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
Public Board Meeting Minutes

Date: February 5-6, 2025

Location: OBSERVATION AND PUBLIC COMMENT IN PERSON:
California Department of Consumer Affairs
1747 North Market Blvd., Room 186
Sacramento, CA 95834

PUBLIC PARTICIPATION AND COMMENT FROM A REMOTE LOCATION: WebEx

Board Members Present:
Seung Oh, PharmD, Licensee Member, President
Jessica Crowley, PharmD, Licensee Member, Vice President
Trevor Chandler, Public Member, Treasurer
Renee Barker, PharmD, Licensee Member (via Webex on 2/6/25)
Jeff Hughes, Public Member
Kartikeya "KK" Jha, RPh, Licensee Member
Jason "J." Newell, MSW, Public Member
Satinder Sandhu, PharmD, Licensee Member
Maria Serpa, PharmD, Licensee Member
Nicole Thibeau, PharmD, Licensee Member (via WebEx)

Board Members Not Present: Indira Cameron-Banks, Public Member

Staff Present:
Anne Sodergren, Executive Officer
Julie Ansel, Deputy Executive Officer
Corinne Gartner, DCA Staff Counsel
Shelley Ganaway, DCA Staff Counsel
Norine Marks, DCA Staff Counsel (2/5/25 only)
Sara Jurrens, Public Information Officer (2/6/25 only)
Debbie Damoth, Executive Specialist Manager

February 5, 2025

I. Call to Order, Establishment of Quorum, and General Announcements (Including Possible Notifications, Actions, and Disclosures Pursuant to Government Code section 11123.2(j))

President Oh called the Board meeting to order at approximately 11:01 a.m.

Dr. Oh announced the resignation of Jason Weisz who has served as a Board member since 2020. The Board thanked Mr. Weisz for his years of service to the Board and to California consumers.

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.

Dr. Oh provided emergency routes in the event of an emergency.

Roll call was taken. The following Board members were physically present in Sacramento: Jessi Crowley, PharmD, Licensee Member; Trevor Chandler, Public Member; Renee Barker, PharmD, Licensee Member; Jeff Hughes, Public Member; KK Jha, RPh, Licensee Member; Jay Newell, MSW, 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.

II. Discussion and Possible Action Related to 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

Dr. Oh provided an overview of the relevant meeting materials for this agenda item. He thanked stakeholders for engaging in the rulemaking process and providing comments. He also thanked Dr. Serpa, Dr. Barker, and Board staff for reviewing the comments and developing recommendations for the Board's consideration today.

Dr. Serpa thanked President Oh for the opportunity to assist the Board in reviewing the comments received during the recent 15-day written comment period for the second modified text, which closed on January 27, 2025. Dr.

Serpa thanked those who commented during the 15-day comment period, noting that the comments and recommendations received were helpful to the Board as it considers and develops the proposed text. She also thanked Dr. Barker for sharing her expertise and time working with staff to develop the recommended proposed third modified text.

Dr. Serpa reminded those present that the development of the regulations began in 2019 with a series of public meetings convened by the Enforcement and Compounding Committee and the Board. In November 2019, in light of the delays with USP, the Board released a Policy Statement to provide stakeholders with guidance on the applicability of the Board's compounding regulations and USP compounding chapters while appeals were pending before the USP Committee. Following the USP consideration of appeals and finalization of the Chapters, the Enforcement and Compounding Committee resumed its efforts to review the Board's compounding regulations in January 2023, providing again numerous opportunities for stakeholders to participate in the Board's development of the proposed regulations.

Dr. Serpa added that in the most recent 15-day comment period, the Board received a wide range of comments, with some commenters seeking changes to lessen the standards of existing federal law, some seeking to lessen standards proposed, and others seeking additional clarification of the text. She continued that consideration and reflection of the Board's consumer protection mandate remained at the forefront of the assessment and recommendation.

Dr. Serpa noted that again, proposed modifications to the text were being recommended based on comments received during the 15-day comment period to the second modified text, and that a legend was included on the proposed third modified text to assist readers in navigating the changes. She added that a number of nonsubstantive changes were also being proposed to correct grammar issues, improve readability, and address typos.

Dr. Serpa began her overview of the changes being recommended to the regulatory text in response to comments received with proposed Article 4.5 related to nonsterile compounding. She highlighted the following recommendations being offered by staff in response to comments received:

- Section 1735.3 was reordered to clarify the requirements in response to public comment.
- Section 1735.9(c) related to labeling was removed in response to public comment that it was not necessary.
- Section 1735.11(a)(2) was amended to remove SOP requirements related to the methods of complying with other requirements addressed in the SOPs.
- Three changes were recommended related to compounding with flavoring agent, including a minor recommendation in section 1735.1(i) to clarify that the exemptions to Board regulations relate to facilities that

solely add a flavoring agent. In addition, it was recommended the Board establish a requirement for such facilities to develop an SOP defining how a pharmacy would notify the Board of a complaint related to the use of a flavoring agent. Finally, a recommendation was made to provide additional flexibility related to the documentation requirement related to the use of a flavoring agent.

Members were provided the opportunity to comment. Members discussed proposed changes to the following sections:

- 1735.1 and written comments from the Rheumatology Alliance and California Medical Association (CMA) including the letter from the Medical Board of California. Members discussed adding language to exclude profession applicability of the compounding language. Members determined the list would have to be all inclusive and noted each healing arts board determined how they regulate their licensees. Additionally, the Medical Board of California was not requesting changes.
- 1735.1(d) related to a reasonable quantity safeguarded by a 14-day supply. It was clarified that a reasonable quantity and 14-day supply were two separate issues related to veterinary office use and one individual use.
- 1735.1(e) related to requirements for pharmacists to verify and document that a prescribed compounded drug product is clinically significant and concerns about redundancy and delays in dispensing and treatment. Members discussed the pharmacists' responsibility to confirm the clinical need and indication for the medication. The proposed language was consistent with the construct and recognition as the pharmacist being the drug therapy expert. Members also discussed FDA requirements for compounding essentially a copy.
- 1735.1(e)(1)(C) related to documentation describing conditions being maintained in a readily retrievable format and possibly updating the language to include "and/or." Members were advised the use of "and/or" was not favored in regulatory language. As the intent of the Board was to include both, it was determined to address this as a nonsubstantive change.
- 1735.1(g) related to language regarding the requirement to provide consultation. Members discussed consultation requirements. While some members thought subdivision (g) may have been duplicative of CCR section 1707.2 and should be removed, the purpose of the subdivision was to add proper use, storage, handling, and disposal of compounded nonsterile products (CNSPs) and related supplies furnished. Members discussed and agreed to removing "shall be provided to the patient and/or patients' agent" so the subdivision read "In addition to provisions in section 1707.2, consultation includes proper use, storage, handing, and disposal of the CSNP and related supplies furnished."

- 1735.4 related to water use. A member was concerned about the cost to upgrade all water lines for washing materials and supplies. Clarification was provided noting the change only applied to the final rinse of equipment. Members noted plumbing must be free of defects that may contribute to contamination of any CNSPs.
- 1735.5(a) related to documenting the name of the cleaning agent and sanitizing agent. Members discussed this was current practice for CNSPs and required by USP.
- 1735.7(c)(1) related to manufacturers referenced. Current regulation allows for the documentation of the supplier. Comments received indicated noting the supplier should be sufficient information required in the event of a recall. Members discussed that FDA documents call out requiring the information in the proposed text for recalls. Some members wanted the current regulations to remain, while other members wanted Board regulations to be updated to require what FDA documents required.
- 1735.10 related to establishing beyond use dates (BUDs) as comments suggest the Board is requiring testing to be done in-house, which would increase costs. Members clarified stability testing didn't have to be done in-house, and it was acceptable practice to use stability tests completed by others, provided the testing completed was exactly the same as the products used including additives, processes, and container closures.
- 1735.15 related to flavoring and comments about USP 795. Members discussed that USP clearly states adding a flavoring agent is compounding. The Board calls it compounding and has specific requirements when adding a flavoring agent was the only compounding done by a facility.
- 1735.15(a)(1) and (2) related to flavoring. Members wondered if both (a)(1) and (a)(2) needed to be included. It was clarified that the facility was able to determine what was acceptable through documentation in the SOPs.

Dr. Serpa next began an overview of the changes being recommended to the regulatory text in response to comments received on proposed Article 4.6 related to sterile compounding. She highlighted the following recommendations being offered by staff in response to comments received:

- Section 1736(g) updated the definition of quality. The recommended change aligns with the definition of current law and the definition used in section 1735.
- Section 1736.4(e) was clarified to specify that compounding may be performed consistent with immediate use provisions in the event a compounding environment fails to meet requirements.

Dr. Serpa added the Board continued to receive a number of comments specifically related to compounding using active pharmaceutical ingredients on the FDA Category 1 Bulks list, noting that the substances on this list are distinct

from substances authorized under section 503A. She noted it was important to remind members that the Board's regulations do not ban, prohibit, or limit these substances. The Board's regulations provide a legal pathway that navigates the federal law and federal guidance related to use of bulk substances and insanitary conditions and the USP requirements related to bulk substances. This is a confusing area of law and the Board has received requests for guidance from licensees. The Board continues to receive comments that the Board is adding requirements. Dr. Serpa emphasized the proposed regulations were reiterating federal law, guidance, and the provisions of USP. The Board's proposed regulations in this area rely on other provisions of USP to provide this legal path forward providing access and patient safety. The Board received previous presentations on the subject that were available for viewing on the Board's website.

Members were provided the opportunity to comment.

Members discussed sterile compounding of glutathione and methylcobalamin and the availability of the products. Concern was raised regarding the feasibility of the pathway being provided in the proposed regulations and costs related to required testing as comments suggested testing could cost $40,000. They discussed the ability of pharmacies to use previously conducted testing provided the master formula and elements matched that of the study. A member provided research from a national company that conducted testing from September 2024 that identified API testing per lot number for glutathione at $16.10 per vial and for methylcobalamin at $8.06 per vial. The member added the company also completed stability studies at a one-time fee of $5,000-$10,000 and noted glutathione and methylcobalamin have studies in the marketplace. Members discussed studies being conducted regarding glutathione and concerns about inability to get glutathione for clinical drug testing. Discussion continued noting clinical drug testing would be regulated by the FDA and wasn't included in the jurisdiction of the Board.

The Board took a lunch break from 1:06 p.m. – 2:00 p.m. Roll call was taken. The following Board members were physically present in Sacramento: Jessi Crowley, PharmD, Licensee Member; Trevor Chandler, Public Member; Renee Barker, PharmD, Licensee Member; Jeff Hughes, Public Member; KK Jha, RPh, Licensee Member J. Newell, MSW, 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.

Members resumed their discussion about Category 1 bulk drug substances and discussed adding language to provide an exemption for IRB-approved research studies as the Board did not want to limit research. A suggestion was made to add to proposed section 1736.9(e)(2)(i), "or stability information for a patient

enrolled in a clinical trial that is approved by a US Department of Health and Human Services registered institutional review board (IRB)."

Members also discussed proposed section 1736.1(b)(2) related to immediate use after facility failures. Some members wanted to ensure the SOPs allowed for greater flexibility than 48 hours after identified failure. Members advised this proposed language allows for more flexibility than current regulation.

Members discussed updating section 1736.1(g) to mirror the changes made in the corresponding nonsterile section.

Members discussed clarifying requirements for stability studies and were referred back to the requirements of USP.

Members further discussed comments regarding Category 1 bulk drug substances. A member was concerned the financial issues for smaller pharmacies and clinics.

Dr. Serpa then provided an overview of the changes being recommended to the regulatory text in response to comments received on proposed Article 4.7 related to hazardous drugs. She highlighted the following recommendations being offered by staff in response to comments received:

- Section 1737.5 was updated to remove the language related to the use of a passthrough based on public comment that the Building Commission will be reevaluating this requirement.
- Section 1737.6 was updated to clarify language regarding consideration of the use of wipe sampling.
- Section 1737.7 was updated to remove some provisions related to gloves in subdivision (a) and (b) based on the comments received and further review of the provisions in the Chapter that already covered the issue. Dr. Serpa advised the Board received a request to change the provisions in (c) but that recommendation was not accepted.

Members were provided the opportunity to comment. Members appreciated the changes related to pass throughs and gloves.

Finally, Dr. Serpa provided an overview of the changes being recommended to the regulatory text in response to comments received on proposed Article 4.8 related to radiopharmaceuticals. She highlighted the following recommendations being offered by staff in response to comments received:

- Section 1738(c) was updated to clarify that the pharmacist-in-charge (PIC) may also serve as the designated person. The recommended change was in line with changes made to the other articles during the 15-day comment period.

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

Motion: 1. Accept the Board staff recommended responses to comments received during the 15-day comment period to the second modified text as presented.
2. Approve the recommended third modified text as directed by the Board for a 15-day comment period, including making the changes discussed in section 1735.1(g) related to consultation (and counterpart provisions in the articles on sterile compounding and hazardous drugs); the changes suggested to section 1736.9(e)(2)(A)(i) regarding stability information related to a patient enrolled in a clinical trial; and delegation of authority to the executive officer to make technical and nonsubstantive changes before the text is released.
3. Additionally, should additional comments be received during the comment period to the third modified text, delegate to Members Serpa and Barker authority to review the comments with staff to offer recommendations to the Board for consideration at a future meeting.

M/S: Serpa/Barker

Members were provided the opportunity to comment. Members thanked Dr. Serpa and Dr. Barker for including the additional 15-day comment period. Dr. Oh clarified that the items he raised for discussion were for the purpose of ensuring these issues were discussed at the Board level.

Members of the public in Sacramento were provided the opportunity to comment.

Members heard comments from representatives of CVS Health, Hims and Hers, Pacific Compounding, CMA, and Volunteer Fire Foundation. Comments included concern that pharmacies who do minimal compounding (*e.g.*, magic mouthwash) wouldn't be included in the exemption provided for flavoring; regarding section 1735.1(e) requesting clarification if labeling was sufficient verification and requested an FAQ with Board provided samples under essentially a copy provision; requesting rejection of part two of the motion, consider what would happen when USP is revised and modify the language to repeal compounding regulations; request to reject the motion and exempt physicians; and concern nebulized glutathione is not available.

Members also heard comments from individuals including a retired fire chief officer and fire fighter. Comments included concerns about obstructing glutathione access and personal accounts that nebulized glutathione helped their health.

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

Members heard comments from representatives of CSHP; stopthebop.org; Outsourcing Facility Association; Kaiser Permanente; Councilmember of Cloverdale; member of Alliance for Pharmacy Compounding; gotlongcovid.org; Integrated Healer Action Network; and Naturopathic Doctor Association. Comments received included support of bringing the regulation to final version; lack of access of nebulized glutathione; confusion around section 1735.1(e); requested proof of testing at rates provided; empirical data to support recommended changes; imposition of stability study testing requirements and active pharmaceutical ingredient or bulk drug testing requirements on Category 1 drugs that go beyond USP or FDA standards; and request to send back to Committee to redo regulations.

Members also heard comments from individuals including fire fighters/first responders and their families, pharmacists and intern pharmacists, nurses cancer survivors, physicians, and naturopathic doctors. Comments received included concern about limited access to glutathione including personal accounts of benefits from glutathione; clarification that IRB stands for institutional and not investigational review board; clarification that consultations are mandatory; restore access to glutathione for patients with chronic illnesses including Lyme disease, long COVID, bronchiectasis, people with grand mal seizures; lack of support from stakeholders; lack of effectiveness of tablets versus intravenous; endotoxin issue referred to was an issue of using dietary grade materials; inspectors shutting down licensed sterile compounding pharmacies; glutathione accessed in 49 other states; concerns the Board was not aware of the needs of the public and should vote down the regulation; and concerns with immediate use provisions and quality definition/reporting.

The Board took a break from 4:00 p.m. - 4:15 p.m. Roll call was taken. The following Board members were physically present in Sacramento: Jessi Crowley, PharmD, Licensee Member; Trevor Chandler, Public Member; Renee Barker, PharmD, Licensee Member; Jeff Hughes, Public Member; KK Jha, RPh, Licensee Member J. Newell, MSW, 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.

The public comment period on the motion resumed. Members heard comments from individuals including a patient with muscular dystrophy, fire fighters/first responders and their families, a family physician, a naturopath, and a medical director. Comments received included concerns that access to Category 1 bulk drug substances shouldn't be limited; many patients depend on glutathione; proposed regulation will not protect the public; and recommended voting against.

DCA Counsel Gartner offered some clarifying comments to members, noting that to the extent public comment indicated that Category 1 substances (*e.g.*, glutathione, methylcobalamin, *etc.*) were FDA approved or have been determined to be safe or effective by the FDA, that was not accurate. The FDA's interim policy regarding these substances is an enforcement discretion policy, which is not the same as saying the FDA has approved or authorized these substances. Ms. Gartner reminded members

that when these substances came before the Pharmacy Compounding Advisory Committee in 2021 and 2022, the FDA recommended that neither glutathione and methylcobalamin be included on the 503A bulks list. She added that although the committee ultimately voted to recommend inclusion of both substances on the list, the votes were not unanimous, and that the FDA's final decision on whether these substances should be included on the 503A bulks list was still pending.

Members were provided the opportunity to comment having received public comment. Members thanked the public for their engagement and thanked fire fighters for their service. Members were hopeful that the FDA would make a decision on the substances on the Category 1 list. Some members voiced concern for safety from deadly endotoxins and unintended consequences.

Members also discussed the impact of not moving forward with the regulations. A member recommended removing text related to the Category 1 Bulk List component. The Board discussed if the Category 1 Bulk List component was removed and was reminded while it wouldn't be in regulation, it would still be in federal law and would still need to be enforced. Members discussed the option of enforcement discretion and were reminded that the entirety of the situation was assessed during inspections.

Members discussed the proposed language in section 1735.12(b) and the possibility of removing the word "potential" but determined that would not add clarity.

Members discussed the proposed language in section 1735.15(b), noting that the language refers to FDA approved products. It was clarified that if a facility is doing compounding other than adding flavoring, Board compounding regulations and USP 795 would need to be followed.

Support: 8 Oppose: 2 Abstain: 0 Not Present: 1

Board Member	Vote
Barker	Support
Cameron-Banks	Not Present
Chandler	Support
Crowley	Support
Hughes	Oppose
Jha	Support
Newell	Support
Oh	Support
Sandhu	Support
Serpa	Support
Thibeau	Oppose

III. Closed Session Matters

Open session concluded at approximately 5:49 p.m. The Board took a break from 5:49 p.m. until 5:58 p.m. The Board did not go into closed session.

IV. Reconvene in Open Session to Adjourn for the Day

The Board meeting reconvened into open session and adjourned the meeting at 5:58 p.m.

President Oh called the second day of the Board meeting to order at approximately 9:00 a.m. 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.

Roll call was taken. The following Board members were physically present in Sacramento: Trevor Chandler, Public Member; Jeff Hughes, Public Member; KK Jha, RPh, Licensee Member J. Newell, MSW, Public Member; Satinder Sandhu, PharmD, Licensee Member; Maria Serpa, PharmD, Licensee Member; and Seung Oh, PharmD, Licensee Member. Renee Barker, PharmD, Licensee Member, and Nicole Thibeau, PharmD, Licensee Member, participated via WebEx. Dr. Barker and 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.

V. 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. The Board heard a comment from a member of the public who spoke about concerns that COVID-19 vaccines were killing people at alarming rates.

Member Crowley arrived at the meeting at approximately 9:08 a.m.

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

The Board heard a comment from a board certified geriatrics pharmacist who spoke in support of remote order processing including remote order entry. He requested the Board continue supporting legislation regarding this issue.

A representative of CCAP requested a discussion on burglaries and robberies in pharmacies on a future agenda.

The Board heard a comment from a member of the public concerned about deaths related to COVID-19 vaccines.

A representative of CPhA advised CPhA was posting resources on their website and requested the Board provide the resources on their website. The representative also provided an update related to pharmacists' services and billing.

Members were provided the opportunity to comment.

Members agreed with discussing and understanding the issue related to robberies in pharmacies to see how the Board might be able to assist with this issue.

Members agreed with having a discussion about the information on the CDC website that may be taken down, specifically ACIP guidelines as that is how pharmacists are able to immunize.

VI. Recognition and Celebration of Pharmacists Licensed in California for 40 Years

President Oh advised the Board's recognition of pharmacists licensed in California for over 40 years was posted on the Board's website and pharmacists were provided with a certificate when they reach this significant milestone. President Oh invited pharmacists licensed for 40 years or more to identify themselves and be recognized by the Board. Pharmacist Reis participated via WebEx and was recognized for having been licensed for over 40 years. President Oh thanked all pharmacists who worked in pharmacy serving the consumers of California.

VII. Approval of Board Meeting Minutes

a. November 6-7, 2024 Board Meeting

Dr. Oh referenced the draft minutes from the November 6-7, 2024 Board meeting. Members were provided an opportunity to comment; however, no comments were made.

Motion: Approve the November 6-7, 2024 Board meeting minutes as presented in the meeting materials.

M/S: Chandler/Thibeau

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 comment was received requesting edits related to item (b) of the Enforcement and Compounding Committee Report. Chairperson Serpa of the Enforcement and Compounding

Committee agreed that the name of the presentation be updated as requested by the commenter.

Amended Motion: Approve the November 6-7, 2024 Board meeting minutes as presented in the meeting materials with the change of the name of the presentation cited in the Enforcement and Compounding Committee Meeting Report.

M/S: Chandler/Thibeau

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

Support: 10 Oppose: 0 Abstain: 0 Not Present: 1

Board Member	Vote
Barker	Support
Cameron-Banks	Not Present
Chandler	Support
Crowley	Support
Hughes	Support
Jha	Support
Newell	Support
Oh	Support
Sandhu	Support
Serpa	Support
Thibeau	Support

b. December 4, 2024 Board Meeting

Dr. Oh referenced the draft minutes from the December 4, 2024 Board meeting. Members were provided an opportunity to comment; however, no comments were made.

Motion: Approve the December 4, 2024 Board meeting minutes as presented in the meeting materials.

M/S: Chandler/Barker

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

Support: 10 Oppose: 0 Abstain: 0 Not Present: 1

Board Member	Vote
Barker	Support
Cameron-Banks	Not Present
Chandler	Support
Crowley	Support
Hughes	Support
Jha	Support
Newell	Support
Oh	Support
Sandhu	Support
Serpa	Support
Thibeau	Support

c. December 18, 2024 Disciplinary Petition Committee Meeting

Dr. Oh referenced the draft minutes from the December 18, 2024 Disciplinary Petition Committee meeting. Members were provided an opportunity to comment; however, no comments were made.

Motion: Approve the December 18, 2024 Disciplinary Petition Committee meeting minutes as presented in the meeting materials.

M/S: Chandler/Newell

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

Support: 10 Oppose: 0 Abstain: 0 Not Present: 1

Board Member	Vote
Barker	Support
Cameron-Banks	Not Present
Chandler	Support
Crowley	Support
Hughes	Support
Jha	Support
Newell	Support
Oh	Support
Sandhu	Support
Serpa	Support
Thibeau	Support

d. January 8, 2025 Board Meeting

President Oh announced the minutes of the January 8, 2025 Board meeting would be considered at a future Board meeting.

VIII. Report by the California Department of Consumer Affairs

The Board heard a report from Manager Specialist Judie Bucciarelli on behalf of the Department of Consumer Affairs.

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 representative of Kaiser Permanente thanked Executive Officer Sodergren for proactively reaching out to Kaiser Permanente as they had a pharmacy close to the Los Angeles fires.

IX. Presentation by the Office of the Attorney General on the Disciplinary Process

The Board heard a presentation from Deputy Attorneys General Kristina Jarvis and Nicole Trama regarding the disciplinary process.

Members were provided the opportunity to comment. Members requested additional information about the public reproval process. Ms. Jarvis and Ms. Trama provided an explanation.

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

The Board took a break from 10:30 a.m. to 10:45 a.m.

Roll call was taken. The following Board members were physically present in Sacramento: Jessi Crowley, PharmD, Licensee Member; Trevor Chandler, Public Member; Jeff Hughes, Public Member; KK Jha, RPh, Licensee Member J. Newell, MSW, Public Member; Satinder Sandhu, PharmD, Licensee Member; Maria Serpa, PharmD, Licensee Member; and Seung Oh, PharmD, Licensee Member. Renee Barker, PharmD, Licensee Member, and Nicole Thibeau, PharmD, Licensee Member, participated via WebEx. A quorum was established.

X. Presentation: Addressing the Crisis: Improving Addiction Medicine Access at Pharmacies. Presenters include Hector De Leon; Brian Hurley, MD; Gillmore Chung, MD; Aimee Moulin, MD and Casey Alrich

The Board next heard a presentation on improving addiction medication access at pharmacies.

Members were provided the opportunity to comment.

Members and the presenters discussed that corresponding responsibility is a complex issue in the context of the opioid crisis. Members added that prescriber notes in the file can really help pharmacists as getting ahold of doctors can be a challenge. Some issues with buprenorphine were discussed. Members also discussed safety concerns for pharmacists.

Members discussed options for providing education for pharmacists about the difference between opioids and buprenorphine through the Communication and Public Education Committee. A member was interested in having pharmacies provide test strips to allow for drugs to be tested before use to ensure fentanyl was not present. A member suggested the possibility for creating continuing education to help educate pharmacists.

Members discussed class and culture issues. The issue of people who were addicted to substances versus those who were not aware of their addictions was also discussed.

Members discussed the importance of communication and cultural competency so that everyone was included in the education and there were no groups of people left out. Members suggested working with the Medical Board of California to help doctors and pharmacists collaborate to help patients.

Members of the public participating in Sacramento were provided the opportunity to comment.

A representative from a consulting group working with California Bridge on the issue voiced appreciation for the discussion.

A representative from CPhA appreciated the dialogue and added that CPhA would provide more continuing education and communication specific to this issue.

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

A physician assistant from Highland Hospital Emergency Department appreciated the conversation. The commenter urged the Board to reconsider policies that subject buprenorphine prescriptions to the same scrutiny as other opioid prescriptions.

A representative from the National Campaign to Protect People in Pain commented how important it was to treat addiction and for everyone in healthcare to be sensitive to patients with chronic pain.

Member Crowley left the meeting at 11:45 a.m.

An opioid stewardship pharmacist in a large academic medical center commented in appreciation of the Board entertaining modification to the red flags. She added 40% of pharmacies do not keep suboxone in stock. In California Schedule III drugs can be filled two days early but many refuse to follow this law which impacts emergency room wait times. The commenter urged the Board to provide education on this issue.

A pharmacist representative of Kaiser Permanente requested the Board consider agendizing an item regarding potential tension between a pharmacist's obligation to exercise their corresponding responsibility and the obligation not to delay dispensing a legitimate prescription that could lead to complaints and investigations.

A California Bridge and ER doctor addiction specialist appreciated that the Board is listening and encouraged the Board to collaborate with physicians, noting suboxone can save lives.

The Board took a lunch break from 11:51 a.m. to 12:45 p.m. Roll call was taken. The following Board members were physically present in Sacramento: Trevor Chandler, Public Member; Jeff Hughes, Public Member; KK Jha, RPh, Licensee Member J. Newell, MSW, Public Member; Satinder Sandhu, PharmD, Licensee Member; Maria Serpa, PharmD, Licensee Member; and Seung Oh, PharmD, Licensee Member. Renee Barker, PharmD, Licensee Member, and Nicole Thibeau, PharmD, Licensee Member, participated via WebEx. A quorum was established.

XI. Presentation on Proposed Follow-up Statewide Study to Describe Trends and Access to PrEP in California. Presenters include Stefano Bertozzi, MD PhD; Jerika Lam, PharmD; Ayako Miyashita Ochoa, JD; and Lauren Hunter, PhD.

The Board then heard a presentation about the proposed follow-up statewide study to describe trends and access to PrEP in California.

Members were provided the opportunity to comment.

Members discussed the importance of the treatment and critical barriers to providing it including reimbursement, long-acting injectables (LAIs) being covered as a medical benefit not a pharmacy benefit, billing being difficult and tedious, PBM requirements, large HMOs not covering LAIs, and liability and other risks and considerations related to the mode of administration. Concern was also expressed that if Gilead moves patient assistance programs to mail order pharmacy, this would also become a barrier to access.

Members discussed the survey design, the impact the removal of information from federal websites might have, and dissemination of the results once the survey has concluded.

Ms. Sodergren suggested adding the issue to a future agenda item for the Communication and Public Education Committee.

Dr. Bertozzi asked if the Board could request representatives of the larger chains to come before the Board to discuss policy changes within the chains to help improve access. President Oh indicated the Board would be willing to try. Dr. Sandhu indicated he could help facilitate this discussion.

Members of the public participating in Sacramento were provided the opportunity to comment.

A representative of CPhA commented in appreciation for the presentation and spoke in support of staying current with the guidelines for HIV PEP and PrEP. The representative added with AB 317 (Weber, Chapter 322, Statutes of 2023), PEP and PrEP was one of the covered pharmacy services and the need to ensure the reimbursements are happening so the services can be provided.

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

XII. Discussion and Consideration of Waiver of Pharmacy Law Provisions Consistent with the Authority in Business and Professions Code Section 4062 in Response to State of Emergency Related to the Palisades Fire

President Oh advised Business and Professions Code section 4062 provides authority for the Board to waive application of any provisions of Pharmacy Law or its regulations during a declared federal, state, or local emergency under specified conditions. The Board, through an adopted policy, has delegated authority to the Board President to issue a waiver for up to 30 days. In response to the governor's proclamation of a state of emergency related to the Los Angeles area fires, and consistent with delegated authority, the Board issued three specific waivers of Pharmacy Law. The first waiver provided flexibility to increase the number of pharmacy technicians a pharmacist may supervise. The second waiver provided flexibility for pharmacy personnel to perform some functions from outside of a licensed pharmacy. The third waiver allowed for the delivery of drugs to an alternate location.

Dr. Oh noted that as conditions remained very dynamic and it was anticipated there will be long term impacts, this item was placed on the agenda for the Board to consider if additional action was appropriate. The approach offered in the meeting materials would provide the Board President with additional delegated authority to extend current waivers and issue new waivers related to the emergency declaration through the end of the fiscal year, June 30, 2025, or until the end of the declared emergency, whichever is sooner.

Members were provided the opportunity to comment.

Members discussed the benefits and drawbacks of having waivers of the ratio requirement and remote processing applied statewide. Some members were concerned about allow remote processing throughout California while others were worried the waivers may not be broad enough.

Motion: Consistent with the Board's authority in Business and Professions Code section 4062(b), and the January 7, 2025 Emergency Declaration, delegate authority to the Board President to extend current waiver(s) and issue new waivers related to the January 7, 2025 Emergency Declaration through June 30, 2025, or until the end of the declared emergency, whichever is sooner.

M/S: Thibeau/Sandhu

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

Members of the public participating via WebEx were provided the opportunity to comment. A representative of CCAP and a pharmacist commented in support of the motion and keeping the language broad.

Support: 9 Oppose: 0 Abstain: 0 Not Present: 2

Board Member	Vote
Barker	Support
Cameron-Banks	Not Present
Chandler	Support
Crowley	Not Present
Hughes	Support
Jha	Support
Newell	Support
Oh	Support
Sandhu	Support
Serpa	Support
Thibeau	Support

XIII. Organizational Development Committee Report

President Oh advised the meeting materials include updated information on the Board's budget for fiscal year 2024/25 which began July 1. The Board's authorized expenditures were anticipated to be about $35.2 million this year. The Board's fund condition indicated that it was projected that the Board fund will slowly decrease. According to the report provided by the DCA, the Board's fund currently has 6.3 months in reserve. Dr. Oh reminded members that under the provisions of Business and Professions Code section 4400(p), the Board shall seek to maintain a reserve equal to approximately one year's operating expenditures. As the Board's new fee structure became effective in January 2025, the Board would continue to monitor the fund and if necessary, would make adjustments in future years.

Dr. Oh advised Board member attendance and mail vote information was also included the meeting materials. Dr. Oh thanked members for their time and commitment to protecting California consumers.

Dr. Oh advised the Board had 11 vacant staff positions. Recruitments were ongoing and he receives regular updates on recruitments as part of weekly meetings with the Executive Officer and monthly as part of the Organizational Development Committee Meetings.

Members were provided the opportunity to comment. A member asked about the new legislative director position. Ms. Sodergren advised the position was filled.

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

XIV. Executive Officer Report

Ms. Sodergren provided an overview of the licensing and enforcement statistics. She noted the semi-annual CPJE stats were provided. She advised the Sunset Report was

submitted on January 6, 2025. The Board's Sunset Hearing could be scheduled for March 11, 2025.

Ms. Sodergren referred to meeting materials that reflected 50% of pharmacists and pharmacy technicians renewed their license online for the fourth quarter of calendar year 2024. The Board anticipates the number to increase. An issue was reported with the online vendor. A temporary solution with DCA addresses the issue until a permanent solution can be implemented.

Ms. Sodergren reported the Board's pharmacist-in-charge training was finalized and should be posted on the Board's website. A subscriber alert would be sent out with directions on how to sign up when the training was ready.

Ms. Sodergren advised based on the data provided by DCA, the Board anticipated approximately 190 licensees meet the criteria of the governor's executive order related to fees for licensees impacted by the LA fires. The Board initiated direct outreach to the licensees and associations.

Ms. Sodergren reported with the execution of the contract with the Institute for Safe Medication Practices, implementation activities were underway for the medication error reporting system and communication to licensees would be released soon.

Ms. Sodergren advised a list of pending regulations was provided.

Members were provided the opportunity to comment. Member Serpa commented that she renewed online and found it helpful and quick. Member Thibeau asked if the Board monitored trends in licensing. Ms. Sodergren advised this was generally done annually at the end of the year with a three year comparison.

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

XV. Closed Session Matters

Open session concluded at approximately 2:15 p.m. The Board entered closed session at approximately 2:25 p.m. Closed session ended at 3:28 p.m.

XVI. Reconvene in Open Session to Adjourn the Meeting

The Board reconvened into open session and adjourned the meeting at 3:28 p.m.