Attachment IV.

a. July 31-August 1
Board Meeting
Mintues

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: July 31 – August 1, 2024

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
Renee Barker, PharmD, Licensee Member (7/31/24 only, via WebEx)
Indira Cameron-Banks, Public Member (7/31/24 only)
Jeff Hughes, Public Member
Kartikeya "KK" Jha, 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
Trevor Chandler, Public Member, Treasurer
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
Jennifer Robbins, DCA Regulations Counsel
Norine Marks, DCA Staff Counsel
Debbie Damoth, Executive Specialist Manager
Sara Jurrens, Public Information Officer

July 31, 2024

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

President Oh called the Board meeting to order at approximately 1:00 p.m. President Oh thanked former Board Member Jose De La Paz whose term ended June 1, 2024. 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: Indira Cameron-Banks, Public Member; Jeff Hughes, Public Member; KK Jha, Licensee Member; J. Newell, Public Member; Satinder Sandhu, PharmD, Licensee Member; Maria Serpa, PharmD, Licensee Member; and Seung Oh, PharmD, Licensee Member. Renee Barker, PharmD, Licensee Member participated via WebEx. Dr. Barker disclosed that no persons over 18 years old were present in the room with her as she participated in the meeting remotely via WebEx. A quorum was established.

President Oh reminded members participating via WebEx to remain visible with cameras on throughout the open session of the meeting. Dr. Oh advised if members needed to temporarily turn off their camera due to challenges with internet connectivity, they must announce the reason for their nonappearance when the camera was turned off.

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

President Oh announced the Board would accept public comment for items not on the agenda and provided instructions on how the public could provide comment.

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

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

Members heard multiple comments expressing concern about maintaining access to glutathione and methylcobalamin/B-12 injections for fire fighters and patients with long COVID, Lyme disease, and other chronic illnesses. President Oh and DCA Counsel Gartner advised the present comment period was for items not on the agenda or future agenda items, and requested that commenters wishing

to comment on agendized items save their comments for the comment period specific to that agendized item.

A civil engineer and pain patient advocate commented about his written comment submitted to the Board regarding state and federal governments' mistargeted and failed war on the opioid epidemic related to the ongoing shortages of controlled substances made worse by the settlement with major drug distributors.

A member of the public provided comment advocating for people injured by COVID vaccines.

A representative of closed-door pharmacies requested clarification regarding AB 1286 and asked if it was the intent of the Board to require California licensed nonresident pharmacies located outside the state to report errors for only their California patients or any patient that the pharmacy serves that may reside in other states.

An advanced practice pharmacist recommended that advanced practice pharmacists be given the ability to order samples as noted in Business and Professions Code (BPC) section 4061 for the distribution of drugs as a sample. Additional clarification was requested for California Code of Regulations (CCR), division 17, title 16, section 1730.1 as to who is able to attest to the 1,500 hours required to be an advanced practice pharmacist as supervisor practitioner, program director or health facility administer were identified but supervising practitioner was not defined.

A representative of CSHP and pharmacists requested a future agenda item be added clarifying the outcome of AB 352 regarding protected activities and subsequent letter from the Attorney General to CVS including what information can be released without a search warrant.

Board Member Nicole Thibeau joined the meeting via WebEx at approximately 1:36 p.m. Dr. Thibeau noted no one over the age of the 18 was in the room with her as she participated in the meeting.

Enforcement and Compounding Committee Chairperson Serpa thanked the commenter regarding controlled substances and access. Dr. Serpa stated it would be on a future agenda for the Enforcement and Compounding Committee.

Dr. Serpa also indicated interest in learning more about the use of samples by advanced practice pharmacists including the historical and current use.

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

President Oh reminded those present that the Board recognizes pharmacists that 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. President 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.

IV. 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, Including Review of Any Comments Received During the 45-Day Comment Period and Regulation Hearing

President Oh turned the meeting over to Enforcement and Compounding Committee Chairperson Serpa to guide the Board through review of the proposed regulations.

Chairperson Serpa thanked President Oh for the opportunity to assist the Board to navigate through the comments received during both the 45-day written comment period, which closed on June 3, 2024, and at the regulation hearing held on June 18, 2024. Dr. Serpa reported tremendous engagement by interested stakeholders and thanked everyone who submitted comments. Dr. Serpa also thanked staff who worked on reviewing the comments and providing recommendations, noting that staff spent approximately 200 hours on review and consideration of comments. Dr. Serpa added the Board has a very dedicated staff of subject matter experts.

Dr. Serpa reminded all present that the development of the regulations began in 2019. In anticipation of new and revised USP Chapters becoming effective in 2020, meetings began in February 2019, with a series of public meetings convened by the Enforcement and Compounding Committee. The first Committee meeting focused on education on the proposed revisions to USP 795, Pharmaceutical Compounding – Nonsterile Preparations. This was followed by additional educational meetings including in March 2019, when a Committee meeting was convened to focus on education on the proposed revisions to USP 797, Pharmaceutical Compounding – Sterile Preparations, and in April 2019, when a Committee meeting was convened to focus on education on the new proposed Chapter 800 – Hazardous Drugs – Handling in Healthcare Settings. In addition, in June 2019, a Committee meeting was held focusing on education on the provisions of new proposed Chapter 825 – Radiopharmaceuticals –

Preparation, Compounding, Dispensing, and Repackaging. Following these educational meetings, in July 2019, the Committee considered proposed amendments to regulations related to pharmaceutical compounding of nonsterile preparations.

Dr. Serpa reported the Committee also met on September 5 and 24, 2019, at which times the Committee and stakeholders focused on discussion and consideration of proposed regulations related to pharmaceutical compounding of sterile preparations. During the meetings in July and September 2019, the Committee engaged in a collaborative process with the public, reviewing and editing proposed text during these meetings in response to comments received from stakeholders. On November 5, 2019, in light of the delays with USP, the Committee considered a Draft Policy Statement to provide stakeholders with guidance on the applicability of Board compounding regulations and USP compounding chapters while appeals were pending before the USP.

Dr. Serpa believed it was important to note that in addition to the Committee meetings, stakeholders were also provided with an opportunity to provide feedback to the Board during Board meetings in 2019.
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 2023.

Specifically, in January 2023, the Committee and stakeholders received a presentation providing an overview of federal requirements for compounding under section 503A of the Food, Drug, and Cosmetic Act, as well as a presentation on USP Chapter 825 regarding Radiopharmaceuticals. Following the presentations, the Committee and stakeholders considered proposed regulations related to radiopharmaceuticals using the same collaborative process as used in 2019 of reviewing and editing the proposed text during the meeting.

In February 2023, the Committee and stakeholders received a presentation on USP Chapter 795 – Pharmaceutical Compounding – Nonsterile Preparations. Following this presentation, the Committee and stakeholders considered draft proposed regulation text. As with the approach taken in 2019, the language was reviewed and considered in a very collaborative manner, with edits being made during the meeting based on stakeholder feedback.

In March 2023, the Committee and stakeholders received a presentation on USP Chapter 797 – Pharmaceutical Compounding – Sterile Preparations. Following the presentation, the Committee and stakeholders considered draft proposed regulation text related to pharmaceutical compounding of sterile preparations.
In April 2023, the Committee and stakeholders received a presentation on USP Chapter 800 – Hazardous Drugs – Handling in Healthcare Settings. Following the

presentation, the Committee and stakeholders considered draft proposed regulation text related to hazardous drugs.

The proposed regulations were considered by the full Board during its April 19-20, 2023 meeting, and the Board voted at that time to initiate this rulemaking related to nonsterile compounding, sterile compounding, handling of hazardous drugs, and radiopharmaceuticals. To address an issue related to respirators and medical surveillance, minor changes were approved by the Board during its September 2023 meeting.

Dr. Serpa continued that, understanding that the USP Chapters became effective on November 1, 2023, and that the Board's proposed regulations would not yet be effective, the Board released an updated Policy Statement on September 12, 2023, providing stakeholders with additional guidance. She shared this historical information to highlight that there have been numerous opportunities for discussion and exchange with respect to these regulations.

Dr. Serpa explained that she planned to review each article and solicit feedback from members on the comments and staff recommendations in segments to assist in the discussion. She noted there were many proposed modifications to the text providing clarifications and updates based on comments received during the 45-day comment period and public hearing. These proposed modifications were marked with double underline for additions or double strikethrough for deletions to the originally proposed language previously approved for noticing by the Board in April 2023.

Dr. Serpa thanked everyone for their comments and participation to improve the proposed regulations and make them clearer. She was hopeful after review of all the articles, there would be a general consensus among members for a motion to approve a 15-day public comment period for modified text to amend the language as discussed. Once there was a motion and second, and Board member comment on the motion, public comment would be opened on the motion for all articles.

Dr. Serpa reminded all 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 did not repeat federal law or USP standards, but clarified the Board's standards for compounding, augmenting the federal law and USP standards. Dr. Serpa also noted that while the proposed regulations appeared to be entirely new, many of the concepts were in existing California regulations. Since the compounding regulations were being renumbered and new articles created to match the USP format, the regulations were being reorganized.

Members were provided the opportunity to comment before Dr. Serpa began the review; however, no comments were made.

Proposed Article 4.5 – Nonsterile Compounding

Dr. Serpa advised staff were offering minor recommendations in 1735(a) related to approved labeling to clarify the definition only applies when applicable. Staff also recommended that 1735.1(b) be deleted. With that change, renumbering of the language in this section would be necessary. Staff further recommended an increase to the 14-day supply for antibiotics for veterinary patients in (e)(1). This recommendation was directly in response to comments received during the 45-day comment period and subsequent hearing that were specific in nature. Also in this section, staff recommended including an exemption to consultation requirements in subdivision (h) in specific settings. This change would address an issue raised by a number of commenters regarding consultation requirements. Further, staff recommended a nonsubstantive conforming change in subdivision (i) of section 1735.1.

Members were provided the opportunity to comment on sections 1735 and 1735.1. Members discussed if the definition of "essentially a copy" in 1735(d) was the current definition, and were reminded that terms were being included in the Board's proposed regulations if they weren't exactly the same as USP's definition. Members discussed wanting to be clear so that it wasn't left to interpretation. Members also discussed allowing for compounding when there were shortages related to section 1735.1 (f)(1)(A) and further explained the process was more complex in dealing with other vendors and wholesalers. They discussed the key part including "produces for that patient a clinically significant difference as determined by practitioner, compounding pharmacist and dispensing pharmacist" included in section 1735.1 (f)(1)(B). For a drug that couldn't be acquired and not on the FDA or ASHP shortage list, a significant issue would be lack in continuity of care. Members agreed this wording could be clarified. The intent for section 1735.1(f)(1)(B) was to provide more guidelines rather than limitations and the members agreed to clarify this point while not overstepping what was allowed in federal law. They also discussed clarifying that the compounding and dispensing pharmacist could be the same person.

Dr. Serpa next reviewed section 1735.2 and noted that in response to public comments received, staff recommended a change in subdivision (a) to ensure consistency with language in other provisions of the law related to direct supervision and control. She noted staff also recommended the deletion of subdivision (b), and conforming changes made in the section, which was also in response to comments received. Changes were also being recommended to focus on the core competencies established in the USP Chapter in response to comments received.

Dr. Serpa continued that recommendations to amend section 1735.3 were also made to update the language and clarify some of the requirements. These changes were in response to comments received that highlighted where the Board's regulation language could be more concise.

Members were provided the opportunity to comment on changes to sections 1735.2 or 1735.3.

Members discussed the proposed changes. Related to proposed section 1735.3, some members expressed concern about potential Health Insurance Portability and Accountability Act (HIPAA) implications of asking about employee medical conditions, as well as who was responsible for asking about the medical conditions of the employee prior to compounding. Members discussed that USP requires that the "designated individual" is responsible for evaluating whether individuals should be excluded from compounding, and the Board's regulations couldn't be lesser than USP standards, but that the Board wanted to specifically place this responsibility on the supervising pharmacist. Regarding the HIPAA/privacy concern, counsel provided the regulation didn't require the supervising pharmacist to ask any specific questions, rather they could fulfill their responsibility by a visual examination of the employee. Members discussed how the regulation states the goal and the standard operating procedures (SOPs) would address how it was done by the pharmacy's personnel. Members were advised the obligation for the compounding personnel to self-report any potential issue was already included in the USP chapter and didn't have to be repeated in the Board's regulations.

Continuing with her review, Dr. Serpa advised minor changes were recommended in sections 1735.4, 1735.5, and 1735.6. Additionally, section 1735.7 included conforming language to changes made earlier in the article related to supervision and control. She highlighted the change in section 1735.7(c) being recommended. Dr. Serpa added that based on the comments received, the requirement was not clear in the original language proposed, and she was hopeful that the recommended text would clarify that the compounding record did not need to be maintained in the electronic system as a single record. However, if requested by the Board, it needed to be produced as a single document. Dr. Serpa highlighted this change because of the numerous comments received.

Members were provided the opportunity to comment on changes to sections 1735.4, 1735.5, 1735.6, and 1735.7; however, no comments were provided.

Dr. Serpa next explained there was a recommendation to update the text in section 1735.8 to clarify that both compounding and dispensing pharmacists are responsible for the compounded product. She noted some commenters asked about scenarios where the compounding pharmacist and the dispensing

pharmacist were the same, and observed that there was nothing in the language that requires two different pharmacists to be involved. When there are two different pharmacists involved, they share responsibility for the provisions in this section. She added that section 1735.9 included some recommended minor changes as well as a significant change to the labeling requirement in subdivision (c), which as recommended would provide an exemption to the labeling requirement for a nonsterile compounded product that would be administered in specific settings. This was another area where the Board received comments and the recommended language was in direct response to those comments.

Members were provided the opportunity to comment on changes to sections 1735.8 and 1735.9. A member requested clarification of the second sentence in section 1735.8 to remove the redundant "and" and "or" verbiage.

Proceeding with her review of proposed Article 4.5, Dr. Serpa noted staff recommend amending section 1735.10 to clarify what information needed to be available to the Board upon request. Changes were also recommended in section 1735.11 related to SOPs, most notably new provisions in paragraphs (F) and (G) under 1735.11(a)(2). The Board received comments about how a facility should handle review of complaints received if the PIC was not available. Given the comments, it appeared best to specify that the facility's SOP needed to prescribe how such a situation would be handled. In addition, changes were offered in response to comments regarding concerns with facility or equipment failures that could impact compounding. Dr. Serpa advised in her experience working in a large health system, they stressed disaster or downtime preparedness. She added the changes recommended in this section would require SOPs be in place in the event of a failure to ensure the facility has a back-up plan to follow. Dr. Serpa believed allowing the facility to plan for these eventualities and develop their own solution for their respective facilities made more sense than the Board prescribing how such issues should be resolved.

Members were provided the opportunity to comment on changes to sections 1735.10 and 1735.11.

Members discussed SOPs determining which pharmacist was responsible for review in section 1735.11. A few grammatical errors were pointed out and a request was made to include the names of USP chapters with the numbers when referenced. A question was raised about the benefit of incorporating USP chapters. The Committee had determined the additional USP chapters were added when it was relevant to the section to provide additional information and reference for licensees.

Dr. Serpa next provided that comments were received about section 1735.12 suggesting the proposed language was not clear. Staff were recommending clarifying text to align with the federal definitions. In addition, nonsubstantive

changes were offered in sections 1735.13 and 1735.14 which Dr. Serpa believed may address some of the comments received to these sections.

Members were provided the opportunity to comment on changes to sections 1735.12, 1735.13, and 1735.14.

Members discussed changing the reference to 72 hours to three business days. The Committee decided upon hours because business days was not commonly defined nor consistent.

Members also discussed the audit trail requirement in 1735.14(b) and agreed language would be conformed to Board policy of three years.

The Board took a break from 2:46 p.m. to 3:01 p.m. Roll call was taken. The following Board members were physically present in Sacramento: Indira Cameron-Banks, Public Member; Jeff Hughes, Public Member; KK Jha, Licensee Member; J. Newell, 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.

Proposed Article 4.6 – Sterile Compounding

Moving on to the review of proposed Article 4.6, Dr. Serpa first noted that many of the requirements in the proposed text are carryovers from existing regulations and expressed disappointment that some of the commenters appeared to be seeking a lessening of the Board's current standards, which she did not believe was appropriate. Dr. Serpa stated it was important to note that there appeared to be in part a misunderstanding of what federal law provides, as well as the national standards specifically related to sterile compounding. She highlighted that she found the responses from staff very helpful to comments received in some of these areas and was hopeful others found them educational as well. Dr. Serpa added for anyone looking for a reminder about the federal requirements, the presentation received in January 2023 was livestreamed and the video was available on the Board's website.

Dr. Serpa provided in section 1736, the recommended changes to the text included an additional sentence to emphasize the definitions were to supplement definitions included in the USP Chapters to address some of the comments received related to items within the USP Chapter. She also added a conforming change is subdivision (a) was being offered. In section 1736.1 and throughout the article, the introduction language in each section was also changed to harmonize with the structure of the language and for each of the articles, along with conforming changes.

Dr. Serpa added that as requested in comments, the recommended text was providing clarification on the documentation requirements where immediate use provisions were applied. Many comments suggested information would need to be documented twice or potentially create delays in patient care which was never the intent of the language. A significant addition was suggested in (b)(1) that would provide new authority for immediate use provisions for up to 24 hours in the event of equipment failure. This change was in response to comments and a provision that was not allowed under current regulations.

Dr. Serpa continued the language related to "essentially a copy" was modified to provide provisions for drug shortages. The similar exemption established in the nonsterile article related to consultation in specified settings was also being recommended in response to comments.

Members were provided the opportunity to comment on changes to sections 1736 and 1736.1.

Members agreed with addressing essentially a copy and making sure it was necessary. Related to section 1736.1(b), members appreciated the staff recommendation to make it more open and harmonizing. Members wanted to ensure that for section 1736.1(e) "clinically significant" wasn't determined by an inspector. Members recommended rewording for clarity section 1736.1(b)(1) to clarify that SOPs for what your redundancy downtime procedures are and what you are being limited to in 24 hours.

Dr. Serpa noted recommended changes in sections 1736.2 and 1736.3 included conforming changes being made in response to comments. Section 1736.4 included clarifying language in (e) and no changes were being recommended in section 1736.5.

Members were provided the opportunity to comment on changes to sections 1736.2, 1736.3, 1736.4, and 1736.5.

A member asked to have "sufficiently similar" clarified in section 1736.2(b)(1), (2), and (3). Members discussed this was challenging but could be watched. Members also discussed the requirements for section 1736.2(d) be changed to 21 or 30 days as 14 days was not enough time to allow for incubation. Discussion confirmed any failure of compounding testing would prohibit the personnel from compounding which was added as a result of public comment.

Dr. Serpa provided that recommended changes in section 1736.6(a) established provisions for how to address a situation where a laboratory was unable to identify growth to the genus level. She noted the Board received a number of comments in this area and highlighted that the language proposed by the Board was consistent with ASHP guidance "Pharmacy Environmental Monitoring

Implementation Toolkit." A correction was made to CETA guide revision date. There were no proposed changes to the text in sections 1736.7 or 1736.8.

Members were provided the opportunity to comment on changes to sections 1736.6, 1736.7, and 1736.8.

Members discussed proposed changes to section 1736.6(a) and determined to revert back to what the Board had before the proposed regulation changes. Boards staff would do a gap analysis to see what USP had and what the Board had to ensure that the Board's proposed regulations covered USP requirements.

Continuing on, Dr. Serpa identified significant comments related to section 1736.9, some of which may have stemmed from the complex nature of federal law and the USP national standards related to components. She noted there were recommended changes related to this issue as the Board attempts to thread the needle between federal law and national standards. Dr. Serpa added the proposed regulation text was not intended to create barriers to effective treatments, but rather was intended to provide flexibility as practices evolve and research supports emerging treatments. If the recommended change to subdivision (f) were approved by the Board and enacted, this would establish a means by which a facility could compound using an FDA Category 1 bulk drug substance. The FDA Category 1 list includes bulk drug substances nominated for use in compounding but in the process of being evaluated by FDA and thus not yet approved for compounding. The proposed language in subdivision (f) reflected authority to perform such compounding with guardrails to reduce the potential for patient harm. Dr. Serpa added there would be new SOP requirements. In addition, there were recommended changes to update the language in response to comments related to excipients. Lastly, there is a nonsubstantive change necessary to correct the typographical error at the end of subdivision (e).

Members were provided the opportunity to comment on section 1736.9.

A member expressed concern for the availability of compounding injectable and nebulized glutathione and methylcobalamin. Members discussed that the text being proposed creates a path for these items to be compounded. There was discussion regarding 1736.9(d) and the requirement that the COA include the manufacturer's name and address. It was clarified that this requirement derives from the FDA's guidance about the need to know bulk suppliers.

Dr. Serpa advised there were no changes being recommended to section 1736.10. She added in response to comments received, changes were recommended for section 1736.11 related to the compounding record, similar to the change made in the nonsterile article. Dr. Serpa added the language in (c)(1) was recommended to be removed as the USP Chapter already established the

requirement and again conforming changes were being made related to supervision and control.

Members were provided the opportunity to comment on sections 1736.10 and 1736.11.

A member expressed general concern about tying so many other USP Chapters to the regulation.

Dr. Serpa advised that the changes being recommended to section 1736.12 were conforming changes and nonsubstantive. She added recommended changes in section 1736.13 provided clarification on labeling that applies for CSPs administered by infusion and again provided an exemption to labeling requirements in specified settings.

Members were provided the opportunity to comment on sections 1736.12 and 1736.13.

A member requested clarification in section 1736.12(b) and was interested to see if changes to section 1736.13(a)(3) addressed comments received.

Dr. Serpa reported recommended changes in section 1736.14 were offered in response to comments received. Dr. Serpa added this was another area where some public comment appeared to be seeking lessening of the Board's current regulations. She was hopeful the staff's responses to comments received helped to provide education. Dr. Serpa provided recommended changes to the text provide clarification about the requirements for testing to align with the USP Chapter. She advised no changes were recommended to sections 1736.15 or 1736.16.

Members were provided the opportunity to comment on sections 1736.14, 1736.15, and 1736.16.

Discussion included noting that section 1736.14(c) read awkwardly and should be further reviewed.

Dr. Serpa continued that recommended changes in section 1736.17(a)(2)(E) primarily were offered to implement the new proposed authority to compound with FDA Category 1 bulk drug substances. She noted where such compounding occurs, additional SOPs would be required to detail the methods by which compliance would be confirmed in specified areas. Dr. Serpa highlighted the reliance upon the clinical judgment of the pharmacist responsible for developing these SOPs. In subdivision (b), she noted a recommended change to the SOPs specifically related to facility or equipment downtime or failure. This was in part to support the recommended changes that allow for immediate use provisions and

to ensure the facility has a backup plan in place. Similar to the recommended change in the nonsterile article, there were recommended changes in the text that would require an SOP to specify the provisions for timely review of complaints related to potential quality problems in the event the PIC was not available. Dr. Serpa added changes recommended in section 1736.18 were similar to recommended changes in the nonsterile article based on comments submitted.

Members were provided the opportunity to comment on sections 1736.17 and 1736.18.

Members discussed concern with tying to USP 1163, noted that the reference to 72 hours should be increased, and observed that the USP chapter titles should be added.

Dr. Serpa reported the recommended change to section 1736.19 was in response to a comment and a nonsubstantive change was being offered in Section 1736.20. The recommended changes in section 1736.21 were added in part in response to comments received.

Members were provided the opportunity to comment on sections 1736.19, 1736.20, and 1736.21.

A member commented hoping to clarify three years for section 1736.20(b).

Proposed Article 4.7 – Handling of Hazardous Drugs

Dr. Serpa next moved to proposed Article 4.7, and highlighted that the USP chapter was not solely related to compounding; however, the focus of the Board's regulation for Hazardous Drugs included provisions beyond compounding only where deemed necessary to preserve either the compounding environment or to prevent areas of cross contamination. She noted there were a number of requirements beyond the Board's jurisdiction that a facility must be aware of, including Title 8 Industrial Relations and Title 24 Building Standards Code. Dr. Serpa continued in this Article, conforming changes were made related to providing exemptions to consultation requirements and labeling in specified settings. Changes were made in the introductory language for each section to be consistent among the articles. These recommended changes were in sections 1737 - 1737.4.

Members were provided the opportunity to comment on sections 1737-1737.4.

Members discussed having more clarity in separating hazardous drug compounding and a regular pharmacy setup that should follow USP Chapter 800 standards. They discussed the challenge where employees, patients, and the environment all needed to be protected. A concern was raised about having

regulations lesser than USP or not as safe because of implementation challenges while others thought it was narrower rather than lesser standards. Members discussed a need to educate and noted cases where the PIC may not have the expertise.

Dr. Serpa provided some of the changes in the recommended text in section 1737.5 were in response to comments received. These recommended changes could also reduce costs that were anticipated in the original language. Dr. Serpa wanted to ensure participants read the staff's responses to comments received because she believed some commenters may not be fully aware of some of the provisions in the California building code regarding compounding facilities. Dr. Serpa noted some of the changes recommended were to more closely align with the current building code. The proposed changes in this section also provide for delayed implementation for some requirements consistent with requests from commenters. She noted the required transition to a HEPA purge type pass-through would no longer be required but a facility shall consider use of such a pass-through prior to installing a new HD pass-through. She added additional changes were recommended in section 1737.6 in response to comments received. Dr. Serpa clarified the Board was no longer detailing the process for environmental wipe sampling for HD surface residue but requiring the facility to develop their own SOP to address their respective facilities.

Members were provided the opportunity to comment on sections 1737.5 – 1737.6; however, no comments were made.

Dr. Serpa advised recommended changes to section 1737.7 were offered in response to public comment and should result in lesser cost impacts than initially identified related to gloves. There were also nonsubstantive changes recommended. She noted that one additional nonsubstantive change not highlighted currently in the text in subdivision (b) should also be made to be consistent with the description of type of gloves. Nonsubstantive changes were also recommended in section 1737.8.

Members were provided the opportunity to comment on sections 1737.5 – 1737.6.

A member commented that the proposed language for section 1737.7 could cause a lot of confusion among non-compounding pharmacists. A member also requested a nonsubstantive change to proposed section 1737.8, noting a concern about requiring the designated person to be involved in cases where the policy has already been developed.

Dr. Serpa advised changes were recommended in section 1737.9 in response to comments and a change to align with training in core competencies as with the other Articles was also recommended. In addition, in response to comments received, a wording change was recommended in 1738.10 along with

nonsubstantive changes. Recommended changes in 1737.11 included changes to labeling exemption in specified settings similar to the nonsterile and sterile articles as well as other nonsubstantive changes. Nonsubstantive changes were also recommended in Section 1737.12.

Members were provided the opportunity to comment on sections 1737.9 – 1737.12; however, no comments were made.

Dr. Serpa reported there was a significant recommended change in section 1737.13 related to the use of HD preparation mats in response to comments received and noted the change would reduce potential cost impact for those facilities not currently using mats. In section 1737.14, the changes were nonsubstantive or providing clarification. In response to comments received, changes were recommended in section 1737.15 including removal of additional requirements for the decontamination of container closures.

Members were provided the opportunity to comment on sections 1737.13 – 1737.15.

Members discussed the requirement for the gloves to be provided to patients when hazardous drugs were dispensed to the patient by the pharmacist. Some members thought the pharmacist should be required to provide the gloves while others thought it should be up to the clinical judgment of the pharmacist to determine what was needed for the patient.

Dr. Serpa provided nonsubstantive changes were recommended in section 1737.16 as well as removal of the requirement to maintain a list of staff properly trained for cleanup of HD spills. The section still required an SOP on the availability of a qualified person during times HDs were handled. This change was recommended in response to comments received. Nonsubstantive and clarifying changes were also recommended in section 1737.17.

Members were provided the opportunity to comment on sections 1737.16 – 1737.17; however, no comments were made.

Proposed Article 4.8 – Radiopharmaceuticals

Moving on to the final proposed article, Dr. Serpa advised that recommended changes similar to the other articles were being proposed for Article 4.8. The changes in sections 1738 through 1738.4 were nonsubstantive changes to conform language and language was added related to supervision and control. Dr. Serpa added it was recommended that provisions related to demonstrated competency and failure in ongoing evaluation and training be incorporated similar to provisions in the other articles.

Members were provided the opportunity to comment on sections 1738 – 1738.4; however, no comments were made.

Dr. Serpa provided nonsubstantive changes were offered in section 1738.5 as well as the deletion of subdivision (j) as the requirement was already established in the USP Chapter. Recommended changes in section 1738.6 were similar to the recommended changes in the sterile compounding language related to trending for growth of microorganisms in subdivision (b) along with some clarifying language. The recommended change established requirements for incubators without manufacturers' specifications like in sterile compounding requirements.

Members were provided the opportunity to comment on sections 1738.5 – 1738.6; however, no comments were made.

Dr. Serpa noted nonsubstantive changes were offered in sections 1738.7 and 1738.9 and conforming changes were recommended in section 1738.9 clarifying the record requirement, like the changes recommended in nonsterile and sterile compounding requirements. Nonsubstantive changes were also in sections 1738.10, 1738.11, 1738.12, and 1738.13.

Members were provided the opportunity to comment on sections 1738.7 – 1738.13; however, no comments were made.

Dr. Serpa added section 1738.14 included conforming changes to align with changes made in the other articles related to adverse drug experiences and provisions for review of complaints in the event the PIC was not available. In response to a comment received, delivery delays were removed from complaints reportable to the Board.

Members were provided the opportunity to comment on section 1738.14.

A member confirmed changes made in other articles regarding the time would be conformed throughout the proposed language.

Having completed review and discussion of the changes being recommended to the proposed regulations, Dr. Serpa invited members to make a motion.

Motion: Accept the Board staff recommended responses to the comments as the responses of the Board and approve the modified text consistent with the discussion of the Board, including further amending sections 1735.9 (regarding the audit trail), 1736.2 (regarding a change from 14 days to 30 days), and 1736.6 (regarding returning to original regulatory language and ensuring no gap with USP requirements), adding an introductory sentence to the article on hazardous drugs that the following requirements apply to the compounding of

hazardous drugs, and addressing the discussion regarding "essentially a copy," for a 15-day public comment period. Delegate to the executive officer the authority to make technical or non-substantive changes as needed.

M/S: Barker/Oh

Counsel confirmed if the motion was approved and there was a subsequent 15-day comment period, the comment period would be for the changes made in modified text.

Members of the public were provided the opportunity to comment.

Public comment was received in Sacramento.

A representative of the California Society of Dermatology and Dermatological Surgery inquired if the proposed regulations applied to dermatologists.

Representatives from Hims & Hers Health; CVS Health; Walgreens; California Naturopathic Doctors Association; and Volunteer Fire Foundation in Sonoma County had concerns that the proposed language wasn't ready and/or a 15-day comment period wasn't enough time.

Some commenters thought the language needed additional clarity while others were concerned about access to glutathione.

Public comment was received via WebEx.

Multiple comments were received expressing concerns with: access being restricted for glutathione and methylcobalamin; moving the proposed language forward as presented; a 15-day comment period not being long enough; and the proposed language exceeding USP requirements without scientific proof. Multiple comments also requested exemption for non-pharmacist compounding personnel such as doctors.

Technical comments were heard requesting specific changes to sections:

- 1735.1 and 1736.1(e)(1)(C) regarding documenting drug shortages as being excessive;
- 1736.2(d) supporting the change from 14 to 30 days;
- 1737.6 recommending reverting "shall" to "should";
- 1738.5(d) noting the inability or prevention to be able to prepare radiopharmaceuticals in an SRPA noting in a clean room if the HVAC goes down, the clean room is turned into an SRPA where radiopharmaceuticals should be able to be prepared and dispensed provided there is a PEC that is ISO 5 class;

- 1738.6 noting USP already addressed pathogenicity as being excessive; and
- 1738.14(b) regarding the 72 hours complaint that is an aggressive timeline for investigation and would appreciate the "complaint" to be defined and a form to be provided to the PIC for completion.

A representative of the California Orthopedic Association requested clarification if the proposed regulations were intending to alter current practice to allow orthopedic surgeons to mix a medication with lidocaine.

Representatives from Kaiser Permanente; Scripts Health; Alliance for Pharmacy Compounding; CPhA; UCSF; Cedar Sinai; Sutter Health; CSHP; and Highland Hospital requested the Board to withdraw the proposed rulemaking or return the proposed language to the Committee and/or provide the public with more time to respond to modified text. Some commenters recommended repealing the current compounding regulations and relying only on USP.

Having receipt public comment, Dr. Serpa thanked participants and reviewed the regulatory process. She clarified the Board of Pharmacy regulates pharmacists and pharmacies but not other health care practitioners. Dr. Serpa encouraged those individuals to talk to their respective licensing boards about how they interpret their law and USP standards.

Dr. Serpa asked if a 45-day comment period could be considered if the current motion was voted down. Counsel confirmed a 45-day comment period would be acceptable. Following discussion, the motion was amended to provide for a 45-day comment period.

Motion: Accept the Board staff recommended responses to the comments as the responses of the Board and approve the modified text consistent with the discussion of the Board, including further amending sections 1735.9 (regarding the audit trail), 1736.2 (regarding a change from 14 days to 30 days), and1736.6 (regarding returning to original regulatory language and ensuring no gap with USP requirements), adding an introductory sentence to the article on hazardous drugs that the following requirements apply to the compounding of hazardous drugs, and addressing the discussion regarding "essentially a copy," for a 45-day public comment period. Delegate to the executive officer the authority to make technical or non-substantive changes as needed.

M/S: Barker/Oh

Members continued to discuss the amended motion. Members also discussed personal experiences with chronic illness and loss due to occupational cancer

and stated they were moved and concerned after hearing public comments. Counsel provided an overview of the rulemaking process, including explaining how modified text would be prepared and shared with the public. Members expressed that additional education would be helpful, and discussed options available to the Board, including sending the proposed regulations back to Committee and continuing discussion at the September Board meeting.

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

Representatives of Walgreens and CVS Health expressed concern with only allowing comments on the modified text during any future comment period. Counsel confirmed that while the notice of modified text would request that comments be confined only to the most recent changes, at any point, the Board could review or respond to comments submitted to the Board outside of the modified text.

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

Multiple members of the public requested that the Board send the proposed language back to Committee; hold a stakeholder meeting; and vote down the motion, withdraw the current regulation, and initiate a new regulation to repeal Articles 4 and 7.5 and simply rely on USP.

A public commenter asked the Board if the proposed regulations would affect their ability to access IV glutathione and methylcobalamin.

Having heard additional public comment, members continued discussing options available to the Board moving forward. Following discussion, the Board proceeded to vote on the motion.

Support: 3 Oppose: 6 Abstain: 0 Not Present: 3

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

With the motion having failed, the Board continued discussing options and possible new motions.

Motion: Put this item on for discussion at the September 12, 2024 Board meeting to consider the modified text that was presented at the July 31, 2024 Board meeting, with additional modifications consistent with the Board's discussion at the July meeting. Delegate to Dr. Serpa and Dr. Barker to work with the executive officer and Board staff to ensure that the modifications that are presented to the Board at the September meeting reflect the discussion at the July meeting.

M/S: Hughes/Barker

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

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

Comments were received asking the Board to consider the ability for chronically ill patients to participate in the process and in support of the motion.

A representative of Kaiser Permanente asked the members to consider how they wish to see compounding regulated in California, and what attributes of patients and pharmacists in California make our state so different from other states that just rely on USP.

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

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

The meeting adjourned at 7:49 p.m.

August 1, 2024

President Oh called the second day of the Board meeting to order at 9:01 a.m. President Oh advised those present that the Board would be convening in closed session as the first item of business, and further noted that several items on the agenda would not be considered at today's meeting in the interests of time.

Roll call was taken. The following Board members were physically present in Sacramento: Jeff Hughes, Public Member; KK Jha, Licensee Member; J. Newell, 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. Member Thibeau advised the Board of her need to participate remotely at today's meeting, and stated that no one else over 18 years of age was present in the room with her.

A quorum was established. President Oh noted that today Member Thibeau, who was attending and participating remotely, counts toward the quorum, as permitted by Government Code section 11123.2(j), and advised that based on Member Thibeau's description of the circumstances relating to her need to participate remotely at the meeting, the Board must take action as required by Government Code section 11123.2(j).

Motion: Approve Member Thibeau's attendance and participation from a remote location at today's meeting, and authorize that her attendance and participation from a remote location shall count toward the establishment of a quorum as permitted by section 11123.2(j) of the Government Code.

M/S: Oh/Serpa

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

Support: 7 Oppose: 0 Abstain: 0 Not Present: 5

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

The Board then convened in closed session at approximately 9:08 a.m.

The Board reconvened in open session at approximately 10:54 a.m. Dr. Oh again reviewed agenda items that would not be addressed at the meeting in the interests of time and referenced meeting materials for those agenda items. Dr. Oh also announced the Licensing Committee would be scheduling another meeting for September 4, 2024, to discuss the standard of care proposal.

Roll call was taken. The following Board members were physically present in Sacramento: Jeff Hughes, Public Member; KK Jha, Licensee Member; J. Newell, 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.

Dr. Oh reminded members participating via WebEx to remain visible with cameras on throughout the open session of the meeting. Dr. Oh advised if members needed to temporarily turn off their camera due to challenges with internet connectivity, they must announce the reason for their nonappearance when the camera was turned off.

V. Discussion and Possible Action Related to Proposed Amendment to California Code of Regulations, Title 16, Section 1709.1 Related to Designation of Pharmacist-in-Charge, Including Review of Comments Received During the 15-Day Comment Period

Dr. Oh reminded those present that in January 2022, the Board approved proposed regulation text to amend California Code of Regulations, title 16, section 1709.1. The formal rulemaking process did not begin until November 2023, with the 45-day public comment period ending January 1, 2024. Dr. Oh recalled during the February 2024 Board meeting, the Board considered comments

received and voted to amend the text in response to comments received. The subsequent 15-day comment period ended May 14, 2024. Dr. Oh stated that today the Board had the opportunity to review the comments received and the staff recommended responses. Dr. Oh noted that he had reviewed the information and agreed with the staff recommended response.

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

Motion: Accept the staff recommended comment response and adopt the regulation text as noticed on April 29, 2024. Additionally, delegate to the executive officer the authority to make nonsubstantive changes as may be required by control agencies to complete the rulemaking file.

Title 16. Board of Pharmacy
Proposed Text

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

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

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

§ 1709.1. Designation of Pharmacist-In-Charge

(a) The pharmacist-in-charge (PIC) of a pharmacy shall be employed at that location and shall have responsibility for the daily operation of the pharmacy. Prior to approval of the board, and as part of the application and notice process set forth in Section 1709 of this Division ("application"), a pharmacy shall submit its proposed PIC. The PIC shall have completed the board-provided Pharmacist-in-Charge Overview and Responsibility training course within two years prior to the date of application. The PIC shall complete an attestation statement in compliance with this section. For purposes of this section, a completed attestation statement shall include all of the following: name of the proposed pharmacist-in-charge, the individual's license number, a statement that they

have read Sections 4036.5, 4081, 4113, and 4330 of the Business and Professions Code and this section, and a statement identifying the date that the proposed PIC took the board's training course, and a declaration signed under penalty of perjury of the laws of the State of California that the information provided by the individual is true and correct.

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

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

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

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

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

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

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

M/S: Serpa/Newell

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

Support: 7 Oppose: 0 Abstain: 0 Not Present: 5

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

VI. Approval of Board Meeting Minutes

a. April 24-25, 2024 Board Meeting

Dr. Oh referenced the draft minutes from the April 24-25, 2024 Board meeting.

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

Motion: Approve the April 24-25, 2024 Board meeting minutes as presented in the meeting materials.

M/S: Serpa/Sandhu

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

Support: 7 Oppose: 0 Abstain: 0 Not Present: 5

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

b. March 13, 2024 Disciplinary Petition Committee Meeting

Dr. Oh referenced the draft minutes from the March 13, 2024 Disciplinary Petition Committee meeting.

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

Motion: Approve the March 13, 2024 Disciplinary Petition Committee meeting minutes as presented in the meeting materials.

M/S: Thibeau/Sandhu

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

Support: 7 Oppose: 0 Abstain: 0 Not Present: 5

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

c. May 8, 2024 Disciplinary Petition Committee Meeting

Dr. Oh referenced the draft minutes from the May 8, 2024 Disciplinary Petition Committee meeting.

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

Motion: Approve the May 8, 2024 Disciplinary Petition Committee meeting minutes as presented in the meeting materials.

M/S: Serpa/Sandhu

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

Support: 7 Oppose: 0 Abstain: 0 Not Present: 5

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

VII. Report by the California Department of Consumer Affairs

President Oh advised the report by the Department of Consumer Affairs would be provided in writing. The report can be found here: https://pharmacy.ca.gov/meetings/agendas/2024/24_jul_bd_mat_vii.pdf.

VIII. Presentation on the Pharmacists Recovery Program

President Oh advised the Pharmacist Recovery Program presentation would not be heard during today's Board meeting and may be heard at a future meeting.

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

President Oh advised that this item would not be discussed and considered at today's Board meeting and may be discussed at a future meeting.

XII. Enforcement and Compounding Committee

Chairperson Serpa provided the Board with a summary of the Committee's work at the July 17, 2024 meeting. Dr. Serpa thanked fellow members Vice-Chair Barker, Ms. Cameron-Banks, Dr. Oh, and Dr. Thibeau.

a. Summary of Presentation on Board's Inspection Program
b. Summary of Presentation on Board's Citation Program

c. Summary of Presentation on Quality Assurance Reports Received Pursuant to California Code of Regulations, Title 16, Section 1711(f) Related to the Use ofAutomated Drug Delivery Systems

Dr. Serpa advised summaries of presentations heard by the Enforcement and Compounding Committee regarding the Board's Inspection Program; the Board's Citation Program; and the Quality Assurance Reports Received Pursuant to CCR, Title 16, Section 1711(f) Related to the Use of Automated Drug Delivery Systems were included in the meeting materials.

d. Draft Policy Statement Related to IV Hydration Clinics

Dr. Serpa referred to meeting materials related to IV hydration clinics including relevant sections of federal law that establish the conditions under which compounded human drug products are exempt from three sections of the federal Food, Drug, and Cosmetic Act. Additional background information on the issue of IV hydration clinics, including information about warnings released by the FDA involving instances of drug products being compounded under insanitary conditions, was also included. Dr. Serpa stated that these materials highlighted that many warnings stem from compounding occurring at sites that are not regulated by the Board, including IV hydration clinics.

Dr. Serpa recalled that as discussed during the April 2024 Board meeting, IV hydration clinics appear to be operating in a number of settings, including beauty salons, mobile vans, and gymnasiums, and appear to lack appropriate oversight, use of appropriate equipment, and proper storage, placing patients at risk. Examples of this practice are seen in media and advertising offering IV hydration in the workplace, home, or hotels in California and across the nation.

Dr. Serpa reported that Board staff have observed inspections in some IV hydrations clinics and report witnessing alarming practices placing consumers at risk. Staff also report challenges with conducting investigations because even basic patient information, administration information, *etc.* is not maintained and/or provided to the Board. Given the risk to patients, and the documented harm, this issue was brought before the Committee to consider the issue and determine if there are any actions the Board should take to protect patients.

Dr. Serpa continued that following prior discussion by the Committee and the Board, it was determined appropriate that the Board should have a greater role in monitoring this practice, and that the Board should start with the development of a policy statement to educate consumers about IV hydration clinics and some potential risks, without creating undue concern for patients that have a medical condition that requires such treatment. Dr. Serpa referenced meeting materials that included a draft policy statement that included changes made following the Committee meeting. The Committee was recommending approval of the policy statement.

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

Committee Recommendation: Recommend approval of the draft policy statement consistent with the Committee's discussion and delegation to the Chair and EO to finalize the draft for consideration by the Board at the July 31-August 1 Board meeting.

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

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

Support: 7 Oppose: 0 Abstain: 0 Not Present: 5

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

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

Dr. Serpa advised this agenda item would be discussed at a future meeting.

f. Enforcement Statistics

Dr. Serpa advised this agenda item would not be discussed at the meeting and referenced meeting materials containing enforcement statistics.

XIII. Licensing Committee

Chairperson Oh provided a report on the Licensing Committee's work at its July 18, 2024 meeting and thanked fellow Committee members Mr. Chandler, Dr. Barker, Dr. Crowley, Dr. Sandhu, and Mr. Weisz.

a. Proposed Amendment to Business and Professions Code (BPC) Sections 4038 and 4115.5 Related to Pharmacy Technician Trainees

Chairperson Oh recalled that the Committee has received presentations on and discussed pharmacy technician training programs, including employer-based training programs, and that Committee members have noted what appeared to be great variability in the quality of employer-based programs and suggested perhaps the need for greater oversight of such training programs.

Dr. Oh referenced meeting materials that noted that the definition of "pharmacy technician trainee" is currently limited to a person enrolled in a pharmacy technician training program operated by a California public postsecondary education institution or by a private postsecondary vocational institution. Thus, under current law, the definition does not extend to an individual completing an employer based-training program.

Dr. Oh added that as shared during the Committee meeting, it was important to note that while the definition is proposed to be expanded to encompass additional training programs, the provisions for a training program would remain consistent, including requirements that a training program cover all knowledge and understanding of different pharmacy practice settings and laws and regulations governing the practice of pharmacy. Dr. Oh explained that he was highlighting this to ensure there was a clear understanding that an employer-based training program

couldn't be solely focused on that specific pharmacy or type of pharmacy. Dr. Oh noted that this is because once issued, a pharmacy technician license allows the pharmacy technician to work in a variety of settings, not just the pharmacy where they completed the employer-based training. Dr. Oh reminded all those present that the provisions related to externship requirements for a pharmacy technician trainee would apply irrespective of the individual's pathway to functioning as a pharmacy technician trainee. He noted that he was again highlighting this to ensure a clear understanding of the hour limitations established in the existing law and the applicability of those provisions.

Dr. Oh referenced that the meeting materials included a copy of the draft statutory language as well as the Committee's recommendation which served as the motion before the Board.

Committee Recommendation: Recommend amendment to Business and Professions Code Section 4038(b) to read: "A pharmacy technician trainee" is a person who is enrolled in a pharmacy technician training program operated by a California public postsecondary education institution or by a private postsecondary vocational institution approved by the Bureau for Private Postsecondary and Vocational Education or an accredited employer-based pharmacy technician training program."

Proposed Amendments Related to Pharmacy Technician Trainees

Business and Professions Code Section 4038 is amended as follows:
4038.
(a) "Pharmacy technician" means an individual who assists a pharmacist in a pharmacy in the performance of his or her pharmacy related duties, as specified in Section 4115.

(b) A "pharmacy technician trainee" is a person who is enrolled in a pharmacy technician training program operated by a California public postsecondary education institution or by a private postsecondary vocational institution approved by the Bureau for Private Postsecondary and Vocational Education or an accredited employer-based pharmacy technician training program.

Business and Professions Code Section 4115.5 is amended as follows:
4115.5.
(a) Notwithstanding any other law, a pharmacy technician trainee may be placed in a pharmacy to complete an externship for the purpose of obtaining practical training required to become licensed as a pharmacy technician.

(b) (1) A pharmacy technician trainee participating in an externship as described in subdivision (a) may perform the duties described in subdivision (a) of Section 4115 only under the direct supervision and control of a pharmacist.

(2) A pharmacist supervising a pharmacy technician trainee participating in an externship as described in subdivision (a) shall be directly responsible for the conduct of the trainee.

(3) A pharmacist supervising a pharmacy technician trainee participating in an externship as described in subdivision (a) shall verify any prescription prepared by the trainee under supervision of the pharmacist by initialing the prescription label before the medication is disbursed to a patient or by engaging in other verification procedures that are specifically approved by board regulations.

(4) A pharmacist may only supervise one pharmacy technician trainee at any given time.

(5) A pharmacist supervising a pharmacy technician trainee participating in an externship as described in subdivision (a) shall certify attendance for the pharmacy technician trainee and certify that the pharmacy technician trainee has met the educational objectives established by the training program ~~by a California public postsecondary education institution or the private postsecondary vocational institution in which the trainee is enrolled, as established by the institution~~.

(c) (1) Except as described in paragraph (2), an externship in which a pharmacy technician trainee is participating as described in subdivision (a) shall be for a period of no fewer than 120 hours and no more than 140 hours.

(2) When an externship in which a pharmacy technician trainee is participating as described in subdivision (a) involves rotation between a community and hospital pharmacy for the purpose of training the student in distinct practice settings, the externship may be for a period of up to 340 hours.

(d) An externship in which a pharmacy technician trainee may participate as described in subdivision (a) shall be for a period of no more than six consecutive months in a community pharmacy and for a total of no more than 12 months if the externship involves rotation between a community and hospital pharmacy. The externship shall be completed while the trainee is enrolled in ~~a course of instruction at the institution~~the training program.

(e) A pharmacy technician trainee participating in an externship as described in subdivision (a) shall wear identification that indicates the pharmacy technician trainee's status as a trainee.

Counsel recommended that the Board consider voting down the motion so that another motion could be made that encompassed the proposed amendments to BPC section 4115.5 as well.

Members were provided the opportunity to comment. Members confirmed the recommendation was to vote down the current motion.

Members of the public were provided the opportunity to comment.

Comment received in Sacramento expressed concern with the word "accredited," stating that it was limiting. The commenter also questioned if the 1:1 training ratio included trainees who are doing computer-based training.

Comments received via WebEx spoke in favor of the accreditation requirement as employer-based training was usually specific to the employer. Another commenter inquired how the Board tracked training programs and if training programs should submit their curriculum to the Board directly or through the students' application.

Support: 0 Oppose: 7 Abstain: 0 Not Present: 5

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

With the motion having failed, the Board continued its discussion. Dr. Oh noted that at the Committee meeting, there was a robust discussion about

accredited versus not accredited, and that the Committee landed on "accredited" to take a one step approach and provide more opportunities for pharmacy technicians to be trained. Members had questions about the process. Staff clarified this would create an opportunity to those in an accredited employer-based training program to gain hands-on experience during their training program.

Members continued to discuss who would be providing the accreditation or registration for the training programs. President Oh noted that since this was a statutory proposal, it would go through the legislative process, such that further wordsmithing of the language would likely occur.

Motion: Pursue amendment to Business and Professions Code Sections 4038(b) and 4115.5 related to pharmacy technician trainees consistent with the Board's discussion.

M/S: Serpa/Sandhu

Members of the public were provided the opportunity to comment.

Comment received in Sacramento expressed concern with the word "accredited" in the language.

Comments received via WebEx spoke in favor adding "accredited by an entity approved or recognized by the Board of Pharmacy."

Members were provided the opportunity to comment.

Staff suggested amending the motion to provide that the language added to BPC section 4038(b) state: "or a Board-approved accredited employer-based program." Members Serpa and Sandhu, who made the motion and second, were agreeable.

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

Members discussed the intent of the language to have employer-based training programs accredited.

Motion: A proposal to amend Business and Professions Code Section 4038(b) to expand to allow for a pharmacy technician trainee in an employer-based pharmacy technician training program accredited by an agency approved by the Board and

conforming changes to Business and Professions Code Section 4115.5.

M/S: Sandhu/Hughes

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

Members of the public were provided the opportunity to comment via WebEx. Commenters spoke in support of the new motion.

Support: 6 Oppose: 0 Abstain: 1 Not Present: 5

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

b. Survey Results Received Related to the Pharmacist to Pharmacy Technician Ratio

Dr. Oh reiterated the Committee was considering the issue of the pharmacist to pharmacy technician ratio. The meeting materials detailed the current law related to ratios. He noted members routinely receive public comment indicating that California has one of the most restrictive ratios. Dr. Oh reminded all present that a review of various state ratios does not necessarily provide an equal comparison as jurisdictions have varying approaches on provisions for services within a pharmacy, including where some jurisdictions require all pharmacy personnel to be licensed as a pharmacy technician if performing even basic functions such as data entry, which was not the case in California.

Dr. Oh highlighted this only to remind all that when comments were received, context matters. He provided background that during the January 2024 Licensing Committee meeting, members reviewed and approved a draft survey to solicit feedback from pharmacists on this topic. The survey was active March 6-25, 2024. The Board received over 5,100 responses. During the April 2024 Licensing Committee meeting, the Committee received a presentation on results of the survey. During the July 2024 Licensing Committee meeting, additional data from the survey was received. Dr. Oh noted that slides highlighting the additional data were included in the meeting materials.

Dr. Oh thanked the experts within the DCA Office of Professional Examination Services for working to develop and deploy the survey and evaluate the survey results, and for compiling the additional data for consideration. He added the data appears to support that the ratio established for the institutional setting remains appropriate. In the noninstitutional setting, he believed the data either supports the current ratio, or a ratio of 1:2. After consideration, members reached agreement that a change to the current ratio in the noninstitutional or community pharmacy setting was appropriate.

Committee Recommendation: Amend Business and Professions Code section 4115(g) to change the ratio of pharmacist to pharmacy technician to 1:2 in the outpatient pharmacy setting, with a pharmacist having the ability to refuse to supervise the second pharmacy technician, and further providing that the Board may, by regulation, establish a different ratio applicable to different outpatient pharmacy practice settings.

Proposal to Amend BPC Section 4115 as follows.
(a) A pharmacy technician may perform packaging, manipulative, repetitive, or other nondiscretionary tasks only while assisting, and while under the direct supervision and control of, a pharmacist. The pharmacist shall be responsible for the duties performed under their supervision by a technician.

(b) (1) In addition to the tasks specified in subdivision (a) a pharmacy technician may, under the direct supervision and control of a pharmacist, prepare and administer influenza and COVID-19 vaccines via injection or intranasally, prepare and administer epinephrine, perform specimen collection for tests that are classified as waived under CLIA, receive prescription transfers, and accept clarification on prescriptions under the following conditions:

> (A) The pharmacy has scheduled another pharmacy technician to assist the pharmacist by performing the tasks provided in subdivision (a).

(B) The pharmacy technician is certified pursuant to paragraph (4) of subdivision (a) of Section 4202 and maintains that certification.

(C) The pharmacy technician has successfully completed at least six hours of practical training approved by the Accreditation Council for Pharmacy Education and includes hands-on injection technique, the recognition and treatment of emergency reactions to vaccines, and an assessment of the pharmacy technician's injection technique.

(D) The pharmacy technician is certified in basic life support.

(2) "CLIA" means the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a; Public Law 100-578).

(c) This section does not authorize the performance of any tasks specified in subdivisions (a) and (b) by a pharmacy technician without a pharmacist on duty.

(d) This section does not authorize a pharmacy technician to perform any act requiring the exercise of professional judgment by a pharmacist.

(e) The board shall adopt regulations to specify tasks pursuant to subdivision (a) that a pharmacy technician may perform under the supervision of a pharmacist. Any pharmacy that employs a pharmacy technician shall do so in conformity with the regulations adopted by the board.

(f) A person shall not act as a pharmacy technician without first being licensed by the board as a pharmacy technician.

(g) (1) A pharmacy with only one pharmacist shall have no more than ~~one~~ two pharmacy technicians performing the tasks specified in subdivision (a). A pharmacy with only one pharmacist shall have no more than one pharmacy technician performing the tasks specified in subdivision (b). If a pharmacy technician is performing the tasks specified in subdivision (b), a second pharmacy technician shall be assisting a pharmacist with performing tasks specified in subdivision (a). ~~The ratio of pharmacy technicians performing the tasks specified in subdivision (a) to any additional pharmacist shall not exceed 2:1, except that~~ ~~t~~hisThis ratio shall not apply to personnel performing clerical functions pursuant to Section 4116 or 4117. This ratio is applicable to all practice settings, except for an inpatient of a licensed health facility, a patient of a licensed home health agency, as specified in paragraph (2), an inmate of a correctional facility of the Department of Corrections and Rehabilitation, and for a person receiving treatment in a facility operated by the State Department of State Hospitals, the State Department of Developmental Services, or the Department of Veterans Affairs. The Board may adopt regulations establishing for different community pharmacy practice settings a ratio different than those established in this paragraph.

(2) The board may adopt regulations establishing the ratio of pharmacy technicians performing the tasks specified in subdivision (a) to pharmacists applicable to the filling of prescriptions of an inpatient of a licensed health facility and for a patient of a licensed home health agency. Any ratio established by the board pursuant to this subdivision shall allow, at a minimum, at least one pharmacy technician for a single pharmacist in a pharmacy and two pharmacy technicians for each additional pharmacist, except that this ratio shall not apply to personnel performing clerical functions pursuant to Section 4116 or 4117.

(3) A pharmacist scheduled to supervise a second pharmacy technician may refuse to supervise a second pharmacy technician if the pharmacist determines, in the exercise of their professional judgment, that permitting the second pharmacy technician to be on duty would interfere with the effective performance of the pharmacist's responsibilities under this chapter. A pharmacist assigned to supervise a second pharmacy technician shall notify the pharmacist-in-charge in writing of their determination, specifying the circumstances of concern with respect to the pharmacy or the pharmacy technician that have led to the determination, within a reasonable period, but not to exceed 24 hours, after the posting of the relevant schedule. An entity employing a pharmacist shall not discharge, discipline, or otherwise discriminate against any pharmacist in the terms and conditions of employment for exercising or attempting to exercise in good faith the right established pursuant to this paragraph.

(h) Notwithstanding subdivisions (a) to (c), inclusive, the board shall by regulation establish conditions to permit the temporary absence of a pharmacist for breaks and lunch periods pursuant to Section 512 of the Labor Code and the orders of the Industrial Welfare Commission without closing the pharmacy. During these temporary absences, a pharmacy technician may, at the discretion of the pharmacist, remain in the pharmacy but may only perform nondiscretionary tasks. The pharmacist shall be responsible for a pharmacy technician and shall review any task performed by a pharmacy technician during the pharmacist's temporary absence. This subdivision shall not be construed to authorize a pharmacist to supervise pharmacy technicians in greater ratios than those described in subdivision (g).

(i) The pharmacist on duty shall be directly responsible for the conduct of a pharmacy technician supervised by that pharmacist.

(j) In a health care facility licensed under subdivision (a) of Section 1250 of the Health and Safety Code, a pharmacy technician's duties may include any of the following:

(1) Packaging emergency supplies for use in the health care facility and the hospital's emergency medical system or as authorized under Section 4119.

(2) Sealing emergency containers for use in the health care facility.

(3) Performing monthly checks of the drug supplies stored throughout the health care facility. Irregularities shall be reported within 24 hours to the pharmacist-in-charge and the director or chief executive officer of the health care facility in accordance with the health care facility's policies and procedures.

Members were provided the opportunity to comment. A member spoke in support of the motion and encouraged the Licensing Committee to explore a separate discussion regarding ratios for institutional settings and other practice settings.

Members of the public were provided the opportunity to comment. Members heard public comment in support of the motion from commenters located in Sacramento and via WebEx.

Support: 7 Oppose: 0 Abstain: 0 Not Present: 5

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

The Board took a lunch break from 11:58 a.m. to 12:45 p.m. Roll call was taken. The following Board members were physically present in Sacramento: Jeff Hughes, Public Member; KK Jha, Licensee Member; J. Newell, 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.

c. Proposal to Establish Reinstatement of a Retired Pharmacist License, Including Proposed Amendment to BPC Section 4200.5

Dr. Oh recalled that following a request from the public, the Board referred this item to the Licensing Committee for consideration. He summarized background information found in the meeting materials, noting that public comment suggested that the Board consider development of a step-down licensure process for pharmacists getting ready to retire. It was suggested through public comment that the Board consider the approach used by Nevada.

Dr. Oh continued that during previous discussion, the Licensing Committee, considered provisions in Nevada's law that provide that a pharmacist who has been registered with Nevada for at least 50 years was not required to pay renewal fees after that time. Following feedback from members during the April 2024 Board meeting, staff reviewed additional provisions that allow for reinstatement of a license from an inactive status. The staff's understanding was that Nevada relies on the reactivation provisions when restoring a previously retired pharmacist license.

Dr. Oh noted that the meeting materials included a copy of proposed amendments to Business and Professions Code section 4200.5 that would establish limited provisions for restoration of a retired license. The Licensing Committee noted the proposal as drafted was similar in concept to both the Nevada model, but also current provisions in the Board's law related to reactivating an inactive pharmacist license.

Committee Recommendation: Recommend amendment to BPC section 4200.5 to establish a process to reinstate a retired license, as presented.

Proposed Amendments Related to Retired Pharmacist License

Business and Professions Code Section 4200.5 is amended as follows:
4200.5.

(a) The board shall issue, upon application and payment of the fee established by Section 4400, a retired license to a pharmacist who has been licensed by the board. The board shall not issue a retired license to a pharmacist whose license has been revoked.

(b) The holder of a retired license issued pursuant to this section shall not engage in any activity for which an active pharmacist's license is required. A pharmacist holding a retired license shall be permitted to use the titles "retired pharmacist" or "pharmacist, retired."

(c) The holder of a retired license shall not be required to renew that license.

(d) The holder of a retired license may request to restore their pharmacist license to active status within three years of issuance of the retired license. Such a request must be accompanied by the renewal fee established by Section 4400(e) and demonstration that, within the two years preceding the request for restoration, the pharmacist has successfully completed continuing education consistent with the requirements set forth in Section 4231(b).

(e) If more than three years have elapsed since the issuance of the retired license, ~~I~~in order for the holder of a retired license issued pursuant to this section to restore their ~~his or her~~ license to active status, they~~he or she~~ shall be required to reapply for licensure as a pharmacist as consistent with the provisions of 4200. ~~pass the examination that is required for initial licensure with the board.~~

Members were provided the opportunity to comment.

A member thanked the Licensing Committee for their work.

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

Support: 7 Oppose: 0 Abstain: 0 Not Present: 5

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

d. Compounding by Pharmacy Technicians Outside of Pharmacies, Including Proposed Amendment to BPC Section 4115

Dr. Oh reported that the Licensing Committee discussed the requirements for licensure for a pharmacy technician. By definition, pharmacy

technicians work in a pharmacy under the direct supervision and control of a pharmacist. He added that federal law, Section 503A of the Food, Drug, and Cosmetic Act, makes clear that authority to compound a drug preparation is in part predicated on compliance with USP compounding chapters. He provided the reminder that USP General Chapter 797 describes the minimum requirements that apply to all persons who prepare compounded sterile preparations and all places where sterile preparations were compounded. This included pharmacists and pharmacy technicians compounding in all places including those areas outside of a pharmacy.

Dr. Oh advised the Committee's past discussion of this topic included consideration of a number of policy questions. A summary of the discussion was included in the meeting materials. He highlighted that members agreed it was the Board's role to safeguard the health and safety of the public and this role is memorialized in Business and Professions Code Section 4008.

Dr. Oh advised that during the Committee's July 2024 meeting, the members considered a proposal to amend Business and Professions Code section 4115 to establish clear authority for a pharmacy technician to compound under the direct supervision and control of a pharmacist OUTSIDE of a licensed pharmacy with the establishment of a notification requirement. The notification requirement would assist the Board in directing resources to those locations for inspections. Draft proposed language was provided in the meeting materials.

Committee Recommendation: Recommend amendment to BPC section 4115 related to pharmacy technicians compounding outside of a licensed pharmacy, as presented.

ARTICLE 7. Pharmacies [4110 – 4126.10]
(Article 7 added by Stats. 1996, Ch. 890, Sec. 3.)

4115.
(a) A pharmacy technician may perform packaging, manipulative, repetitive, or other nondiscretionary tasks only while assisting, and while under the direct supervision and control of, a pharmacist. The pharmacist shall be responsible for the duties performed under their supervision by a technician.

(b) (1) In addition to the tasks specified in subdivision (a) a pharmacy technician may, under the direct supervision and control of a pharmacist, prepare and administer influenza and COVID-19 vaccines via injection or intranasally, prepare and administer epinephrine, perform specimen collection for tests that are classified as waived under CLIA, receive prescription transfers, and accept clarification on prescriptions under the following conditions:

(A)The pharmacy has scheduled another pharmacy technician to assist the pharmacist by performing the tasks provided in subdivision (a).

(B) The pharmacy technician is certified pursuant to paragraph (4) of subdivision
(a) of Section 4202 and maintains that certification.

(C) The pharmacy technician has successfully completed at least six hours of practical training approved by the Accreditation Council for Pharmacy Education and includes hands-on injection technique, the recognition and treatment of emergency reactions to vaccines, and an assessment of the pharmacy technician's injection technique.

(D) The pharmacy technician is certified in basic life support.

(2) "CLIA" means the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a; Public Law 100-578).

© This section does not authorize the performance of any tasks specified in subdivisions
(a) and (b) by a pharmacy technician without a pharmacist on duty.

(d) This section does not authorize a pharmacy technician to perform any act requiring the exercise of professional judgment by a pharmacist.

(e) The board shall adopt regulations to specify tasks pursuant to subdivision (a) that a pharmacy technician may perform under the supervision of a pharmacist. Any pharmacy that employs a pharmacy technician shall do so in conformity with the regulations adopted by the board.

(f) A person shall not act as a pharmacy technician without first being licensed by the board as a pharmacy technician.

(g) (1) A pharmacy with only one pharmacist shall have no more than one pharmacy technician performing the tasks specified in subdivision (a). A pharmacy with only one pharmacist shall have no more than one pharmacy technician performing the tasks specified in subdivision (b). If a pharmacy technician is performing the tasks specified in subdivision (b), a second pharmacy technician shall be assisting a pharmacist with performing tasks specified in subdivision (a). The ratio of pharmacy technicians performing the tasks specified in subdivision (a) to any additional pharmacist shall not exceed 2:1, except that this ratio shall not apply to personnel performing clerical functions pursuant to Section 4116 or 4117. This ratio is applicable to all practice settings, except for an inpatient of a licensed health facility, a patient of a licensed home health agency, as specified in paragraph (2), an inmate of a correctional facility of the Department of Corrections and Rehabilitation, and for a person receiving treatment in a facility operated by the State Department of State Hospitals, the State Department of Developmental Services, or the Department of Veterans Affairs.

(2) The board may adopt regulations establishing the ratio of pharmacy technicians performing the tasks specified in subdivision (a) to pharmacists applicable to the filling of prescriptions of an inpatient of a licensed health

facility and for a patient of a licensed home health agency. Any ratio established by the board pursuant to this subdivision shall allow, at a minimum, at least one pharmacy technician for a single pharmacist in a pharmacy and two pharmacy technicians for each additional pharmacist, except that this ratio shall not apply to personnel performing clerical functions pursuant to Section 4116 or 4117.

(3) A pharmacist scheduled to supervise a second pharmacy technician may refuse to supervise a second pharmacy technician if the pharmacist determines, in the exercise of their professional judgment, that permitting the second pharmacy technician to be on duty would interfere with the effective performance of the pharmacist's responsibilities under this chapter. A pharmacist assigned to supervise a second pharmacy technician shall notify the pharmacist-in-charge in writing of their determination, specifying the circumstances of concern with respect to the pharmacy or the pharmacy technician that have led to the determination, within a reasonable period, but not to exceed 24 hours, after the posting of the relevant schedule. An entity employing a pharmacist shall not discharge, discipline, or otherwise discriminate against any pharmacist in the terms and conditions of employment for exercising or attempting to exercise in good faith the right established pursuant to this paragraph.

(h) Notwithstanding subdivisions (a) to (c), inclusive, the board shall by regulation establish conditions to permit the temporary absence of a pharmacist for breaks and lunch periods pursuant to Section 512 of the Labor Code and the orders of the Industrial Welfare Commission without closing the pharmacy. During these temporary absences, a pharmacy technician may, at the discretion of the pharmacist, remain in the pharmacy but may only perform nondiscretionary tasks. The pharmacist shall be responsible for a pharmacy technician and shall review any task performed by a pharmacy technician during the pharmacist's temporary absence. This subdivision shall not be construed to authorize a pharmacist to supervise pharmacy technicians in greater ratios than those described in subdivision (g).

(i) The pharmacist on duty shall be directly responsible for the conduct of a pharmacy technician supervised by that pharmacist.

(j) In a health care facility licensed under subdivision (a) of Section 1250 of the Health and Safety Code, a pharmacy technician's duties may include any of the following:

(1) Packaging emergency supplies for use in the health care facility and the hospital's emergency medical system or as authorized under Section 4119.

(2) Sealing emergency containers for use in the health care facility.

(3) Performing monthly checks of the drug supplies stored throughout the health care facility. Irregularities shall be reported within 24 hours to the pharmacist-in-charge and the director or chief executive officer of the health care facility in accordance with the health care facility's policies and procedures.

(k) Notwithstanding the definition of a pharmacy technician in 4038(a), a pharmacy technician may, outside of a licensed pharmacy, perform compounding activities only under the direct supervision and control of a pharmacist. The board shall be notified in writing by the supervising pharmacist of the location where such compounding activities occur.

Members were provided the opportunity to comment. Members spoke in support of the Committee recommendation and recommended additional education for the benefit of the regulated public.

Members of the public were provided the opportunity to comment.

There were no comments provided by participants in Sacramento. Comments heard via WebEx spoke in favor of the motion but advised compounding could only be done by the pharmacist and suggested referencing the duties of the pharmacy technicians be listed.

Support: 7 Oppose: 0 Abstain: 0 Not Present: 5

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

e. Summary of Presentation on Central Fill Pharmacy Models in Use in California

Dr. Oh advised this agenda item would not be discussed.

f. Proposed Amendment to California Code of Regulations, Title 16, Section 1707.4 Related to Central Fill Pharmacies

Dr. Oh advised following the presentations and discussions over several Committee meetings, members considered proposed changes to the Board's central fill regulation. Draft proposed language recommended by the Licensing Committee was included in the meeting materials.

Dr. Oh summarized some of the proposed changes, noting that they were intended to clarify the current regulations where some comments have suggested the language was not clear or sought guidance on how to interpret or implement the language. Throughout the language the reference to "refill" was removed as the prior language appeared to have conflicting language causing confusion about the ability of central fill pharmacies to fill new prescriptions.

Dr. Oh continued that the proposed change in 1707.4(a) sought to clarify that both the central fill pharmacy and the other pharmacy were both licensed by and operated within California. He believed this was providing clarity only as the existing language of the regulation specifically included the term "within this state." He noted prior public comment suggested it should not limit these provisions to pharmacies located in California. He believed that would be an expansion to current regulations.

Next, Dr. Oh reviewed the proposed change in section 1707(a)(2)(B), stating this was intended to clarify that the originating and central fill pharmacies have the flexibility to include the name and address of both pharmacies if they so choose. He noted the pharmacy identified on the prescription label would need to have sufficient staff and access to all information necessary to assist a patient.

Dr. Oh added another proposed change in section 1707.4(a)(5) would establish a permissive requirement for the originating pharmacy to perform final product verification prior to dispensing and allows for the final product verification to be done by viewing photographs in lieu of a physical visual inspection.

He noted the last proposed change was in section 1707.4(b), which provided a definition of central fill pharmacy.

Committee Recommendation: Recommend initiation of a rulemaking to amend California Code of Regulations, title 16, section 1707.4 as proposed to be amended. Authorize the executive officer to further refine the language consistent with the Committee's discussion and to make any nonsubstantive changes prior to presenting the proposed rulemaking to the Board.

Title 16. Board of Pharmacy

PROPOSED REGULATORY LANGUAGE

Central Fill Pharmacies

Proposed changes to the current regulation language are shown by ~~strikethrough~~ for

deleted language and underline for added language.

Amend Section 1707.4 to Article 2 of Division 17 of Title 16 of the California Code

of Regulations to read as follows:

§ 1707.4. Procedures for ~~Refill~~ Central Fill Pharmacies.

(a) A central fill pharmacy located in California and licensed by the B~~b~~oard may process a request for ~~refill of a~~ prescription medication received by ~~a~~ another pharmacy within this state, provided:
(1) The pharmacy that is to refill the prescription medication either has a contract with the pharmacy which received the prescription or has the same owner as the other pharmacy.
(2) The prescription container:
(A) is clearly labeled with all information required by ~~S~~sections 4076 and 4076.5 of the Business and Professions Code; and
(B) as applicable, clearly shows the name and address of the pharmacy ~~re~~filling the prescription medication and/or the name and address of the pharmacy which receives the ~~refilled prescription~~ medication to dispense to the patient. Nothing in this subsection should be interpreted as preventing inclusion of the name and address of both pharmacies.
(3) The patient is provided with written information indicating that the prescription may be filled at a central fill pharmacy, and written information, either on the prescription label or with the prescription container, that describes which pharmacy to contact if the patient has any questions about the prescription or medication.
(4) Both pharmacies maintain complete and accurate records ~~of the refill~~, including:
(A) the name of the pharmacist who ~~re~~filled the prescription;
(B) the name of the pharmacy ~~re~~filling the prescription; and
(C) the name of the pharmacy that received the prescription ~~refill request~~.
(5) The pharmacy which ~~re~~fills the prescription and the pharmacy to which the ~~refilled~~ prescription is provided for dispensing to the patient shall each

be responsible for ensuring the order has been properly filled. Pharmacists working at the originating pharmacy ~~must~~ may perform final product verification prior to dispensing, ~~which may~~ including throughe review of photographs of the final product in lieu of physical visual verification. A pharmacist shall not be required to perform final product verification where product verification by a pharmacist is performed at the time of stocking the automated dispensing device, if the dispensing device is not further accessed by pharmacy personnel.
(6) The originating pharmacy is responsible for compliance with the requirements set forth in ~~S~~sections 1707.1, 1707.2, and 1707.3 of the California Code of Regulations.
~~(b) Nothing in this section shall be construed as barring a pharmacy from also filling new prescriptions presented by a patient or a patient's agent or transmitted to it by a prescriber.~~
(b) For purposes of this section, a central fill pharmacy is defined as a California-licensed pharmacy that, pursuant to a contract or on behalf of a pharmacy under common ownership, prepares and packages prescriptions for another pharmacy to dispense to the patient.

Credits
NOTE: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4063, 4076, 4076.5, 4081, and 4333, Business and Professions Code.

Members were provided the opportunity to comment. Members clarified the pharmacist may provide final verification allowing the pharmacy the flexibility. Members discussed activities related to mail order or closed-door pharmacies. One member expressed confusion about the originating pharmacy language, and another stated that in their view, the central fill pharmacy doesn't need to be located in California.

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

Public comment was heard in support of not limiting central fill pharmacies to being located in California. There were also comments agreeing with the confusion of the "originating pharmacy" verbiage. Additional comments indicated that requiring written notification may delay patients receiving medication. Comments further indicated the tense the language was written was incorrect and "photographs" should be changed to "image."

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

Public comment was heard in agreement with confusion of the "originating pharmacy" verbiage. The Board also heard comment in favor of the central fill providing refills and shipping outside of California.

Support: 0 Oppose: 7 Abstain: 0 Not Present: 5

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

Members discussed possible changes to the motion to include the pharmacy within the state under section 1707.4(a) to change to "another pharmacy within or outside of the state;" under section 1707.4 (a)(3) to require the notice that central fill may be used but not to delay patient care; clarifying verbiage of "originating" pharmacy; change "photograph" to "image;" and to state dispensing device was not further accessed by pharmacy personnel after final verification and the labeled prescription bottle. Members discussed updating the names of originating and receiving pharmacy.

Motion: Amend California Code of Regulations section 1707.4 as included in the meeting materials with the additional changes to proposed amendments as detailed. Delegate to the Chair of the Licensing Committee to work with the executive officer to incorporate changes consistent with the Board's discussion today.

M/S: Serpa/Newell

Members of the public were provided the opportunity to comment in Sacramento. Comments were received in favor of the changes and new motion.

Members of the public were provided the opportunity to comment via WebEx. Comments were received in support of the new motion and requested clarification that the wording about the label being attached to the correct product.

Support: 7 Oppose: 0 Abstain: 0 Not Present: 5

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

g. Licensure and Other Requirements for Nonresident Pharmacies, Including Proposed Amendment to BPC Section 4112

Dr. Oh expressed his continued concern about the Board's inability to effectively regulate nonresident pharmacies, including mail order pharmacies. Nonresident pharmacies can create unique challenges for patients. He recalled investigations that resulted in discipline stemming from these challenges, placing patients at risk. Dr. Oh added over the last two years the Board has referred 11 nonresident pharmacies to the Office of the Attorney General for formal discipline and issued 39 citations. Additionally, the Board took disciplinary action on 12 nonresident pharmacies. He noted the underlying violations vary in egregiousness and include extremely serious causes of action including clearly excessive furnishing of controlled substances. Dr. Oh reminded the Board that there was currently no requirement for pharmacists working in these nonresident pharmacies, and providing services to California patients, to be licensed in California.

Dr. Oh recalled the Board had previously voted and would be pursuing a statutory change to require the PIC of a nonresident pharmacy to be licensed in California. During the July 2024 Licensing Committee meeting, the Committee continued its discussion of this issue and considered proposed amendments to Business and Professions Code section 4112. Dr. Oh shared some states have implemented changes to eliminate law and jurisprudence examinations including recent actions by Michigan and North Dakota to allow pharmacists licensed in Canada to reciprocate licensure without taking the NAPLEX.

Dr. Oh advised the Licensing Committee was recommending changes to Business and Professions Code section 4112 to update requirements for pharmacists working in a nonresident pharmacy who were not licensed in California, as well as to establish provisions for mandatory inspections of nonresident pharmacies. He referenced meeting materials that included a copy of the text recommended by the Committee. Dr. Oh highlighted the language DID NOT require all pharmacists working in nonresident pharmacies to be licensed in California but it DID establish certain parameters that apply in order for pharmacists who were not licensed in California to provide services to California patients. As proposed, the language would prohibit a pharmacist whose license has been revoked in any jurisdiction from providing services to California patients, unless the license was subsequently reinstated or reissued.

Committee Recommendation: Recommend the Board pursue a statutory change to BPC section 4112 to update the requirements for nonresident pharmacies consistent with the Committee's discussion.

Proposal to Amend BPC 4112 As Follows:

4112.

(a) Any pharmacy located outside this state that ships, mails, or delivers, in any manner, controlled substances, dangerous drugs, or dangerous devices into this state shall be considered a nonresident pharmacy.

(b) A person may not act as a nonresident pharmacy unless he or she has obtained a license from the board. The board may register a nonresident pharmacy that is organized as a limited liability company in the state in which it is licensed.

(c) A nonresident pharmacy shall disclose to the board the location, names, and titles of (1) its agent for service of process in this state, (2) all principal corporate officers, if any, (3) all general partners, if any, and (4) all pharmacists who are dispensing controlled substances, dangerous drugs, or

dangerous devices to residents of this state. A report containing this information shall be made on an annual basis and within 30 days after any change of office, corporate officer, partner, or pharmacist.

(d) All nonresident pharmacies shall comply with all lawful directions and requests for information from the regulatory or licensing agency of the state in which it is licensed as well as with all requests for information made by the board pursuant to this section. The nonresident pharmacy shall maintain, at all times, a valid unexpired license, permit, or registration to conduct the pharmacy in compliance with the laws of the state in which it is a resident. As a prerequisite to registering with the board, the nonresident pharmacy shall submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the state in which it is located.

(e) All nonresident pharmacies shall maintain records of controlled substances, dangerous drugs, or dangerous devices dispensed to patients in this state so that the records are readily retrievable from the records of other drugs dispensed.

(f) Any pharmacy subject to this section shall, during its regular hours of operation, but not less than six days per week, and for a minimum of 40 hours per week, provide a toll-free telephone service to facilitate communication between patients in this state and a pharmacist at the pharmacy who has access to the patient's records. This toll-free telephone number shall be disclosed on a label affixed to each container of drugs dispensed to patients in this state.

(g) A nonresident pharmacy shall not permit a pharmacist to manufacture, compound, furnish, sell, dispense, or initiate the prescription of a dangerous drug or dangerous device, or to provide any pharmacy-related service, to California patients under any of the following conditions:

(1) The pharmacist's ~~whose~~ license has been revoked by any jurisdiction and has not been subsequently reinstated. ~~by the board to manufacture, compound, furnish, sell, dispense, or initiate the prescription of a dangerous drug or dangerous device, or to provide any pharmacy-related service, to a person residing in California~~.

(2) If the pharmacist is not licensed in California, they have not successfully passed the North American Pharmacist Licensure Examination or the Multi-state Jurisprudence Examination.

(h) The board shall adopt regulations that apply the same requirements or standards for oral consultation to a nonresident pharmacy that operates pursuant to this section and ships, mails, or delivers any controlled substances, dangerous drugs, or dangerous devices to residents of this state, as are applied to an in-state pharmacy that operates pursuant to Section 4037 when the pharmacy ships, mails, or delivers any controlled

substances, dangerous drugs, or dangerous devices to residents of this state. The board shall not adopt any regulations that require face-to-face consultation for a prescription that is shipped, mailed, or delivered to the patient. The regulations adopted pursuant to this subdivision shall not result in any unnecessary delay in patients receiving their medication.

(i) The registration fee shall be the fee specified in subdivision (a) of Section 4400.

(j) The registration requirements of this section shall apply only to a nonresident pharmacy that ships, mails, or delivers controlled substances, dangerous drugs, and dangerous devices into this state pursuant to a prescription.

(k) A nonresident pharmacy licensed pursuant to this section shall be subject to inspection by the board as a condition of renewal once every four years, unless the board determines more frequent inspections are necessary. In addition to paying the fees established in Section 4400, the nonresident pharmacy shall deposit, when notified by the board, a reasonable amount, as determined by the board, necessary to cover the board's estimated costs of performing the inspection. If the required deposit is not received or if the actual costs of the inspection exceed the amount deposited, the board shall issue an invoice for the remaining amount and shall not take action on the renewal application until the full amount has been paid to the board. If the amount deposited exceeds the amount of actual and necessary costs incurred, the board shall remit the difference to the applicant.

(l) Nothing in this section shall be construed to authorize the dispensing of contact lenses by nonresident pharmacists except as provided by Section 4124.

Members were provided the opportunity to comment and commented in support of the motion.

Members of the public were provided the opportunity to comment in Sacramento. Comments were heard indicating this was not an issue for the Board to be concerned with and the Board should focus on pharmacies in California. Additional comment was heard expressing concern that the CPJE is not offered in all states, so if this moves forward there will need to be a phased-in approach to allow for implementation.

Members of the public were provided the opportunity to comment via WebEx. Commenters encouraged the Board to focus on inspecting pharmacies in California and recognize home state board of pharmacy's inspections. Another commenter thought the language was confusing and recommended not moving forward.

Support: 7 Oppose: 0 Abstain: 0 Not Present: 5

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

h. Proposed Amendments to Pharmacy Law to Transition to a More Robust Standard of Care Model for Some Pharmacist-Provided Patient Care Services

Dr. Oh advised the discussion on this item was postponed and reminded those present that a standalone Licensing Committee meeting would be held on September 4, 2024, to discuss this issue.

i. Senate Bill 523 (Leyva, Chapter 630, Statutes of 2022) Related to Contraception Access, Including Possible Amendment to BPC Sections 4052 and 4052.3

Dr. Oh advised Senate Bill 523 made changes to expand coverage of contraception by a health care service plan contract or health insurance policy. As part of these changes, OTC FDA approved contraceptive drugs were now covered under specified conditions. Dr. Oh advised that, regrettably, implementation of the policy goal of the measure had not been realized because of reimbursement requirements, most notably a requirement by payors to have a prescription to reimburse for medications. To remedy this, the Committee was recommending a change to Business and Professions Code section 4052.3, and potentially a conforming change to Business and Professions Code section 4052. Dr. Oh noted if the Board's standard of care proposal was enacted, the proposed changes would no longer be necessary. Meeting materials included the proposed text.

Committee Recommendation: Recommend amendment to Business and Professions Code sections 4052 and 4052.3 consistent with the Committee's

discussion.

Proposal to amend BPC 4052.3 as follows:

4052.3.
(a) (1) Notwithstanding any other law, a pharmacist may furnish prescription-only self-administered hormonal contraceptives in accordance with standardized procedures or protocols developed and approved by both the board and the Medical Board of California in consultation with the American Congress of Obstetricians and Gynecologists, the California Pharmacists Association, and other appropriate entities. The standardized procedure or protocol shall require that the patient use a self-screening tool that will identify patient risk factors for use of self-administered hormonal contraceptives, based on the current United States Medical Eligibility Criteria (USMEC) for Contraceptive Use developed by the federal Centers for Disease Control and Prevention, and that the pharmacist refer the patient to the patient's primary care provider or, if the patient does not have a primary care provider, to nearby clinics, upon furnishing a prescription-only self-administered hormonal contraceptive pursuant to this subdivision, or if it is determined that use of a self-administered hormonal contraceptive is not recommended.

(2) The board and the Medical Board of California are both authorized to ensure compliance with this subdivision, and each board is specifically charged with the enforcement of this subdivision with respect to its respective licensees. This subdivision does not expand the authority of a pharmacist to prescribe any prescription medication.

(b) (1) Notwithstanding any other law, a pharmacist may furnish emergency contraception drug therapy in accordance with either of the following:

(A) Standardized procedures or protocols developed by the pharmacist and an authorized prescriber who is acting within his or her scope of practice.

(B) Standardized procedures or protocols developed and approved by both the board and the Medical Board of California in consultation with the American Congress of Obstetricians and Gynecologists, the California Pharmacists Association, and other appropriate entities. The board and the Medical Board of California are both authorized to ensure compliance with this clause, and each board is specifically charged with the enforcement of this provision with respect to its respective licensees. This subdivision does not expand the authority of a pharmacist to prescribe any prescription medication.

(2) Prior to performing a procedure authorized under this subdivision, a pharmacist shall complete a training program on emergency contraception that consists of at least one hour of approved continuing education on emergency contraception drug therapy.

(3) A pharmacist, pharmacist's employer, or pharmacist's agent shall not directly charge a patient a separate consultation fee for emergency contraception drug therapy services initiated pursuant to this subdivision, but may charge an administrative fee not to exceed ten dollars ($10) above the retail cost of the drug. Upon an oral, telephonic, electronic, or written request from a patient or customer, a pharmacist or pharmacist's employee shall disclose the total retail price that a consumer would pay for emergency contraception drug therapy. As used in this paragraph, total retail price includes providing the consumer with specific information regarding the price of the emergency contraception drugs and the price of the administrative fee charged. This limitation is not intended to interfere with other contractually agreed-upon terms between a pharmacist, a pharmacist's employer, or a pharmacist's agent, and a health care service plan or insurer. Patients who are insured or covered and receive a pharmacy benefit that covers the cost of emergency contraception shall not be required to pay an administrative fee. These patients shall be required to pay copayments pursuant to the terms and conditions of their coverage. This paragraph shall become inoperative for dedicated emergency contraception drugs if these drugs are reclassified as over-the-counter products by the federal Food and Drug Administration.

(4) A pharmacist shall not require a patient to provide individually identifiable medical information that is not specified in Section 1707.1 of Title 16 of the California Code of Regulations before initiating emergency contraception drug therapy pursuant to this subdivision.

(c) For each emergency contraception drug therapy or prescription-only self-administered hormonal contraception initiated pursuant to subdivisions (a) or (b) of this section, the pharmacist shall provide the recipient of the drug with a standardized factsheet that includes, but is not limited to, the indications and contraindications for use of the drug, the appropriate method for using the drug, the need for medical followup, and other appropriate information. The board shall develop this form in consultation with the State Department of Public Health, the American Congress of Obstetricians and Gynecologists, the California Pharmacists Association, and other health care organizations. This section does not preclude the use of existing publications developed by nationally recognized medical organizations.

(d) Notwithstanding any other law, a pharmacist may furnish FDA-approved over-the-counter contraceptives without the need to comply with the standardized procedures or protocols required by subdivision (a)(1) for prescription-only self-administered hormonal contraceptives.

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

Members of the public were provided the opportunity to comment in Sacramento. The Board heard comments in support of the motion.

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

Support: 7 Oppose: 0 Abstain: 0 Not Present: 5

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

j. Licensing Statistics

Dr. Oh advised this agenda item would not be discussed.

President Oh then turned the meeting over to Nicole Thibeau, Vice Chair of both the Communication and Public Education Committee and the Legislation and Regulation Committee, to provide reports from those committees.

XIV. Communication and Public Education Committee

a. Transition to a New Website Template

Dr. Thibeau advised this agenda item would not be discussed.

b. Talk to the Expert Consumer Poster and Public Education Campaign

Dr. Thibeau advised this agenda item would not be discussed.

c. Draft Educational Material Related to IV Hydration Clinics

Dr. Thibeau provided that in recent years, the U.S. Food and Drug Administration (FDA) has released warnings about instances of drug products being compounded under insanitary conditions. Many of these warnings stem from compounding occurring in sites that were not regulated by the Board or other regulatory agencies, including IV hydration clinics. Although business models vary, such clinics have been identified as operating in a variety of locations, including mobile vans, beauty salons, and gymnasiums. These locations generally do not have the appropriate equipment, storage, or classified areas, nor do they have authorized healthcare professionals performing the sterile compounding.

Dr. Thibeau continued that the Enforcement and Compounding Committee considered a draft policy statement during its July 17, 2024 meeting on compounding at IV hydration clinics. During the July 18, 2024 meeting of the Communication and Public Education Committee, members reviewed draft educational materials intended to be provided to personnel at IV hydration clinics as well as made available on the Board's website. The focus of the education was around legal requirements and patient safety considerations for such clinics. During the meeting, members generally spoke in support of the concept of the education and requested that staff work to refine the materials. Members requested that staff work with Member Barker to incorporate edits requested by the Committee and to provide an updated version for the Board's consideration.

Dr. Thibeau noted that following the meeting, staff had an opportunity to work with Member Barker. Some of the significant changes made to the document include reorganizing the information and simplifying the language to more explicitly state the potential harm to patients and highlighting the relevant sections of USP 797 – Pharmacy Compounding – Sterile Preparations. Consistent with the request from the Enforcement and Compounding Committee, staff will also be exploring the ability to create an educational video. Board staff will continue to engage with other healing arts boards on the materials and will continue to offer co-branding of the document with programs that are interested. Included in the

meeting materials were the updated draft information sheet intended to provide guidance to compounding facilities that were not regulated by the Board.

Members were provided the opportunity to comment. Members commented in favor of the materials and recommended a few minor edits. It was recommended to change "walk in" to "in home"; identify the licensee search for location and personnel; change the reference to compounder as the general public does not understand the term; and add risk to patients in the document.

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

d. Communication and Public Education Activities by Staff
   1. *The Script*
   2. Staff Outreach
   3. Fake Botox
   4. News Media Inquiries

Dr. Thibeau advised this agenda item would not be discussed.

XV. Legislation and Regulation Committee

Vice Chairperson Thibeau advised the legislature was currently on Summer Recess and reconvenes August 5, 2024. She added meeting materials noted the Board's position on pending legislation as applicable, with a few new measures. As included in the meeting materials, the Committee was recommending changes to the Board's position in a few areas. Dr. Thibeau added there were a few measures that were no longer for discussion included as they did not meet legislative deadlines, including Assembly Bill 3026 and Assembly Bill 3146. Additionally, during the April 2024 discussion it was determined that the Committee and Board did not need to monitor some measures, though staff would continue to monitor. An example of such a measure is Assembly Bill 82 related to dietary supplements for weight loss and over the counter diet pills. Specifically related to Assembly Bill 82, the measure continues to move and will be considered by the Senate Appropriations Committee on August 5.

Dr. Thibeau advised the report would only include discussion and consideration of AB 3063 (McKinnor, 2024) and SB 1089 (Smallwood-Cuevas, 2024). She referred to the meeting materials for other items included on the agenda.

<u>AB 3063 (McKinnor, 2024)</u>

Dr. Thibeau advised AB 3063 was similar to AB 782 from last year and reminded the Board that it had initially established an Oppose Unless Amended position in the hopes the Board could work with the author's office to discuss implementation challenges that some pharmacies may have indicated they would experience as a means to facilitate the policy goal of the measure without creating a conflict with state and federal law and national standards. Regrettably, that did not occur.

Dr. Thibeau noted that the primary difference between the two measures was that AB 3063 included a sunset date, meaning that conflict would only exist until January 1, 2030. As previously discussed, inclusion of the sunset date did not address the Board's concerns.

Following the Committee's discussion, the Board ratified the Oppose Unless Amended position established by President Oh as part of the April 2024 Board meeting. Since that time, staff conveyed amendments to the author's office for consideration. Specifically, the amendments would have focused on actions to facilitate implementation of the USP requirements. Regrettably, those amendments were not accepted. As such, Dr. Thibeau believed a change to an Oppose position was appropriate.

Dr. Thibeau reported that as was noted during the Committee meeting, there was published research that demonstrates the impacts of flavoring agents on medications. As an example, in published research entitled, Interactions and incompatibilities of pharmaceutical excipients with pharmaceutical ingredients, a comprehensive review, "Most excipients have no direct pharmacological action but they can impart useful properties to the formulation. However, they can also give rise to inadvertent and/or unintended effects such as increased degradation of the drug. Physical and chemical interactions between drugs and excipients can affect the chemical nature, the stability and bioavailability of drug products, and consequently, their therapeutic efficacy and safety." Such a conclusion reinforces the importance of compliance with the national standards, most notably provisions for establishing beyond-use dates. After considering the measure, the Committee offered a recommendation to change the Board's position to Oppose.

Committee Recommendation: Establish an Oppose Position

Members were provided the opportunity to comment. Members reiterated that the Board was not opposed to using flavoring and noted there was a pathway for flavoring being proposed in the Board's compounding regulation language.

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

Support: 7 Oppose: 0 Abstain: 0 Not Present: 5

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

SB 1089 (Smallwood-Cuevas, 2024)
Dr. Thibeau reported that the Committee and Board had not previously discussed this measure as it was not identified in advance of notice requirements. As indicated in the meeting materials, and as related to the Board's regulated public, the measure would require a pharmacy to provide advanced notice of closures to employees and specified agencies. Through his delegated authority, President Oh established a support if amended position, requesting the Board be included in the list of agencies that receive notification of closure. She noted the amendment sought was consistent with the Board's policy in this area where the Board was seeking amendments to regulations to require such notification. Dr. Thibeau reported the author accepted the Board's amendment, and the Board was now included as one of the agencies to receive such reports under specified conditions. She continued that given this change, the Committee was recommending that the Board update its position to Support.

Committee Recommendation: Support

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

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

Members of the public were provided the opportunity to comment via WebEx. The Board heard comment warning that this bill could have unintended consequences for pharmacy staffing. The Board also heard background from one of the measure's sponsors.

Support: 7 Oppose: 0 Abstain: 0 Not Present: 5

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

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

Dr. Oh noted that in preparation for completion of the Board's legislative report, the Board had the opportunity to identify issues for potential inclusion in the Board's report. He added the Board already had identified a number of issues and was looking to see if any additional issues may be appropriate. Dr. Oh didn't believe it was appropriate to make decisions but rather request that staff perform research on the concepts and offer recommendations for consideration at a future meeting.

Dr. Oh referenced meeting materials containing recommendations offered by Kaiser. He agreed the items should be researched by staff with a recommendation being offered at a future meeting, noting that he shared some concerns raised by Kaiser related to pharmacy technicians and agreed some clean-up language was appropriate. Members noted agreed with these recommendations.

Dr. Oh referenced meeting materials containing a request from the CPC to change the title of Advanced Practice Pharmacist to Advanced Pharmacist Practitioner. Members spoke in support of this change.

Dr. Oh then asked for members to share ideas to be explored. Members recommended adopting specific language that would notify the consumer they were free to access any pharmacy. Members also noted agreement with items 1 (establish all self-assessment requirements in statute), 2 (consideration of increased citation and fine authority for mail order pharmacies for repeated violations of materially similar provisions within five years), 4 (evaluate the issue of pharmacy deserts and actions the Board can take to expand pharmacy services to these areas), and 8 (consider payor activities (including auditing practices) that negatively impact patient access) in the meeting materials.

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

Members of the public were provided the opportunity to comment via WebEx. The Board heard comment in support of items 3 (consider what changes to pharmacy law are necessary to address incorporation of AI into pharmacy practice) and 6 (consideration of the proliferation of pharmacy delivery services including, for example, DoorDash, Uber, *etc.*) in the meeting materials. A representative of Kaiser also commented to reiterate the importance of their third recommendation, stating that it was directed toward reducing the volume of paper records pharmacies were required to keep, as this has become a significant space and cost issue.

XVII. Organizational Development Committee Report

This agenda item was not discussed.

XVIII. Executive Officer Report

This agenda item was not discussed.

XIX. Closed Session

Open session concluded at approximately 2:21 p.m. Following a break, the Board convened in closed session at approximately 2:33 p.m.

XXI. Adjourn for the Day

The Board reconvened into open session and adjourned the meeting at 3:32 p.m.

Attachment IV.

b. September 12, 2024
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: September 12, 2024

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
Trevor Chandler, Public Member, Treasurer
Renee Barker, PharmD, Licensee Member
Jeff Hughes, Public Member
Kartikeya "KK" Jha, Licensee 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
Jason "J." Newell, MSW, Public 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
Jennifer Robbins, DCA Regulations Counsel
Norine Marks, DCA Staff Counsel
Debbie Damoth, Executive Specialist Manager

September 12, 2024

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

President Oh called the Board meeting to order at approximately 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. Dr. Oh announced that as explained in the subscriber alert recently issued by the Board, the Board expects significant public comment regarding agenda item VI regarding the proposed compounding regulations. Additionally, the Board received a significant number of requests from interested stakeholders to take items on the agenda out of order and consider agenda item VI first. Dr. Oh explained that while the Board was not obligated to do so, at his discretion he does have the flexibility to take items out of order and, accordingly, the Board would proceed to consider agenda item VI as the next item of business after general announcements. Further, as it was anticipated that there would be significant public comment at the meeting, in the interests of time, public comment time would be limited to two minutes per speaker. Dr. Oh also advised that WebEx public comment would be taken before in person public comment during public comment periods.

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; 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.

President Oh reminded members participating via WebEx to remain visible with cameras on throughout the open session of the meeting. Dr. Oh advised if members needed to temporarily turn off their camera due to challenges with internet connectivity, they must announce the reason for their nonappearance when the camera was turned off.

President Oh then turned the meeting over to Maria Serpa, Chairperson of the Enforcement and Compounding Committee, to guide the Board through the compounding regulations and proposed changes to the modified text.

VI. 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, Handling of Hazardous Drugs and Radiopharmaceuticals, Including Review of Any Comments Received During the 45-Day Comment Period and Regulation Hearing

Chairperson Serpa thanked President Oh for the opportunity to assist the Board through its discussion on the comments received during both the 45-day written comment period, which closed on June 3, 2024, and the regulation hearing held on June 18, 2024. Dr. Serpa was pleased to report that she along with Member Renee Barker, PharmD, consistent with the Board's direction, considered the additional comments from the Board members during the July 31, 2024 Board meeting and were offering additional changes to the proposed modified text.

Member Sandhu arrived at approximately 9:08 a.m.

Dr. Serpa verified everyone was referencing the appropriate materials including the correct version of the proposed modified text. Dr. Serpa was advised there was information in the public domain that did not reflect the current language under consideration by the Board. She highlighted this because it appeared to also be an issue during the last meeting where individuals were commenting about prior versions of the regulation language and not the most up to date information. Dr. Serpa verified the current proposed modified text included a footer at the bottom of each page with the date of August 29, 2024. She noted if the footer was unable to be viewed, the correct version under consideration could also be identified by looking at section 1736.9 related to components and equipment and confirming that the language being viewed referenced the provisions providing authority for a pharmacy to compounding using bulk substances in subdivision (e)(2). Dr. Serpa requested staff display this on the meeting slide as well to assist individuals that were participating via WebEx.

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

Dr. Serpa provided a reminder that many of these proposed regulations were not new and were currently in effect. She added the Committee was suggesting that prior regulations be repealed and rearranged into the new USP outline format and to include new or clarifying information to the new USP Chapters that were effective November 1, 2023.

Dr. Serpa recalled that at the July 2024 Board meeting, the Board dedicated over six hours of discussion to the proposed regulations, and suggested that today the focus be on the proposed modifications resulting from that discussion. She added that the memo included as part of this agenda item highlights the changes that were made as directed by the Board to the proposed modified text since the July 2024 Board meeting. Dr. Serpa referred to meeting materials, attachment 2 that

included the same proposed modified text with changes highlighted in yellow to make it easy for members and interested stakeholders to identify the new recommendations. There were recommended changes to each of the articles. She intended to quickly review substantive changes and solicit feedback from members. Following the review of all the proposed changes, she was hopeful a consensus would be reached, and action could be taken. Dr. Serpa appreciated everyone's diligence in reviewing and considering the information both from the July 2024 Board meeting as well as the September 2024 Board meeting. She believed it was in the best interest of consumers and other stakeholders to move forward today so the Board could initiate another formal comment period and again provide all interested parties with an opportunity to provide written comments consistent with the legal requirements. This approach would ensure all interested parties could engage in the regulatory process, their concerns were documented, and they could see a written response to all of their respective comments during a future Board meeting, or as part of the final rulemaking file.

Dr. Serpa began by reviewing changes made to proposed article 4.5 Nonsterile Compounding. She noted recommended changes to the requirements in section 1735.1(e) related to determinations of clinically significant difference. Additional recommended changes included clarifying language in section 1735.3 related to potential contaminating conditions, since based on the Board's discussion it appeared necessary to include the requirement of USP Chapter 795 to avoid some of the confusion previously heard during public comment. The documentation retention requirement in in section 1735.14(b)was also clarified.

Members were provided the opportunity to comment regarding proposed modified text in article 4.5 Nonsterile Compounding; however, no comments were made.

Dr. Serpa then reviewed proposed article 4.6 Sterile Compounding, noting there were nonsubstantive changes clarifying language on the criteria for compounding under immediate use provisions in the event of an equipment failure in section 1736.1(b)(2). Also included were additional conditions for a health care facility to compound essentially a copy of a commercially available product, again consistent with the Board's direction. Dr. Serpa hoped this was clearer as this was always the Board's intent. The proposed modifications also included deletion of requirements in section 1736.6 for identification to the genus level, regardless of the CFU count, and updated the requirements for compounding with bulk drug substances included on the interim 503A Category 1 Bulks Drug Substances List. Dr. Serpa stated that the proposed language did allow for the compounding of FDA Category 1 bulk drug substances, including glutathione and methylcobalamin. She highlighted this again because there was information in the public domain that the Board was banning these substances. Dr. Serpa noted the Board was challenged to assure both patient safety and to not create a barrier to potential emerging treatments for which FDA component

review was still in process. She added the proposed regulations provide a path forward to access these components while the FDA is still making its determinations.

Members were provided the opportunity to comment regarding the proposed modified text in article 4.6 Sterile Compounding.

Member discussion included a request for all USP chapter names be added as previously requested. It was agreed that could be a nonsubstantive change. Members also appreciated the clarifications and modifications made regarding FDA Category 1 bulk drug substances. A question was asked if the "essentially a copy" provisions allowed a pathway for a patient who had an allergy to an inactive ingredient. It was agreed that was within the pharmacist's judgment and allowed. There was an additional question about environmental sampling. It was noted that the November 2023 USP required additional sampling but the section was removed from the proposed text. Another question was asked about section 1736.9(e) and does it now allow FDA Category 1 bulk drug substances to be compounded without having emergency use needed. Dr. Serpa explained that additional changes to that section were made to make it clearer than an emergency is not required if the conditions of (e)(2) are met.

Dr. Serpa continued that, consistent with the direction of the Board, the scope of proposed article 4.7 Hazardous Drugs was now limited to facilities where hazardous drug compounding was performed and, in some instances, would also apply to facilities that perform "other manipulations" of antineoplastic HDs that pose risks to the compounding environment and a heightened risk for cross contamination. These "manipulations" of antineoplastic HDs were specifically mentioned in USP 800 and included tablet splitting or crushing as examples.

Members were provided the opportunity to comment regarding the proposed modified text in article 4.7 Hazardous Drugs.

Members were appreciative of the changes made to this article to clarify and reduce confusion. Clarification was provided with regard to the title format being changed to match USP. Typographical errors were provided to staff for nonsubstantive changes. It was clarified that gloves were required to be provided to the patient when dispensing a compounded antineoplastic hazardous drug. Section 1737.7(a) was requested to be clarified as a nonsubstantive change.

Dr. Serpa noted the final proposed article 4.8 Radiopharmaceuticals included changes made in other articles, including clarification on documentation retention requirements and deletion of provisions related to identification to the genus level to trend for growth.

Members were provided the opportunity to comment regarding the proposed modified text in article 4.8 Radiopharmaceuticals; however, no comments were made.

Dr. Serpa stated that, as it appeared that Board agreed on the proposed modified text, she would entertain a motion. After brief discussion on the framework for the motion, the following motion was made.

Motion: 1. Accept the Board staff recommended initial comment responses (from 45-day comment period and hearing) and updated supplemental responses as provided.

2. Approve the recommended updated modified regulation text as directed by the Board for a 15-day comment period, repeal sections 1708.3, 1708.4, 1735 et seq and 1751 et seq of the Board's current regulations, and add sections 1735 et seq, 1736 et seq, 1737 et seq, and 1738 et seq.

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 present recommended changes to the Board in response to the additional comments.

4. Further, should no adverse comments be received during the comment period, authorize the executive officer to take all steps necessary to adopt the proposed regulations at sections 1735 et seq, 1736 et seq, 1737 et seq, and 1738 et seq and complete the rulemaking process. Finally, 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.

M/S: Barker/Crowley

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

Multiple comments were received from members of the public stating there was still not a clear path forward for the public to receive glutathione and methylcobalamin for patients suffering from chronic illness and preventing cancer.

Representatives from stopthebop; Alliance for Pharmacy Compounding; Kaiser Permanente; Cloverdale City Council; Cedar Sinai; Sutter Health; Pacific Compounding Pharmacy; UCSD Health; Integrated Healers Action Network; and

Huntington Health commented in favor of aligning with USP standards only. Comments also suggested that the Board has failed to provide evidence proving that the proposed regulations are necessary, and requested an extended comment period beyond 15 days.

A representative of the California Orthopedic Association requested clarification if these proposed regulations would apply to orthopedic surgeons mixing medications for joint injections.

Comments were also received requesting technical changes to certain of the proposed sections:

- Requested clarification if building requirements would be required related to the secondary engineering control and allowed for retrofitting or mitigating factors.
- 1735.4(b) recommended aligning with USP 795.
- 1736.1(b) would force the nurses to do the compounding noting 24 hours would not allow for weekends to be addressed.
- Identified as unacceptable to require reporting of each instance of immediate use compounding associated with an engineering control failure to the Board which has no benefit or value to adding safety to the public and would result in unintended consequences of having nurses conducting the compounding.
- 1736.1(b)(2) commented the Board will miss the intent of maintaining public safety with this requirement as compounding would be forced to nurses.
- 1736.2(d) commented for compounders to cease compounding if any component of training and competency evaluation was failed could lead to dangerous scenarios and requested leniency.
- 1736.9(e)(2)(ii) recommended removing the word "required."
- 1736.12(c) recommended the Board add a period after "has established in USP" and delete "Chapter 85 Bacterial Endotoxins" to facilitate a seamless transition when USP Chapter 86 becomes compendial.

The Board took a break from 10:38 a.m. to 10:55 a.m. Roll call was taken. The following Board members were physically present in Sacramento: Jessi Crowley, PharmD, Licensee Member; Renee Barker, PharmD, Licensee Member; Jeff Hughes, Public Member; KK Jha, RPh, Licensee 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.

Member Chandler returned to the meeting at approximately 11:04 a.m.

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

Multiple comments were received from members of the public stating there was still not a clear path forward for the public to receive glutathione and methylcobalamin for patients suffering from chronic illness and preventing cancer.

Representatives from CVS Health; Walgreens; lymedisease.org; California Naturopathic Doctors Association; California Society of Dermatology and Dermatologic Surgery; and Volunteer Fire Foundation commented in favor of aligning with USP standards only. Comments also suggested that the Board has failed to provide evidence proving that the proposed regulations are necessary, and requested an extended comment period beyond 15 days.

Comments were received requesting technical changes to the proposed sections:

- Reference to AMDUCA would serve to prohibit the compounding of animal preparations from bulk API in California which would devastate the veterinary community and severely limit animal patients' access to life-saving compounded medications.
- Hazardous drug section pertains to only compounding and not handling or other manipulations that was added without discussion.
- 1735.12(b) issue regarding potential quality issues were too extreme.
- 1737.9 requested to abandon or limit the training requirements.

A representative of the California Society of Dermatology and Dermatologic Surgery requested clarification if the proposed regulations applied to dermatologists and dermatologist surgeons.

A representative of CMA requested the Board not adopt the regulations without an amendment to explicitly exclude physician compounding.

Members were provided the opportunity to comment.

Members discussed the importance of ensuring that bulk drug substances that are still under review by the FDA, such as glutathione and methylcobalamin, are free from toxins and contaminates. Members stated that there have been documented cases of patient injury from APIs containing toxins, and as written the proposed regulations include testing requirements that will help protect patients. It was asked why the proposed regulations were above USP standards. Members discussed the Board has had a long history of higher standards than USP. Some members also expressed a desire to have a longer comment period, while others stated that action was the critical next step as current Board regulations and USP standards were in conflict which was confusing to the regulated public. Members discussed the proposed language was reordered to align with USP and included new language to allow for compounding of Category 1 bulk substances. Members also discussed 24-hour compounding in a health care setting when there is a breakdown of equipment, and

enhancements added in addition to clarifying requirements of USP. Members discussed why 24 hours was required for immediate use and how the Board needed feedback from the regulated public on the need for more than 24 hours. Members discussed the AMDUCA reference and how the Board worked with the California Veterinary Medical Board and CVMA to incorporate adjustments requested during previous written comment period. Members thought it would be helpful identify the sections that exceed current California law. Concerns were also raised that there were so many public comments against the proposed language. Members discussed the importance of ensuring the proposed regulations were written to ensure patient safety regardless of the time required.

Members discussed the possibility of relying solely on USP but were advised USP doesn't speak to what is used to compound as that was regulated by the FDA. USP only speaks about how to compound. Members discussed the current regulations and USP do not provide for access to FDA Category 1 bulk drug substances whereas the proposed regulations provide a pathway for access. A question was raised about what other states do. Members discussed holding high standards for compounding in California. Members discussed their responsibility for approving regulations that protected the public from unsafe compounding . Members discussed the dangers to patients when multiple sources provide these ingredients, which have no USP drug monograph, with unknown quantities and qualities of excipients. When these ingredients are compounded into a product for a patient who already has higher than normal amount of toxic exposure, the ingredient and the process should be known before compounding. Members expressed a desire to receive scientific data and information about standards that exist as well as the possibility of delayed implementation. It was confirmed that the two areas that have potential impact on institutions have delayed implementation written into the regulations. Members discussed how the policy statement includes enforcement discretion.

Members discussed what would happen if the proposed language wasn't advanced. The Board's current regulations would continue to be in conflict with current USP effective November 2023 and the confusion would continue to exist. They discussed the regulatory process that allowed changes through the comment period and allowed for staff to collect information requested by the Board. Members were concerned 15 days would not be enough time. Counsel noted the Legislature determined that a15-day comment period for modified text was sufficient. Additionally, there can be multiple modified text comment periods.

Support: 3 Oppose: 6 Abstain: 0 Not Present: 3

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

The motion having failed, Member Chandler made the following motion:

Motion: Send the proposed language back to Committee

M/S: Chandler/

Members discussed process issues with sending it back to Committee as well as the desire to have the full Board participate in the discussion. No second on the motion was made. Member Serpa then proposed a different motion as follows:

Motion: 1. Accept the Board staff recommended initial comment responses (from 45-day comment period and hearing) and updated supplemental responses as provided.

2. Approve the recommended updated modified regulation text as directed by the Board for a 30-day comment period, repeal sections 1708.3, 1708.4, 1735 et seq and 1751 et seq of the Board's current regulations, and add sections 1735 et seq, 1736 et seq, 1737 et seq, and 1738 et seq.

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 present recommended changes to the Board in response to the additional comments.

4. Further, should no adverse comments be received during the comment period, authorize the executive officer to take all steps necessary to adopt the proposed regulations at sections 1735 et seq, 1736 et seq, 1737 et seq, and 1738 et seq and

complete the rulemaking process. Finally, 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.

M/S: Serpa/Jha

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

Comments were received from members of the public requesting assembling a stakeholder task force; providing evidence from the Board staff; and recommending collaborating with other states.

Representatives from Kaiser Permanente; Pacific Compounding Pharmacy; Sutter Health; stopthebop; Alliance for Pharmacy Compounding; and Cloverdale City Council commented in favor of aligning with USP standards only without providing evidence for proposed regulations. Comments also encouraged the Board to vote down the motion.

A comment was received asking if the California restrictions helped the consumers of California.

A representative of CSHP commented California regulations restricting compounding into California does make a difference. The commenter stated it did because contaminated product was not allowed to come into California from the NECC disaster where 100 people died. This was prevented because of the Walnut Creek pharmacy compounding issue in California 10 years before NECC where four people died. After that tragic event, California State Board of Pharmacy took action and promulgated the existing sterile compounding regulations. The commenter concluded the increased standards for California did make a difference.

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

Comments were received from members of the public including wanting to make their own choice on what chemicals they put into their bodies; respecting right to make a decision for their body; sending back to Committee and adopting USP; and understanding why 49 states only follow USP.

Representatives from Walgreens and California Naturopathic Doctors Association commented in favor of aligning with USP standards only without providing evidence for proposed regulations.

Members were provided an opportunity to comment.

Members discussed how the new language impacted the enforcement of the compounding of glutathione but that was difficult to determine as the language had not been finalized. Counsel provided there was not a lot of clarity in the current regulations and as it stands cases are being decided in context of case specific adjudications. Members discussed having a special meeting to discuss this topic and reviewed the value of the regulatory process that allows the Board to respond to the public comment in writing. Members also discussed adding additional subject matter experts and collaborating with other states.

Support: 2 Oppose: 7 Abstain: 0 Not Present: 3

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

The Board took a lunch break from 1:05 p.m. to 1:50 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; Satinder Sandhu, PharmD, Licensee Member; Maria Serpa, PharmD, Licensee Member; and Seung Oh, PharmD, Licensee Member. Nicole Thibeau, PharmD, Licensee Member participated via WebEx.

President Oh thanked everyone for their participation. Dr. Oh advised in an effort to provide additional education, the discussion would be continued at the November 2024 Board meeting.

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

President Oh announced the Board would now accept public comment for items not on the agenda and provided instructions on how the public could provide comment.

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

A representative of CSHP requested exploring reimbursements for pharmacists practicing outside of a pharmacy.

A representative of Pacific Compounding Pharmacy asked if the Board would be willing to consider as an agenda item requiring wholesalers of APIs to provide the manufacturer of the API on their COAs.

A representative of stopthebop commented about requests for reasonable accommodations.

A member of the public agreed with the previous commenter and requested glutathione be available to the public.

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

A member of the public asked why the discussion regarding compounding was being moved to the November 2024 Board Meeting.

Members were provided the opportunity to comment. Members wished to see discussion on a future agenda regarding AB 317 implementation and the potential to broaden reimbursement to pharmacists practicing outside of a pharmacy; delays of patients getting time sensitive medication because of auditing by the PBMs related to PEP; and wholesalers being required to provide the manufacturer of APIs on COAs.

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

President Oh reminded those present that the Board recognizes pharmacists that 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. President 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.

IV. Discussion and Possible Action Related to Awarding Contract for Medication Error Reporting Consistent with Provisions of Business and Professions Code Section 4113.1

President Oh reminded those present that, as required by Business and Professions Code section 4113.1, the Board must approve an entity to receive reports of medication errors from community pharmacies. Consistent with the state contracting process, following discussion at several public meetings, a Request for Proposal, or RFP, was finalized and posted in July 2024. Following the due date for proposal submission as established in the RFP, responses received were evaluated based on the evaluation criteria set forth in the RFP.

Dr. Oh advised it was his understanding the proposals were recently scored and a vendor was selected. Consistent with the statute, before a contract can be awarded, the Board must formally approve the vendor. Dr. Oh advised the successful vendor through the competitive bidding process was ISMP. He thanked Dr. Serpa for representing the Board through the process.

Members were provided the opportunity to comment and requested additional information on the process. Counsel provided information regarding the process regarding adherence to the state contracting process and evaluation criteria used through consensus.

Motion: Approve ISMP as the entity approved by the Board under Business and Professions Code section 4113.1.

M/S: Serpa/Chandler

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

A representative of CSHP applauded the Board for their selection.

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

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

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

V. Discussion and Possible Action Related to Proposed Amendment to California Code of Regulations, Title 16, Section 1749(c), Pharmacy Technician Fee Schedule

Dr. Oh referenced meeting materials including background on the Board's proposed changes to California Code of Regulations, title 16, section 1749(c) related to pharmacy technician fees. He noted the 45-day comment period ended on September 9, 2024. As no comments were received, no action was required by the Board.

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

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

VII. Closed Session

Open session concluded at approximately 2:17 p.m. Following a break, the Board entered closed session at approximately 2:30 p.m.

VIII. Reconvene in Open Session to Adjourn the Meeting

The Board reconvened into open session and adjourned the meeting at 2:48 p.m.

Attachment IV.

c. August 23, 2024
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: August 23, 2024

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:
Jessi Crowley, PharmD, Licensee Member, Chair
Trevor Chandler, Public Member
Kartikeya "KK" Jha, RPh, Licensee Member
Satinder Sandhu, PharmD, Licensee Member
Maria Serpa, PharmD, Licensee Member

Committee Members Not Present: Jay Newell, MSW, Public Member

Staff Present:
Anne Sodergren, Executive Officer
Corinne Gartner, DCA Staff Counsel
Debbie Damoth, Executive Specialist Manager

August 23, 2024

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

Chairperson Crowley called the meeting to order at approximately 9:02 a.m.

Dr. Crowley 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. Crowley 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; KK Jha, RPh, Licensee Member; Satinder Sandhu, PharmD, Licensee Member; Maria Serpa, PharmD, Licensee Member; and Jessi Crowley, PharmD, Licensee Member. A quorum was established.

Dr. Crowley 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 Patrice Huber presided over the hearings.

a. Natalya Ignatyeva, RPH 86139

The Committee took a break from 9:49 a.m. to 10:04 a.m. Roll call was taken. The following Committee members were present via WebEx: KK Jha, RPh, Licensee Member; Satinder Sandhu, PharmD, Licensee Member; Maria Serpa, PharmD, Licensee Member; and Jessi Crowley, PharmD, Licensee Member. A quorum was established.

b. Sheldon Borson, Jr., RPH 45970

Petitioner Borson's camera was not working during the hearing. Counsel provided there was no legal requirement of having the petitioner on camera but if as a policy matter the Committee was not comfortable proceeding without seeing the petitioner, the Committee could decide to continue the hearing until a later time.

Members discussed the options available to the Committee. Members expressed that, historically, the petitioner was always present in person or on camera as it was felt this was important to judge the testimony. The Committee consensus was that members were uncomfortable moving forward with the petitioner present by audio only.

Motion: To continue the hearing to a later date because the Board was uncomfortable continuing without seeing the petitioner on camera.

M/S: Sandhu/Serpa

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.

Support: 4 Oppose: 0 Abstain: 0 Not Present: 2

Board Member	**Vote**
Chandler	Not Present
Crowley	Support
Jha	Support
Newell	Not present
Sandhu	Support
Serpa	Support

IV. Closed Session

Open session concluded at approximately 10:13 a.m. The Committee entered closed session at approximately 10:18 a.m. and ended closed session at approximately 10:27 a.m.

V. Reconvene in Open Session to Adjourn for the Day

The Committee reconvened into open session and adjourned the meeting at approximately 10:27 a.m.