



**STANDARD OF CARE COMMITTEE
 MEETING MINUTES**

- DATE:** May 3, 2023
- LOCATION:** Note: Pursuant to the provisions of Government Code section 11133, neither a public location nor teleconference locations are provided. Public participation also provided via WebEx
- COMMITTEE MEMBERS PRESENT:** Maria Serpa, Licensee Member, Vice Chair
 Renee Barker, Licensee Member
 Jessi Crowley, Licensee Member
 Nicole Thibeau, Licensee Member
- COMMITTEE MEMBERS NOT PRESENT:** Seung Oh, Licensee Member, Chair
 Indira Cameron-Banks, Public Member
- STAFF MEMBERS PRESENT:** Debbie Damoth, Executive Specialist Manager

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

Vice Chairperson Serpa called the meeting to order at 9:01 a.m. Vice Chairperson Serpa reminded everyone present that the Board is a consumer protection agency charged with administering and enforcing Pharmacy Law. Dr. Serpa advised where protection of the public was inconsistent with other interests sought to be promoted, the protection of the public shall be paramount. The meeting moderator provided instructions on how to participate during the meeting, including the process to provide public comment.

Vice Chairperson Serpa advised President Seung Oh and Executive Officer Anne Sodergren were unable to attend the meeting as they were testifying at the capitol regarding Board business. Vice Chairperson Serpa took roll call. Members present included: Renee Barker, Licensee Member; Jessi Crowley, Licensee Member; Nicole Thibeau, Licensee Member; and Maria Serpa, 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 the opportunity to provide comments for items not on the agenda; however, no comments were made.

III. Discussion, Consideration and Approval of Draft Committee Minutes from the February 1, 2023, Meeting

Vice Chairperson Serpa referenced the draft minutes for the February 1, 2023, Standard of Care Committee Meeting in the meeting materials.

Members were provided the opportunity to comment.

Vice Chairperson Serpa requested on the first paragraph of page 19 to change “(e.g., universal health)” to “(e.g., access to electronic health records).”

Motion: Approve the February 1, 2023, Standard of Care Committee Meeting minutes with corrections.

M/S: Thibeau/Crowley

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

Support: 4

Oppose: 0

Abstain: 0

Not Present: 2

Committee Member	Vote
Barker	Support
Cameron-Banks	Not Present
Crowley	Support
Oh	Not Present
Serpa	Support
Thibeau	Support

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

Vice Chairperson Serpa recalled since March of 2022, the Committee had received presentations, learned about actions taken in other jurisdictions, reviewed research, surveyed pharmacists, and considered policy questions. Dr. Serpa reiterated appreciation for participation in this process. Dr. Serpa thanked individuals who provided written comments and advised the comments had been disseminated to members and posted on the Board's website. Dr. Serpa advised the Committee would be reviewing the updated draft of the legislative report that incorporated the changes requested during our February 2023 Committee meeting. Dr. Serpa realized that for some, this report may seem to go too far, and for others, not far enough. Dr. Serpa advised as the Committee completed the review of the final draft, Dr. Serpa would open for public comment throughout the meeting as the various portions of the report were discussed. Dr. Serpa ensured the public comments received on Monday were reviewed and noted the comments were posted on the Board's website. Dr. Serpa advised changes from the prior version were identified with underline to reflect new text and strikethrough to reflect text being removed as well as noted formatting changes had been made.

Members were provided the opportunity to ask questions or comment on the Background and Pharmacy Profession sections. Vice Chairperson Serpa indicated being comfortable with the changes. No comments were made by Members.

Members of the public were provided the opportunity to comment on the Background and Pharmacy Profession sections.

A pharmacist Emeritus Dean requested the word "permanent" that was added to the Pharmacy Profession section be deleted as the practice of pharmacy was not permanent.

Members were provided the opportunity to ask questions or comment on the Committee Process and Presentations Received sections; however, no comments were made.

Members of the public were provided the opportunity to comment on the Committee Process and Presentations Received sections.

A pharmacist Emeritus Dean commented that there was a conflict between what the Department of Consumer Affairs stated regarding violations of standard of care. The commenter noted DCA stated that a violation of statutes or rules/regulations was a violation of standard of care while the Medical Board said that was not the case.

Members were provided the opportunity to ask questions or comment on the Information on other Jurisdiction Process and Research Reviewed sections; however, no comments were made.

Members of the public were provided the opportunity to comment on the Information on other Jurisdiction Process and Research Reviewed sections; however, no comments were made.

Vice Chairperson Serpa added the Definitions section was new. Dr. Serpa noted this section was added based on prior discussions. Dr. Serpa appreciated the inclusion of the definitions and believed they were appropriate and helpful.

Members were provided the opportunity to ask questions or comment on the Definitions section; however, no comments were made.

Members of the public were provided the opportunity to comment on the Definitions sections.

The Committee heard a comment from a retired pharmacist pointing out the additional information that the use of the hybrid model was not understood and pointed to the information provided as additional information to clarify by adding one statement.

Vice Chairperson Serpa noted during the February 2023 Committee meeting, there was significant discussion on some of the questions in the Policy Question section and wanted to ensure the summary captured the essence of the discussion. Dr. Serpa reiterated the intent of the discussion was not to rediscuss the issues but to confirm the summary information was correct. Dr. Serpa appreciated the additional language incorporated as it provided needed context especially with the updated response to Policy Questions #8 and #11.

Members were provided the opportunity to ask questions or comment on the Information on other Policy Questions section.

Member Thibeau commented the staff did a great job taking the complex topic and making the report concise.

Members of the public were provided the opportunity to comment on the Information on other Policy Questions sections.

A pharmacist representative of CSHP noted a typing error on Policy Question #11 to change "medial" should be changed to "medical."

A pharmacist representative from UCSF School of Pharmacy commented on Policy Question #5. The pharmacist was concerned with the added language of “to expand or change scope of practice” noting standard of care model wasn’t expanding scope of practice and later stated “and allow pharmacists to utilize the full range of their training and skill.” The pharmacist was worried about having it in the record and could prohibit the ability to get the standard of care model approved.

A pharmacist emeritus Dean commented that Policy Question #4 was written so that a reader believes in the first part of the statement or the second part of the statement. The pharmacist requested removing the word “yes” from the answer. The pharmacist commented on Policy Question #7 that the Board establishes the criteria for licensure but shouldn’t be involved in establishing criteria for specialization or certifications noting the profession does that and was beyond the scope of the Board of Pharmacy.

A pharmacist representative from Cedar Sinai commented on Question #4 where there was a reference to compounding that states “it does not appear appropriate to allow additional pharmacist discretion beyond current provisions.” and requested discussing it. The pharmacist noted the sterile compounding standards USP 797 and associated 800 had been vetted extensively over the past several years. The pharmacist noted they are quite comprehensive and have enhanced monitoring of both individuals and facilities to support safe sterile compounding. The commenter added additional requirements serve as a barrier to sterile compounding in acute care health systems that are running over census in most Californian hospitals and are faced with the need to ensure timely safe compounding. The increased requirements support more outsourcing noting a view of 483s on the FDA website demonstrates that almost every single facility that’s compounding and specifically ones that are used by California pharmacies that do undergo a Board inspection and are licensed in California. The pharmacist noted nothing replaces responsibility of the health care setting where there is not only the responsibility of the pharmacist-in-charge (PIC) but annual licensure and ongoing observation and direct supervision of staff. By increasing the regulatory requirements rather than taking a standard of care approach creates impetus for outsourcing for organizations that have recalls noting it was alarming how many 483s deal with aseptic technique. The pharmacist noted while the 483s are licensed by the Board of Pharmacy and respect that, the ongoing supervision of aseptic technique and conformance with USP 797 was much more closely observed at a much lower BUD posing much less risk of contamination and risk to patients. The pharmacist commented in favor of using the standard of care to support the adoption of national guidelines for sterile compounding and not create additional barriers to acute health care systems that are treating high census of patients. The commenter noted the Akorn recall included injectables which often times requires

more compounding and additional requirements are barriers especially given the national technician workforce shortages.

Members were provided an opportunity to comment after public comment.

Member Crowley agreed with the comments regarding Policy Question #4 and suggested the removal of “yes” and leaving the remaining statement as presented. Dr. Crowley agreed with the typo with the Policy Question #11.

Vice Chairperson Serpa noted appreciation for the changes made to the Recommendation section of the report. Dr. Serpa believed the changes reflected were consistent with the prior discussion and provided necessary clarification. Dr. Serpa added specific to the written comments received were provided by two individuals but submitted on one comment. Dr. Serpa noted the language provided by Emeritus Dean Robinson may provide more clarity and could be considered as additional edits if the Committee was agreeable. Dr. Serpa didn't agree with the changes offered by Dr. Steve Gray. Dr. Serpa noted the report terms offered in bold font were specifically done as a reference to terms previously defined in the report. Dr. Serpa believed the clarifying language was inconsistent and not needed in this section. Dr. Serpa reiterated the definitions should remain as presented.

Members were provided the opportunity to ask questions or comment on the Information on other Policy Questions section; however, no comments were made.

Members of the public were provided the opportunity to comment.

A pharmacist representative of CVS Health commented the recommendations were not consistent with the Board's position taken on SB 524 at the April 2023 Board Meeting and recommended revisiting the position of SB 524.

A pharmacist representative of CSHP commented that as SB 524 was amended to no longer have “treat” in the “test and treat” legislation and didn't believe a change in the Board's position of SB 524 was warranted.

Members were an opportunity to comment after public comment.

Member Crowley commented on Dr. Robinson's edits. Dr. Crowley did not agree with Dr. Robinson's recommendation to change “could” to “would” as discussions concluded that it “could” benefit patients and the word “could” was more appropriate. Dr. Crowley agreed with the recommendation to change “make specified” to “utilize professional judgment in making patient care decisions.”

Vice Chairperson Serpa advised the Next Steps section of the report was also new and added based on prior Committee discussion. Dr. Serpa agreed with the information as detailed.

Members were provided the opportunity to ask questions or comment on the Information on other Next Steps section; however, no comments were made.

Members of the public were provided the opportunity to comment on the Information on other Next Steps sections.

A representative of CPhA thanked the Committee and staff on thoughtful and diligent work to move to the standard of care. The representative appreciated the next steps portion and timeline with determinations by the end of the calendar year. The representative appreciated the engagement suggested with the California Department of Health Care Services, Department of Insurance and Department of Managed Care to remove barriers for reimbursement for health care services provided. The representative looked forward to working with the Board.

A pharmacist Emeritus Dean commented the Board for the Next Steps and recommended removing the last phrase of the sentence "rather than other health care providers." noting it didn't appear to be needed and recommended removing the change.

Members were provided the opportunity to comment after hearing public comment.

Vice Chairperson Serpa thought the last sentence could be a good discussion for the full Board as the intent was to include additional pharmacy services in addition to those current services provided.

Member Barker suggested changing to "in addition to other health care providers" and agreed opening up to other discussion at Board meeting.

Members were provided the opportunity to ask questions or comment on the Information on other Acknowledgement and Attachment sections; however, no comments were made.

Members of the public were provided the opportunity to comment on the Information on other Acknowledgement and Attachment sections; however, no comments were made.

Vice Chairperson Serpa provided Members with an opportunity to provide final thoughts noting the final draft would be considered as part of the Board Meeting scheduled for May 17, 2023, and provided the following summary of issues to be addressed noting that the Committee was not presenting a recommendation but would be presenting the report. Members were provided an opportunity to add additional comments; however, no comments were made.

Vice Chairperson Serpa provided a summary of issues to address:

- In Policy Question #4 to remove the word “yes” in the answer.
- In Policy Question # 11, correct the typing error of “medial” to “medical” practices.
- In the Recommendation section to add the phrase by Emeritus Dean Robinson but not change the word “could” to “would” so that “could” remained:

Recommendations. [after SoC's Suggested Revisions. (with DRobinson's edits shown)] The Board respectfully concludes that a hybrid enforcement model remains appropriate for the regulation of the practice of pharmacy for consumer protection. The Board recommends, based on the information received and considered, that California patients will benefit from pharmacists gaining additional independent authority to provide patient care services, not limited to the traditional dispensing tasks performed at licensed facilities, consistent with their respective education, training, and experience. Further, the Board recommends revisions to certain provisions detailing a pharmacist's authorized scope of practice for specified clinical patient care services and the transition to a standard of care model where sufficient safeguards are in place to ensure pharmacists retain autonomy to ~~make specified~~ utilize professional judgement in making patient care decisions. Under those conditions, the Board believes that transitioning to greater use of a standard of care model ~~could~~ would benefit patients by providing expanded and timely access to patient care from suitably educated, trained and experienced health care providers ~~that are readily accessible in communities~~.

Drobinson

- In the Next Steps, consider rewording the last phrase in the last sentence to provide the intent to remove barriers for reimbursement for health care services by pharmacists for those current services and services identified in the future.

On behalf of Chairperson and President Seung Oh, Vice Chairperson and Vice President Serpa thanked everyone for their participation throughout the process adding this would be the final meeting of the ad hoc committee. Dr. Serpa added

President Oh would work with staff to determine next steps based on the direction of the Legislature. Dr. Serpa noted future work in this area would be completed through the Licensing Committee.

V. Adjournment

The meeting adjourned at 9:52 a.m.