



**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  
Enforcement and Compounding Committee Meeting Minutes**

**Date:** July 17, 2024

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

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

PUBLIC PARTICIPATION AND COMMENT FROM  
REMOTE LOCATIONS VIA WEBEX

**Board Members**

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

**Board Members Not**

**Present:** Indira Cameron-Banks, Public Member  
Jeff Hughes, Public Member

**Staff Present:**

Anne Sodergren, Executive Officer  
Julie Ansel, Deputy Executive Officer  
Corinne Gartner, DCA Counsel  
Jennifer Robbins, DCA Counsel  
Debbie Damoth, Executive Specialist Manager

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

Chairperson Serpa called the meeting to order at approximately 9:00 a.m. As part of the opening announcements, Chairperson Serpa reminded everyone that the Board is a consumer protection agency charged with administering and enforcing Pharmacy Law. Department of Consumer Affairs' staff provided instructions for participating in the meeting.

Roll call was taken. The following members were present via WebEx: Renee Barker, Licensee Member; 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 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 were provided the opportunity to comment via WebEx.

A civil engineer and pain advocate commented on ongoing controlled substances shortages made worse by the state attorney generals' nationwide opioid settlement with the three major drug distributors. The commenter requested prioritization of the agenda item to discuss the injunctive threshold issue.

A representative of CSHP and individual pharmacist requested the discussion of enforcement of AB 352 related to the letter from the attorney general's office to CVS Pharmacy.

Members were surveyed to see if they wanted to add any of the suggested items to a future agenda.

Chairperson Serpa noted the issue related to thresholds would be included on a future agenda.

Members discussed adding to a future agenda item enforcement of AB 352 and the letter to CVS Pharmacy. Members were cautioned against providing legal advice at the meetings and the agenda item would be taken under advisement.

**III. Approval of Draft Minutes from the April 11, 2024 Enforcement and Compounding Committee Meeting**

The draft minutes of the April 11, 2024 Enforcement and Compounding Committee meeting were presented for review and approval.

**Motion:** Approve April 11, 2024 Enforcement and Compounding Committee meeting minutes as presented

**M/S:** Oh/Barker

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

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

<b>Board Member</b>	<b>Vote</b>
Barker	Support
Cameron-Banks	Not Present
Hughes	Not Present
Oh	Support
Serpa	Support
Thibeau	Support

**IV. Presentation on Board's Inspection Program**

Chairperson Serpa recalled 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. On an annual basis, 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 without any additional resources.

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.

Following the presentation, members were provided the opportunity to comment. Members thought the presentation was informative, were pleased to see the improvement without additional staff, and thanked the staff for their diligent work. A member discussed the decrease in pharmacies from 2020 to current fiscal year trending down approximately 10 percent and expressed interest in learning more about the trending decrease.

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

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

A pharmacist applauded the Board for improving toward the goal of inspecting every pharmacy every four years and thought it would be interesting to compare pre-COVID and post-COVID statistics. The pharmacist asked for the Board to report on how pharmacies are offering telephone service six days a week when pharmacies are often open five days a week. The pharmacist agreed needing to understand why pharmacies are decreasing.

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

## **V. Presentation on Board's Citation Program**

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, all of which represent non-disciplinary outcomes. She highlighted when the Board takes disciplinary action, it was done through the provisions of the Administrative Procedure Act. 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 including the use of orders of abatement. Ms. Sodergren highlighted the appeal process and appeal outcomes. Ms. Sodergren reviewed top violations by license type as well as related to duty to consult.

Following the presentation, members were provided the opportunity to comment. A member noticed the fines collected were lower than the fines assessed and inquired why this was the case. Ms. Sodergren provided sometimes fines are spread out across fiscal year or were reduced through the appeal process.

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 commentor asked if the medication error was for lack of having a medication error report or if an actual medication error occurred.

A pharmacist commented the report was helpful to share with pharmacy students and requested more information on a term unfamiliar to the commenter as "citation for misuse of pharmacy education or pharmacist education" and requested examples be provided.

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

The Committee took a break from 10:20 a.m. to 10:35 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. A quorum was established.

**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 referenced meeting materials noting the Board was required to submit a report to the Legislature on the regulation of automated drug delivery systems (ADDS) as part of the upcoming sunset evaluation process. At the July 2023 Committee meeting, members received the first presentation related to the findings of the quality assurance (QA) reports received when Dr. Serpa expressed concern about what appeared to be a lack of compliance with reporting requirements. However, based on review of the presentation, Dr. Serpa was pleased to report that the issue appears to have at least in part been addressed. Dr. Serpa thanked everyone 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 the requirement for the Board to report the public safety concerns related to the ADDS as part of the sunset review process. Dr. Dang provided information about the ADDS Quality Assurance Reporting requirements and ADDS medication error reporting requirements.

Dr. Dang provided an overview of the data collected from July 2023 to April 2024. She reviewed the four types of ADDS related medication errors by ADDS location including inside a pharmacy; under California Department of Public Health's (CDPH) General Acute Care Hospital license; at long-term care and psychiatric health facilities; and at correctional clinics and jails. Dr. Dang provided a summary of work the Board is continuing to complete related to ADDS.

Following the presentation, members were provided the opportunity to comment; however, no comments were made.

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

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

A pharmacist representative of Kaiser Permanente requested with the passage of AB 1286 requiring medication errors in outpatient settings be reported to the Board and CDPH requires robust hospital medication error reduction program that once the report is made to the legislature, the

requirement for ADDS medication errors to be required to the Board was redundant and requested it be deleted.

## **VII. Discussion on Draft Policy Statement Related to IV Hydration Clinics**

Chairperson Serpa referenced relevant sections of federal law that establish the conditions under which compounded human drug products are exempt from three sections of the federal Food, Drug and Cosmetic Act in the meeting materials. Also provided was some background information on the issue of IV hydration clinics, including information about warnings released by the FDA involving instances of drug products being compounded under insanitary conditions. The materials highlighted that many warnings stem from compounding occurring at sites that are not regulated by the Board, including IV hydration clinics.

Dr. Serpa recalled at the April 2024 April Committee meeting, IV hydration clinics appeared to be operating in a number of settings, including beauty salons, mobile vans, and gymnasiums, and appear to lack appropriate oversight, use of appropriate equipment, and proper storage, placing patients at risk. These issues were occurring across the nation, including in California. Dr. Serpa noted Board staff have observed inspections in some IV hydrations clinics and report witnessing alarming practices placing consumers at risk. Staff also report challenges with conducting investigations because even basic patient information (administration information, etc.) was not maintained and/or provided to the Board.

Given the risk to patients and the documented harm, Dr. Serpa recalled this issue was brought before the Committee to consider the issue and determine if there were any actions the Board should take to protect patients and was determined the Board should have a greater role in monitoring this practice starting with the development of a policy statement to educate consumers about IV hydration clinics and some potential risks, without creating undue concern for patients that have a medication condition that requires such treatment. Dr. Serpa referenced meeting materials that included a draft policy statement with the approved statement including contact information for the various healing arts boards to aid consumers in understanding more for those programs as well. She reviewed the draft and believed it was appropriate. Dr. Serpa believed it provided education and action steps consumers can take to protect themselves.

Members were provided the opportunity to comment.

Dr. Barker thought it was a great place to start with the draft policy and made suggestions to clarify key words and add examples to other key words. She suggested adding that there can be little or no evidence that these mixtures work. Dr. Barker also recommended moving the caution of risk to the beginning of the document as well as referencing FDA's 2021 statement "FDA Highlights Concerns of Compounding of Drug Products by Medical Offices and Clinics under Insanitary Conditions" as a reference or resource.

**Motion:** Recommend the approval of the draft policy statement consistent with the committee's discussion and authorizing the executive officer to make changes working with the Enforcement and Compounding Committee Chairperson

**M/S:** Barker/Oh

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

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

The Board heard comments from the public recommending hearing how other health care professional boards are handling the issue and making sure the tone was appropriate for the seriousness of the issue. Other comments received included asking if this would address all types of infusion.

Dr. Serpa advised the statement would include the other health care professional boards with contact information.

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

<b>Board Member</b>	<b>Vote</b>
Barker	Support
Cameron-Banks	Not Present
Hughes	Not Present
Oh	Support
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)**

Chairperson Serpa recalled as part of the Committee's discussion on implementation of Assembly Bill 1286 and based on the comprehensive nature of the measure, the development of frequently asked questions (FAQs) was deemed appropriate. Dr. Serpa added the FAQs were initially approved during the February 2024 Board meeting and noted that additional questions may need to be added. The Committee considered and approved updates at the April 2024 Committee meeting. Meeting materials include additional updates for consideration including the new questions 8 and 19 and highlighted in yellow.

Members were provided the opportunity to comment. Members discussed the confusion and the unintended consequences of providing the FAQ 19. The Committee agreed to remove the FAQ 19. Staff was directed to schedule discussion for the Board to evaluate the statutory requirement in Business and Professions Code (BPC) section 4115(b)(1). It was noted that the discussion related to the BPC section 4115 (b)(1) telephone transfers would pair well with the discussion of pharmacy technician training and authorization at a differ Committee.

**Motion:** Recommend approval of the additional FAQs related to Assembly Bill 1286 without question 19

**M/S:** Oh/Thibeau

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

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

The Board heard comments from the public supporting the removal of question FAQ #19 and appreciated clarification of the statute as well as clarifying training elements in BPC 4115. The Board also heard comments regarding FAQ #8 if nonresident pharmacies only need to report errors regarding California residents.

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

<b>Board Member</b>	<b>Vote</b>
Barker	Support
Cameron-Banks	Not Present
Hughes	Not Present
Oh	Support
Serpa	Support
Thibeau	Support

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

Chairperson Serpa referenced meeting materials containing the Enforcement and Compounding Committee's ten strategic objectives as well as updates on the objectives, highlighting efforts over the past year. Dr. Serpa was proud of the Committee's accomplishments towards its strategic objectives and was looking forward to continued efforts, including activities related to reducing medication errors which is core to the Board's consumer protection mandate.

Dr. Serpa also acknowledged the progress staff made to meeting the strategic objective in 2.3 and believed great strides were made to reach the four-year benchmark. Currently, 79.7% of pharmacies have been inspected within the 4-year period. She highlighted that only 0.3% of licensed pharmacies have never been inspected and presumed those facilities would be prioritized in the coming year and looked forward to continued pursuit of this strategic objective.

Dr. Serpa highlighted that while the Committee's work was complete in strategic goal 2.5 specifically related to consideration of further use of a Standard of Care Enforcement Model, with submission of the legislative report, work in this general area continues through the Licensing Committee who was considering provisions related to a more robust standard of care practice model for pharmacists.

Dr. Serpa believes as the Committee continued work related to strategic objective 2.8, it may be appropriate to focus some efforts on education of nonresident pharmacies. This would serve as a nice complement to the work being undertaken by the Licensing Committee related to the regulation of nonresident pharmacies.

Dr. Serpa added the work related to strategic objective 2.10 resulted in the initiation of the formal rulemaking process to update the Board's

compounding regulations and was proud of the work completed as a Committee. Dr. Serpa appreciated all of the engagement received from interested parties and looked forward to discussing the regulations during the July 31-August 1, 2024 Board meeting.

Dr. Serpa believed it may be appropriate to add a new strategic objective aimed at evaluating the barriers to patient consultation. Appropriate patient consultation would reduce medication errors and also improve patient understanding of medication adherence and safety and address challenges with low medication health literacy rates.

Members were provided the opportunity to comment. Members congratulated staff for their hard work resulting in progress. Members discussed adding a strategic goal to enhance patient consultation compliance by evaluating barriers to consultation to provide patient education and reduce medication errors. Members discussed working with the Communication and Public Education Committee to ensure consumers know and understand the importance of consultation.

**Motion:** To add Strategic Goal 2.11 – enhance patient consultation compliance by evaluating barriers to consultation to provide patient education and reduce medication errors.

**M/S:** Oh/Thibeau

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

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

The Board heard comments from the public supporting the progress of the Committee and supporting the consultation goal. Comment was received in support of a study for the value of pharmacist consultation.

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

<b>Board Member</b>	<b>Vote</b>
Barker	Support
Cameron-Banks	Not Present
Hughes	Not Present
Oh	Support
Serpa	Support
Thibeau	Support

**X. Review and Discussion of Enforcement Statistics**

Chairperson Serpa referenced meeting materials that included a summary of enforcement statistics for fiscal year 2023/24 as well as three-year comparison data. The Board has initiated 3,183 complaints and closed 3,237 investigations. As of July 1, 2024, the Board has 1,662 field investigations pending. The materials provide a breakdown of the average timeframe for the various stages of the field investigation process. Dr. Serpa noted improvement in the average time for cases pending supervisor review and thanked everyone that contributed to reduce that review time.

Dr. Serpa noticed the Board has realized a 5% growth in investigations received as well as an increase in the number of cases closed with insufficient evidence. Staff have advised that this trend in part can be explained by an increase in consumer complaints received that are non-jurisdictional such as customer service issues.

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

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

**XI. Future meeting dates and adjournment**

Chairperson Serpa thanked everyone for their time and participation, noting the next meeting was currently scheduled for October 16, 2024.

**X. Adjournment**

The meeting adjourned at 12:10 p.m.