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
Enforcement and Compounding Committee Meeting Minutes

Date: October 19, 2023

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

PUBLIC PARTICIPATION AND COMMENT FROM REMOTE LOCATIONS VIA WEBEX

Board Members Present: Maria Serpa, PharmD, Licensee Member, Chair
Renee Barker, PharmD, Licensee Member, Vice Chair
Seung Oh, PharmD, Licensee Member
Jignesh Patel, Licensee Member

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

Staff Present: Anne Sodergren, Executive Officer
Julie Ansel, Assistant Executive Officer
Rebecca Bon, DCA Counsel
Corinne Gartner, DCA Counsel
Sara Jurrens, Public Information Officer
Debbie Damoth, Executive Specialist Manager

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

Chairperson Serpa called the meeting to order at approximately 9:00 a.m. As part of the opening announcements, Chairperson Serpa reminded everyone that the Board is a consumer protection agency charged with administering and enforcing Pharmacy Law. Department of Consumer Affairs' staff provided instructions for participating in the meeting.

Roll call was taken. Members present: Renee Barker, Licensee Member; Seung Oh, Licensee Member; Jig Patel, Licensee Member; and Maria Serpa, Licensee Member. A quorum was established.

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

Members of the public were provided the opportunity to provide comment.

No public comment was made by meeting participants in the Sacramento location.

A pharmacist commented via WebEx requesting the discussion of enforcement of the patient-centered label requirements for nonresident pharmacies shipping into California.

Members were provided the opportunity to add items to a future agenda.

President Oh deferred to the chairperson and executive officer to evaluate the potential agenda item. Chairperson Serpa thought there could be a discussion on patient-centered labels and their respective use in different license categories. Dr. Serpa requested a report from staff and that the issue be added to a future agenda item.

III. Discussion, Consideration, and Approval of Draft Minutes from the July 18, 2023 Enforcement and Compounding Committee Meeting

The July 18, 2023 Enforcement and Compounding Committee meeting minutes were presented for review and approval.

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

Motion: Approve the July 18, 2023 Enforcement and Compounding Committee meeting minutes as presented.

M/S: Oh/Patel

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

Support: 4 Oppose: 0 Abstain: 0 Not Present: 1

Board Member	Vote
Barker	Support
Cameron-Banks	Not Present
Oh	Support
Patel	Support
Serpa	Support

IV. Discussion and Consideration of Enrolled or Recently Signed Legislation Impacting the Practice of Pharmacy

Chairperson Serpa advised the Legislation and Regulation Committee and the Board considered a number of measures that impact the practice of pharmacy over the course of the year. While some measures have a direct impact on the operations of the Board, others are more general to the practice of pharmacy without any real touch points to the Board or its operations.

Chairperson Serpa highlighted the Committee would not be discussing measures that the Board established a position on but that either did not pass, became two-year bills, or for which no implementation activities for the Board are required. Dr. Serpa encouraged participants interested in learning about the outcome of the additional measures to attend the November 1-2, 2023 Board meeting to receive an update during the report from the Legislation and Regulation Committee.

A. Assembly Bill 663 (Haney, Chapter 539, Statutes of 2023)

Chairperson Serpa recalled the Board established a support position on Assembly Bill 663. The measure expands provisions for the use of a mobile unit that is deployed as an extension of a county-owned, or other authorized entity's, pharmacy. Under the provisions of the measure, effective January 1, 2024, the pharmacist-in-charge (PIC) will have the authority to allow for the use of more than one mobile unit. Further, mobile units will have the ability to carry controlled substances approved by the FDA for treatment of opioid use disorder. Dr. Serpa agreed with staff's recommendation to update the Frequently Asked Questions (FAQs) related to this program. She also agreed that highlighting the changes in the Board's webinar

was appropriate, as was inclusion of the information in a future issue of *The Script*.

Members were provided the opportunity to ask questions or comment on implementation provisions. However, no comments were made.

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

B. Assembly Bill 782 (McKinnor, 2023)

Chairperson Serpa advised Assembly Bill 782 would have exempted from the definition of compounding, the adding of a flavoring agent. As the Governor vetoed the measure, discussion on implementation was not necessary.

C. Assembly Bill 1286 (Haney, Chapter 470, Statutes of 2023)

Chairperson Serpa provided Assembly Bill 1286 was the Board's patient safety measure. Dr. Serpa agreed with the recommendation that staff develop FAQs related to the various provisions for review by the Enforcement and Compounding Committee at the next meeting. Dr. Serpa also agreed that updates to the self-assessment form and the Board's pharmacy law webinar were appropriate, as was an article in a future issue of *The Script*.

Chairperson Serpa believed the process to be used by the Board to approve an entity to receive the medication error reports would be the part that required the most discussion. Dr. Serpa noted that until the Board approved such an entity, medication error reporting would not begin, and encouraged the Committee to move quickly and thoughtfully. Dr. Serpa recalled prior discussions involved the Board using a single entity for the medication error reporting to allow for aggregation of the information.

Chairperson Serpa added if a contract was necessary to facilitate approval, state laws governing contracting will most likely dictate the process. Dr. Serpa further noted that a presentation from the Agency for Healthcare Research and Quality (AHRQ), as the lead

federal agency charged with improving the safety and quality of healthcare for all Americans, might be helpful.

Members were provided the opportunity to ask questions or comment on implementation provisions.

President Oh agreed with the implementation approach presented and was proud of the work done to date. Dr. Oh agreed the AHRQ presentation would be helpful. Dr. Oh encouraged significant outreach presentations to assist licensees in understanding the significant changes in law.

Member Barker agreed with the significance of the measure and having stakeholder events to allow for education, questions, and comments.

Members agreed that sending an alert to inform licensees of the implementation plan would also be helpful.

Member Patel agreed with the implementation plan and that much education and communication needs to be done.

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

A representative from CPhA agreed with member comments and suggested breaking pieces of the legislation into webinars, FAQs, and announcements. The representative agreed an enforcement date for the medication error reporting would be helpful to prevent panic on January 1, 2024. The representative encouraged inviting ISMP and PSOs to the conversation. The representative noted many were excited about the PIC authority but were hesitant about how it would be enforced and how they would be protected from retaliation.

A pharmacist representative of Kaiser commented about areas in the measure for possible clean up at a later time. Specifically, the commenter noted section 4 of the bill, related to pharmacy technicians taking on additional tasks if certain conditions were met, which made sense for pharmacy technicians preparing and administering vaccines but it was not clear how the training related

to pharmacy technicians receiving prescription transfers and accepting clarifications on prescriptions. The representative suggested cleaning up the language so that the training was required for pharmacy technicians administering injections but not required for pharmacy technicians accepting clarifications on prescriptions and accepting transfers. The representative also asked if the Board would be going through the regulations process for selecting an organization to receive medication error reports.

A pharmacist recommended providing an enforcement target date for medication error reporting would be helpful as well as clarifying if the reporting of errors would be retroactive to January 1, 2024. The pharmacist expressed concerns for the provisions in the bill that offer relief for staff stress (*e.g.*, additional pharmacy technician for giving immunizations, etc.) that shouldn't be delayed.

A representative of CCAP commented licensees should know if the medication error reporting will be retroactive to January 1, 2024.

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

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

D. Assembly Bill 1341 (Berman, Chapter 276, Statutes of 2023)

Chairperson Serpa advised Assembly Bill 1341 would authorize until January 1, 2025, a pharmacist to furnish COVID-19 oral therapeutics. Because this measure included an urgency clause, the provisions became effective immediately upon the governor's signature. Dr. Serpa agreed with the implementation steps identified by staff as detailed in the meeting materials.

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.

A representative from CCAP asked when the authorization for pharmacists to furnish COVID-19 oral therapeutics expires. Executive Officer Sodergren explained that, per Business and Professions Code section 4052.04(f), that section shall remain in effect until January 1, 2025, but noted there were other provisions in the measure that had different sunset dates.

A representative of CPhA commented that this measure, in combination with last year's bill regarding CLIA-waived tests, allows for "test-to-treat" involvement by pharmacists, and this would resonate with many pharmacists if provided in educational materials.

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

E. Assembly Bill 1557 (Flora, Chapter 141, Statutes of 2023)

Chairperson Serpa recalled that in response to the COVID-19 public health emergency, the Board issued a waiver to extend conditions for remote processing. During the intervening period, the Board learned that some hospitals did not have pharmacists on site 24hours a day, making it impossible to meet federal requirements for medication chart order review, which would place patients at risk. To address this issue, the Board sponsored this measure, which was signed by the governor earlier this year. Because the measure included an urgency clause, the provisions became effective upon signature of the governor. Dr. Serpa agreed with the implementation activities identified by staff in the meeting materials and highlighted that the Licensing Committee continues its discussion about the potential to further expand provisions for remote processing, including as part of its meeting on October 18, 2023.

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.

A pharmacist commented the measure established that the service must be provided by a pharmacist in California. The commenter noted some hospitals were contracting with other hospitals outside of California. The commenter thought it needed to be communicated and considered to give those hospitals time to meet the statutory requirements.

A pharmacist commented in appreciation of the Board's actions to use the federal emergency to provide a waiver until the bill could be passed; however, the emergency ended August 9, 2023, and the bill went into effect on September 1, 2023. The pharmacist expressed hope that no enforcement actions would be taken for that intervening period.

A commenter asked if this bill applied to outside retail pharmacies that service hospitals or skilled nursing facilities. Dr. Serpa commented that, in reading the bill, it was very clear what entities were covered.

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

F. Senate Bill 345 (Skinner, Chapter 260, Statutes of 2023)

Chairperson Serpa provided Senate Bill 345 was supported by the Board and will prohibit a healing arts board from denying an application for a license or imposing discipline upon a license of a health care practitioner based on a civil judgement, criminal conviction, or disciplinary action in another state, if that action would have been lawful if provided in California. Dr. Serpa agreed

the implementation activities should include education on the provisions with inclusion of the measure in the Board's webinar and a future issue of *The Script*. Dr. Serpa appreciated staff coordinating with the Office of the Attorney General.

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; however, no comments were made.

G. Senate Bill 816 (Roth, Chapter 723, Statutes of 2023)

Chairperson Serpa advised Senate Bill 816 was sponsored by the Board and recasts the Board's fee schedule consistent with the findings of the independent fee audit. Dr. Serpa noted with the effective date for the new fees being January 1, 2025, the Board should have sufficient time to update its regulation language in California Code of Regulations (CCR) section 1749 to ensure consistency between the statute and related regulation. Dr. Serpa agreed with staff comments that education on the changes was appropriate and highlighted that updates will be necessary to Board application and renewal instructions and forms.

Members were provided the opportunity to comment.

President Oh requested the rulemaking process be started now as the Board had experienced delays in the rulemaking process in the past.

Members discussed that at future meetings, there could be discussions on contingency plans if regulations were not in place in time, and to which committee the fee language would go through when ready.

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; however, no comments were made.

V. Discussion and Consideration of Proposed Revisions to Frequently Asked Questions Related to Inventory Reconciliation

Chairperson Serpa provided the Board has developed several FAQs in a variety of areas as a means to educate licensees and assist licensees in understanding the Board's thinking on specified topics. As pharmacy law continues to be very dynamic, when changes in the law occur, updates to the FAQs may be necessary.

Chairperson Serpa recalled that effective January 1, 2023, the Board's inventory reconciliation requirements were updated; however, the FAQs released have not yet been updated to incorporate the new requirements. A draft of the updated FAQs was included in the meeting materials. Dr. Serpa thanked Supervising Inspector Janice Dang for her work on updating the FAQs and stated her belief that the Committee had a solid foundation from which to consider updates to the FAQs. Dr. Serpa added that she had reviewed the draft FAQs and was comfortable with the information as presented.

Members were provided the opportunity to comment.

Member Patel thanked staff for updating the FAQs.

President Oh requested for the first question, third bullet, to add the phrase "reportable" before controlled substance loss. Dr. Serpa believed that was the intent.

Member Barker asked if the bullets could be replaced with a lettering sequence (*e.g.*, a, b, c, etc.). Dr. Serpa agreed with the outline format.

President Oh requested a compilation of codes referenced in the back of the document. Members agreed with hyperlinks for the codes.

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.

A pharmacist commenter provided a personal historical recollection of actions similarly taken for self-assessment documents.

Members requested staff work with counsel to finalize the updated FAQs in advance of the November 1-2, 2023 Board meeting.

VI. Discussion and Consideration of Proposed Revisions to Pharmaceutical and Sharps Waste Programs

Chairperson Serpa referenced that the meeting materials provided a background on the product stewardship programs and provided a high-level summary. California law requires the establishment of pharmaceutical waste and sharps waste stewardship programs as a means to provide safe and convenient disposal options for pharmaceutical and home-generated sharps waste at no cost to consumers. Dr. Serpa noted that although CalRecycle was the primary regulator for the stewardship programs, the Board has a limited role in evaluating the stewardship plans for compliance with pharmacy law, as well as to develop a list and description of drugs or sharps that are covered under the law.

Chairperson Serpa reported that as part of the Board's implementation of the measure, FAQs were developed to assist stakeholders with gaining an understanding of the program requirements, the Board's role, and definitions of some of the provisions of the law. Since the release of the FAQs, staff have continued to receive additional questions that suggest additional changes to the FAQs were appropriate. Dr. Serpa referred to the meeting materials that contained a copy of the proposed updated version of the FAQs, noting the proposed changes were highlighted. To ensure a common understanding, the proposed changes were in question one and question three as well as adding two additional questions, number 17 and 18. Dr. Serpa thanked Inspector Fang and counsel for their work to update these FAQs.

Members were provided the opportunity to comment.

President Oh indicated the first question should read "it sells" rather than the printed "is sells." Dr. Serpa believed the comment to be a nonsubstantive change.

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

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

VII. Discussion and Consideration of Enforcement Statistics

Chairperson Serpa referenced the enforcement statistics for the first quarter of the fiscal year included in the meeting materials. The Board received 765 complaints and closed 764 investigations. The Board revoked 11 licenses, accepted the disciplinary surrender of four licenses, formally denied one application and imposed other levels of discipline against 25 licensees and/or applicants. Dr. Serpa added as of October 1, 2023, the Board had 1,396 field investigations pending. The materials provided a breakdown of the average timeframe for the various stages of the field investigation process.

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

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

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

VIII. Future Meeting Dates

Chairperson Serpa thanked everyone for their time and participation, noting the next meeting was currently scheduled for January 23, 2024. Dr. Serpa asked that stakeholders monitor the Board's website for updates.

IX. Adjournment

The meeting adjourned at 10:02 a.m.