# Attachment V.

## a. January 8, 2025
## Board Meeting

**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
# DRAFT Public Board Meeting Minutes

**Date:** January 8, 2025

**Location:** OBSERVATION AND PUBLIC COMMENT IN PERSON:
California Department of Consumer Affairs
1625 North Market Blvd., First Floor Hearing Room
Sacramento, CA 95834

PUBLIC PARTICIPATION AND COMMENT FROM A REMOTE LOCATION: WebEx

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

**Board Members Not Present:**
Indira Cameron-Banks, Public Member
Nicole Thibeau, PharmD, Licensee Member
Jason Weisz, 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 Regulations Counsel
Jennifer Robbins, DCA Regulations Counsel
Sara Jurrens, Public Information Officer
Debbie Damoth, Executive Specialist Manager

**January 8, 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 9:00 a.m. Dr. Oh provided information regarding emergency exit routes from the hearing room for the benefit of those attending the meeting in person. He also announced that the Enforcement and Compounding Committee meeting and the Communication and Public Education Committee meeting scheduled for January 9, 2025, were both cancelled. Dr. Oh further announced that the Board had released a subscriber alert that morning regarding the state of emergency for the Palisades fire in Los Angeles County, and that additional subscriber alerts would be sent if waivers were issued as a result of the state of emergency.

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; Renee Barker, PharmD, Licensee Member; Jeff Hughes, Public Member; J. Newell, MSW, Public Member; Satinder Sandhu, PharmD, Licensee Member; Maria Serpa, PharmD, Licensee Member; and Seung Oh, PharmD, Licensee Member. Jessi Crowley, PharmD, Licensee Member, and KK Jha, RPh, Licensee Member, participated via WebEx. Dr. Crowley and Mr. Jha each 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. 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. There were no pharmacists identifying themselves to be recognized for 40 years of service as a pharmacist. Dr. Oh thanked and congratulated pharmacists who had been licensed as a pharmacist for over 40-years. Dr. Oh thanked all pharmacy staff who worked in pharmacy serving the consumers of California.

## III. 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, and Review of Comments Received During the 30-Day Comment Period**

Dr. Oh advised that in response to the Board's 30-day comment period on the proposed regulations regarding sterile and nonsterile compounding, hazardous drugs, and radiopharmaceuticals, the Board continued to receive significant engagement from interested stakeholders. He recalled that during the September 2024 Board meeting, members requested additional education on this complex area of practice. He further noted that at the November 2024 Board meeting, consistent with the Board's request and as agendized, the Board received presentations on relevant legal requirements and background on compounding, and that the presentations are available on the Board's website.

Dr. Oh noted that the meeting materials included the modified text released for the 30-day comment period, comments received during the 30-day comment period, staff recommended responses to comments received, a letter from the Medical Board of California, and staff recommended second modified text dated January 8, 2025.

Dr. Oh thanked stakeholders for continuing to engage in the rulemaking process. He also thanked Members Serpa and Barker for reviewing the comments received and working with staff to provide recommendations for the Board's consideration today. Dr. Oh noted that he had reviewed the information and looked forward to the Board's discussion and action. Dr. Oh then asked Dr. Serpa to provide an overview of the recommended changes.

Dr. Serpa thanked stakeholders for their responses and noted that the comments and recommendations received were very helpful to the Board as it considers modifications to the proposed text. Dr. Serpa also thanked Dr. Barker for sharing her expertise and time.

Dr. Serpa reminded all present that the development of these 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 provided a reminder that the Board has a statutory mandate to review Board regulations when USP is updated, and noted that although the Board started this review early, it was now well beyond the November 1, 2023, date that the updated USP chapters became compendial.

Dr. Serpa again thanked those who provided written comments to the proposed regulations. She expressed concern that some commenters appeared to be seeking changes to lessen the standards of existing law and noted that in considering all comments received, the Board must reflect on its consumer protection mandate.

Dr. Serpa reminded those present that the proposed regulations were to clarify or make more specific California compounding regulations in light of USP chapter updates that became effective November 1, 2023. The proposed regulations generally do not repeat federal law or USP standards but clarify the Board's standards for compounding along with the federal law and USP standards. She added as a further reminder that the proposed regulations have been reorganized to follow the organizational format of the USP chapters.

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:

- Minor recommendations in section 1735, compounding definitions, to make clear that the pharmacist-in-charge (PIC) can serve as the designated person. It was also recommended that the definition of "essentially a copy" be further amended to clarify that a pharmacist is responsible for verifying and documenting the clinical significance determined by the prescriber.
- Modifications to section 1735.1(d) to allow an increase to a 14-day supply for veterinary patients. In addition, after discussion with the Board's veterinarian expert, staff recommend a change to 1735.1(e)(2) to reflect some of the provisions included in the Guidance for Industry #256 consistent with comments received. Also in this section, staff recommend including expanded conditions for health care facilities to compound a commercially available product under specific conditions, and the addition of new language related to facilities that limit compounding to combining a flavoring agent as specified, including a general exemption from the Board's nonsterile compounding requirements except where specified.
- Clarification is being recommended in section 1735.6(a) related to manufacturer specifications for use of equipment.
- A recommendation is made to remove the requirement in section 1735.7(c)(1) related to inclusion of the date and time of compounding for determining the beyond use date.

- Modification of section 1735.12(a) to remove the requirement for a written procedure for responding to out of range temperatures in some specified situations.
- Addition of new section 1735.15 specifically related to flavoring agents.

Members were provided an opportunity to comment. Members discussed ensuring section 1735.1(e)(1)(A) was consistent with federal law; specific changes that may need to be made to sections 1735.11(a)(2)(F) and 1735.12; UC Health's comments to these sections of the proposed regulations; and the new provisions regarding flavoring.

Dr. Serpa continued with an overview of the changes being recommended to Article 4.6 regarding sterile compounding. She noted that many of the requirements in the proposed text exist in the Board's current regulations, and that the recommended text would actually establish greater flexibilities for pharmacies than what is currently allowed. Dr. Serpa again expressed concern that some commenters continue to appear to be seeking a lessening of the Board's current standards or changes that run afoul of federal law and national standards. She provided a reminder about the presentations on these topics that the Board received in January 2023 and November 2024 and added that these presentations were available for viewing on the Board's website. Dr. Serpa then highlighted the following recommendations being offered by staff in response to comments received:

- Minor recommendations in section 1736 to clarify that the PIC can serve as the designated person. It was also recommended that the definition of "essentially a copy" be further amended to clarify that a pharmacist was responsible for verifying and documenting the clinical significance determined by the prescriber.
- In section 1736.1:
    - Changes were recommended to subdivision (b) to provide additional flexibility to facilities to compound under immediate use provisions under specified conditions for up to 48 hours, and to provide additional flexibilities for a critical access hospital to perform such compounding for up to 120 hours.
    - In subdivision (d)(2) the proposed modified text extends the supply for an animal patient to a 7-day supply.
    - Changes were recommended similar to those made in the nonsterile article to include provisions of the Guidance for Industry #256 related to compounding for veterinary patients.
    - Changes were recommended for provisions for using nonsterile components in a sterile preparation.
    - Clarifications to provisions in subdivision (h) were also recommended.

Members were provided an opportunity to comment on the changes being recommended to sections 1736 and 1736.1. Members discussed UC Health's comment to section 1736.1(b). Members also agreed that section 1736.1(b)(3)

should be updated to include "after attempts to remediate pursuant to the facility's SOPs are unsuccessful."

Dr. Serpa then continued reviewing Article 4.6 and highlighted the following additional changes being proposed by staff in response to comments received:

- Minor changes to sections 1736.2 and 1736.3 to provide clarity on gloving requirements and provisions for transferring competencies between facilities.
- Staff recommended removal of the language related to classified and unclassified air and the requirement for dynamic interactions to be controlled through an HVAC system in section 1736.4(e).
- Additional clarifying language is proposed to be added to section 1736.13 regarding rate of infusion of admixed sterile products.
- Changes to section 1736.17(a)(2)(F) to provide clarification that the facility's SOPs did not need to require that the facility itself perform the specified testing; rather, a facility could rely upon such testing performed by other specified entities, if the testing results are provided to the facility.
- Removal of proposed text in section1736.21 related to compounding allergenic extracts was being recommended. Dr. Serpa notes that based on comments received and consideration of the proposed regulation text, it became apparent that the proposed language is not needed as the USP chapter does not allow for the compounding of a stock allergy solution.

Dr. Serpa concluded her overview of the changes being recommended to Article 4.6 in response to comments received by noting that there are no additional changes being proposed to the provisions addressing sterile compounding of 503A Category 1 bulk drug substances. She reiterated that the Board's goal is not to limit access to these products but rather to provide a clear and safe path forward to compound with these chemicals.

Members were provided the opportunity to comment. Members discussed the legal definition of "shall be typically maintained" in section 1736.4(c)(1); changes that might need to be made to section 1736.18(c) to be consistent with the counterpart provision in Article 4.5; adding a timeframe to maintain records of three years to section 1736.17(h); and changes that may need to be made to section 1736.20(b). Members also discussed UC Health's comments to the proposed regulatory text in these sections.

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

- Throughout the article, where the proposed modified text previously referenced requirements for "other manipulations" in the compounding of HDs, it was being recommended that this be limited instead to crushing or splitting tablets or opening capsules of antineoplastic hazardous drugs.

- In response to a request from CalOSHA, it was recommended that the Board's regulations include a reminder of safety and health requirements included in Title 8 Industrial Relations.
- It was recommended that section 1737.2 be restructured to accurately reflect the different responsible personnel in the various types of facilities licensed by the Board.
- It was recommended that provisions related to wipe sampling be reworded to more clearly state that wipe sampling was not required; however, the determination about whether wipe sampling was appropriate for a facility must be appropriately documented.
- It was recommended that section 1737.7(c) be changed to extend allowances for outer gloves for use when preparing multiple HD preparations of the same drug or preparing multiple HD preparations for a single patient. After consideration, it was determined that such a provision will not create a risk to patients and could provide for easier workflows for licensees and a lower cost.
- Section 1737.11 was proposed to be amended to add subdivision (c) to provide for additional flexibility in the labeling requirements for a compounded antineoplastic HD if it will be administered within a health care facility.
- It was recommended that provisions related to disposable preparation mats and handling of more than one HD preparation in a PEC also be further modified under similar conditions to those described in the outer gloving provisions.
- Section 1737.14 was proposed to be amended to provide clarity in the language. Subdivision (b) was reworded to make clear that necessary gloves must be offered to a patient. It was recommended that an exemption to this requirement be provided for compounded antineoplastics preparations that will be administered within a licensed health care facility.

Members were provided the opportunity to comment. In addition to recommending some technical/nonsubstantive changes, members also discussed refining the language in section 1737.14(b) to make it clear that the pharmacy does not need to provide the gloves for free.

Dr. Serpa continued with an overview of the changes being recommended to Article 4.8 related to radiopharmaceuticals. Dr. Serpa noted that very few comments were received related to these provisions, and that staff's recommended changes in response to comments received included:

- Removal of the prohibition on compounding in an SRPA in section 1738.5.
- Removal of some of the language initially proposed in section 1738.10(c).
- In section 1738.14(b), it was recommended that the required notification to the Board be extended from 72 to 96 hours.

Members were provided the opportunity to comment. Members discussed adding "hours" to section 1738.14(b) after "96."

Dr. Serpa concluded her remarks by discussing the timeline for the proposed regulations and the impact of delays on licensees. She noted that if the Board does not move forward quickly, the current regulatory package will expire, requiring the Board to start the process again. She emphasized that in her view, this would not be a productive use of the Board's time and would mean continued confusion for licensees. She then proposed a motion to approve the second modified text for noticing.

The Board took a break from 10:30 a.m. to 11:10 a.m. Roll call was taken. The following Board members were physically present in Sacramento: Trevor Chandler, Public Member; Renee Barker, PharmD, Licensee Member; Jeff Hughes, Public Member; J. Newell, MSW, Public Member; Satinder Sandhu, PharmD, Licensee Member; Maria Serpa, PharmD, Licensee Member; and Seung Oh, PharmD, Licensee Member. Jessi Crowley, PharmD, Licensee Member, and KK Jha, RPh, Licensee Member, participated via WebEx. Quorum was established.

Dr. Serpa stated that she wanted to clarify the motion she made before the break and asked that the specific changes to be made to the second modified text based on the Board's discussion be reviewed. Ms. Sodergren then provided a summary of the proposed changes based on the Board's discussion:

Article 4.5:

- Amend section 1735.1(e)(1)(A) so that it reads "in short supply at the time of compounding or within 60 days of the end of the shortage"
- Amend section 1735.11(a)(2)(F) to remove "and all adverse drug experiences"
- Amend section 1735.12(b) to remove "or the occurrence of an adverse drug experience"
- Amend section 1735.12(c) to remove "all adverse drug experience events," replace "by the pharmacist-in-charge" with "consistent with the facility's SOPs," and remove "or occurrence of an adverse drug experience event"

Article 4.6:

- Amend section 1736.1(b)(3) to add "after attempts to remediate pursuant to the facility's SOPs are unsuccessful"
- Amend section 1736.17(h) to add a three-year record retention requirement
- Amend section 1736.20(b) to add "modified" to the second sentence to read "modified or relied upon"

Article 4.7:

- Amend section 1737.5(d) to add "containment"

- Amend section 1737.14(b) to add "is exempt from this requirement" to the last sentence and to change verbiage to reflect the policy that the pharmacy is not required to provide gloves for free.

Article 4.8:

- No substantive changes

The changes having been reviewed, Dr. Serpa proceeded to restate the motion.

**Motion:** Accept the Board staff recommended responses to comments received during the 30-day comment period as presented. Approve the recommended second modified text as discussed by the Board for a 15-day comment period. Delegate to the Chair of the Enforcement and Compounding Committee to work with the staff to finalize the update consistent with the discussion and policy of the Board and to make technical or nonsubstantive changes as needed. Additionally, should additional comments be received during the comment period, 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/Jha

Members were provided with the opportunity to comment. Members discussed the change to section 1735.12(c) to remove "adverse drug experiences" and the request from the California Medical Association to confirm that physicians are excluded from the scope of the proposed regulations. Ms. Sodergren noted the letter from the California Medical Board that was included in the meeting materials, which clarified that the Medical Board was the regulator who could take action against their licensees.

Members of the public participating from Sacramento were provided the opportunity to comment. The Board heard comments from representatives of CVS Health, Pacific Compounding Pharmacy, FlavorRx, Volunteer Fire Foundation, and CMA. Comments received expressed appreciation for the changes made to the proposed regulations; thanked the Board for taking the issue of flavoring seriously; urged the Board to make the pathway for compounding 503A Category 1 bulk drug substances such as glutathione less onerous; expressed continued concern about how the proposed regulations will apply to physicians; and requested specific changes to the regulatory text.

Members of the public participating via WebEx were then provided the opportunity to comment. The Board heard comments from members of the

public including pharmacists, patients, and pharmacy technicians, and from representatives of interested stakeholders including UC San Diego Health, UCLA Health, CVMA, Kaiser Permanente, Outsourcing Facility Association, APC, Scripps, Hartley Medical Center, Sutter Health, stopthebop, gotlongcovid, and Integrative Healers Action Network. Multiple comments thanked the Board for their ongoing efforts to collaborate with stakeholders. Other comments voiced opposition to the regulations in their entirety and asked the Board to vote down the motion; suggested the Board was not relying on scientific evidence; urged the Board to reduce barriers to access to 503A Category 1 substances such as methylcobalamin and glutathione; raised specific concerns about glove and passthrough requirements; expressed concern about adoption of the regulations being further delayed and the impact that would have on California sterile compounding pharmacies that ship into other states; questioned the requirement to prove clinical significance; and requested specific changes to the proposed regulatory text.

Members were provided the opportunity to comment after having heard public comment. Members discussed looking at the glove and passthrough issues again if the modified text was approved. Stakeholders were also encouraged to submit all comments in writing should there be a 15-day comment period, as this would allow for the Board to respond to all comments. Members also discussed the importance of remaining mindful that the proposed regulations cover a wide spectrum of compounding practices; whether language should be added to specifically exempt licensees of other healing arts boards; the negative impacts of further delays in finalizing the regulations; the pathway the proposed regulations provide to safely compound 503A Category 1 bulk drug substances; and the next steps in the regulatory process.

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

| 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 | Not Present |
| Weisz | Not Present |

The Board took a lunch break from 12:51 p.m. to 1:45 p.m. Roll call was taken. The following Board members were physically present in Sacramento: Trevor Chandler, Public Member; Renee Barker, PharmD, Licensee Member; Jeff Hughes, Public Member; J. Newell, MSW, Public Member; Satinder Sandhu, PharmD, Licensee Member; Maria Serpa, PharmD, Licensee Member; and Seung Oh, PharmD, Licensee Member. Jessi Crowley, PharmD, Licensee Member, and KK Jha, RPh, Licensee Member, participated via WebEx. A quorum was established.

## IV. Discussion and Possible Action Related to Proposed Amendment to California Code of Regulations, Title 16, Section 1708.2 Related to Discontinuance of Business and Review of Comments Received During the 45-Day Comment Period

Dr. Oh recalled that in April 2024, the Board approved proposed regulation text to amend section 1708.2, related to the Board's discontinuance of business requirements. The 45-day comment period began November 15, 2024, and concluded December 30, 2024. The meeting materials included the proposed text released for the 45-day comment period, comments received, staff prepared responses to comments, and staff recommended modifications to the proposed text. Dr. Oh stated that he had reviewed the materials and agreed with the staff recommendations, including the recommendations to the proposed modified text.

Members were provided the opportunity to comment. Members agreed with the change from 30 days to 45 days to align with Business and Professions Code (BPC) section 22949.92.1 and with the addition of the exemption for inpatient hospital pharmacies, with one member recommending that the phrase "inpatient hospital pharmacy" be replaced with "general acute care hospital pharmacy". Members also discussed whether the regulation should expressly permit electronic notice; whether the PIC or the pharmacy owner should have the burden of certifying compliance with the regulation; and whether the requirement from BPC section 22949.92.1 to post a written notice of the closure in a conspicuous location at the entrance to the pharmacy should be added to the regulation.

Following the Board's discussion, Ms. Sodergren confirmed that changes to the proposed modified regulation text (in addition to staff-recommended changes still applicable following the Board's discussion) should also include amending (b)(4) to update that the owner is responsible, and the owner or PIC, if still available, shall certify compliance; amending (b)(5) to change "inpatient hospital pharmacy" to "general acute care hospital pharmacy"; and adding a new paragraph/subdivision to set forth the statutory requirement to post a

written notice of the closure (including the planned closure date) in a conspicuous location at the entrance of the establishment.

**Motion:** Accept the Board staff's recommended comment responses and modified text consistent with the Board's discussion, and notice the modified text for a 15-day comment period. Additionally, if no adverse comments are received during the 15-day comment period, authorize the executive officer to take all steps necessary to complete the rulemaking and adopt the proposed regulation at Section 1708.2 as noticed. Further, delegate to the executive officer the authority to make technical or nonsubstantive changes as may be required by the Control agencies to complete the rulemaking file.

**Department of Consumer Affairs Title 16.**
**Board of Pharmacy**

**Modified Regulation Text Discontinuance of Business**

Proposed changes made to the current regulation language are shown by ~~strikethrough~~ for deleted language and underline for added language.

Modified changes made to the proposed regulation language are shown by ~~double~~ ~~strikethrough~~ for deleted language and double underline for added language.

**Amend section 1708.2 of Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

(a) Any permit holder shall contact the ~~b~~Board prior to transferring or selling any dangerous drugs, devices, or hypodermics inventory as a result of termination of business or bankruptcy proceedings (individually or collectively referred to as a "closure") and shall follow official instructions given by the ~~b~~Board applicable to the transaction.

(b) In addition to the requirements in (a), a pharmacy that shall cease operations due to a closure (cessation or substantial cessation) shall complete the following:

(1) At least ~~30~~ 45 days in advance of the closure, provide written notice to patients that have received a prescription within the last year. At a minimum, this notice shall include:

(A) the name of the patient and if one exists and is known to the pharmacy, the name of the legal representative of the patient,

(B) the name and physical address of the pharmacy closure,

(C) the name of the pharmacy where patient records will be transferred and maintained, and

(D) information on how to request a prescription transfer prior to closure of the pharmacy.

(2) Reverse all prescriptions for which reimbursement was sought but the prescriptions are not picked up by patients,

(3) Provide the Board with a copy of the notice specified in subsection (b)(1), and

(4) The pharmacist-in-charge shall certify compliance with the requirements in this section. In the event the pharmacist-in-charge is no longer available, the owner must certify the compliance, along with a pharmacist retained to perform these functions.

(5) An inpatient hospital pharmacy that is owned by a health facility as defined in Section 1250 of the Health and Safety Code, and meets the requirements of Business and Professions Code section 22949.92(a)(1)(B)(iii), shall be exempt from the requirements of subdivision (b).

NOTE: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4080, 4081, 4113, 4332, ~~and~~ 4333, 22949.92, and 22949.92.1, Business and
Professions Code; and Section 11205, Health and Safety Code.

**M/S:** Crowley/Sandhu

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

Members of the public via WebEx were provided the opportunity to comment. A pharmacist representative from Kaiser Permanente commented that it was unclear where the Board landed on the issue of allowing the notice to be given electronically and encouraged the Board to provide flexibility and include language in the regulation text that would allow the notice to patients to be given in a form in which the pharmacy regularly communicates with its patients, which could include electronic communication.

Ms. Robbins confirmed that the addition of language (in line with the statutory requirement) regarding the form of communication (written/electronic) being consistent with the patient's preference was included in the Board's discussion and that the motion therefore didn't need to be amended in order for that change to be made to the proposed regulation text.

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

| 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 | Not Present |
| Weisz | Not Present |

**V. Discussion and Possible Action Related to Proposed Amendment to California Code of Regulations, Title 16, Section 1711 Related to Quality Assurance Programs and Review of Comments Received during the 15-Day Comment Period**

Dr. Oh reminded those present that in January 2023, the Board approved proposed regulation text to amend section 1711, related to quality assurance (QA) programs. Dr. Oh further recalled that as part of the Board's Medication Error Reduction and Workforce Committee, this ad hoc committee had taken a deep dive into the issue of medication errors, and that one of action item identified was the need to update the Board's QA regs that have largely remained unchanged for two decades.

Dr. Oh noted that the Board's 45-day comment period closed on September 23, 2024, and that during the November 6-7, 2024 Board meeting, following consideration of the comments received, the Board voted to further modify the proposed text and initiate a 15-day comment period. He continued that, as noted in the meeting materials, the Board received comments during the comment period. The meeting materials included several items including the proposed regulation text released for the 15-day comment period, comments received during the 15-day public comment period, staff recommended responses, and possible motion language.

Dr. Oh stated that he had reviewed the materials and had a concern about the requirement in (e)(2)(D) to track the number of patient consultations given, noting that it can be challenging for some pharmacies to precisely track this metric.

Members were provided the opportunity to comment. Members discussed estimated versus actual number of consultations and agreed to changing (e)(2)(D) to require the estimated number of patient consultations given.

**Motion:** Accept the Board staff's recommended comment responses, modify the regulation text in subdivision (e)(2)(D) to allow for an estimate of the number of consultations, and notice the modified text for a second 15-day comment period. Additionally, if no adverse comments are received during the second 15-day comment period, authorize the executive officer to take all steps necessary to complete the rulemaking to adopt the proposed regulation at section 1711 as noticed. Further, delegate to the executive officer the authority to make technical or nonsubstantive 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 underline for added language.

Modified regulation text to the proposed regulation text is indicated with a ~~double strikethrough~~ for deletions and a double underline 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~~section 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/Hughes

Members of the public in Sacramento were provided the opportunity to comment. A representative from CCPC commented that these reports should not be made to the Board and urged the Board to change the regulation to require reporting to a Board-approved entity.

Members clarified that the QA regulations do not require reporting to the Board, except in the case of QA records related to the use of ADDS.

Members of the public via WebEx were provided the opportunity to comment. A representative of UCLA Health commented that even an

estimated number of patient consultations may not be available as this is typically not something pharmacies track.

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

| 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 | Not Present |
| Weisz | Not Present |

## VI. Report on Appointment to Research Advisory Panel of California pursuant to Health and Safety Code Section 11480

Dr. Oh advised that Health and Safety Code Section 11480 establishes the Research Advisory Panel of California to review and authorize research projects into the nature and effects of cannabis and hallucinogenic drugs. Dr. Oh further stated that this item was added to the agenda to advise members that he recently appointed Dr. Kelly Lee, PharmD. to serve as the Board's new representative on the panel. Historically, the Board's appointment to the panel has served until retirement; however, Dr. Oh appointed Dr. Lee for a three-year period, and as part of the appointment, he requested an annual presentation to the Board to ensure that, moving forward, the Board has an understanding of the work completed by the panel.

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

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

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

Dr. Oh announced the Board would now accept public comment for items not on the agenda and provided instructions on how the public could provide comments. Dr. Oh also confirmed that members had received the written comments received related to this agenda item.

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

The Board heard comments from a member of the public requesting that the Board add a future agenda item about the problems of vaccines administered by pharmacies.

A former Public Information Officer from CDPH commented that vaccines were killing and harming people of color at a higher rate and requested that a discussion of this issue be added to a future agenda.

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

A representative of CSHP requested a future agenda item for the consideration of retraining of pharmacy inspectors who perform inspections for sterile compounding.

A pain patient advocate commented that the previous agenda item regarding the injunctive relief provisions of the national opioid settlement has not been adequately addressed and urged the Board to take action on this issue.

Members were provided the opportunity to comment.

Enforcement and Compounding Committee Chair Dr. Serpa advised that the concerns raised by the commenter regarding the injunctive relief provisions of the opioid settlement was an ongoing issue being monitored and will be on a future committee agenda item.

Dr. Serpa requested that Executive Officer Sodergren correct the record regarding the training of the Board's inspectors. Ms. Sodergren explained that Board inspector staff receive a significant amount of ongoing training in sterile compounding.

## VIII. Closed Session Matters

Open session concluded at approximately 2:44 p.m. The Board entered closed session at approximately 2:56 p.m.

## IX. Reconvene in Open Session to Adjourn for the Day

The Board reconvened into open session and adjourned the meeting at 3:10 p.m.

# Attachment V.

## b. February 5-6, 2025 Board Meeting

**California State Board of Pharmacy**
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

# California State Board of Pharmacy
# Department of Consumer Affairs
# DRAFT 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.

**February 6, 2025**

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.

# Attachment V.

## c. March 6, 2025
## Board Meeting

**California State Board of Pharmacy**
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

# California State Board of Pharmacy
# Department of Consumer Affairs
# DRAFT Public Board Meeting Minutes

**Date:** March 6, 2025

**Location:** OBSERVATION AND PUBLIC COMMENT IN PERSON:
California Department of Consumer Affairs
1747 N. 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
Trevor Chandler, Public Member, Treasurer
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)

**Board Members Not Present:**
Jessica Crowley, PharmD, Licensee Member, Vice President
Indira Cameron-Banks, Public Member

**Staff Present:**
Anne Sodergren, Executive Officer
Julie Ansel, Deputy Executive Officer
Lori Martinez, Chief of Legislation, Policy, and Public Affairs
Corinne Gartner, DCA Staff Counsel
Shelley Ganaway, DCA Staff Counsel
Norine Marks, DCA Staff Counsel
Jennifer Robbins, DCA Regulations Counsel
Sara Jurrens, Public Information Officer
Debbie Damoth, Executive Specialist Manager

## 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 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; 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. 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 to the Third Modified Text

President Oh advised a history of the rulemaking was detailed in the meeting materials and included in the Initial Statement of Reasons. Dr. Oh reminded members during the February 2025 Board meeting, the Board voted to further amend the proposed regulation text based on comments received. Consistent with delegated authority, Members Serpa and Barker reviewed comments received and worked with staff to provide recommendations for the Board's consideration today. Dr. Oh thanked Dr. Serpa, Dr. Barker, and Board staff for their expertise, support, and leadership navigating through this very complex area of pharmacy practice. Dr. Oh then asked Dr. Serpa to review the recommended changes.

Dr. Serpa thanked President Oh for the opportunity to assist the Board to navigate through the comments received during the recent 15-day written comment period

for the third modified text, which closed on February 21, 2025. Dr. Serpa noted there were fewer comments received during this 15-day public comment period, and many of the comments received had already been considered by the Board on several occasions.

Dr. Serpa thanked stakeholders who submitted comments. The comments continue to demonstrate that for some, the regulations may go too far, and for others, the regulations do not go far enough to protect consumers. Comments were received from several new organizations for the first time during this comment period who expressed concerns the proposed regulations allow too many opportunities to compound medications.

Dr. Serpa advised as the recommended proposed fourth modified text demonstrates, specific comments and recommendations were very helpful to the Board as it considers modifications to the proposed text based specifically on comments received. Dr. Serpa thanked Dr. Barker for sharing her expertise and time working with staff to help develop recommendations for the Board's consideration today.

Dr. Serpa provided an overview of the process used to develop the regulations, noting that some comments appear to continue to suggest that the Board has not engaged in a transparent process in the development and promulgation of the regulations.

Dr. Serpa noted when reviewing the comments, consideration and reflection of the Board's consumer protection mandate was at the forefront of the assessment and recommendation. Dr. Serpa noted there were recommendations to make changes in three areas based on comments received during the most recent 15-day comment period to the third modified text.

- Section 1736.1(b)(2) and (b)(3) related to immediate use provisions were clarified based on a comment received requesting clarification on when reporting to the Board was required.
- Changes are recommended to the regulatory provisions related to sterile compounding using Category 1 bulk drug substances. Specifically, section 1736.9(e) is changed, 1736.9(f) is added, 1736.17(a)(2)(C) is changed, and 1736.17(a)(2)(E) and (F) are removed. The proposed text in subdivision (e) of section 1736.9 was taken directly from the USP Chapter requiring that, in addition to the certificate of analysis (COA) required in subdivision (d), all active pharmaceutical ingredients (API) and other components need to be evaluated for suitability in the sterile compounded preparation. The proposed

text in subdivision (f) of section 1736.9 provides the legal pathway to compound using 503A Category 1 bulk drug substances, and specifies that a facility's standard operating procedures (SOPs) must establish the process to determine the quality of the APIs, which was again consistent with the requirements in USP Chapter 797. Dr. Serpa noted the significant change in approach in the related proposed regulation text in section 1736.17 regarding SOPs. The SOPs must include the methods used to determine and approve components, including components that are 503A Category 1 bulk drug substances; however, the methods required to be in compliance with specified USP Chapters were no longer listed. Dr. Serpa reminded members while specific details were no longer included in the proposed regulations, USP Chapter 797 requires that, along with a COA that includes specifications, test results are required to show all components including those substances on the Category 1 bulks list, meets expected quality. Dr. Serpa referenced meeting materials identified as Addendum 1 to address the comments received and responses to explain this further.

- Section 1737.7, subdivision (a) related to the provisions for using gloves. The proposed changes to the regulation text directly reflect the language found in USP.

Dr. Serpa summarized the approach in promulgating these regulations was to clarify and make more specific the requirements of state and federal law, federal guidance, and the national standards. While repetition of federal law and USP in the proposed regulations was generally avoided, there were some exceptions where provisions of the national standards were restated as a direct result of public comment that asked for clarification and where it appeared that there was a general unfamiliarity with the USP standards. When this was done, the USP standard was repeated to underscore the requirements of the USP chapter or to ensure there was a comprehensive understanding of the requirement.

Members were provided the opportunity to comment.

Dr. Barker believed the most recent changes add clarification and still addressed the mandate for consumer safety.

Dr. Oh thanked Dr. Serpa, Dr. Barker, Executive Officer Sodergren and staff who worked on this text.

**Motion:** 1. Accept the Board staff recommended responses to comments to the third modified text received during the 15-day comment period as the responses of the Board as presented.
2. Approve the recommended fourth modified text dated 2.28.2025 for a 15-day comment period, delegating 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, 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; however, no comments were made.

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

Members heard comments from representatives of Pacific Compounding Pharmacy and Volunteer Fire Foundation. Comments included appreciation for the substantial changes; recommended text was not substantiated by evidence that will cause improved patient safety; appreciation of the transparency of the process but didn't meet the intent of the rulemaking process; concern for fewer compounding pharmacies; and unavailability of glutathione from 503A pharmacies.

Members also heard comments from individuals including a fire fighter and a compounding pharmacist. Comments included personal accounts of using glutathione and availability for fire fighters and general public; and several areas of regulations that were ambiguous.

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

Members heard comments from representatives of Alliance for Pharmacy Compounding, Kaiser Permanente, FlavoRx, stopthebop.org; CMA, gotlongcovid.org; and Sutter Health. Comments included appreciation for the changes; encouraged the Board to delay moving forward; concern for enforcement actions against pharmacies compounding APIs; imposition of unnecessary restrictions on immediate use compounding exceeding federal and USP standards that do not improve patient

safety; lack of evidence to support changes; encouraged deleting current compounding regulations and only to use USP; progress made on the flavoring issue; want the exemption for all flavoring; relief of some of the restrictions removed; request to withdraw the rulemaking package; requested clarification regulations do not include physicians; regulations go beyond USP and will prohibit ability to take care of patients; appreciation to the Board for the opportunity to comment.

Members also heard comments from individuals including Cloverdale Councilmember, fire fighters/first responders and their families, Lyme disease patient, physician, mother, patient allergic to COVID vaccines, pharmacist, acupuncturist, naturopath doctors, and patient with grand mal seizures. Comments included requested staying with current regulation; concern for lack of access for chronic illness patients; personal account of glutathione benefits; remove barriers for glutathione; concern for access to patients; inability to get self-administered glutathione for fire fighters; IV access was better than medication taken orally; concern for access to treatment for people with chronic illnesses and fire fighters; withdraw rulemaking; concern for essentially a copy and immediate use language; concern for affordability and accessibly of glutathione.

The Board took a break from 10:46 a.m. – 11:02 a.m. Roll call was taken. The following Board members were physically present in Sacramento: Trevor Chandler, Public Member; Renee Barker, PharmD, Licensee Member; Jeff Hughes, Public Member; 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. The Board heard a comment from a nurse impacted by the Altadena fire concerned about the access to glutathione.

President Oh commented that while he was comfortable with the previous approach of outlining required testing for Category 1 bulk drug substances, he was more comfortable with relying on the professional and clinical judgment of pharmacists.

DCA Counsel Gartner offered some clarifying comments to members. She noted public comments were made indicating Category 1 bulk drug substances including methylcobalamin and glutathione were safe and effective treatments. Ms. Gartner reminded members methylcobalamin and glutathione have not been found by the FDA to be safe or effective, rather, these substances are still under evaluation by the FDA. To the extent that public comment suggested methylcobalamin and glutathione were FDA approved or authorized, that was not the case. The FDA's

approach was that they have articulated an interim policy pursuant to which methylcobalamin and glutathione, which otherwise could not be used in compounding, could be used, and the FDA will exercise enforcement discretion with respect to that compounding as long as certain conditions were met.

As some commenters called methylcobalamin and glutathione vitamins or nutrients as opposed to drugs, Ms. Gartner clarified that under federal law, these substances are considered bulk drug substances which was the same as an active pharmaceutical ingredient. Ms. Gartner also noted that public comment suggested 503B outsourcing facilities can only produce office stock and can't distribute pursuant to individual prescriptions, and she clarified that under the law outsourcing facilities do have the option of compounding drug products pursuant to prescriptions for individual patients.

Finally, Ms. Gartner addressed comments about overreach by the Board as far as regulating physicians, *etc.*, reminding members that there were limits on who the Board can regulate. Pursuant to Business and Professions Code section 4170(c), the Medical Board of California and other healing arts boards are specifically charged with the enforcement of pharmacy law with respect to their respective licensees.

Members were provided the opportunity to comment.

Members discussed concerns about access and cost to the patient which was related to approval by FDA. Some members were concerned about the flavoring access and availability. USP clarified that flavoring was compounding and the Board couldn't change what USP determined regarding flavoring.

Members also discussed public comments that expressed concerns about enforcement by inspectors. Ms. Sodergren explained with the shift to a standard of care enforcement model, the Board was embracing a less prescriptive approach, based on pharmacists using their professional judgment based on best practices. Ms. Sodergren provided patient consultation as an area where pharmacy law currently uses this model. Ms. Sodergren provided an overview of the investigative process used by inspectors during pharmacy inspections noting the individual inspector wouldn't make the determination whether or not there was enforcement action taken.

Members discussed the concern of compounding pharmacies closing. It was noted that nationally business practices changed over time and pharmacies in general were closing. Additionally, USP changed guidance effective November 1, 2023, where some pharmacies made business decisions to no longer compound.

Members discussed the importance of comments received by the Board. Distinction was made that anything injected or inhaled must be sterile and if it was not sterile, it can cause harm to the patient.

**Support: 7 Oppose: 2 Abstain: 0 Not Present: 2**

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

## III. Discussion and Possible Action Related to Proposed Amendment to California Code of Regulations, Title 16, Section 1708.2 Related to Discontinuance of Business, Including Review of Comments Received During the 15-Day Comment Period

President Oh recalled that in April 2024, the Board approved proposed regulation text to amend section 1708.2. The 45-day comment period began November 15, 2024, and concluded December 30, 2024. A subsequent 15-day comment period began on February 10, 2025, and ended February 25, 2025. Dr. Oh noted that the meeting materials included the proposed text released for the 15-day comment period, comments received, staff prepared responses to comments, and staff recommended modifications to the proposed text. Dr. Oh confirmed that members had the opportunity to review the information, and noted that he agreed with the staff recommendations, including recommendations to the proposed modified text.

Members were provided the opportunity to comment. A member asked if the proposed exemption under subdivision (b)(6) applied only to correctional facilities or if it included pharmacies in health care systems. It was clarified that correctional pharmacies dispensing only to patients of the California Department of Corrections and Rehabilitation are exempt from the statutory requirement being implemented in the regulation, so they will be exempt from the regulation's requirements. Members discussed that specialty and home health care pharmacies typically were licensed separately so the exemption wouldn't apply to them.

**Motion:** Accept the Board staff's recommended comment response and modified text, and notice the second modified text for a second 15-day comment period. Additionally, if no adverse comments are received during the second 15-day comment period, authorize the executive officer to take all steps necessary to complete the rulemaking and adopt the proposed regulations at section 1708.2 as noticed. Further, 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**

**Second Modified Regulation Text Discontinuance of Business**

Proposed changes made to the current regulation language are shown by ~~strikethrough~~ for deleted language and underline for added language.

Modified changes made to the proposed regulation language are shown by ~~double strikethrough~~ for deleted language and double underline for added language.

Second modified changes made to the proposed regulation language are shown by ~~*italicized double strikethrough*~~ for deleted language and *italicized double underline* for added language.

**Amend section 1708.2 of Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

(a) Any permit holder shall contact the ~~b~~Board prior to transferring or selling any dangerous drugs, devices, or hypodermics inventory as a result of termination of business or bankruptcy proceedings (individually or collectively referred to as a "closure") and shall follow official instructions given by the ~~b~~Board applicable to the transaction.

(b) In addition to the requirements in (a), a pharmacy that shall cease operations due to a closure (cessation or substantial cessation) shall complete the following:

(1) At least ~~30~~ 45 days in advance of the closure, provide written notice to patients that have received a prescription within the last year, in a form in which the pharmacy regularly communicates or advertises to its patients. At a minimum, this notice shall include:

(A) the name of the patient and if one exists and is known to the pharmacy, the name of the legal representative of the patient,

(B) the name and physical address of the pharmacy closure,

(C) the name of the pharmacy where patient records will be transferred and maintained, and

(D) information on how to request a prescription transfer prior to closure of the pharmacy.

(2) Reverse all prescriptions for which reimbursement was sought but the prescriptions are not picked up by patients,
(3) Provide the Board with a copy of the notice specified in subsection (b)(1), and
(4) The owner shall be responsible for compliance with the requirements of this section. The owner, the pharmacist-in-charge, if available, shall certify compliance with the requirements in this section. In the event the pharmacist-in- charge is no longer available, the owner must certify the compliance, along with a pharmacist retained to perform these functions.
(5) Post a written notice of the closure with the planned closure date in a conspicuous location at the pharmacy's entrance.
(6) A general acute care hospital pharmacy that is owned by a health facility as defined in Section 1250 of the Health and Safety Code, and meets the requirements of Business and Professions Code section 22949.92(a)(1)(B)(iii), *and a licensed correctional pharmacy dispensing only to patients of the California Department of Corrections and Rehabilitation*, shall be exempt from the requirements of subdivision (b).

NOTE: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4080, 4081, 4113, 4332, ~~and~~ 4333, 22949.92, and 22949.92.1, Business and Professions Code; and Section 11205, Health and Safety Code.

**M/S:** Thibeau/Newell

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

**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 |

## IV. Discussion and Possible Action Related to Proposed Amendment to California Code of Regulations, Title 16, Section 1711 Related to Quality Assurance Programs, Including Review of Comments Received During the Second 15-Day Comment Period

President Oh advised that in January 2023, the Board approved proposed regulation text to amend section 1711. Dr. Oh recalled that the Board's Medication Error Reduction and Workforce 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 quality assurance (QA) regulations that have largely remained unchanged for two decades. The Board's 45-day comment period closed on September 23, 2024. During the November 6-7, 2024 Board meeting, following consideration of the comments received, the Board voted to further modify the proposed text and initiate a 15-day comment period. In response to comments received during the first 15-day comment period, the Board determined additional changes were appropriate. The second 15-day comment period began January 27, 2025, and ended February 11, 2025. As the meeting materials note, comments were again received.

Dr. Oh ensured that members received the updated recommended responses to comments that were posted on the Board's website earlier that week. He noted that he believed the updated responses would remove some of the confusion that could occur, and that many of the comments received relate to current regulation requirements and appear to suggest that pharmacies represented by the commenter may not be compliant with current legal requirements. Dr. Oh added if accurate, he believed this was troubling. He continued that based on his reading of the comments, it appeared some commenters may be conflating the Board's quality assurance requirements with the medication error reporting requirements established in Business and Professions Code section 4113.1. Dr. Oh noted that the meeting materials included the proposed text released for the second 15-day comment period, comments received, and staff prepared responses to comments. Dr. Oh confirmed that members had the opportunity to review the information. Dr. Oh concluded his introductory remarks by stating that upon review, he agreed with the staff recommended response.

Members were provided the opportunity to comment. Members discussed the value of having a QA program that requires a systematic review of medication errors. Discussion continued about the current QA regulation's purpose 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(s) and any contributing factors such as system or process failures. Members noted most of the regulation is about reporting

individual errors, and the Board needs to further encourage the collective system review approach, potentially by requiring periodic system review. Members discussed the benefits and drawbacks of a minimum requirement versus a prescriptive requirement while also considering the pharmacist-in-charge's workload. Ms. Sodergren advised staff can develop a couple different possible language additions for the Board to consider. Members Jha and Serpa were designated as members to work with Board staff to develop possible options for language to incorporate the Board's discussion.

**Motion:** Defer a decision on the quality assurance program regulations, including responses to comments received during the second 15-day comment period between January 27, 2025 and February 11, 2025., and delegate to Members Jha and Serpa to work with Board staff to develop additional language specifically related to the quality assurance program and its requirements for consideration at a future meeting.

**M/S:** Chandler/Jha

Members of the public participating in Sacramento were provided the opportunity to comment. The Board heard a comment requesting that vaccine administration and VAERS reporting be included in the QA program.

Members of the public participating via WebEx were then provided the opportunity to comment. A representative of Kaiser commented that further expanding the QA regulation requirements to include systematic review of errors would place additional burdens on the pharmacist-in-charge. The commenter noted that the Board was moving to a standard of care model and the regulation already tipped toward being overly prescriptive, which is the opposite of a standard of care approach. A pharmacist provided a personal account of his experience with quality assurance programs. The pharmacist thought entities should be required to look at their errors qualitatively, quantitatively, and system wide. A medication safety officer at an academic medical center commented in support but noted community and institutional pharmacies have requirements to report errors and further regulation seemed redundant.

**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 |

The Board took a lunch break from 12:35 p.m. to 1:30 p.m. Roll call was taken. The following Board members were physically present in Sacramento: Trevor Chandler, Public Member; Renee Barker, PharmD, Licensee Member; Jeff Hughes, Public Member; 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.

**V. Discussion and Possible Action Related to Proposed Addition of Section 1700 Related to Digital Signatures to California Code of Regulations, Title 16, Including Review of Comments Received During the 45-Day Comment Period**

President Oh recalled the Board approved proposed regulation text on April 24, 2024, to add section 1700 to title 16 of the California Code of Regulations, to establish provisions for digital signatures consistent with the provisions established in Government Code section 16.5. Dr. Oh noted the Board's 45-day comment period closed on February 3, 2025. The Board received one comment stating support for the Board's proposal. Dr. Oh referenced meeting materials that included the proposed regulation text released for the 45-day comment period and the comment received. Dr. Oh confirmed members reviewed the information.

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

**Motion:** Adopt the regulation text as noticed on December 20, 2024. Authorize the executive officer to take all steps necessary to complete the rulemaking. Further, 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 Regulation Text**

**Digital Signatures**

**Legend**: Added Text is indicated with an underline.

Add section 1700 to Article 1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1700. Digital Signatures

Consistent with the authority established in Government Code Section 16.5, in any written communication, application or other document in which a signature is required or used, the Board shall accept digital signatures that meet the requirements set forth in the California Code of Regulations, Title 2, section 22003(a).

NOTE: Authority Cited: Section 16.5, Government Code. Reference: Section 16.5, Government Code.

**M/S:** Newell/Sandhu

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

**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 |

## 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; however, there were no pharmacists licensed for 40 years present. President Oh thanked all pharmacists who worked in pharmacy serving the consumers of California.

## VII. 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 comments from a member of the public concerned about the impact of COVID-19 vaccines being administered in California pharmacies.

The Board heard comments from a member of the public concerned that his comments about the COVID-19 vaccines was deferred to the federal government.

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

Members expressed interest in looking into and having discussions about maintaining access to drugs being banned at the federal level.

## VIII. Closed Session Matters

Open session concluded at approximately 1:47 p.m. The Board convened in closed session at approximately 2:02 p.m. and ended closed session at 3:30 p.m.

## IX. Reconvene in Open Session to Adjourn for the Day

The Board reconvened into open session and adjourned the meeting at 3:30 p.m.

# Attachment V.

## d. March 12, 2025
## Disciplinary Petition Committee Meeting

**California State Board of Pharmacy**
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

# California State Board of Pharmacy
# Department of Consumer Affairs
# DRAFT Disciplinary Petition Committee Meeting Minutes

**Date:** March 12, 2025

**Location:** OBSERVATION AND PUBLIC COMMENT IN PERSON:
California State Board of Pharmacy
2720 Gateway Oaks Drive, First Floor Hearing Room
Sacramento, CA 95833

Board of Pharmacy staff members were present at the observation and public comment location.

PUBLIC PARTICIPATION AND COMMENT FROM A REMOTE LOCATION: WebEx

**Committee Members Present:**
Nicole Thibeau, PharmD, Licensee Member, Chair
Trevor Chandler, Public Member
Jeff Hughes, Public Member
Satinder Sandhu, PharmD, Licensee Member
Maria Serpa, PharmD, Licensee Member

**Committee Members Not Present:**
Renee Barker, PharmD, Licensee Member

**Staff Present:**
Anne Sodergren, Executive Officer
Shelley Ganaway, DCA Staff Counsel
Debbie Damoth, Executive Specialist Manager

**March 12, 2025**

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

Chairperson Thibeau called the meeting to order at approximately 9:01 a.m.

Dr. Thibeau 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. Thibeau advised all individuals the meeting was being conducted via WebEx. Department of Consumer Affairs' staff provided general instructions for participating in the meeting via WebEx or phone.

Roll call was taken. The following Committee members were present via WebEx: Trevor Chandler, Public Member; Jeff Hughes, Public Member; Satinder Sandhu, PharmD, Licensee Member; Maria Serpa, PharmD, Licensee Member; and Nicole Thibeau, PharmD, Licensee Member. A quorum was established.

Dr. Thibeau reminded Committee members participating via WebEx to remain visible on camera throughout the open portion of the meeting. If members needed to temporarily turn off cameras due to challenges with internet connectivity, members were reminded to announce the reason for their nonappearance when the camera was turned off.

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

Members of the public were provided with an opportunity to provide comment for items not on the agenda or agenda items for a future meeting.

Members of the public were provided the opportunity to comment in Sacramento; however, there were no members of the public attending at the Sacramento location.

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

## III. Petitions for Reinstatement of Licensure, Early Termination of Probation, or Other Modification of Penalty

Administrative Law Judge Heather Rowan presided over the hearings.

B. Fadi Atef Nassar Ebeid, RPH 69962

The Committee took a break from 10:36 a.m. to 10:51a.m. Roll call was taken. The following Committee members were present via WebEx: Trevor Chandler, Public Member; Jeff Hughes, Public Member; Satinder Sandhu, PharmD, Licensee Member; Maria Serpa, PharmD, Licensee Member; and Nicole Thibeau, PharmD, Licensee Member. A quorum was established.

A. Anita Birosel-McQuigg, RPH 42446

The Committee took a lunch break from 12:30 p.m. to 1:20 p.m. Roll call was taken. The following Committee members were present via WebEx: Trevor Chandler, Public Member; Jeff Hughes, Public Member; Maria Serpa, PharmD, Licensee Member; and Nicole Thibeau, PharmD, Licensee Member. A quorum was established.

Dr. Sandhu joined the meeting at approximately 1:29 p.m.

C. Jamal Darrel Watts, TCH 175811

D. Nirali M. Shah, RPH 73997

## IV. Closed Session

Open session concluded at approximately 3:15 p.m. The Committee entered closed session at approximately 3:25 p.m. and ended closed session at approximately 3:55 p.m.

## V. Reconvene in Open Session to Adjourn for the Day

The Committee reconvened into open session and adjourned the meeting at approximately 3:55 p.m.

# Attachment V.

## e. March 26, 2025
## Board Meeting

**California State Board of Pharmacy**
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

# California State Board of Pharmacy
# Department of Consumer Affairs
# DRAFT Public Board Meeting Minutes

**Date:** March 26, 2025

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

PUBLIC PARTICIPATION AND COMMENT FROM A REMOTE LOCATION: WebEx

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

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

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

**March 26, 2025**

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

Dr. Oh reminded all individuals present that the Board is a consumer protection agency charged with administering and enforcing Pharmacy Law. Where protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount. DCA staff provided instructions on participating via WebEx. Dr. Oh advised about exit routes in the event of an emergency for those present in person.

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

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

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

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

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

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

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

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

**Motion:**
1. Accept the Board staff recommended responses to comments to the fourth modified text received during the 15-day comment period as the responses of the Board as presented.
2. Adopt the fourth modified text dated 2.28.2025.
3. Authorize the executive officer to take all steps necessary to complete the rulemaking process. Delegate to the executive officer the authority to make technical or non-substantive changes as may be required by the Control agencies to complete the rulemaking file.

**M/S:** Serpa/Barker

Members were provided the opportunity to comment.

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

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

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

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

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

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

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

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

Members were then provided the opportunity to comment.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

## IV. Closed Session Matters

The Board did not meet in closed session.

## V. Adjournment

The meeting adjourned at 11:27 a.m.