Assurance reporting requirements.

Dr. Dang provided an overview of the data collected. She reviewed the types of ADDS related medication errors by ADDS location including correctional clinics, skilled nursing facilities, inside a pharmacy, and a few hospitals.

Dr. Serpa noted it appeared there may still be an underreporting of QA records for ADDS and confusion on the reporting requirements. She further noted that over the next year, the Board will continue outreach and education efforts.

Dr. Serpa emphasized that 16 CCR section 1711(d) requires all medication errors discovered are subject to a quality assurance review and for errors related to an ADDS there are two separate reporting requirements. Dr. Serpa reviewed each reporting requirement. Dr. Oh added that for unlicensed

ADDS used in a pharmacy, for purposes of counting and pouring, those medication errors need to be reported at the time of renewal.

Dr. Oh requested inspectors make it priority to remind pharmacies that they must report ADDS medication errors.

Members discussed developing a standardized template for ADDS quality assurance reporting.

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

Members of the public were provided the opportunity to comment via Webex. A hospital pharmacy director commented that clarification is needed on what needs to be reported. Dr. Dang reminded members that there are ADDS FAQs on the website to help clarify. A representative from Scripps Health expressed concern that QA reports were peer reviewed and therefore protected. The representative further expressed concern that licensees may refrain from reporting errors due to fear that doing so may lead to disciplinary action.

Dr. Serpa suggested staff review the FAQs to provide more clarity.

The Committee took a break from 10:56 a.m. to 11:15 a.m. Roll call was taken. The following members were present via Webex: Renee Barker, Licensee Member; Seung Oh, Licensee Member; Nicole Thibeau, Licensee Member; and Maria Serpa, Licensee Member.

VII. Discussion and Consideration of Updates to Frequently Asked Questions Related to the Board's Ask An Inspector Program

Dr. Serpa noted the Board provides a service where inspectors and staff respond to verbal and written inquiries from licensees. The Board has compiled a list of FAQs that it has received through this program. Recommended updates to the FAQs were included in the meeting materials. Dr. Serpa provided a summary of the updates.

Members were provided the opportunity to comment. Dr. Thibeau spoke in support of the updates and suggested a disclaimer be added that the Ask An Inspector Program will not result in an investigation or inspection from the

Board. Dr. Oh recommended adding in a response to question 1 to clarify that an electronic signature is acceptable. Dr. Oh further recommended adding additional language to the Health and Safety code with the caveat that pharmacies can dispense the remaining portion of a controlled substance prescription if it's not dispensed originally within 30 days from the written date. Dr. Oh noted that the response to question 17 may change if the Sunset Bill is approved.

Members discussed various viewpoints related to question 18 and deferred further consideration to a future committee meeting.

Motion: Recommend approval of the updated FAQs related to the Board's Ask An Inspector Program consistent with the Committee's discussion.

M/S: Thibeau/Oh

Members of the public participating in Sacramento and via Webex were provided the opportunity to comment. A member of the public noted that the nametag requirement was not in the pharmacy law book and felt that question 18 adds confusion as healthcare practitioners seems specific to pharmacists and not clear about technicians.

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

Board Member	Vote
Barker	Support
Hughes	Not Present
Oh	Support
Sanchez	Not Present
Serpa	Support
Thibeau	Support

VIII. Discussion and Consideration of Updates to Frequently Asked Questions Related to Assembly Bill 1286 (Haney, Chapter 470, Statutes of 2023)

Dr. Serpa advised FAQs were developed due to the comprehensive nature of Assembly Bill 1286. Last year, the Board approved the Institute for Safe Medication Practices (ISMP) as the entity to receive medication error reports from community pharmacies under BPC 4113.1. Board staff updated the FAQs to include this information as well as information about the California Medication Reporting (CAMER). Meeting materials included the updated FAQs.

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

Motion: Approve FAQs as presented

M/S: Oh/ Thibeau

Members of the public participating from Sacramento and via Webex were provided the opportunity to comment. A representative of Scripps Health felt it was not clear whether they should be licensing hospital pharmacies and requested clarification. Legal counsel directed members to FAQ number one which defined community pharmacy in the statute.

Members were provided the opportunity to comment. Members discussed criteria for hospital (HSP license type) versus out-patient hospital pharmacies (PHY license type).

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

Board Member	Vote
Barker	Support
Hughes	Not Present
Oh	Support
Sanchez	Not Present
Serpa	Support
Thibeau	Support

The Committee took a break from 11:50 a.m. to 11:55 a.m. Roll call was taken. The following members were present via Webex: Renee Barker, Licensee Member;

Seung Oh, Licensee Member; Nicole Thibeau, Licensee Member; and Maria Serpa, Licensee Member.

IX. Discussion and Consideration of the Committee's Strategic Objectives

Dr. Serpa provided an overview of the Committee's strategic objectives. Dr. Serpa was proud of the Committee's accomplishments and looked forward to continued efforts.

Dr. Serpa acknowledged the progress staff made in strategic objective in 2.1, noting the Institute for Safe Medication Practices (ISMP) had been approved by the Board as the entity to receive medication error reports from community pharmacies under BPC 4113.1. Medication errors that occur on or after September 1, 2025, must be reported to the California Medication Error Reporting (CAMER).

Dr. Serpa acknowledged the progress staff made in meeting the strategic objective in 2.3, noting additional assigned routine inspections were made to reach the four-year inspection goal.

Dr. Serpa also acknowledged the progress made in meeting strategic objective 2.4. Proposed amendments to BPC sections 4081 and 4105 were included in the Board's sunset measure, AB 1503. In addition, the Board implemented a new digital process to streamline the investigative process and reduce investigation time frames.

Dr. Serpa next highlighted that the Committee had been working on strategic goal 2.5 for several years, and provisions to transition pharmacist practice to a more robust standard of care practice model were included in AB 1503.

Related to strategic objective 2.8, Dr. Serpa noted that the Board implemented a new learning management system for licensees to complete Board-provided continuing education (CE), including the newly required PIC training course. She further noted that strategic objective 2.10, regarding the Board's compounding regulations, resulted in five formal comment periods, a regulatory hearing, and extensive review and discussion over the course of multiple public meetings. The Board approved final regulatory text in March 2025 and thereafter submitted the final rulemaking file to the Office of Administrative Law.

Finally, Dr. Serpa highlighted that the Committee added strategic objective 2.11, regarding evaluating barriers to consultation, in November of 2024. The Committee will continue to discuss this issue at a future meeting.
Members were provided the opportunity to comment. Members discussed strategic objective 2.5 in relation to the Committee's completed work, noting that further action remains for the Board. Member Barker expressed gratitude for the work being done in meeting strategic objective 2.6.

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

X. Discussion, Consideration, and Possible Action on Proposal to Add New Section 1707.51 Related to Accessible Prescription Drug Labels to Article 2 of Division 17 of Title 16 of the California Code of Regulations

Dr. Serpa recalled during the October 2024 meeting the Committee discussed implementation activities for measures signed by the governor, including Assembly Bill 1902, a measure related to prescription drug label accessibility. During the Committee's March 2025 meeting, the Committee agreed that the Board's regulations should focus on ensuring pharmacies developed policies and procedures to define how compliance with the legislation would be achieved. During the April 2025 Board meeting, Board members spoke in support of the recommended approach. Meeting materials included draft regulation text.

Members were provided the opportunity to comment. Dr. Oh spoke in support of the text agreeing clarification was requested on whether a spoken or verbal label would meet the requirements, given that some individuals do not read Braille. Members were referred to (3) which noted pharmacies should describe the process and the inclusion of any deviations from the law. Members further discussed the possibility of adding FAQs in the future.

Motion: Recommend initiation of a rulemaking to add California Code of Regulations, title 16, section 1707.51 consistent with the Committee's discussion. Authorize the executive officer to further refine the language consistent with the Committee's discussion and make any nonsubstantive changes prior to presenting the proposed rulemaking to the Board.

M/S: Oh/ Thibeau

Members of the public participating via Webex were provided the opportunity to comment. A member of the public asked the Committee to consider the administrative burden placed on licensees and consider the removal of subsection (b), which says the pharmacy personnel must read and sign a copy and maintain a copy in the pharmacy.

Members were provided the opportunity to comment. Members discussed whether (b) should be removed. No consensus was reached on the removal of (b); therefore, the text will be sent to the Board as written.

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

Board Member	Vote
Barker	Support
Hughes	Not Present
Oh	Support
Sanchez	Not Present
Serpa	Support
Thibeau	Support

XI. Discussion and Consideration of Enforcement Statistics

Dr. Serpa advised the meeting materials included a summary of the enforcement statistics for the first eight months of fiscal year 2024/25. The Board initiated 2,850 complaints and closed 2,597 investigations. As of May 31, 2025, the Board had 1,582 field investigations pending. The meeting materials provided a breakdown of the average timeframe for the various stages of the field investigation process.

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

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

XII. Future Committee Meeting Dates

Dr. Serpa advised the next meeting was scheduled for October 16, 2025.

XIII. Adjournment

The meeting adjourned at 12:30 p.m.