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
Public Board Meeting Minutes

Date: March 26, 2025

Location: OBSERVATION AND PUBLIC COMMENT IN PERSON:
1625 N. Market Blvd., First Floor Hearing Room
Sacramento, CA 95834

PUBLIC PARTICIPATION AND COMMENT FROM A REMOTE LOCATION: WebEx

Board Members Present:
Seung Oh, PharmD, Licensee Member, President
Trevor Chandler, Public Member, Treasurer
Renee Barker, PharmD, Licensee Member
Jeff Hughes, Public Member
Ricardo Sanchez, Public Member
Satinder Sandhu, PharmD, Licensee Member
Maria Serpa, PharmD, Licensee Member
Nicole Thibeau, PharmD, Licensee Member (via WebEx)

Board Members Not Present:
Jessica Crowley, PharmD, Licensee Member, Vice President
Kartikeya "KK" Jha, RPh, Licensee Member
Jason "J." Newell, MSW, Public Member

Staff Present:
Anne Sodergren, Executive Officer
Lori Martinez, Chief of Legislation, Policy, & Public Affairs
Corinne Gartner, DCA Staff Counsel
Shelley Ganaway, DCA Staff Counsel
Sara Jurrens, Public Information Officer
Debbie Damoth, Executive Specialist Manager

March 26, 2025

President Oh called the Board meeting to order at approximately 9:00 a.m. Dr. Oh welcomed Ricardo Sanchez back to the Board. Mr. Sanchez served as a Board member from approximately 2014-2023. Dr. Oh also announced Indira Cameron-Banks was no longer on the Board. Dr. Oh thanked Ms. Cameron-Banks for her service to the Board.

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. DCA staff provided instructions on participating via WebEx. Dr. Oh advised about exit routes in the event of an emergency for those present in person.

Roll call was taken. The following Board members were physically present in Sacramento: Trevor Chandler, Public Member; Renee Barker, PharmD, Licensee Member; Jeff Hughes, Public Member; Ricardo Sanchez, Public Member; Satinder Sandhu, PharmD, Licensee Member; Maria Serpa, PharmD, Licensee Member; and Seung Oh, PharmD, Licensee Member. Nicole Thibeau, PharmD, Licensee Member, participated via WebEx. Dr. Thibeau disclosed that no persons over 18 years old were present in the room with them as they participated in the meeting remotely via WebEx. A quorum was established.

Dr. Oh reminded members participating via WebEx to keep their cameras on throughout the open portion of the meeting. Dr. Oh requested members announce the reason for their nonappearance if they needed to turn their camera off temporarily due to internet connectivity issues.

II. Discussion and Possible Action Related to, Including Possible Adoption of, Proposed Regulations, Title 16, California Code of Regulations, Repeal of Sections 1708.3, 1708.4, 1735 et seq., and 1751 et seq. and Addition of Sections 1735 et seq., 1736 et seq., 1737 et seq., and 1738 et seq. Related to Compounded Drug Preparations, Hazardous Drugs, and Radiopharmaceuticals, Including Review of Comments Received During the 15-Day Comment Period to the Fourth Modified Text

President Oh advised the Board would now review comments received in response to the 15-day comment period on the fourth modified text for the proposed regulations regarding sterile and nonsterile compounding, hazardous drugs, andradiopharmaceuticals. Dr. Oh noted the history of the rulemaking was detailed in the meeting materials and the initial statement of reasons. Dr. Oh reminded members that during the March 6, 2025 Board meeting, the Board voted to further amend the proposed regulation text based on comments received. Immediately following the March 6, 2025 meeting, the fourth modified text was released for a 15-day comment

period, which ended on March 21, 2025. Consistent with delegated authority, Members Serpa and Barker reviewed comments received and worked with staff to provide recommendations for the Board's consideration today.

Dr. Oh thanked Dr. Serpa and Dr. Barker for all of their work, expertise, and leadership as the Board navigated through this very complex area of pharmacy practice.

Dr. Oh stated that he had carefully reviewed the comments and looked forward to the Board's discussion and action. He noted that there were no recommendations to further modify the text, and that having reviewed all of the meeting materials, he agreed no further changes to the proposed text were needed.

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

Motion:
1. Accept the Board staff recommended responses to comments to the fourth modified text received during the 15-day comment period as the responses of the Board as presented.
2. Adopt the fourth modified text dated 2.28.2025.
3. Authorize the executive officer to take all steps necessary to complete the rulemaking process. 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.

M/S: Serpa/Barker

Members were provided the opportunity to comment.

Dr. Barker spoke in support of the motion, noting that the text reflects a long and thoughtful process.

Members of the public in Sacramento were provided the opportunity to comment. Members heard comments from representatives of Pacific Compounding Pharmacy and Volunteer Fire Foundation. Comments included appreciation for efforts of the Board; significant concerns on how the pharmacist-in-charge (PIC) was to achieve full compliance with the proposed regulations; lack of scientific evidence for the proposed regulations; request for a motion to repeal current regulations but not adopt the proposed regulations in their place; a personal account of toxin levels before and after glutathione treatments; concerns about firefighters' lack of access to patient-specific

prescriptions for glutathione; and a request for members to ask about the Board's enforcement practices.

Members also heard comments from individuals including firefighters and healing arts practitioners. Comments included personal accounts of the benefits of glutathione; a request that the Board do what is best for consumers of California by not restricting access to compounded glutathione; assertions that glutathione and methylcobalamin when compounded effectively and cleanly are safe to use; and concerns that it's currently difficult to get access to glutathione and the regulations as proposed will make access worse.

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

Members heard comments from representatives of Alliance for Pharmacy Compounding, Kaiser Permanente, CMA, FlavoRx, stopthebop.org, and Petaluma Fire Fighters Local 1415. Comments included urging the Board to not move forward with the regulation package; disappointed the Board hadn't accepted the recommendation to expressly exclude physicians from the regulations; concerns that the regulations may influence the standard of care for physicians; the regulations are unpopular and unnecessary; and an assertion that flavoring shouldn't be considered compounding.

Members also heard comments from individuals including members of the public; a Cloverdale Councilmember; firefighters/first responders and their families; chronic illness patients including patients with Lyme disease, long COVID, and MECFS; a patient allergic to COVID vaccines; and medical providers. Comments included requests that the Board not limit access to glutathione for firefighters and chronic illness patients; put patients before politics; FDA making it more difficult for people in California to access lifesaving treatments; reason for the regulations is because big pharma can't make money from glutathione; regulations as proposed exceed federal guidance; and vote regulations down.

After the Board received public comment, President Oh stated that he believed the Board had been very thoughtful in its consideration of comments received, as reflected in actions that resulted in four revisions to the proposed modified text. He also noted that the Board had complied with the rulemaking requirements established in the law and had benefited greatly from the public engagement and comments received. Dr. Oh thanked members of the public for their participation.

Members were then provided the opportunity to comment.

Members discussed that the Board conducted its review of the proposed regulations by asking difficult questions and ensuring stakeholders' comments were heard. Extra meetings were held to ensure stakeholders' concerns were discussed.

Members also discussed the serious consequences of compounded products not being made to standards. When compounding is done incorrectly, people can die.

Members noted that the new regulations provide a path forward to allow the compounding of 503A Category 1 products, whereas the Board's current regulations do not provide for this.

Members also spoke about compounding pharmacy closures, noting that the extensive changes in USP that took effect on November 1, 2023, may be one of the reasons why pharmacies may have made a business decision to no longer compound, and that as a result, patients are experiencing more difficulty accessing compounded medications including glutathione preparations.

Members noted the importance of the Board's mandate for public protection, and discussed the difference between prescription medications for in-office use and at-home use. The Board currently does not require pharmacies to report to the Board what products they sell; however, the Board will also not make public statements that products are available without verifying that they are in fact available. An additional factor for whether or not a prescription was for in office use or at-home use could include how the product was compounded and the beyond use date (BUD) established based on the type of compounding. Members noted again that the proposed regulations do not ban the compounding of glutathione; rather, the proposed regulations provide a path forward to allow for the compounding of glutathione.

Members continued to discuss access issues for some compounded products, noting the regulations will not change this as access issues are impacted by business practices, changes in USP that occurred in 2022 and became effective on November 1, 2023, types of compounding, *etc*.

Members identified a communication issue between the Board and stakeholders. Members struggled with the enforcement issues raised by stakeholders.

Members discussed how the Board's regulations were to clarify and make more specific federal law and USP. Based on the number of changes by USP, the current regulations were not consistent with USP. Most of the comments were about the Category 1 bulk substances, which are not being banned – but there are many other aspects of compounding that are covered in the proposed regulations.

Members discussed the standard of care approach taken in the fourth modified text and the importance of ensuring compounding was done correctly. Members thanked stakeholders for their comments and the Board staff for their work.

Dr. Oh then highlighted some significant changes made through the rulemaking process. First, related to sterile compounding with bulk drug substances on the FDA 503A Category 1 list, he noted that, as initially noticed, the regulations would have only allowed for such compounding based on approval from a public health officer during emergencies. Through the rulemaking process, changes were made. In the fourth modified text, facilities are no longer required to do specific tests. Rather, facilities must follow federal law, federal guidance, and national standards and have policies to show how they will follow the laws and standards.

Dr. Oh continued his overview of changes made through the rulemaking process by noting the Board had also made significant changes to provisions related to compounding for animal patients, expanding the days' supply pharmacies can provide to a veterinarian for dispensing.

Dr. Oh added that in response to comments received regarding compounding in hospitals, the Board modified the regulations to provide additional flexibilities for hospitals to compound commercially available products, expanded provisions for immediate use compounding including when equipment or environments fail, and allowed the transferring of competency assessments across compounding locations.

Dr. Oh further noted that in response to comments received, the Board also significantly modified the proposed regulation text related to the handling of hazardous drugs. The fourth modified text provides that the regulations only apply to facilities compounding hazardous drugs and, in some instances, facilities that crush HD tables or that open HD capsules. The Board removed language regarding pass-through doors and modified provisions related to changing gloves.

Finally, Dr. Oh highlighted that specifically related to the use of flavoring agents, the fourth modified text provides that facilities that only compound by adding a flavoring agent to an FDA approved drug generally do not need to follow the Board's compounding regulations. Additionally, pharmacists can add flavoring without approval from the prescriber or prescriber's agent.

Dr. Oh concluded his remarks by thanking stakeholders, all Board members, especially Dr. Serpa and Dr. Barker, Board staff, and DCA counsel involved in the rulemaking process.

Support: 7 Oppose: 0 Abstain: 1 Not Present: 3

Board Member	Vote
Barker	Support
Chandler	Support
Crowley	Not Present
Hughes	Support
Jha	Not Present
Newell	Not Present
Oh	Support
Sanchez	Abstain
Sandhu	Support
Serpa	Support
Thibeau	Support

The Board took a break from 11:00 a.m. – 11:17 a.m. Roll call was taken. The following Board members were physically present in Sacramento: Trevor Chandler, Public Member; Renee Barker, PharmD, Licensee Member; Jeff Hughes, Public Member; Ricardo Sanchez, Public Member; Satinder Sandhu, PharmD, Licensee Member; Maria Serpa, PharmD, Licensee Member; and Seung Oh, PharmD, Licensee Member. Nicole Thibeau, PharmD, Licensee Member participated via WebEx. A quorum was established.

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

Members of the public participating from Sacramento were provided the opportunity to comment. A former Board member recommended having a seminar on compounding.

Members of the public participating via WebEx were then provided the opportunity to comment. A naturopathic doctor commented that the Board should review its enforcement approach related to compounding now that the proposed regulations have been adopted.

Members were then provided an opportunity to raise items to place on a future agenda. A member suggested that the Enforcement and Compounding Committee or the Communication and Public Education Committee could discuss providing access and tools to licensees about the complex nature of compounding, such as a two to three hour continuing education course. Another member suggested the Board explore opportunities for pharmacies to self-report products they compound similar to the Board's Health Services Registry. Members voiced support for this idea, and suggested the Board look at accessibility issues more broadly, as in addition to compounding pharmacies closing, many regular pharmacies are closing.

IV. Closed Session Matters

The Board did not meet in closed session.

V. Adjournment

The meeting adjourned at 11:27 a.m.