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: November 6-7, 2024

Location: OBSERVATION AND PUBLIC COMMENT IN PERSON:
COURTYARD SAN DIEGO MISSION VALLEY/HOTEL CIRCLE
595 Hotel Circle South
San Diego, CA 92108

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
Renee Barker, PharmD, Licensee Member
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)
Jason Weisz, Public Member (November 7th only)

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

Staff Present:
Anne Sodergren, Executive Officer
Julie Ansel, Deputy Executive Officer
Corinne Gartner, DCA Staff Counsel
Norine Marks, DCA Regulations Counsel (November 7th only)
Jennifer Robbins, DCA Regulations Counsel (via WebEx)
Debbie Damoth, Executive Specialist Manager

November 6, 2024

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 11:02 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 San Diego: Jessi Crowley, PharmD, Licensee 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. 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. Public Comments on Items Not on the Agenda/Agenda Items for Future Meetings

Members of the public participating from San Diego were provided the opportunity to comment; however, no comments were received.

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

Public comment was received requesting that COVID-19 vaccines stop being administered in California pharmacies.

A representative from CPhA and pharmacist representative of Kaiser Permanente commented about and requested for a future agenda a discussion about the pharmacist licensure examination and residency programs.

Multiple pharmacists commented about specialty pharmacists being able to work remotely and requested this authority be added to the Sunset Report.

Members were provided the opportunity to comment and add an agenda item for a future agenda. The executive officer briefly noted staff were communicating with impacted individuals regarding the pharmacist licensure examination issue.

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

President Oh reminded those present that the Board recognizes pharmacists who have been licensed for 40 or more years by posting the information on the Board's website and providing pharmacists with a certificate.

President Oh invited pharmacists licensed for 40 years or more to identify themselves and be recognized by the Board. However, no pharmacists self-identified as having been a licensed pharmacist in California for 40 years or more. Dr. Oh thanked all pharmacists who worked in pharmacy serving the consumers of California.

IV. Approval of Board Meeting Minutes

a. July 31 – August 1, 2024 Board Meeting

Dr. Oh referenced the draft minutes from the July 31 – August 1, 2024 Board meeting.

Members were provided an opportunity to comment. Dr. Serpa noted a correction on page 3 to remove "advanced practice pharmacists" from the sample discussion.

Motion: Approve the July 31 – August 1, 2024 Board meeting minutes as presented in the meeting materials with corrections discussed.

M/S: Serpa/Sandhu

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

Support: 8 Oppose: 0 Abstain: 1 Not Present: 3

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

b. September 12, 2024 Board Meeting

Dr. Oh referenced the draft minutes from the September 12, 2024 Board meeting.

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

Motion: Approve the September 12, 2024 Board meeting minutes as presented in the meeting materials.

M/S: Crowley/Thibeau

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

Support: 9 Oppose: 0 Abstain: 0 Not Present: 3

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

c. August 23, 2024 Disciplinary Petition Committee Meeting

Dr. Oh referenced the draft minutes from the August 23, 2024 Disciplinary Petition Committee meeting.

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

Motion: Approve the August 23, 2024 Disciplinary Petition Committee meeting minutes as presented in the meeting materials.

M/S: Crowley/Barker

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

Support: 9 Oppose: 0 Abstain: 0 Not Present: 3

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

V. Discussion and Consideration of Waiver Related to Temporary Provisions for Compounding Certain Parenteral Drug Products Consistent with Provisions of Business and Professions Code Section 4062

Dr. Oh noted that Business and Professions Code (BPC) 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. Consistent with this authority, and in response to the public health emergency stemming from the consequences of Hurricanes Helene and Milton, President Oh issued a waiver on October 16, 2024, to support the temporary provisions for compounding certain parenteral drug products following the issuance of federal guidance. As long-term impacts from the hurricanes were anticipated, Dr. Oh believed an extension of the waiver was appropriate.

Members were provided the opportunity to comment. Members discussed the three submissions from California licensed pharmacies that had so far been received under the waiver, including the two submissions the Board had objected to because they did not comply with the provisions of the federal guidance. A member also shared that some IV products listed on the FDA's website have been given extended expiration dates.

Motion: Consistent with the Board's authority in Business and Professions Code section 4062(b), and the declaration of public health emergencies by HHS Secretary Becerra, the Board extends its current waiver, Temporary Provisions for

Compounding Certain Parenteral Drug Products, through January 31, 2025, or until the end of the declared emergency, whichever is sooner.

M/S: Barker/Newell

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

Support: 9 Oppose: 0 Abstain: 0 Not Present: 3

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

VI. Report by the California Department of Consumer Affairs

Dr. Oh introduced and welcomed Melissa Gear, Deputy Director of Board and Bureau Relations with the Department of Consumer Affairs. Ms. Gear provided an update from the Department to the Board.

Following Ms. Gear's report, members were provided the opportunity to comment; however, no comments were made.

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

President Oh then turned the meeting over to Member Serpa, chairperson of the Enforcement and Compounding Committee, to provide a report on the Committee's recent work.

VII. Enforcement and Compounding Committee

a. Updates to Frequently Asked Questions Related to Assembly Bill 1286 (Haney, Chapter 470, Statutes of 2023)

Chairperson Serpa recalled as part of the discussion on implementation of Assembly Bill 1286, given the comprehensive nature of the measure, the Committee determined development of frequently asked questions, or FAQs, was appropriate. FAQs were initially approved during the February 2024 Board meeting and updated at the April 2024 Board meeting. Dr. Serpa added that the meeting materials included updated FAQs reflecting the proposed addition of a question related to reporting medication errors by nonresident pharmacies.

Members were provided the opportunity to comment. Members discussed that another proposed question regarding pharmacy technician initiated transfers had been removed from the FAQs following the Committee's discussion. This issue is now being added to the Sunset Report.

Committee Motion: Recommend approval of the additional FAQs related to Assembly Bill 1286 consistent with the Committee's discussion.

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

Support: 9 Oppose: 0 Abstain: 0 Not Present: 3

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

b. Summary of Presentation on Distribution of Controlled Substances, Wholesalers Perspective, Provided by Leah Lindahl, Vice President State Government Affairs, Healthcare Distribution Alliance and Sara Watson, CPhT, Manager, State Regulatory Outreach, Cardinal Health

Dr. Serpa recalled the Board has received public comments from patients and chronic pain advocates about impacts to patients who were facing challenges receiving their controlled substances. The Committee also received information on actions taken by the DEA to change production quotas for controlled substances, which may have contributed to this issue. At its October 2024 meeting, the Committee heard a presentation on the Distribution of Controlled Substances, Wholesalers Perspective. Dr. Serpa shared that she thought the presentation was very insightful and she encouraged members to review the livestream posted on the Board's website.

Dr. Serpa advised that the presentation explained the required use of thresholds and suspicious order reporting and some of the legal constraints wholesalers experience with interactions with their customers. The presentation also explained that threshold changes were possible and that wholesalers generally have a process to allow customers to make such a request. Following the presentation, the Committee requested both that an article be added to the upcoming issue of *The Script* to provide education on this important issue, and that an alert on the topic be sent out through the subscriber alert system. The Committee also believed a policy statement may be appropriate, as well as collaboration with the Medical Board of California and other programs within the Department of Consumer Affairs to explore additional solutions.

Members were provided the opportunity to comment. A member suggested that in the future the Board might discuss the possible end of the waiver that

allows DEA registered practitioners to prescribe controlled substances via telemedicine without having previously conducted an in-person patient examination. Members agreed the presentation was helpful to understanding that wholesalers can't proactively contact customers about threshold increases but the customers can request one on their own.

Members of the public participating in San Diego 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 Board heard comments from a registered nurse as well as a pharmacist representative of Kaiser Permanente indicating that asking for a threshold increase is an onerous process and pharmacies are often afraid to do it. The commenters expressed that thresholds are insensitive to clinical needs and patients suffer because the process of requesting an adjustment is too slow. The commenters also encouraged the Board to collaborate with the Medical Board of California to approach the AG about the opioid settlement.

Members were provided the opportunity to comment having heard public comment. A member agreed with public comment and supported providing education on this topic to licensees as soon as possible.

c. Draft Report to the Legislature on Automated Drug Delivery Systems as Required by Business and Professions Code Section 4427.8

Dr. Serpa reminded those present that the Board was required to submit a report to the Legislature on the regulation of automated drug delivery systems (ADDS) as part of the upcoming sunset evaluation process. During the July 2023 Committee meeting, members received the first presentation related to the findings of ADDS quality assurance (QA) reports received, which revealed what appeared to be a lack of compliance with reporting requirements. Since that time, staff undertook education of licensees on the reporting requirements. At the July 2024 Committee meeting, the Committee received a presentation with updated data. The Committee reviewed the draft legislative report at the October 2024 meeting and is recommending that the Board approve it.

Members were provided the opportunity to comment. Members applauded the staff on the outreach and education efforts undertaken.

Committee Motion: Recommend approval of the draft legislative report.

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

Support: 9 Oppose: 0 Abstain: 0 Not Present: 3

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

d. Enrolled or Recently Signed Legislation Impacting the Practice of Pharmacy

i. Assembly Bill 1842 (Reyes, Chapter 633, Statutes of 2024) Health Care Coverage: Medication-Assisted Treatment

Dr. Serpa advised the Committee noted general agreement with the implementation activities offered by staff for AB 1842 related to health care coverage for medication-assisted treatment.

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

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

ii. Assembly Bill 1902 (Alanis, Chapter 330, Statutes of 2024) Prescription Drug Labels: Accessibility

Dr. Serpa noted that as part of the Committee's consideration of AB 1902, related to accessibility of prescription drug labels, the Committee discussed the requirements established in the measure and questioned whether the statute is sufficient for self-execution. The Committee requested that staff develop additional information about what is specifically required and if regulations were necessary. Members agreed that education on the provisions was necessary and that staff should

exercise enforcement discretion during the implementation phase by securing compliance through education.

Members were provided the opportunity to comment. Members discussed whether regulations would be necessary to clarify the measure's requirements.

Members of the public participating in San Diego 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 heard from a pharmacist representative of Kaiser Permanente stating that regulations were not necessary but that the definition of timeliness may need to be clarified. Another commenter warned that pharmacies might still face civil liability under the measure even if the Board decides to exercise enforcement discretion.

iii. Assembly Bill 2115 (Haney, Chapter 634, Statutes of 2024) Controlled Substances

Dr. Serpa next discussed AB 2115, which authorizes specified entities to dispense a 72-hour supply of a Schedule II controlled substance for purposes of relieving acute withdrawal symptoms while arrangements were being made for referral for treatment. The Committee agreed with the implementation activities identified by staff.

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

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

Members of the public participating via WebEx were provided the opportunity to comment. Public comment encouraged the Board to provide education on the measure.

iv. Assembly Bill 3063 (McKinnor, 2024) Pharmacies: Compounding

Dr. Serpa then turned to AB 3063 related to adding a flavoring agent to a prescription medication. She noted this was the second year the

governor has vetoed this measure. The Board had opposed the measure as it conflicted with USP standards, but does see a potential need to assist pharmacies to continue to provide flavoring. Dr. Serpa noted the meeting materials included the amendment the Board had requested of the author of AB 3063 to address the Board's concerns. Regrettably, the amendment was not accepted.

Dr. Serpa continued that the Committee was recommending that the Board develop potential statutory language related to flavoring agents and prescription requirements. While this wouldn't change USP requirements, it would allow pharmacies to make flavoring additions without obtaining the prescribers' authorization each time.

Dr. Serpa confirmed that members received the written comments on this item from one of the manufacturers of flavoring agents. She had read the comments and noted that unfortunately the commenter appeared to again be requesting that the Board disregard the national standards. Dr. Serpa stated that she remained steadfast in the belief that the Board needs to focus on assisting pharmacies with operationalizing USP requirements. She believed it was appropriate to remind members that the governor vetoed on two occasions measures that would have changed California law to run contrary to national standards.

Members were provided the opportunity to comment. Members discussed what could be done by the Board to help operationalize compliance with USP standards regarding adding flavoring. Members agreed that it would be helpful for pharmacists to be able to add flavoring without receiving prescriber approval each time. The Board also discussed documentation requirements and that certain medications include flavoring information in the package insert – in which case adding the flavoring is not considered compounding.

Committee Motion: Recommend that the chairperson and staff work together to develop potential statutory language related to flavoring agents and prescription requirements.

Members of the public participating in San Diego were provided the opportunity to comment. The Board heard comments from a representative of FlavoRx who suggested the issue is how the Board decides to enforce USP standards.

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

Comments were received from representatives from Children's Specialty Care Coalition; Kaiser Permanente; Director of Pharmacy at Pioneers Memorial Healthcare District and owner of Desert Pharmacy; and a member of the public. The comments received indicated the Board should adopt a solution allowing for the USP standards to not apply to flavoring; the proposed language wouldn't solve any issues; and concern parents are adding other items to their children's medications.

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

Support: 9 Oppose: 0 Abstain: 0 Not Present: 3

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

v. Senate Bill 164 (Committee on Budgets, Chapter 41, Statutes of 2024) State Government

Dr. Serpa advised SB 164 raised the CURES fee from $9 annually to $15 annually with implementation of the new fees facilitated by the Department of Justice. The Committee agreed with the implementation activities detailed in the meeting materials.

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

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

vi. Senate Bill 954 (Menjiva, 2024) Sexual Health

Dr. Serpa provided SB 954 was vetoed by the governor. This measure was about access to nonprescription contraception. During the Committee meeting, members noted the need to provide education on existing law. A subscriber alert was released in February 2024 describing rights to contraceptive care. This information will also be included in a future issue of *The Script*.

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

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

vii. Senate Bill 966 (Wiener, 2024) Pharmacy Benefits

Dr. Serpa advised SB 966 was also vetoed by the governor and would have established the regulation of pharmacy benefit managers (PBMs) within the California Department of Insurance. As indicated in the meeting materials, the Board identified payor practices that negatively impact patients as a possible issue to include in sunset review.

Members were provided the opportunity to comment. A member expressed disappointment with the veto.

Members of the public participating in San Diego were provided the opportunity to comment. A representative of CPhA commented PBM regulations were necessary.

Members of the public participating via WebEx were provided the opportunity to comment. An individual expressed disappointment in the veto of this measure.

viii. Senate Bill 1067 (Smallwood-Cuevas, 2024) Healing Arts: Expedited Licenses Process: Medically Underserved Area or Population

Dr. Serpa provided SB 1067 was also vetoed by the governor. This was a measure about expediting the licensure process in specified situations. Given the measure was vetoed, the Committee did not discuss the measure.

ix. Senate Bill 1089 (Smallwood-Cuevas, Chapter 625, Statutes of 2024) Addressing Food Injustice: Notice of Grocery and Pharmacy Closures

Dr. Serpa noted SB1089 requires a covered establishment, which includes a pharmacy, to provide 45 days advance notice of any closure to the Board. She noted the Board has a pending regulation to amend 16 CCR Section 1708.2 related to Discontinuance of Business requirements to require at least a 30 day notice. The Committee noted the Board's proposed regulation language should align with the timeframes included in SB 1089. Should the Board agree, staff will work with counsel on the best means to align the reporting requirements with the statutory provisions.

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

Members of the public participating in San Diego 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 UFCW WSC, which sponsored SB 1089, agreed the Board should update the pending regulation to align with the 45-day notification requirement in SB 1089 and requested the Board develop FAQs on how the notice should be made to the Board.

Dr. Serpa noted agreement with the staff's recommendation to update the proposed regulation text to 45 days to align with this new requirement and requested staff work with counsel to determine the appropriate path forward to facilitate the change.

x. Senate Bill 1451 (Ashby, Chapter 481, Statutes of 2024) Professions and Vocations

Dr. Serpa added SB 1451 was not discussed during the Committee meeting. The measure extends provisions for pharmacist-furnished COVID-19 oral medications until January 1, 2026. The measure also

requires a pharmacist to provide, at the request of a customer, documentation specifically designed for veterinary drugs. Dr. Serpa agreed with the implementation activities detailed in the meeting materials. She appreciated the information provided by the Veterinary Medical Board on appropriate resources to include as part of the Board's education. Dr. Serpa also confirmed that members had received the written public comment that was submitted on this item.

Members were provided the opportunity to comment. A member noted the need to collaborate with the Veterinary Medical Board.

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

xi. Senate Bill 1468 (Ochoa Bogh and Roth, Chapter 488, Statutes of 2024) Department of Consumer Affairs

Dr. Serpa noted SB 1468 will require the Board, as well as other DCA healing arts boards that license prescribers, to develop and biannually disseminate educational materials about the federal "Three day rule." This issue was mentioned in AB 2115 which authorizes dispensing of not more than a 3-day supply of narcotic drugs for the purpose of initiating maintenance treatment or detoxification treatment while arrangements were being made for referral for treatment. Dr. Serpa believed it would be appropriate to request that the Communication and Public Education Committee oversee the development of the educational materials if the Department of Consumer Affairs does not coordinate such development.

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

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

e. FDA Actions Related to Implementation of the Drug Supply Chain Security Act

Dr. Serpa noted that background information on the Drug Supply Chain Security Act (DSCSA) was included in the meeting materials. She added that over the years, the Board has received presentations on implementation activities, including a presentation by Josh Bolin with the National Association of

Boards of Pharmacy. She noted the DSCSA included milestones for implementation. For example, by November 27, 2023, the law required all prescription drug packages to be serialized with a unique identifier. The FDA has released a number of guidance documents on DSCSA requirements and recently released information that they were issuing exemptions to small dispensers under specified conditions.

Dr. Serpa noted no action on this item was required but the information was included as a means to ensure licensees and other interested stakeholders remain apprised of activities undertaken by the FDA to implement the DSCSA. She noted the provisions of the DSCSA related to track and trace requirements were very complex and believed it was extremely important for licensees to remain educated on the implementation milestones and FDA's DCSCA-related activities.

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

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

f. Enforcement Statistics

Dr. Serpa noted that the meeting materials included a summary of enforcement statistics for the first three months of fiscal year 2024/25. The Board initiated 706 complaints and closed 764 investigations. As of October 1, 2024, the Board has 1,918 field investigations pending. The 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 San Diego and via WebEx were provided the opportunity to comment; however, no comments were made.

The Board took a lunch break from 12:50 p.m. to 2:00 p.m. Roll call was taken. The following Board members were physically present in San Diego: Jessi Crowley, PharmD, Licensee 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. Quorum was established.

VIII. Licensing Committee

a. Proposed Follow-up Survey on Working Conditions

Dr. Oh recalled that as part of the Board's prior sunset review, the Board committed to conducting a survey on working conditions in community pharmacies. The survey was conducted in 2021 with the data released in December 2021. During the Licensing Committee's October 2024 meeting, the Committee determined that it was appropriate to conduct a follow-up survey to gauge current working conditions and gain insights from pharmacists on the implementation of provisions including AB 1286 related to working conditions. The Committee also determined it would be appropriate to survey pharmacy technicians as well. Experts within DCA's Office of Professional Examination Services (OPES) will again assist the Board if the Board determined a deployment of a survey was again appropriate. Dr. Oh reported that following the October 2024 Committee meeting, he worked with staff to develop the two surveys included in the meeting materials.

Committee Motion: Recommend development and deployment of workforce surveys for pharmacists and pharmacy technicians.

Members were provided the opportunity to comment.

A member suggested adding questions related to consequences if a service isn't provided.

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

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

Comments were heard from representatives of UFCW WSC and CPhA in support of the surveys with recommendations for additional questions to add. The comments also expressed that some questions that ask about

potential violations of law may be concerning for respondents, so the survey materials should reinforce that this will be an anonymous survey that won't be used for enforcement purposes.

Members were provided the opportunity to comment after having heard public comment. A member asked that a question be added if the respondent had control over the scheduling system at their pharmacy.

Support: 9 Oppose: 0 Abstain: 0 Not Present: 3

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

b. Summary of Presentation by the California Pharmacists Association on Assembly Bill 317 (Weber, Chapter 322, Statutes of 2023) Related to Pharmacist Service Coverage

Dr. Oh advised that AB 317 established requirements for health care service plans and certain disability insurers to reimburse the cost of services performed by a pharmacist at an in-network pharmacy or by a pharmacist at an out-of-network pharmacy under specified conditions. At the October 2024 meeting, the Committee received a presentation from representatives of CPhA, one of the bill's sponsors, on the status of implementation. Dr. Oh added the presentation was very informative. Dr. Oh expressed that although it was disheartening to learn about the barriers that continue to exist for pharmacies to receive reimbursement, he remains hopeful. Dr. Oh encouraged everyone to watch the livestream of the October 2024 meeting.

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

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

A pharmacist was encouraged that payers were anecdotally agreeable to reimburse pharmacists working outside of a pharmacy.

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

c. Proposed Changes to Board-Provided Training for Furnishing HIV Preexposure and Postexposure Prophylaxis

Dr. Oh noted that, as detailed in the meeting materials, recent changes in California law have updated the provisions for pharmacist-furnished HIV preexposure prophylaxis, or PrEP. To address these changes, the Board adopted emergency regulations. Additionally, it was appropriate to update the Board's training program to incorporate the changes in statutes as well as the standards for pharmacist-furnished HIV preexposure and postexposure prophylaxis consistent with the statute. Dr. Oh thanked the experts who assisted the Board with updating the training program, including Dr. Betty Dong, Dr. Clint Hopkins, and experts with the Office of AIDS and Department of Health Care Services.

Dr. Oh noted that following approval of the updated training program by the Board, Dr. Dong would finalize the program and quiz so that the training would be deployed on the Board's new learning management system.

Committee Recommendation: Recommend approval of the updated training.

Members were provided the opportunity to comment. A member asked if a pharmacist had already completed the training, would they be required to also complete the updated training. The executive officer noted that she believed there was no requirement under Pharmacy Law to re-take the training but would confer with counsel to confirm.

Members of the public participating in San Diego 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 Board heard public comment from a pharmacist indicating CMS issued a final rule moving PrEP and PEP from Medicare Part D to Medicare Part B where pharmacists do not qualify. Another pharmacist commented that CMS was working on a transition to help pharmacies but asked if the Board would consider expanding the training requirement to also include CDC training. A representative of CPhA opined that while pharmacists who had already completed training on PrEP/PEP were not legally required to complete the updated training, the standard of care may require them to.

Members were provided the opportunity to comment after having heard public comment. Members discussed that the CMS rule would be a barrier to providing PrEP/PEP as Part B was historically for services and now would be for both services and medicine. Additionally, PBMs were taking money back when a pharmacy opens a bottle of PEP which is a 28-day treatment but comes in bottles of 30 tablets which could result in a barrier and delay to treatment.

Support: 9 Oppose: 0 Abstain: 0 Not Present: 3

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

d. Summary of Changes to Pharmacy Application Process

Dr. Oh recalled that the Board still struggles to meet performance measures established for some licensing programs as processing times were impacted by a number of factors including resources available, use of outdated consumer systems as well as, in part, applications that are submitted without the required information. Dr. Oh continued that

at the October meeting, the Committee heard a presentation on draft changes to the community pharmacy application forms, and received additional recommendations as part of public comment. The meeting materials included updated application instructions, applications, and supplemental information all intended to assist licensees with a better understanding of the application process. As indicated in the meeting materials, public comment had suggested that the Board requests too much information, and that there was no real difference between the processing time for temporary and permanent licensure. Dr. Oh expressed appreciation that staff followed up on that issue by providing some data on processing times for temporary and permanent licensure in the meeting materials.

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

Members of the public participating in San Diego 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 suggested that a specific application should be available for nonprofit applicants.

e. Proposed Changes to Application Questions for Individual Licenses

Dr. Oh noted that the meeting materials included background on the federal Lorna Breen Health Care Provider Protection Act, which seeks to address mental health challenges faced by health care professionals. Dr. Oh further shared that he had the opportunity to learn about this Act and the Wellbeing First Champion Challenge during the annual meeting of the National Association of Boards of Pharmacy (NABP). He applauded the goal of reducing stigma, enhancing support systems, and ultimately improving the wellbeing of health care workers.

During the October Committee meeting, members had an opportunity to review the recommendations being offered by staff specific to this issue and agreed that the approach offered was appropriate. Given that the pharmacy technician application is incorporated by reference in regulation, changes to that application would be made via the rulemaking process. All other applications could be updated and implemented more quickly.

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

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

f. Summary of Open Discussion on Payor Practices that Negatively Impact Patient Care

Dr. Oh recalled that the Board previously identified payor practices that negatively impact patient care as a potential issue to raise as part of the Sunset Report. During its October meeting, the Licensing Committee discussed this issue and expressed concerns with certain Pharmacy Benefit Manager (PBM) practices. Dr. Oh noted that as part of the next agenda item, the Board would be considering some potential statutory provisions to address these issues. He also noted that following the Licensing Committee meeting, written comments were received specifically related to this issue, and that we these comments would be considered as part of the later discussion.

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

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

Members of the public participating via WebEx were provided the opportunity to comment. Comments were heard from a representative of CPhA and a pharmacy owner in Los Angeles indicating that lack of reimbursement for pharmacist-provided clinical services was a barrier to these services being offered more widely.

g. Licensing Statistics

Dr. Oh noted that the meeting materials included licensing statistics for the first quarter of the fiscal year. The Board has issued 3,128 permanent licenses, and 470 temporary licenses during this time period, and processed 593 pharmacist exam applications. A total of 696 pharmacist

licenses were issued. Dr. Oh congratulated those individuals who received a license during this period.

Dr. Oh added that, with the exception of the designated representative applications, as of October 4, 2024, the processing times were below the 30-day performance target for processing new applications. He added site application processing times remained beyond the 30-day processing times. He noted continued struggle with staff vacancies in the Licensing unit. He was hopeful changes to the pharmacy application and instructions would ultimately result in improved application processing times and the number of deficient applications is reduced. The Committee continues to monitor the progress made by staff and will continue to report this information to the Board.

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

Members of the public participating in San Diego were provided the opportunity to comment. A representative of CVS Health noted that later in the meeting the Board will consider a nonresident pharmacy inspection requirement, and recommended that the Board focus resources on inspecting pharmacies in California.

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

IX. Discussion of Proposed Issues to Raise as Part of Sunset Report

Dr. Oh noted that the Board has completed significant work to identify areas to raise as part of the Board's report to the Legislature. Dr. Oh expressed that he believed the work was notable and that he was proud to serve on the Board.

Dr. Oh requested that as the Board began its discussion of the draft document presenting new issues, members be respectful of those items where the Board has already taken action. He further noted that this was not a time to provide edits to the language of the draft report but rather to focus on the policy. He noted the Board received a significant number of written comments related to this agenda item. Dr. Oh added the draft included 22 issues for possible inclusion in the Board's legislative report and draft statutory language where indicated. Items previously approved included:

1. Nonresident Pharmacies
2. Pharmacist to Pharmacy Technician Ratio

3. Pharmacy Technicians Compounding Outside of a Pharmacy
4. IV Hydration Clinics
5. Standard of Care Practice Model for Pharmacists
6. Remote Processing
7. Records
8. Hormonal Contraception
9. Ownership Prohibition
10. Retired Licenses
11. Changes to Pharmacy Technician Trainee

Dr. Oh continued that while for some of these items, the Board has already approved statutory language to be offered as part of the legislative report, in others the statutory language has not been approved.

Members were provided the opportunity to comment. Members generally agreed with the policies and proposed statutory language in the draft report, although some members continued to be concerned that the standard of care practice model would be challenging to implement in a retail chain setting, with some members asking if it might be appropriate to create different rules for different practice settings. A member also expressed concerns about regulation of pharmacy delivery services and wanting to ensure that access to these services is maintained for transgender patients and patients who are chronically ill or disabled.

Dr. Oh stated that he believed the legislative proposal specifically related to standard of care included some significant provisions. The Board's proposal in this area streamlined authorities that already existed and created provisions for some new authorities without creating mandates. The proposal included explicit language that pharmacists cannot provide services where they lack sufficient education, training or experience or where the pharmacist staffing of the pharmacy was insufficient to facilitate comprehensive patient care.

Motion: Approve the new issues and draft statutory language not previously approved by the Board as consistent with the Board's policy discussions, and further, to delegate to the Board President and executive officer to finalize this portion of the sunset review with staff for inclusion in the Board's legislative report.

M/S: Oh/Hughes

Members of the public participating in San Diego were provided the opportunity to comment. The Board heard comments from representatives of CSHP, CVS Health, CPhA, Walgreens, and UCSD, and from a member of the public. Multiple commenters expressed support for the transition to a standard

of care practice model for pharmacists. Other comments disagreed with specific provisions of the draft report, including the proposed amendments to BPC sections 4112 and 4303 (regarding nonresident pharmacies) and the proposed addition of sections 4317.6 (establishing fine authority for violations by mail order pharmacies) and 4188 (regarding IV hydration clinics); urged the Board to pursue regulation of PBMs; and offered specific comments on proposed statutory language.

Members of the public participating via WebEx were then provided the opportunity to comment. The Board heard numerous comments from pharmacists, retired pharmacists, pharmacy technicians, members of the public and representatives of interested stakeholders. Some commenters spoke in favor of the transition to a standard of care practice model for pharmacists, while others expressed concerns about implementing the standard of care proposal, especially in the community pharmacy setting. Multiple commenters stated that the Board could move forward with the standard of care proposal while tackling workplace conditions as a separate issue. Other comments urged the Board to regulate PBMs and to expand technician duties; discussed pharmacist to pharmacy technician ratios; and expressed opposition to the Board's attempt to regulate IV hydration clinics.

The Board took a break from 4:00 p.m. to 4:15 p.m. Roll call was taken. The following Board members were physically present in San Diego: Jessi Crowley, PharmD, Licensee 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. Quorum was established.

Following the break the Board continued to hear public comment from individuals participating via WebEx. Numerous additional comments were received from members of the public and representatives of interested stakeholders. Many commenters voiced support for the standard of care proposal. Other comments asked the Board to remove the standard of care proposal from the Sunset Report. Still other comments offered specific amendments to the statutory proposals included in the draft report.

Members were provided the opportunity to comment having heard public comments. Member comments in response to public comment included: consider providing a longer window (such as 90 days) for a nonresident pharmacy to report a change in PIC; support allowing pharmacy technicians to provide immunizations outside a pharmacy under the direct supervision

and control of a pharmacist and expanding the types of immunizations techs can administer; and address AB 317 reimbursement outside of a pharmacy, tackle patient steering, at-cost reimbursement, and strengthening provisions in AB 1286. Some members suggested that the Board consider waiting until we have the results of the follow-up survey on working conditions before moving forward with standard of care proposal, while others didn't want to stop progress on the standard of care proposal, suggesting that workplace conditions issues can be addressed in tandem with moving the proposal forward.

Ms. Sodergren provided an overview of the sunset review process, including explaining that the oversight committees of the Legislature ultimately decide what proposals will move forward as bills. As a result, there will be many opportunities for stakeholders to continue to engage in the legislative process.

Support: 8 Oppose: 1 Abstain: 0 Not Present: 3

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

X. Discussion and Consideration of the Board's Strategic Plan

Dr. Oh provided background on the Board's strategic planning process. The current plan covers 2022-2026. On an annual basis, the Board reviews its strategic plan to confirm the established strategic objectives for each committee remain appropriate or if changes should be considered. This annual review also serves as an opportunity for the Board to evaluate progress in the respective areas.

As Chair of the Licensing Committee, Dr. Oh reported the status of the various objectives established for the Committee. He noted that, as reflected in the meeting materials, the Committee continues activities in support of a number

of the strategic objectives, and stated that he believed work will be completed in the coming year for some objectives including 1.3 and 1.4, and that he looked forward to future updates on several objectives related to business modernization activities. He concluded his report by stating that he believed the Committee's objectives remain appropriate.

Committee members and members were provided an opportunity to comment on Dr. Oh's report; however, no comments were made.

Chair of the Enforcement and Compounding Committee Dr. Serpa provided an overview of that Committee's strategic objectives. Dr. Serpa expressed that she was proud of the Committee's accomplishments and looked forward to continued efforts, including activities related to reducing medication errors which is core to the Board's consumer protection mandate.

Dr. Serpa acknowledged the progress staff have made to meeting the strategic objective in 2.3, stating that she believed great strides were made to reach the four-year benchmark. She noted that currently, 79.7% of pharmacies have been inspected within the 4-year period. Dr. Serpa also highlighted that while the Committee's work was complete in strategic goal 2.5 (specifically related to consideration of further use of a Standard of Care Enforcement Model) with submission of the legislative report, work in this general area continues through the Licensing Committee. Dr. Serpa further noted that work related to strategic objective 2.8 may include focusing some efforts on education of nonresident pharmacies, and added that work related to strategic objective 2.10 resulted in the initiation of the formal rulemaking process to update the Board's compounding regulations.

Dr. Serpa referenced the meeting materials, which included the Committee's recommendation to add a new strategic objective 2.11 – Enhance patient consultation compliance by evaluating barriers to consultation to provide patient education and reduce medication errors.

Committee members and members were provided an opportunity to comment on Dr. Serpa's report. A member spoke in support of the addition of the new strategic objective 2.11.

Chair of the Legislation and Regulation Committee Dr. Crowley then provided that Committee's report on its six strategic objectives. Dr. Crowley referenced the meeting materials, which highlight updates to the respective objectives, and noted that the updates highlight the work of the Board in its policy making efforts to protect California consumers. While there were no specific updates to provider status, she noted the passage of AB 317 provides for

reimbursements under specified conditions which was related in part to the policy goal of provider status.

Committee members and members were provided an opportunity to comment on Dr. Crowley's report; however, no comments were made.

Vice Chair of the Communication and Public Education Committee Dr. Thibeau then provided an update on that Committee's eight strategic objectives and highlighted the Committee's efforts over the past year. The Committee reviewed their objectives and believed they remain appropriate.

Committee members and members were provided an opportunity to comment on Dr. Thibeau's report; however, no comments were made.

As Chair of the Organizational Development Committee, Dr. Oh noted that the meeting materials detailed that Committee's various strategic objectives as well as status updates on the objectives. Several activities have been undertaken in support of the Committee's strategic objectives. He highlighted training completed by Board staff under objective 5.3; business modernization activities related to objective 5.4; and staff's work to update information on the Board's website related to objective 5.6.

Committee members and members were provided an opportunity to comment on Dr. Oh's report; however, no comments were made.

Enforcement and Compounding Committee Recommendation:
Add strategic objective 2.11 enhance patient consultation compliance by evaluating barriers to consultation to provide patient education and reduce medication errors.

Members of the public participating in San Diego were provided the opportunity to comment. A member of the public expressed that she was confused by strategic objective 2.9 and didn't understand how the Board is able to regulate IV hydration clinics.

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

Support: 9 Oppose: 0 Abstain: 0 Not Present: 3

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

XI. Discussion and Possible Action Related to Proposed Amendment to California Code of Regulations, Title 16, Section 1709.1 Related to Designation of Pharmacist-in-Charge, Including Review of Comments Received During the 15-Day Comment Period Initiated to Address Issues Raised by the Office of Administrative Law

Dr. Oh reminded those present that in January 2022, the Board approved proposed regulation text to amend 16 CCR section 1709.1. The most recent comment period closed on November 1, 2024, and supplemental meeting materials regarding this agenda item were posted and released on November 4, 2024. Dr. Oh noted that very few comments were received and he trusted that members had an opportunity to review the comments received and the staff recommended responses. Dr. Oh added that having reviewed the information he agreed with the staff recommended response. Dr. Oh noted the meeting materials had proposed motion language that could be used to adopt the regulation text.

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

Motion: Move to ratify the modifications to the regulatory text published during the second 15-day comment period from October 17, 2024, through November 1, 2024, and accept Board staff-recommended comment responses. Additionally, direct Board staff to take all steps necessary to complete the rulemaking process.

Title 16. Board of Pharmacy
Second Modified Text

Proposed changes to current regulation text are indicated with a ~~single strikethrough~~ for deletions and a single underline for additions.

Modified regulation text to the proposed regulation text is indicated with a ~~double strikethrough~~ for deletions and a double underline for additions.

The second modified regulation text to the regulation text is indicated with a ~~**bold double strikethrough**~~ for deletions and a **bold wavy underline** for additions.

Amend Section 1709.1 of Article 2 of Division 17 of Title 16 of the California Code of Regulations to read:

§ 1709.1. Designation of Pharmacist-In-Charge

(a) The pharmacist-in-charge (PIC) of a pharmacy shall be employed at that location and shall have responsibility for the daily operation of the pharmacy. Prior to approval of the board, and as part of the application and notice process set forth in Section 1709 of this Division ("application"), a pharmacy shall submit its proposed PIC. The PIC shall have completed the board-provided Pharmacist-in-Charge Overview and Responsibility training course**, available on the board's website,** within two years prior to the date of application. The PIC shall complete an attestation statement in compliance with this section. For purposes of this section, a completed attestation statement shall include all of the following: name of the proposed pharmacist-in-charge, the individual's license number, a statement that they have read Sections 4036.5, 4081, 4113, and 4330 of the Business and Professions Code and this section, ~~**and**~~ a statement identifying the date that the proposed PIC took the board's training course, and a declaration signed under penalty of perjury of the laws of the State of California that the information provided by the individual is true and correct. **The board-provided Pharmacist-in-Charge Overview and Responsibility training course shall be approximately 1 hour and shall cover:**
(1) Legal requirements of the role of a PIC
(2) Legal prohibitions for a pharmacy owner to subvert the PIC
(3) Legal requirements/Overview of the self-assessment process
(4) How to prepare for an inspection

(5) Top violations that result in a Cite and Fine

(b) The pharmacy owner shall vest the pharmacist-in-charge with adequate authority to assure compliance with the laws governing the operation of a pharmacy.

(c) No pharmacist shall be the pharmacist-in-charge of more than two pharmacies. If a pharmacist serves as pharmacist-in-charge at two pharmacies, those pharmacies shall not be separated by a driving distance of more than 50 miles.

(d) No pharmacist shall be the pharmacist-in-charge of a pharmacy while concurrently serving as the designated representative-in-charge for a wholesaler or a veterinary food-animal drug retailer.

(e) Notwithstanding subdivision (a), a pharmacy may designate any pharmacist who is an employee, officer or administrator of the pharmacy or the entity which owns the pharmacy and who is actively involved in the management of the pharmacy on a daily basis as the pharmacist-in-charge for a period not to exceed 120 days. The interim PIC shall have completed the board-provided Pharmacist-in-Charge Overview and Responsibility training course, identified in subdivision (a) within two years prior to the date of application. The interim PIC shall complete the attestation statement as identified in subdivision (a). The pharmacy, or the entity which owns the pharmacy, shall be prepared during normal business hours to provide a representative of the board with documentation of the involvement of a pharmacist-in-charge designated pursuant to this subdivision with the pharmacy and efforts to obtain and designate a permanent pharmacist-in-charge.

(f) A pharmacist may refuse to act as a pharmacist-in-charge at a second pharmacy if the pharmacist determines, in the exercise of his or her professional judgment, that assuming responsibility for a second pharmacy would interfere with the effective performance of the pharmacist's responsibilities under the Pharmacy Law. A pharmacist who refuses to become pharmacist-in-charge at a second pharmacy shall notify the pharmacy owner in writing of his or her determination, specifying the circumstances of concern that have led to that determination.

(g) A person employing a pharmacist may not discharge, discipline, or otherwise discriminate against any pharmacist in the terms and conditions of employment for exercising or attempting to exercise in good faith the right established pursuant to this section.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4036.5, 4081, 4113, 4305 and 4330, Business and Professions Code.

M/S: Serpa/Barker

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

Support: 9 Oppose: 0 Abstain: 0 Not Present: 3

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

XII. Discussion and Possible Action Related to Proposed Amendment to California Code of Regulations, Title 16, Section 1711 Related to Quality Assurance Programs, Including Comments Received During the 45-Day Comment Period

Dr. Oh reminded those present that in January 2023, the Board approved proposed regulation text to amend 16 CCR section 1711, related to the Board's Quality Assurance Program. As part of the Board's Medication Error Reduction and Workforce Committee, this ad hoc committee took a deep dive into the issue of medication errors. Through this work, one of the action items identified was the need to update the Board's QA regs that have largely remained unchanged to two decades.

Dr. Oh noted that the Board's 45-day comment period closed on September 23, 2024, and that, as indicated in the meeting materials, the Board received a number of comments. Dr. Oh highlighted that the meeting materials include several items including the proposed regulation text as initially noticed, comments received during the public comment period, staff recommended responses and recommended changes to the proposed text in response to the comments received. Dr. Oh noted that he had reviewed the information and agreed with the staff recommended response.

Given time constraints, Dr. Oh then stated that discussion on this item would resume at 9:00 a.m. on November 7.

XV. Closed Session Matters

Open session concluded at approximately 5:20 p.m. The Board convened in closed session at approximately 5:30 p.m. and ended closed session at 6:51 p.m. The meeting was reconvened in open session and immediately adjourned for the day.

November 7, 2024

President Oh called 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 San Diego: Jessi Crowley, PharmD, Licensee 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; Jason Weisz, Public 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.

The Board resumed discussing this item. President Oh provided introductory remarks similar to those he had provided the previous day.

Members were then provided the opportunity to comment. Members discussed the difference between a "QA plan" versus a "QA program," noting the pending regulation was more of a QA program, with each event reviewed in a silo. Members spoke in support of keeping a QA plan as something to possibly move toward in the future, with the understanding that different pharmacy settings have different levels of infrastructure and different needs, and that a QA plan might not be appropriate for all settings.

Motion: Accept the Board staff's recommended comment responses, and approve the recommended updated modified text as recommended by staff for a 15-day comment period. If the Board does not receive any comments providing objections or adverse recommendations specifically directed at the proposed action or to the procedures followed by the Board in proposing or adopting the action, authorize the executive

officer to take all steps necessary to adopt the proposed regulation at Section 1711 and complete the rulemaking process. Finally, 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.

Department of Consumer Affairs
Title 16. Board of Pharmacy

Proposed Modifications to Regulation Text

Quality Assurance Programs

Proposed changes made to the current regulation language are shown by ~~strikethrough~~ for deleted language and <u>underline</u> for added language. Modified regulation text to the proposed regulation text is indicated with a ~~double strikethrough~~ for deletions and a <u>double underline</u> for additions.

Amend section 1711 to Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows**:**

§ 1711. Quality Assurance Programs.

(a) Each pharmacy shall establish or participate in an established quality assurance program that documents and assesses medication errors to determine cause and an appropriate response as part of a mission to improve the quality of pharmacy service and prevent errors.

(b) For purposes of this section, “medication error” means any variation from a prescription or drug order not authorized by the prescriber, as described in ~~S~~<u>s</u>ection 1716. Medication error, as defined in the section, does not include any variation that is corrected prior to furnishing the drug to the patient or patient's agent or any variation allowed by law.

(c)(1) Each quality assurance program shall be managed in accordance with written policies and procedures maintained in the pharmacy in an immediately retrievable form.

(2) When a pharmacist determines that a medication error has occurred, a pharmacist shall as soon as possible:

(A) Communicate to the patient or the patient's agent the fact that a medication error has occurred and the steps required to avoid injury or mitigate the error.

(B) Communicate to the prescriber the fact that a medication error has occurred.

(3) The communication requirement in paragraph (2) of this subdivision shall only apply to medication errors if the drug was administered to or by the patient, or if the medication error resulted in a clinically significant delay in therapy.

(4) If a pharmacist is notified of a prescription error by the patient, the patient's agent, or a prescriber, the pharmacist is not required to

communicate with that individual as required in paragraph (2) of this subdivision.

(d) Each pharmacy shall use the findings of its quality assurance program to develop pharmacy systems and workflow processes designed to prevent medication errors. An investigation of each medication error shall commence as soon as is reasonably possible, but no later than 2 business days from the date the medication error is discovered. All medication errors discovered shall be subject to a quality assurance review.

(e) The primary purpose of the quality assurance review shall be to advance error prevention by analyzing, individually and collectively, investigative and other pertinent data collected in response to a medication error to assess the cause and any contributing factors such as system or process failures. A record of the quality assurance review shall be immediately retrievable in the pharmacy. The record shall contain at least the following:

(1) The date, location, and participants in the quality assurance review;

(2) The pertinent data and other information relating to the medication error(s) reviewed and documentation of any patient contact required by subdivision (c)~~;~~, including:

(A) The date and approximate time or date range when the error occurred if known or can be determined. If it cannot be determined, the pharmacy shall note “unknown” in the record.

~~(B) The names of staff involved in the error.~~

(~~C~~B) The use of automation, if any, in the dispensing process.

(~~D~~C) The type of error that occurred. To ensure standardization of error reporting, the pharmacies’ policies and procedures shall include the category the pharmacy uses for identifying the types of errors.

(~~E~~D) An outpatient pharmacy report must also document the ~~The~~ volume of workload completed by the pharmacy staff on the date of the error, if known, including clinical functions. If the date of the error is unknown, the average volume of workload completed daily shall be documented. For errors that occur in a community pharmacy, at a minimum the volume of workload records shall include the number of new prescriptions dispensed, the number of refill prescriptions dispensed, the number of vaccines administered, and number of patient consultations given~~, and any other mandatory activities required by the pharmacy employer~~. Prescriptions filled at a central fill location and dispensed at the pharmacy must be documented separately from other prescriptions filled at the pharmacy.

(3) The findings and determinations generated by the quality assurance review; and~~,~~

(4) Recommend changes to pharmacy policy, procedure, systems, or processes, if any. The pharmacy shall inform pharmacy personnel of changes to pharmacy policy, procedure, systems, or processes made as a result of recommendations generated in the quality assurance program. Documentation of the steps taken to prevent future errors shall be maintained as part of the quality assurance report.

(f) The record of the quality assurance review, as provided in subdivision (e) shall be immediately retrievable in the pharmacy for at least ~~one~~ three years from the date the record was created. Any quality assurance record related to the use of a licensed automated drug delivery system must also be submitted to the ~~b~~Board within 30 days of completion of the quality assurance review and any facility with an unlicensed automated drug delivery system must report the quality assurance review to the Board at the time of annual renewal of the facility license.

(g) The pharmacy's compliance with this section will be considered by the ~~b~~Board as a mitigating factor in the investigation and evaluation of a medication error.

(h) Nothing in this section shall be construed to prevent a pharmacy from contracting or otherwise arranging for the provision of personnel or other resources, by a third party or administrative offices, with such skill or expertise as the pharmacy believes to be necessary to satisfy the requirements of this section.

NOTE: Authority cited: Sections 4005 and 4125, Business and Professions Code~~; and Section 2 of Chapter 677, Statutes of 2000~~. Reference: Sections 4125 and 4427.7, Business and Professions Code.

M/S: Crowley/Serpa

Members of the public in San Diego were provided the opportunity to comment. A representative of CPhA spoke in support of future discussion on QA plans.

Members of the public via WebEx were provided the opportunity to comment. A pharmacist spoke in favor of the QA plan.

Support: 10 Oppose: 0 Abstain: 0 Not Present: 2

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

XIII. Organizational Development Committee

Dr. Oh advised the Organizational Development Committee Report was for information only. Meeting materials included updated information on the Board's budget for fiscal year 2023/24 and for the new fiscal year which began July 1, 2024. The Board's authorized expenditures were anticipated to be about 36.3 million dollars this year. The Board's fund condition indicated that it was projected that the Board fund will slowly decrease with DCA projecting a current 6.3 month reserve. Pursuant to BPC section 4400(p), the Board shall seek to maintain a reserve equal to approximately one year's operating expenditures. Dr. Oh continued that as the new fee structure takes effect in January 2025, the Board will continue to monitor the fund make adjustments if needed in future years. Dr. Oh thanked the Board for their time and commitment to protecting California consumers, referencing member attendance and mail vote information included in meeting materials. Dr. Oh reported the Board had 13 vacant staff positions with recruitments ongoing. Meeting dates were included in the meeting materials and subject to change.

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

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

XIV. Executive Officer Report

Ms. Sodergren provided an update on the NABP VI, VII and VIII meeting attended by herself and President Oh. President Oh was re-elected as the District Treasurer. California will host the meeting in 2027. The annual meeting

for NABP will be held in Florida where there may be resolutions that align with California Board actions.

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

Ms. Sodergren continued by providing a regulations updates as included in the meeting materials.

Members were provided the opportunity to comment. A member asked about the status of the self-assessment for outsourcing facilities regulation approved by the Board in 2022. Ms. Sodergren provided there was typically back and forth between DCA and staff on complex regulations as well as regulations in the full rulemaking process with tight deadlines. Ms. Sodergren offered to provide an update with projections.

Members of the public in San Diego were provided the opportunity to comment. The NABP District VIII Chairperson thanked Dr. Oh for his assistance in the District meeting and noted his participation makes the District stronger.

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

The Board took a break from 9:28 a.m. to 9:35 a.m. Roll call was taken. The following Board members were physically present in San Diego: Jessi Crowley, PharmD, Licensee 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; Jason Weisz, Public Member; and Seung Oh, PharmD, Licensee Member. Nicole Thibeau, PharmD, Licensee Member, participated via WebEx. A quorum was established.

XVII. 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 Educational Presentations by Board Counsel and Staff on Federal Law and Background Information, and Consideration of Comments Received During the 45-Day Comment Period and Regulation Hearing

Following brief introductory remarks by President Oh, the Board received a presentation from Board Counsel Corinne Gartner providing an overview of the federal and California requirements for human drug compounding. Ms. Gartner provided general information and background on compounding

followed by an overview of federal law on compounding, including a discussion of the need for an exemption for compounding. Ms. Gartner continued with a summary of the 503A exemption and a discussion of the 503A Bulks List. Ms. Gartner then covered federal guidance on human drug compounding, including an overview of the FDA's interim enforcement policy, and discussed two examples of 503A Category 1 substances. Ms. Gartner next provided an overview of California law relevant to compounding and briefly discussed the proposed compounding regulations currently being considered by the Board.

Members were provided an opportunity to comment. Members expressed appreciation for the presentation and the information provided.

The Board then received a presentation from Board Executive Officer Anne Sodergren. Ms. Sodergren began by reviewing the Board's statutory mandate in BPC section 4001.1 that the protection of the public shall be the highest priority for the California State Board of Pharmacy in exercising its licensing, regulatory, and disciplinary functions. Whenever the protection of the public is inconsistent with other interests sought the be promoted, the protection of the public shall be paramount.

Ms. Sodergren reviewed common questions and answers regarding the proposed compounding regulations to provide background information for meeting participants. Ms. Sodergren continued with an overview of the history of compounding regulations in California and discussed the importance of consumer protection. She then provided an overview of the development of the proposed compounding regulations currently being considered by the Board. Ms. Sodergren provided examples comparing the current regulations and the proposed regulations; reviewed current provisions proposed to be removed because they are now covered by USP; discussed changes made to the proposed regulations in response to comments received; and reviewed examples of items not covered in USP or where USP defers to the state.

Ms. Sodergren next provided an overview of FDA actions related to compounding, including FDA compounding information for states, FDA compounding FAQs, FDA compounding alerts, and FDA warning letters. She also discussed the FDA's interim policy on compounding using bulk drug substances, the FDA guidance regarding insanitary conditions at compounding facilities, and FDA warnings for compounders to know their bulk suppliers.

Ms. Sodergren then reviewed actions taken by other regulators and agencies including NABP and the states of Kentucky, Kansas, and Massachusetts, and provided examples of cases where patients were harmed due to unsafe

compounding. Ms. Sodergren concluded her presentation by reviewing the options available to the Board with respect to the proposed compounding regulations, including offering a staff recommendation as well as possible motion language.

The Board took a break from approximately 10:40 a.m. to 11:00 a.m. Roll call was taken. The following Board members were physically present in San Diego: Jessi Crowley, PharmD, Licensee 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; Jason Weisz, Public Member; and Seung Oh, PharmD, Licensee Member. Nicole Thibeau, PharmD, Licensee Member, participated via WebEx. A quorum was established.

Members were provided the opportunity to comment. Members expressed appreciation for the presentation of complex materials and asked questions to clarify their understanding.

Dr. Barker and Dr. Serpa both spoke briefly about their professional backgrounds and their experience and expertise in compounding. As part of their remarks, both members spoke about the Board's public protection mandate and expressed concerns that some comments received on the pending regulations would, if incorporated into the proposed regulation text, undermine patient safety.

Motion: Accept the Board staff recommended responses as included in the packet, including the updated supplemental responses, to the initial comments from the 45-day comment period and regulation hearing as the responses of the Board and approve the recommended modified regulation text dated August 29, 2024, for a 30-day public comment period, allowing comments to the entire text, not just modified text. Additionally, delegate to Members Serpa and Barker the authority to review comments received to the modified text during the public comment period with staff to present recommended changes and responses at a future Board meeting.

M/S: Oh/Barker

Members were provided the opportunity to comment.

Members discussed a previous motion related to adopting USP. Ms. Sodergren explained that USP compliance was already required under federal and state

law. The gaps that exist in USP would result in gaps in state law related to guidance for bulk substances and parts of USP that defer to the states.

Members also discussed that some public comment appeared to be asking the Board to provide unregulated access to some medications. In the proposed regulations, a pathway is being provided for pharmacies that want to compound bulk drug substances, which provides access while also putting steps in place to ensure patient safety. Members discussed how the provisions added for testing of bulk drug substances came from USP and are important for patient safety.

As part of the discussion, it was clarified that all comments received during the comment period would be considered. Process and timing considerations regarding the regulation package were also discussed, and regulations counsel clarified that the Office of Administrative Law (OAL) and Administrative Procedure Act requires that the rulemaking be submitted to OAL no more than one year after publication.

Members of the public participating in San Diego were provided the opportunity to comment. Comments were heard from members of the public including a medical doctor, a sterile compounding pharmacist, and a naturopathic doctor. Comments were also heard from representatives of interested stakeholder groups including UC San Diego Health, For Hims and Hers Health, CVS Health, Volunteer Fire Foundation, www.stopthebop, San Diego Lyme Alliance, and lymedisease.org. Comments were received thanking the Board for the time and effort dedicated to the regulations. Other comments urged the Board to simply adopt USP standards without more and reduce barriers to access to 503A Category 1 substances such as methylcobalamin and glutathione. Additional comments were received requesting specific changes to the proposed regulatory text. Commenters were reminded to submit such comments in written form during the formal regulation comment period to ensure they can be considered and responded to.

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

Comments were heard from members of the public including an attorney, a Sonoma County Councilmember, physicians, firefighters, and a naturopathic doctor. Comments were also heard from representatives of interested stakeholder groups including APC and CPhA. Comments were received thanking the Board for receiving and incorporating comments to the modified text. Additional comments were received urging the Board to reduce barriers to access to 503A Category 1 substances such as

methylcobalamin and glutathione. Other comments claimed that accounts of patient harm related to compounding were red herrings and that the proposed regulations will make it too hard for compounders to do business in California.

The Board took a break from approximately 12:31 p.m. to 1:15 p.m. Roll call was taken. The following Board members were physically present in San Diego: Jessi Crowley, PharmD, Licensee 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; Jason Weisz, Public Member; and Seung Oh, PharmD, Licensee Member. Nicole Thibeau, PharmD, Licensee Member, participated via WebEx. A quorum was established.

The public comment period for individuals participating via WebEx resumed. Comments were heard from individuals including Sonoma County firefighters and fire captains, veterinarians, an environmental neuroscientist, and a fitness nutritionist. Comments were also heard from representatives of interested stakeholder groups including Kaiser Permanente, CVMA, CMA, Scripps Health, Integrative Healers Action Network, Cedars Sinai, Got Long COVID, and FlavoRx. Comments were received adding continued thanks for engaging and educating the public and making requested changes to the proposed regulations. Other comments urged the Board to simply adopt USP standards without more and reduce barriers to access to 503A Category 1 substances such as methylcobalamin and glutathione. Additional comments were received requesting specific changes to the proposed regulatory text; suggesting the Board was not relying on scientific evidence; warning the Board against overreach and unnecessary overregulation; asking the Board to hold a special meeting; and thanking the Board for bringing medication flavoring back into the discussion.

Members were provided the opportunity to comment after having heard public comment. Members discussed their support for the motion and the 30 day comment period to review all proposed text to allow stakeholders time to comment in writing so that the Board could respond in writing back. A member also expressed concern about adopting USP as California's regulatory standard, given that certain of the Board's current compounding regulations go beyond USP, so adopting USP would mean the Board would be lowering, and creating gaps in, patient safety standards.

Support: 9 Oppose: 0 Abstain: 1 Not Present: 2

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

Direction was provided on how to comment on the modified text. The meeting adjourned at 2:09 p.m.