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 16, 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 REMOTE LOCATIONS VIA WEBEX

Board Members Present:
Maria Serpa, PharmD, Licensee Member, Chair
Renee Barker, PharmD, Licensee Member, Vice Chair
Jeff Hughes, Public Member
Seung Oh, PharmD, Licensee Member
Nicole Thibeau, PharmD, Licensee Member

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

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

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

Chairperson Serpa called the meeting to order at approximately 9:01 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. The following members were present via WebEx: Renee Barker, Licensee Member; Jeff Hughes, Public Member; Seung Oh, Licensee

Member; Nicole Thibeau, Licensee Member; and Maria Serpa, Licensee Member. A quorum was established.

Dr. Serpa reminded Committee members to remain visible with cameras on throughout the open session of the meeting. Dr. Serpa advised if members needed to temporarily turn off their camera due to challenges with internet connectivity, they must announce the reason for their non-appearance when the camera was turned off.

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

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

III. Approval of Draft Minutes from the July 17, 2024 Enforcement and Compounding Committee Meeting

The draft minutes of the July 17, 2024 Enforcement and Compounding Committee meeting were presented for review and approval.

Motion: Approve July 17, 2024 Enforcement and Compounding Committee meeting minutes as presented

M/S: Oh/Barker

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

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

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

IV. Presentation on Distribution of Controlled Substances, Wholesalers Perspective, Provided by Leah Lindahl, Vice President, State Government

Affairs, Healthcare Distribution Alliance and Sara Watson, CPhT, Manager, State Regulatory Outreach, Cardinal Health

Chairperson Serpa referenced meeting materials containing background information. Dr. Serpa recalled the Board receives public comments from patients and chronic pain advocates about impacts to patients who are facing challenges receiving their controlled substances. She noted the Committee also received information on actions taken by the DEA to change allocation quotas for stimulant medications. Dr. Serpa welcomed Leah Lindahl, Vice President, State Government Affairs with the Healthcare Distribution Alliance (HDA), and Sara Watson, State Regulatory Outreach Manager with Cardinal Health, to provide a presentation on the issue from the wholesalers' perspective as part of the Committee's ongoing education.

Ms. Lindahl provided an overview of HDA, which is a national association that represents wholesaler distributors, and discussed the importance of communication with wholesaler distributors.

Ms. Watson reviewed Cardinal Health's Controlled Substance Monitoring Program (CSMP) and the enhancements to the CSMP that Cardinal Health has put into place as a result of the National Opioid Settlement. She highlighted areas of the CSMP including onboarding, thresholds, and reporting, and also discussed resources available.

Members were provided the opportunity to comment.

Members were surprised to hear that wholesalers can't proactively reach out to their pharmacy customers to inform them how to increase their threshold. A member suggested having the wholesalers continue to reach out to their pharmacy customers periodically, in addition to onboarding processes, to provide them with education and remind them of the tools available to them.

Members asked if there were ways for the wholesalers to dynamically look at store closures to anticipate the shifting in prescription volume and adjust thresholds accordingly. Ms. Watson indicated the pharmacy customers would be more aware of these changes and it would a difficult IT solution for the wholesaler to manage on its own. She continued to explain that under the injunctive relief provisions of the National Opioid Settlement wholesalers are prohibited from disclosing anything about thresholds or how they are set. Additionally, if an order hits the threshold, the order would be held and

cancelled, and the Board of Pharmacy would be notified. Ms. Lindahl indicated the DEA was made aware of shortages, but the DEA controls quotas. The presenters were asked if there was a way a wholesaler can supply data going back over time to identify trends in volumes of drugs sold to pharmacies. They were aware of a report but would have to look into seeing if it was available.

Members discussed what could be done through the Board and/or the distributors to change the injunctive relief provisions, as the perception is that the provisions are not helping address the opioid crisis. A member provided an example based on personal experience and expressed concern that patients were suffering when algorithms control over the context and clinical considerations behind specific orders. Ms. Lindahl suggested informing congressional members, and the DEA directly, about these concerns, as well as notifying the wholesaler when shortages are identified so they are aware of changing purchasing patterns. Ms. Lindahl pointed out the injunctive relief terms were dictated to the wholesalers by the Attorneys General and there's likely not an opportunity to change them.

Members also expressed concerns about nomenclature, noting that the term "suspicious order" is scary for the pharmacy making the order, and unintended consequences when thresholds are exceeded and this results in a report to the Board. Ms. Watson advised "suspicious order" was a federal definition from the controlled substance act. She continued education and communication was important. Ms. Watson also advised it does help the wholesaler identify and terminate players with nefarious intentions. Members continued to discuss the impact on patients of a 5-7 day threshold change evaluation and inquired if this timeframe could be adjusted based on patient-specific circumstances. Members were advised the 5-7 day threshold evaluation time is an average turnaround and would be faster if information requested by wholesalers was provided immediately. The timeframe of the injunctive relief was identified as at least 10 years.

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

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

Public comment was received from members of the public including a patient pain advocate, a pharmacist, a pharmacist representative of Kaiser,

and a physician. Public comments expressed concerns including the negative impact to patients of the injunctive relief; impact on non-opioid drugs; lack of consideration of unique patient needs and changes in clinical practice; threshold adjustments not being made fast enough; and appearance that injunctive relief was mysterious and harmful to patients. Comment also requested clarification on the threshold process, application of the injunction relief, and primary/secondary wholesaler contracts.

Ms. Watson provided clarification on the threshold process, indicated three wholesalers were impacted by the injunctive relief, and explained that questions are asked about primary and secondary wholesalers to obtain a full picture of controlled substances purchased.

Public comment also suggested the Board of Pharmacy and the Medical Board of California should work together to try to address these concerning issues.

Members were provided the opportunity to comment after having received public comment.

Dr. Serpa recommended the Board of Pharmacy provide educational materials to licensees, such as a subscriber alert and/or article in *The Script*, to help inform them about their options for adjusting their thresholds. Members and staff were in favor of Dr. Serpa's recommendation. The Committee also discussed having a collaborative discussion with the Medical Board of California as well as the Director of Department of Consumer Affairs (DCA) to engage additional DCA Boards and Bureaus (*e.g.*, Nursing Board, Physician Assistant Board, *etc.*); issuing a policy statement; and continuing to discuss this issue at future meetings.

The Committee took a break from 10:40 a.m. to 10:55 a.m. Roll call was taken. The following members were present via WebEx: Renee Barker, Licensee Member; Jeff Hughes, Public Member; Seung Oh, Licensee Member; Nicole Thibeau, Licensee Member; and Maria Serpa, Licensee Member. A quorum was established.

V. Discussion and Consideration of Draft Report to the Legislature on Automated Drug Delivery Systems as Required in Business and Professions Code (BPC) Section 4427.8

Dr. Serpa advised as included in the meeting materials, the Board was required to submit a report to the Legislature on the use and oversight of

automated drug delivery systems (ADDS) as part of the upcoming sunset evaluation process. During the July 2023 Committee meeting, members received the first presentation related to the findings of quality assurance (QA) reports received, which revealed in part what appeared to be a lack of compliance with reporting requirements. Subsequently, staff undertook education of licensees on the reporting requirements. At the July 2024 Committee meeting, a presentation with updated data was provided.

Dr. Serpa referenced the draft report included in the meeting materials and noted that having reviewed the report, she believed the information was appropriate. She also agreed with the conclusions drawn from the information the Board has received.

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

Motion: Recommend to the Board approval of the draft legislative report as presented.

M/S: Oh/Thibeau

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

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

A pharmacist representative from Kaiser noted the report didn't address the continued need for the licensure of ADDS and recommended removing the ADDS error reporting requirement.

Members were provided the opportunity to comment after having received public comment. Dr. Serpa advised as part of the report, the Board found there were concerns with ADDS in skilled nursing facilities and jails.

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

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

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

Chairperson Serpa referenced meeting materials discussing enrolled legislation that was either signed or vetoed by the governor and including recommendations of Board staff on implementation activities.

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

Dr. Serpa agreed the implementation activities identified by staff were appropriate.

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

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

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

Dr. Serpa requested members comment on some of the issues raised in the meeting materials, including if the Committee believed development of regulations appeared appropriate.

Some members believed regulations were not needed while other members believed further clarification of the statute's provisions would be helpful. Members discussed having resources available to the regulated public, such as an article in the newsletter and updates to

the self-assessment form, as well as asking staff to consider if regulations might be required.

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

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

A pharmacist representative from Kaiser believed the statute provided sufficient detail and a regulation was not required. The pharmacist encouraged the Board to exercise reasonableness for enforcing "timely manner" as identified in the statute.

Members were provided the opportunity to comment. Dr. Serpa requested staff develop possible regulation text as a way of continuing the discussion.

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

Dr. Serpa agreed that the implementation activities recommended by staff were appropriate regarding AB 2115, which authorizes specified entities to dispense a 72-hour supply of a schedule II controlled substance for purposes of relieving acute withdrawal symptoms while arrangements are being made for referral for treatment.

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

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

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

A pharmacist commented that this lifesaving rule deserved a lot of attention for patients addicted to opioids and transitioning to a treatment program.

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

Dr. Serpa advised AB 3063, relating to adding a flavoring agent to a prescription medication, had been vetoed, noting this was the second year the governor has vetoed this measure. The Board had opposed the measure, as it conflicted with USP standards. Dr. Serpa noted the meeting materials included the amendment the Board had requested of the author to address the Board's concerns. Regrettably, the amendment was not accepted. Dr. Serpa appreciated the question posed in the meeting materials and was interested in member's thoughts on the suggestion that the Board sponsor legislation in line with the amendment offered to the author's office, with the ultimate goal of assisting pharmacies with implementation challenges they may face in complying with national standards. The proposed legislation would not change USP requirements but would allow pharmacies to make flavoring additions without obtaining the prescribers' authorization each time.

Members were provided the opportunity to comment. Members discussed the proposed statutory language.

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

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

Public comment was received from a pharmacist and representatives of Kaiser and FlavorRx. Comments indicated the proposed language would not make it easier to offer flavoring.

Members were provided the opportunity to comment after receiving public comment. Members were interested in working with stakeholders to make a path forward while following UPS Chapters and noted the Board was not trying to ban or take away flavoring. The FDA, and FAQs from USP, make it clear that adding flavoring is generally considered compounding. Members agreed the current statutory proposal was at least a starting point for future discussion.

Motion: Recommend that the chairperson and staff work

together to develop potential statutory language in line with the Board's prior requested amendment related to flavoring agents and prescription requirements.

A flavoring agent may be added to a prescribed FDA approved drug in an oral liquid dosage form at the request of a patient or patient's agent without consultation with the prescriber or their authorized agent. A pharmacist performing such action must provide documentation on the prescription record.

M/S: Oh/Barker

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

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

A representative from FlavoRx disagreed with the Board's understanding that the FDA generally considered flavoring to be compounding.

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

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

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

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

Dr. Serpa advised implementation of SB 164, which increases the CURES fee from $9 annually to $15 annually, would be facilitated by the Department of Justice.

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

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

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

Dr. Serpa advised this measure would have included provisions prohibiting a retail establishment from refusing to furnish nonprescription contraception to a person based solely on age and was vetoed by the governor. Dr. Serpa didn't believe the measure required discussion by the Committee.

Members were provided the opportunity to comment. A member asked if there was space for education on current law regarding access to contraception. DCA Counsel would have to research the question and report back.

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

Members of the public were provided the opportunity to comment via WebEx. A pharmacist supported the idea of educating the public on current law in this area.

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

Dr. Serpa noted Senate Bill 966 was vetoed by the governor and would have established the regulation of Pharmacy Benefit Managers within the California Department of Insurance. She noted that as included in meeting materials, the Board has identified payor practices that negatively impact patients as a possible sunset issue and that this will be discussed at the October 2024 Licensing Committee meeting.

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

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

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

Dr. Serpa noted the governor vetoed this measure, which would have required the Board, and other DCA healing arts boards, to develop a process to expedite the licensure process by giving priority review to applications for which the applicant demonstrates that they intend to practice in a medically underserved area or serve a medically underserved population.

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

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

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

Dr. Serpa advised Senate Bill 1089 will require a covered establishment, which includes a pharmacy, to provide 45 days' advance notice of any closure to the Board. She added the Board has a pending regulation to amend California Code of Regulations (CCR), title 16, section 1708.2 related to Discontinuance of Business to require at least 30 days' notice of any closure to the Board. Dr. Serpa believed it was appropriate to update the Board's proposed regulation language to align with the timeframes included in the measure.

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

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

Executive Officer Sodergren advised to update the regulation text to align with the Committee's intent, it would be helpful for staff to work with counsel on the best way to effectuate the change. Members agreed and discussed having strong education on the topic for the regulated public.

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

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

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

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

VII. Discussion and Consideration of FDA Actions Related to Implementation of the Drug Supply Chain Security Act

Chairperson Serpa referenced meeting materials including background information on the Drug Supply Chain Security Act (DSCSA). The Board has received presentations on implementation activities, including a presentation by Josh Bolin with the National Association of Boards of Pharmacy. Dr. Serpa further reminded those present that the DSCSA included milestones for implementation. Most recently, by November 27, 2023, the law required all

prescription drug packages to be serialized with a unique identifier. Dr. Serpa continued that the FDA has released a number of guidance documents on the DSCSA and recently released information that they are issuing exemptions to small dispensers under specified conditions.

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

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

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

VIII. Discussion and Consideration of Enforcement Statistics

Dr. Serpa advised the meeting materials included a summary of enforcement statistics for the first three months of fiscal year 2024/25. The Board has initiated 706 complaints and closed 764 investigations. As of October 1, 2024, the Board has 1,918 field investigations pending. The materials provide a breakdown of the average timeframe for the various stages of the field investigation process.

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

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

IX. Future meeting dates and adjournment

Chairperson Serpa thanked everyone for their time and participation, noting the next meeting was currently scheduled for January 8, 2025.

X. Adjournment

The meeting adjourned at 11:57 a.m.