



**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:** March 27, 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  
Ricardo Sanchez, Public Member  
Nicole Thibeau, PharmD, Licensee Member

**Board Members Not**

**Present:** Jeff Hughes, Public Member

**Staff Present:**

Anne Sodergren, Executive Officer (WebEx)  
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 9:01 a.m. As part of the opening announcements, Dr. Serpa welcomed Board Member Ricardo Sanchez back to the Board. 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; Ricardo Sanchez, Public 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 registered nurse thanked the Board for sharing information about how to increase thresholds and requested an audit on the process asking pharmacists if they knew they could ask for the increase and if they tried to request an increase, how the process went. The registered nurse also asked the Committee to follow up with other healing arts board on the policy statement.

Dr. Serpa advised the policy statement with other health care professional boards was still being developed.

Members were provided the opportunity to comment. A member requested the thresholds discussion be added as a periodic reminder for the Communication and Public Education Committee.

## **III. Approval of Draft Minutes from the October 16, 2024 Enforcement and Compounding Committee Meeting**

The draft minutes of the October 16, 2024 Enforcement and Compounding Committee meeting were presented for review and approval. Members were provided the opportunity to comment.

**Motion:** Approve October 16, 2024 Enforcement and Compounding Committee meeting minutes as presented.

**M/S:** Oh/Barker

Members of the public participating 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 registered nurse commented that Ms. Lindhal's statement about the injunctive terms on page 4 of the draft minutes should be clarified.

**Amended Motion:** Approve October 16, 2024 Enforcement and Compounding Committee meeting minutes with any necessary amendments after staff confirm whether Ms. Lindahl's statement is accurate.

**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: 5   Oppose: 0   Abstain: 0   Not Present: 1**

<b>Board Member</b>	<b>Vote</b>
Barker	Support
Hughes	Not Present
Oh	Support
Sanchez	Support
Serpa	Support
Thibeau	Support

**IV. Discussion and Consideration of Implementation of Assembly Bill 1902 (Alanis, Chapter 330, Statutes of 2024) Prescription Drug Labels: Accessibility**

Dr. Serpa recalled during the October 2024 Committee meeting, the Committee discussed possible implementation activities for a number of measures signed by the governor, including Assembly Bill 1902, a measure

related to prescription drug label accessibility. During the initial discussion there was discussion about the need to develop regulations to implement the requirements. Dr. Serpa noted that today the Committee had the opportunity to continue this discussion, and that the meeting materials included questions intended to assist the Committee.

*Policy Question #1 - The law specifies that the accessible prescription label be made available in a timely manner comparable to other patient wait times and lasting for at least the duration of the prescription. Should the Board further define through regulation the phrase, "in a timely manner comparable to other patient wait times?" Staff note that depending on the type of pharmacy (e.g., mail order, community pharmacy, closed door pharmacy, etc.), the parameters for "timely manner" could require different provisions.*

Dr. Serpa agreed with the information from staff that if the Committee determined a definition was appropriate, the Committee may need to provide different provisions for the various types of pharmacy business models.

Members were provided the opportunity to comment. Members appreciated the intent of the measure. There was consensus that due to the different pharmacy practice settings (e.g., independent, community chain, etc.), "timely manner" should be determined by the pharmacy's policies and procedures, so each specific facility could define how it can best meet the requirements. Members expressed concerns about being overly prescriptive in regulations, and also discussed these labels possibly becoming a barrier to access.

Members of the public participating 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. The Committee heard comments from representatives of Kaiser Permanente and CPhA. Comments were received agreeing with the approach to meet the requirements through policies and procedures; suggesting the Committee recommend changes to the statute to resolve the tension between directions from the statute and pharmacy operations; and asking the Committee to consider an exemption for non-chain community pharmacies.

Members were provided the opportunity to comment having heard public comment. Members inquired if the Board had the authority to provide exemptions. Counsel noted this was probably not within the Board's authority. Members discussed exploring agreements between pharmacies. Members noted compliance with the statute would require interaction and discussion with the patients.

*Policy Question #2 – The law specifies that the accessible prescription label must be appropriate to the disability and language of the person making the request through the use of audible, large print, Braille, or translated directions.*

*a. Should the Board further define through regulation how a pharmacy will determine what is appropriate to the disability?*

Dr. Serpa noted it may be appropriate to consider a requirement for the pharmacy to develop a policy defining how it meets the requirements. Such an approach would allow each pharmacy to develop the process that works best for their business model.

Members were provided the opportunity to comment. Members agreed that the Board should not define how pharmacy personnel were to determine what was appropriate as it should be determined through policies and procedures and the pharmacist would need to interact with the patient to determine what would be appropriate for the patient.

*b. Should the Board establish a minimum font size to define "large print?"*

Dr. Serpa noted it may be appropriate for the Board to establish a minimum large print size.

Members were provided the opportunity to comment. Members discussed referring to an organization that defines this, but the consensus was to keep the regulation flexible and simple to allow for changes in standards.

*c. Should the Board specify that the accessible prescription label needs to be in the patient centered format?*

Dr. Serpa noted that she was leaning towards providing flexibility for pharmacies to determine how best to meet the individual patient's needs, especially if the Board's patient-centered label requirements would ultimately make it more difficult for the patient.

Members were provided the opportunity to comment. Members continued to support a flexible approach over a prescriptive approach and agreed the pharmacy's policies and procedures should determine what was appropriate for patients.

*d. Staff note that it may be appropriate to establish requirements for pharmacies to develop policies and procedures to provide guidance to pharmacists on how to identify the appropriate accessible prescription label.*

Dr. Serpa agreed with the staff recommendation that at a minimum the Board should require pharmacies to develop policies and procedures that provide guidance to pharmacists on how to identify the appropriate accessible prescription labels.

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

Members of the public participating 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. The Committee heard comments from representatives of Kaiser Permanente and CPhA. Comments were received in support of adopting a national standard where available; asking if a regulation was required at all; and focusing on a standard of care approach.

*Policy Question #3 - The law requires that accessible prescription labels must conform to the format specific best practices established by the United States Access Board and the National Standards for Culturally and Linguistically Appropriate Services (CLAS) in Health and Health Care (also referred to as the National CLAS Standards). Should the Board further define through regulation how a pharmacy will educate pharmacists about these standards? Staff note that it may be appropriate to establish requirements for pharmacies to develop policies and procedures to provide guidance to pharmacists on how to evaluate for compliance with these standards.*

Members were provided the opportunity to comment. Members continued to support a regulatory approach that required each pharmacy to develop policies and procedures to provide guidance to pharmacists on how to

evaluate for compliance with these standards. Members also discussed the possibility of developing an FAQ to assist with education.

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

Dr. Serpa advised the topic would be brought to the full Board as a part of the Committee report. Following discussion by the full Board, if there appeared to be general agreement, Dr. Serpa would work with staff on developing proposed regulation text that could be considered at a future Committee meeting.

**V. Discussion, Consideration, and Possible Action on Updates to Self-Assessment Forms Incorporated by Reference**

**a. Community Pharmacy/Hospital Outpatient Pharmacy Self-Assessment Form 17M-13, California Code of Regulations (CCR), Title 16, Section 1715(c)**

**b. Hospital Pharmacy Self-Assessment Form 17M-14, CCR, Title 16, Section 1715(c)**

**c. Wholesaler/Third-Party Logistics Provider Self-Assessment Form 17M-26, CCR, Title 16, Section 1784(c)**

**d. Automated Drug Delivery System Self-Assessment Form 17M-112, CCR, Title 16, Section 1715.1 e. Surgical Clinic Self-Assessment Form 17M-118, Business and Professions Code Section 4192**

Dr. Serpa advised as indicated in the meeting materials, the Board previously approved a number of changes to the self-assessment forms based on changes that became effective in 2024. Regrettably, many of these changes were not yet final through the rulemaking process. Dr. Serpa recommended that the Committee focus today's discussion on the proposed updated drafts that include changes effective in 2025. If the Committee and Board agreed the proposed updates were appropriate, staff could post the updated versions on the Board's website and work with counsel on the best path forward to facilitate the rulemaking process for those forms that require update through regulation.

Dr. Serpa recalled the Board included in its sunset report a proposal to pursue a statutory change to establish the self-assessment process in statute. Should that occur, the Board would be in a position to implement updated versions of the self-assessment forms in a more streamlined manner.

Dr. Serpa provided an overview of proposed changes to the community pharmacy and hospital outpatient pharmacy self-assessment.

Members were provided the opportunity to comment. Member discussed the proposed changes and next steps.

Dr. Serpa advised she would work with staff to refine the form for consideration by the Board at the next Board meeting.

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

Dr. Serpa then provided an overview of proposed changes to the inpatient hospital self-assessment.

Members were provided the opportunity to comment. Members discussed where the regulations were in the process and what forms could be updated.

Members of the public participating 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 pharmacist comment on the three-day rule discussed in the proposed changes.

Dr. Serpa next reviewed the changes to the wholesaler/3PL self-assessment form. The only proposed changes were nonsubstantive.

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

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

Dr. Serpa then reviewed the changes to the ADDS self-assessment form, noting that if the Board was successful in securing the statutory change to establish the self-assessment process in statute, some of the challenges with displaying changes over various versions of forms would be addressed.



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

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

Finally, Dr. Serpa reviewed the proposed changes to the surgical clinic self-assessment form.

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

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

The Committee took a break from 10:27 a.m. to 10:45 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. Discussion and Consideration of Petition Request Forms Used for Petitions for Reinstatement of a License, Petitions for Modification of Penalty, and Petitions for Early Termination of Probation**

Dr. Serpa advised the meeting materials provided background information on this item, including the relevant sections of the law that establish the general parameters for petitioning the Board for changes in a penalty or seeking reinstatement of a license. As the meeting materials noted, in 2023 staff made changes to the petition forms. Following implementation of the revised forms, it appeared there was an opportunity to evaluate the information requested and determine if additional changes were appropriate. Dr. Serpa discussed some concepts with staff in advance of the meeting, noting one potential change was to consolidate the forms into a single petition. Dr. Serpa believed such an approach may make it easier for petitioners and ensure the Board receives consistent information. Dr. Serpa believed the proposed new consolidated form was a good starting place for the Committee discussion. She noted that question 15 might need to be updated to require petitioners to provide proof of required continuing education related to pharmacy law, ethics, and cultural competency.

Member Sanchez re-joined the meeting at 10:48 a.m.

Members were provided the opportunity to comment. Members appreciated the new form. Discussion noted question 16 should be updated to include minimum requirements for licensee written letters of recommendation.

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

Dr. Serpa agreed to work with staff to further refine the proposed form to present to the Board in April 2025.

## **VII. 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 2,099 complaints and closed 1,971 investigations. As of March 1, 2025, the Board had 1,495 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 in Sacramento and via WebEx were provided the opportunity to comment; however, no comments were made.

## **VIII. Future Committee Meeting Dates**

Dr. Serpa advised the next meeting was scheduled for June 11, 2025.

## **IX. Adjournment**

The meeting adjourned at 10:55 a.m.