

August 30, 2023

Board Meeting Minutes



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: August 30, 2023

Locations: Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
1st Floor Hearing Room
Sacramento, CA 95833

California Contractors State Licensing Board
12501 East Imperial Highway, Suite 600, Hearing Room
Norwalk, CA 90650

Fresno Water Resources Building
3374 East Shields Ave, Room 1013
Fresno, CA 93726

Alfred E. Alquist Building, Auditorium
100 Paseo De San Antonio
San Jose, CA 95113

Department of Rehabilitation
150 S. Los Robles Ave., Suite 300
Third Floor Conference Room #312
Pasadena, CA 91101

California Contractors State Licensing Board
9246 Lightwave Ave., Ste 130
San Diego, CA 92123

Board Members

Present: Seung Oh, Licensee Member, President
Jessica Crowley, Licensee Member, Vice President
Renee Barker, Licensee Member
Indira Cameron-Banks, Public Member
Kartikeya "KK" Jha, Licensee Member
Jignesh Patel, Licensee Member
Maria Serpa, Licensee Member
Nicole Thibeau, Licensee Member

Jason Weisz, Public Member

Board Members

Not Present:

Trevor Chandler, Public Member, Treasurer
Jose De La Paz, Public Member

Staff Present:

Anne Sodergren, Executive Officer
Julie Ansel, Assistant Executive Officer
Corinne Gartner, DCA Counsel
Rebecca Bon, DCA Counsel
Trang Song, PharmD, Inspector
Debbie Damoth, Executive Specialist Manager

August 30, 2023

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

President Oh called the Board Meeting to order at approximately 9:02 a.m. President 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.

President Oh advised all individuals the meeting was being conducted via WebEx and in person at multiple locations. Dr. Oh advised participants watching the webcast could only observe the meeting. Dr. Oh noted anyone interested in participating in the meeting must join the WebEx meeting using the instructions posted on the Board's website. Department of Consumer Affairs' staff provided general instructions for the WebEx Board Meeting.

Roll call was taken. Board Members present at the Sacramento location: Maria Serpa, Licensee Member; and Jig Patel, Licensee Member. Board Member present at the San Jose location: Renee Barker, Licensee Member. Board Member present at the Fresno location: KK Jha, Licensee Member. Board Members present at the Pasadena location: Indira Cameron-Banks, Public Member; Jessi Crowley, Licensee Member; and Nicole Thibeau, Licensee Member. Board Members present at the San Diego location: Jason Weisz, Public Member; and Seung Oh, Licensee Member. Board staff verified there were no Board Members present at the Norwalk location. A quorum was established.

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.

No public comment was made by meeting participants in the Sacramento, San Jose, Fresno, Pasadena, San Diego, or Norwalk locations.

Public comment was received via WebEx.

The Board heard comments from pharmacists and representatives of UCSD, Sutter Health, and Cedars Sinai regarding concerns about the proposed compounding regulations including proposed section 1736.1 regarding immediate use compounding; seven specific issues related to proposed sections 1736 and 1737; the impact on shortages of products and of 503Bs on compounding; the significant costs and operational burdens that the proposed compounding regulations would impose on facilities (e.g., segregated compounding areas to require 20 degrees or cooler, changing outer gloves between every single compound, using respirators that were mandated, requiring sterile mats, etc.); the impact of drug shortages and recalls on workforce; and consideration that experts developed USP. The commenters requested additional opportunities for comment and input prior to implementation of the new compounding regulations.

The Board heard comments from pharmacists requesting the Board introduce legislation to allow specialty pharmacy to be included in remote processing as well as to continue the discussion related to remote processing in specialty pharmacies.

The Board heard comments from a representative of CSHP requesting guidance for hospital pharmacies should the pending remote processing bill not be signed by the governor.

Member Crowley left the meeting at 9:21 a.m. and returned at 9:25 a.m.

Members were provided the opportunity to provide comment after public comment was taken and to add items to future agendas. Enforcement and Compounding Committee Chairperson Serpa addressed the compounding regulations comments noting the draft regulations were undergoing the rulemaking process. Dr. Serpa added hearings would be scheduled and encouraged participation and written comments when the draft regulations were published for comment. President Oh noted an agenda item would be scheduled for the September Board Meeting that would address some of the issues raised.

III. Closed Session

Open session concluded at approximately 9:27 a.m. The Board entered closed session at approximately 9:33 a.m. and ended closed session at 10:59 a.m.

IV. Adjournment

The Board resumed open session for the purposes of adjourning at 11:00 a.m. The Board Meeting concluded at approximately 11:01 a.m.

September 12, 2023

**Board Meeting
Minutes**



California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
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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: September 12, 2023

Locations: Department of Consumer Affairs
1625 N. Market Blvd.
1st Floor Hearing Room
Sacramento, CA 95834

Hotel Dena, Pasadena Los Angeles, A Tribute Portfolio Hotel
Magnolia Room
303 Cordova Street
Pasadena, CA 91101

California Contractors State Licensing Board
9246 Lightwave Ave., Suite 130
San Diego, CA 92123

Board Members

Present: Seung Oh, Licensee Member, President
Jessica Crowley, Licensee Member, Vice President
Trevor Chandler, Public Member, Treasurer
Renee Barker, Licensee Member
Indira Cameron-Banks, Public Member
Jose De La Paz, Public Member
Kartikeya "KK" Jha, Licensee Member
Jignesh Patel, Licensee Member
Maria Serpa, Licensee Member
Nicole Thibeau, Licensee Member

Board Members

Not Present: Jason Weisz, Public Member

Staff Present: Anne Sodergren, Executive Officer
Julie Ansel, Assistant Executive Officer

Corinne Gartner, DCA Counsel
Rebecca Bon, DCA Counsel
Noelle Randall, Inspector
Debbie Damoth, Executive Specialist Manager

September 12, 2023

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

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

President Oh advised all individuals the meeting was being conducted via WebEx and in person at multiple locations. Dr. Oh advised that participants watching the webcast could only observe the meeting. Dr. Oh noted anyone interested in participating in the meeting must join the WebEx using the instructions posted on the Board's website. Department of Consumer Affairs' staff provided general instructions for participating in the meeting via WebEx or phone.

Roll call was taken. Members present at the Sacramento location: Trevor Chandler, Public Member; Renee Barker, Licensee Member; KK Jha, Licensee Member; Jig Patel, Licensee Member; Maria Serpa, Licensee Member; and Seung Oh, Licensee Member. Members present at the Pasadena location: Jose De La Paz, Public Member; Nicole Thibeau, Licensee Member; and Jessi Crowley, Licensee Member. Board staff verified there were no Board members present at the San Diego location. A quorum was established.

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.

The Board took a break from 9:06 a.m. to 9:08 a.m. while the Pasadena location completed getting set up.

A pharmacist made a comment about his license being associated with a public record on the Board's website and requested removal of his name from the record.

Member Cameron-Banks joined the meeting at approximately 9:18 a.m.

No public comment was made by meeting participants in the Pasadena or San Diego locations.

Public comment was received via WebEx.

The Board heard comments from pharmacists requesting that the Board continue the discussion about remote processing in specialty pharmacies and introduce legislation to allow specialty pharmacy to be included in remote processing.

Members were provided the opportunity to provide comment after public comment was taken and to add items to future agendas. No items were added to future agendas.

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

President Oh reminded members that several years ago, the Board changed its recognition program for pharmacists and currently recognizes pharmacists that have been licensed for 40 or more years. Dr. Oh noted that the information was posted on the Board's website and pharmacists were provided with a certificate.

President Oh noted that prior to transitioning to remote meetings, the Board routinely provided an opportunity for pharmacists licensed for 40 years to attend a Board meeting and be recognized by the Board. Dr. Oh continued that although the Board has returned to remote meetings, the Board would still like to provide an opportunity for pharmacists that have been licensed in California for 40 years to receive recognition. No pharmacists identified themselves for recognition in the Sacramento, Pasadena, or San Diego locations, or via WebEx. Board Member Serpa recognized Dr. Dan LeGrady, who was issued a pharmacist license in 1973. President Oh thanked and congratulated pharmacists who have been licensed for over 40-years, and thanked all staff who work in pharmacy serving the consumers of California.

IV. Approval of Board and Ad Hoc Committee Meeting Minutes

a. April 19-20, 2023 Board Meeting

President Oh referenced the draft minutes from the April 19-20, 2023 Board meeting.

Members were provided with an opportunity to comment.

Motion: Approve the April 19-20, 2023 Board meeting minutes subject to correction based on staff confirming Member Chandler's attendance.

M/S: Crowley/Patel

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

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

Board Member	Vote
Barker	Support
Cameron-Banks	Support
Chandler	Support
Crowley	Support
De La Paz	Support
Jha	Support
Oh	Support
Patel	Support
Serpa	Support
Thibeau	Support
Weisz	Not Present

b. May 3, 2023 Standard of Care Ad Hoc Committee Meeting

President Oh referenced the draft minutes from the May 3, 2023 Standard of Care Ad Hoc Committee meeting.

Members were provided with an opportunity to comment.

Motion: Approve the May 3, 2023 Standard of Care Ad Hoc Committee meeting minutes as presented in the meeting materials.

M/S: Chandler/Patel

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

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

Board Member	Vote
Barker	Support
Cameron-Banks	Support
Chandler	Support
Crowley	Support
De La Paz	Support
Jha	Support
Oh	Support
Patel	Support
Serpa	Support
Thibeau	Support
Weisz	Not Present

c. May 17, 2023 Board Meeting

President Oh referenced the draft minutes from the May 17, 2023 Board meeting.

Members were provided with an opportunity to comment.

Motion: Approve the May 17, 2023 Board meeting minutes as presented in the meeting materials.

M/S: Chandler/Patel

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

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

Board Member	Vote
Barker	Support
Cameron-Banks	Support
Chandler	Support
Crowley	Support
De La Paz	Support
Jha	Support
Oh	Support
Patel	Support
Serpa	Support
Thibeau	Support
Weisz	Not Present

d. June 7, 2023 Medication Error Reduction and Workforce Ad Hoc Committee Meeting

President Oh referenced the draft minutes from the June 7, 2023 Medication Error Reduction and Workforce Ad Hoc Committee Meeting.

Members were provided with an opportunity to comment. President Oh thanked Chairperson Thibeau for all of her work on the Medication Error Reduction and Workforce Ad Hoc Committee.

Motion: Approve the June 7, 2023 Medication Error Reduction and Workforce Ad Hoc Committee meeting minutes as presented in the meeting materials.

M/S: Patel/Thibeau

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

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

Board Member	Vote
Barker	Support
Cameron-Banks	Support
Chandler	Support
Crowley	Support
De La Paz	Support
Jha	Support
Oh	Support
Patel	Support
Serpa	Support
Thibeau	Support
Weisz	Not Present

e. June 21, 2023 Board Meeting

President Oh referenced the draft minutes from the June 21, 2023 Board meeting.

Members were provided with an opportunity to comment.

Motion: Approve the June 21, 2023 Board meeting minutes as presented in the meeting materials.

M/S: Patel/Chandler

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

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

Board Member	Vote
Barker	Support
Cameron-Banks	Support
Chandler	Support
Crowley	Support
De La Paz	Support
Jha	Support
Oh	Support
Patel	Support
Serpa	Support
Thibeau	Support
Weisz	Not Present

V. Discussion and Consideration of the Board’s Strategic Plan

President Oh recalled that the Board's strategic planning session occurred as part of the Board's September 2021 meeting. The Board annually reviews its strategic plan to confirm that the established objectives for each committee remain appropriate or if changes should be considered. The annual review also serves as an opportunity for the Board to evaluate progress in the respective areas. Dr. Oh added that except for the Organizational Development Committee, committees completed a review in their respective goal areas prior to the meeting, and committee chairs would now provide the Board with an update.

As the chair of the Licensing Committee, President Oh reported the status of the Licensing Committee's strategic objectives. Dr. Oh noted that efforts were underway for many of the objectives, with some crossing multiple years. Dr. Oh reported that strategic objective 1.6 related to the audit of the CPJE had been marked complete; that over the coming year, the focus will be on strategic objectives 1.2 related to various pharmacy practice settings and 1.3 related to authorized duties of a pharmacy technician; and that strategic objectives 1.7, 1.8, and 1.9 were tied to the Board's business modernization activities.

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

Maria Serpa, chairperson of the Enforcement and Compounding Committee, then reported on that committee's nine strategic objectives. Dr. Serpa advised that the meeting materials included updates on the objectives, adding that the committee was making good progress toward achieving the goal established in strategic objective 2.3 relating to performing routine inspections.

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

Next, Jessi Crowley, chairperson of the Legislation and Regulation Committee, reported on that committee's six strategic objectives. Dr. Crowley referenced meeting materials that included updates for the respective strategic objectives, highlighting the work of the Board's policy making efforts to protect California consumers. Dr. Crowley noted that strategic objectives 3.1, related to advocating for provider status, and 3.4, related to identifying opportunities to leverage pharmacists to increase access points for care, didn't have an update. Specifically related to 3.4, Dr. Crowley noted that after some of the working conditions were addressed through Assembly Bill 1286, it may be appropriate for the committee to consider ways to increase patient access to care, and that the work done by the Standard of Care Ad Hoc Committee, and the Board's legislative report, presented some areas of consideration related to this objective. Dr. Crowley reported that the committee believed the strategic objectives remained appropriate and was not recommending any changes.

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

Nicole Thibeau, vice chairperson of the Communication and Public Education Committee, then reported on that committee's eight strategic objectives. Dr. Thibeau noted meeting materials that included updates on the objectives and highlighted the committee's efforts over the past year. Dr. Thibeau reported that the committee reviewed the objectives and believed they remained appropriate, noting further discussion in the agenda related to the proposed consumer education campaign to support the release of the Notice to Consumers poster, which is consistent with strategic objective 4.1.

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

President Oh then reported on the Organizational Development Committee. This committee is composed of the president and vice president of the Board and supported by the executive officer, and as such does not meet in public. Dr. Oh referred to meeting materials detailing the committee's strategic objectives and status updates as well as several activities that were undertaken in support of the committee's strategic objectives. Dr. Oh highlighted some of the training completed by Board staff under objective 5.3, and objective 5.4 related to business modernization

activities. Dr. Oh thanked staff for their work to update information on the Board's website as noted in activities related to strategic objective 5.6.

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

Members of the public were then provided the opportunity to comment on this agenda item; however, no comments were made.

Members were provided the opportunity to add any final comments; however, no comments were made.

VI. Discussion and Consideration of Draft Notice to Consumers Poster, Consistent with the Proposed Changes to Title 16, California Code of Regulations section 1707.6

President Oh then turned the meeting over to Nicole Thibeau, vice chairperson of the Communication and Public Education Committee, to provide a summary of the committee's discussion on the draft Notice to Consumers poster. Dr. Thibeau first thanked committee members, including Chair Jason Weisz, Renee Barker, Jose De La Paz, and KK Jha. Dr. Thibeau reminded members that the Board provides a copy of the Notice to Consumers poster to all pharmacies, and that the Board initiated a rulemaking to update the text of the poster to reflect the Board's efforts on reducing medication errors, including actions a consumer can take to prevent errors. Dr. Thibeau reported that while the rulemaking was undergoing post adoption review, updates to the poster were necessary to reflect the new regulation text. Dr. Thibeau noted that the language included on the poster must remain consistent with the regulation text; however, design and formatting of the poster could be changed.

Dr. Thibeau further reported that during the July 2023 committee meeting, the committee provided feedback to staff requesting some formatting changes to aid readers as well as an alternative potential means to convey that the QR code was used to access the notice in other languages. Dr. Thibeau advised that the updated draft notice incorporating the changes recommended by the committee was included in the meeting materials and displayed on the slide.

Dr. Thibeau advised that during the meeting, the committee also noted agreement with staff's recommendations to expand the number of languages that will be available for download on the website, and to develop a consumer education campaign that would coincide with the release of the poster.

Members were provided the opportunity to comment.

President Oh commented that he liked the design.

Member Crowley requested that the website for the translation page be added to the poster for the benefit of patients who do not have access to smart phones and couldn't access the QR code.

Member Chandler requested adding "Translation" in Chinese next to "Translation" in English and Spanish.

Member Jha requested adding "Translation" in Punjabi as well.

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

Members were provided the opportunity to add any final comments; however, no comments were made.

The Board took a break from 9:54 a.m. to 10:00 a.m. Roll call was taken. Members present at the Sacramento location: Renee Barker, Licensee Member; Trevor Chandler, Public Member; KK Jha, Licensee Member; Jig Patel, Licensee Member; Maria Serpa, Licensee Member; and Seung Oh, Licensee Member. Members present at the Pasadena location: Indira Cameron-Banks, Public Member; Jessi Crowley, Licensee Member; Jose De La Paz, Public Member; and Nicole Thibeau, Licensee Member. No members were present at the San Diego location. A quorum was established.

VII. Discussion and Consideration of Draft Proposed Policy Statement Related to Implementation of USP General Chapters 795 Pharmaceutical Compounding – Nonsterile Preparations; 797 Pharmaceutical Compounding – Sterile Preparations; 800 Hazardous Drugs – Handling in Healthcare Settings; and 825 Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging

President Oh returned the meeting to Maria Serpa, chairperson of the Enforcement and Compounding Committee, to report on the committee's discussion of the draft proposed policy statement. Chairperson Serpa recalled that, effective November 1, 2023, changes to USP Chapters 795 and 797 and new chapters 800 and 825 become compendial. Dr. Serpa noted that for the past several years, as changes have occurred with the process to establish new USP chapters and revise existing chapters, the Board has released statements to provide licensees with information on the Board's policy during the transition period. Dr. Serpa referenced the draft policy statement in the meeting materials. Dr. Serpa noted that during the Enforcement and Compounding Committee meeting, some revisions to the policy statement were proposed, and a recommendation was made that the Board approve the policy statement as revised. Dr. Serpa noted a typographical error in the policy statement's first sentence—it says "included" and should instead say "including"—and requested that if the statement is approved, staff correct the error before releasing. Dr. Serpa added that the committee's recommendation served as the motion.

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

Committee Recommendation (Motion):

Recommend approval of the proposed policy statement.

Draft Compounding Policy Statement

In light of the November 1, 2023, compendial date for several USP General Chapters, included General Chapter 795 Pharmaceutical Compounding – Nonsterile Preparations, 797 Pharmaceutical Compounding – Sterile Preparations, 800 Hazardous Drugs – Handling in Healthcare Settings and 825 Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging, the California State Board of Pharmacy (Board) wishes to update its stakeholders on its policy related to licensees transitioning to the updated USP General Chapters as well as actions under consideration by the Board.

There are several provisions of state and federal law governing the practice of pharmacy. Most notably related to compounding are provisions in the Federal Food, Drug and Cosmetic Act including exemptions provided under Section 503A; California Sherman Food, Drug, and Cosmetic Act; and several provisions within the Business and Professions Code including Sections 4126.8 and 4342.

As required by law, the Board has undertaken a review of its compounding regulations and identified changes necessary to clarify or make more specific requirements of Federal Law and USP General Chapters. These efforts resulted in the Board voting, as part of its April 2023 Board Meeting, to promulgate new regulations that are in addition to USP Standards. Additional information is available [here](#). The effective date of the newly updated state regulations is yet to be determined.

During this intervening period, the Board encourages licensees to begin transitioning to the new standards established in USP to ensure compliance with state and federal law. It is the Board's expectation that as compounding practices transition to new requirements, including provisions related to establishing beyond use dates (BUDs), that standard operating procedures must be updated and staff appropriately trained prior to implementing new practices and BUDs.

Members of the public were provided the opportunity to comment at the Sacramento location.

A compounding pharmacist and compounding pharmacy owner commented that they were confused if the transition to USP needed to be by November 1, 2023, or if transition over time was allowed by the policy statement. The pharmacist

recommended applying the Office of Administrative Law (OAL) emergency rulemaking process to clarify direction or rewording the policy statement.

Members of the public were provided the opportunity to comment at the Pasadena, and San Diego locations; however, no comments were made.

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

The Board heard additional comments from the public, including comments from a pharmacist representative from Kaiser requesting that the policy statement be further refined.

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

Member Chandler asked if it would be appropriate to address the comments made by the public. Dr. Serpa advised that the Board can assist the regulated public by adopting a policy statement but cannot include in the policy statement implications that the Board's regulations were not enforceable. Dr. Serpa added the Board can imply that the Board is working through a transition period.

Member Barker understood the limitations of the Board but also understood the concerns expressed by the commenters..

Member Jha agreed with Members Chandler and Barker as well as needing to provide additional guidance.

Chairperson Serpa explained this was discussed at the committee meeting but was very difficult to provide from the Board's perspective. Dr. Serpa noted that the last sentence was added to the policy statement to help the regulated public understand the Board's expectations.

Member Chandler asked about the implications of not having a policy statement. Dr. Serpa noted the Board was not required by law to provide a policy statement but was doing so for patient safety and to assist the regulated public. Dr. Serpa believed without a policy statement, there would be more confusion for the regulated public.

President Oh requested that inspectors be as consistent as possible during the transition period.

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

Board Member	Vote
Barker	Support
Cameron-Banks	Support
Chandler	Support
Crowley	Support
De La Paz	Support
Jha	Support
Oh	Support
Patel	Support
Serpa	Support
Thibeau	Support
Weisz	Not Present

VIII. Discussion and Consideration of Recommendations to Delete Previously-Approved New Regulation Text from Proposed 16 CCR sections 1737.7, subdivision (e) Related to the use of Respirators and 1737.18 Related to Medical Surveillance

President Oh again turned the meeting over to Maria Serpa, chairperson of the Enforcement and Compounding Committee, to report on a recommendation from staff to delete previously-approved new regulation text. Chairperson Serpa advised that USP Chapter 800 provides standards for the safe handling of hazardous drugs to minimize the risk of exposure to healthcare personnel, patients, and the environment. Dr. Serpa added that consistent with the action taken by the USP Compounding Expert Committee, USP Chapter 800 becomes compendial on November 1, 2023.

Chairperson Serpa recalled that the Enforcement and Compounding Committee met on several occasions to consider the new and revised USP Chapters and the Board's regulations to determine, in the interest of public safety, where changes were appropriate. Dr. Serpa further recalled that at the April 2023 Board meeting, the Board approved language, which included proposed new Article 4.7 titled Hazardous Drugs. Consistent with the Board's motion at the April 2023 meeting, staff prepared the rulemaking file to initiate the rulemaking process. The Board's motion delegated authority to the chair of the Enforcement and Compounding Committee and the executive officer to make any nonsubstantive changes or clarifying changes necessary and consistent with the Board's policy.

Chairperson Serpa advised that staff subsequently identified two specific areas of the Board-approved language that may be appropriate to be removed to avoid potential conflict with CalOSHA requirements. Dr. Serpa added that the changes being proposed exceed the delegated authority provided to the chair and executive officer, such that action by the Board was necessary to remove the language.

Chairperson Serpa highlighted that the agenda item being discussed was very narrow and specific and was not intended to open a discussion of the entirety of the rulemaking. Dr. Serpa noted that opportunities for public comment on the rulemaking

in its entirety would occur through the formal rulemaking process, including the 45-day comment period, planned regulation hearing, and subsequent discussion and consideration by the Board of the comments received.

Chairperson Serpa stated that the specific language for consideration was included in the meeting materials. Dr. Serpa added the discussion and action were limited to (1) if it was appropriate to remove subdivision (e) of proposed section 1737.7 related to the use of respirators, and (2) if it was appropriate to remove section 1737.18 related to medical surveillance. Dr. Serpa noted that she appreciated staff bringing this issue forward to the Board and agreed with the recommendation.

Members were provided the opportunity to comment.

Member Barker in Sacramento thanked staff for the recommendation.

Member Crowley in Pasadena asked if the PPE section was new or existing language. Dr. Serpa advised that there were parts of the PPE section in existing regulation, but it was reorganized into a new section and some items were added.

There was no comment from members at the San Diego location.

Motion: Prior to initiation of the formal rulemaking process, update the previously-approved regulation text for proposed Article 4.7, section 1737.7 removing subsection (e) related to the use of respirators and removing section 1737.18 related to medical surveillance.

Recommended deletions to proposed language reflected with ~~double strikethrough~~.

1737.7. Personal Protective Equipment (PPE).

In addition to the standards in USP Chapter 800, Hazardous Drugs – Handling in Healthcare Setting shall meet the following requirements of this article.

- (a) Two pairs of gloves that meet the ASTM D-6978 standard shall be worn for handling HD waste, cleaning HD spills, and performing routine cleaning in HD areas.
- (b) The outer pair of gloves that meets the ASTM D-6978 standard chemotherapy gloves shall be changed every 30 minutes during HD compounding unless otherwise recommended by the manufacturer's documentation. Documentation from the manufacturer shall be readily retrievable. For sterile HD compounding, both pairs of gloves labeled to meet the ASTM D-6978 standard shall be sterile.
- (c) Outer gloves used for HD compounding shall be changed between each different HD preparation.

(d) PPE shall be removed to avoid transferring contamination to skin, the environment, and other surfaces. PPE worn during compounding shall be disposed of in the proper waste container before leaving the C-SEC. SOPs shall detail the donning and doffing of PPE and where it takes place in the C-SEC.

~~(e) An appropriate full facepiece, chemical cartridge type respirator, or powered air purifying respirator (PAPR) shall be worn when there is a risk of respiratory exposure to HDs, including when:~~

~~(1) Attending to HD spills larger than what can be contained with a spill kit~~

~~(2) Deactivating, decontaminating, and cleaning underneath the work surface of a C-PEG~~

~~(3) There is a known or suspected airborne exposure to powders or vapors.~~

Note: Authority cited: Sections 4001.1, 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4114, 4115, 4126.8 and 4127, Business and Professions Code.

1737.18. Medical Surveillance.

~~In addition to the standards in USP Chapter 800, Hazardous Drugs Handling in Healthcare Setting shall meet the following requirements of this article. Elements of a medical surveillance program shall be consistent with the entity's Human Resource policies, and employees handling HDs must be aware of the program.~~

Note: Authority cited: Sections 4001.1, 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4114, 4115, 4126.8 and 4127, Business and Professions Code.

M/S: Barker/Patel

Members of the public were provided the opportunity to comment at the Sacramento location.

A compounding pharmacist and compounding pharmacy owner commented in appreciation of this being reviewed and in support of the motion.

Members of the public in the Pasadena and San Diego locations 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 compounding pharmacist commented in appreciation of this being reviewed and in support of the motion.

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

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

Board Member	Vote
Barker	Support
Cameron-Banks	Support
Chandler	Support
Crowley	Support
De La Paz	Support
Jha	Support
Oh	Support
Patel	Support
Serpa	Support
Thibeau	Support
Weisz	Not Present

The Board took a break from 10:39 a.m. to 10:45 a.m. Roll call was taken. Members present at the Sacramento location: Renee Barker, Licensee Member; Trevor Chandler, Public Member; KK Jha, Licensee Member; Jig Patel, Licensee Member; Maria Serpa, Licensee Member; and Seung Oh, Licensee Member. Members present at the Pasadena location: Indira Cameron-Banks, Public Member; Jessi Crowley, Licensee Member; Jose De La Paz, Public Member; and Nicole Thibeau, Licensee Member. No members were present at the San Diego location. A quorum was established.

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

President Oh turned the meeting over to Administrative Law Judge Jessica Wall to preside over the hearings on four petitions.

- a. Nimesh M. Patel, RPH 52508

The Board took a lunch break from approximately 12:10 p.m. to 1:00 p.m. Roll call was taken. Members present at the Sacramento location: Renee Barker, Licensee Member; Trevor Chandler, Public Member; KK Jha, Licensee Member; Jig Patel, Licensee Member; Maria Serpa, Licensee Member; and Seung Oh, Licensee Member. Members present at the Pasadena location: Indira Cameron-Banks, Public Member; Jessi Crowley, Licensee Member; Jose De La Paz, Public Member; and Nicole Thibeau,

Licensee Member. No members were present at the San Diego location. A quorum was established.

- b. Fred Ibarra, TCH 40995
- c. The Diennet Pharmacy, PHY 44310

The Board took a break from approximately 2:27 p.m. to 2:33 p.m. Roll call was taken. Members present at the Sacramento location: Renee Barker, Licensee Member; Trevor Chandler, Public Member; Jig Patel, Licensee Member; Maria Serpa, Licensee Member; and Seung Oh, Licensee Member. Members present at the Pasadena location: Indira Cameron-Banks, Public Member; Jessi Crowley, Licensee Member; Jose De La Paz, Public Member; and Nicole Thibeau, Licensee Member. No members were present at the San Diego location. A quorum was established.

Member Chandler left and Member Jha returned at approximately 2:38 p.m.

- d. Afifi G. Armanyous, RPH 45321

X. Closed Session

Open session concluded at approximately 3:19 p.m. The Board entered closed session at approximately 3:24 p.m. and ended closed session at 4:50 p.m.

XI. Adjournment

The Board resumed open session at 4:51 p.m., at which time the meeting was adjourned.