



LEGISLATION AND REGULATION COMMITTEE MEETING MINUTES

DATE: July 17, 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

COMMITTEE MEMBERS PRESENT: Jessi Crowley, PharmD, Licensee Member, Chair
Nicole Thibeau, PharmD, Licensee Member, Vice Chair
Kartikaya "KK" Jha, Licensee Member
Maria Serpa, PharmD, Licensee Member

**COMMITTEE MEMBERS NOT
PRESENT:** Trevor Chandler, Public Member

STAFF MEMBERS PRESENT: Anne Sodergren, Executive Officer
Julie Ansel, Assistant Executive Officer
Shelley Ganaway, DCA Staff Counsel
Jennifer Robbins, DCA Staff Counsel
Debbie Damoth, Executive Specialist Manager

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

Chairperson Crowley called the meeting to order at 2:05 p.m. Chairperson Crowley reminded all present that the Board is a consumer protection agency charged with administering and enforcing Pharmacy Law. The meeting moderator provided instructions on how to participate during the meeting, including the process to provide public comment.

Chairperson Crowley took roll call. The following members were present: KK Jha, Licensee Member; Maria Serpa, Licensee Member; Nicole Thibeau, Licensee Member; and Jessi Crowley; Licensee Member. A quorum was established.

Dr. Crowley reminded Committee members to remain visible with cameras on throughout the open session of the meeting. Dr. Crowley 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 were provided the opportunity to provide comments on items not on the agenda; however, there were no comments made.

Members of the public via WebEx were provided the opportunity to provide comments on items not on the agenda.

An opioid stewardship pharmacist at UC Davis asked the Board to clarify which California laws prohibit methadone dispensing from inpatient hospital pharmacies to patients under the new DEA 72-hour rule updated in 2022. Business and Professions Code (BPC) section 4126.5 states a pharmacist may furnish dangerous drugs only to a patient or another pharmacy pursuant to a prescription or as otherwise authorized by law. The pharmacist asked the Board to comment if the new DEA exception 21 CFR 1306.07 qualifies as otherwise allowed by law; and if dispensing from a hospital would be permitted under AB 2115 if and when it was passed in the Senate.

A pharmacist requested a status on the Board approved regulation for title 16, California Code of Regulation (CCR) section 1709.1 related to pharmacist-in-charge (PIC) qualifications.

Staff will confer with counsel before giving guidance to the Chair regarding a future agenda item related to methadone. The commenter was advised the subject of methadone was discussed at the April 2024 Legislation and Regulation Committee meeting minutes under SB 1468 about education.

III. Approval of the April 11, 2024, Committee Meeting Minutes

Members were provided the opportunity to provide comments on the draft minutes. Dr. Serpa requested a change to page 14 correcting the statement that Dr. Serpa thought opposed unless amended (OUA) would be better than oppose position.

Motion: Approve the April 11, 2024, Legislation and Regulation Committee meeting minutes with changes requested.

M/S: Serpa/Thibeau

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

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

Board Member	Vote
Chandler	Not Present
Crowley	Support
Jha	Support
Serpa	Support
Thibeau	Support

IV. Discussion and Consideration of Pending Legislation Impacting the Practice of Pharmacy, the Board's Jurisdiction, or Board Operations

Chairperson Crowley advised there were a number of measures included on the agenda. Dr. Crowley added having already passed several legislative deadlines, the legislature was currently on Summer Recess and reconvened August 5, 2024. Dr. Crowley noted a number of the proposals included on the agenda were previously discussed and referenced the meeting materials noting the Board's position. She advised new measures were also included where the Board established a position through the delegated authority of the President. Dr. Crowley added a few measures were no longer included as they did not meet legislative deadlines, including Assembly Bill 3026 and Assembly Bill 3146. Dr. Crowley reminded at the April 2024 Committee meeting, it was determined that the Committee and Board did not need to monitor some measures though staff would continue to monitor (e.g., Assembly Bill 82 related to dietary supplements for Weight Loss and Over the Counter Diet Pills). Dr. Crowley advised related to Assembly Bill 82, the measure continued to move and would be considered by the Senate Appropriations Committee on August 5.

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

a. Assembly Bill 164 (Committee on Budget, 2024) State Government

Dr. Crowley advised AB 164 was a companion measure with Senate Bill 164 as it contained similar provisions. Neither measure was previously considered by the Committee or Board. The measure was included to ensure the Board and the Board's regulated public were aware of a change in the annual CURES fee. Specifically, as Chaptered the CURES fee will increase from \$9 annually to \$15 annually. Given this legislation, as an example, a pharmacist will be assessed a \$30 CURES fee each renewal cycle, beginning with licenses that expire on or after July 1, 2025.

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

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

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

b. Assembly Bill 1842 (Reyes) Health Care Coverage: Medication-Assisted Treatment

Dr. Crowley advised AB 1842 would prohibit a health care service plan or health insurer from requiring prior authorization or step therapy for a naloxone or other opioid antagonist approved by the FDA or a buprenorphine or long-acting injectable naltrexone for detoxification or maintenance treatment of a substance use disorder. The Board established a support position on this measure. At the April 2024 Committee meeting, the Board noted having a long history of supporting measures that facilitate better access to naloxone and other medication assisted treatments. Dr. Crowley believed the Board's current support position remained appropriate and did not recommend changes.

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

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

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

c. Assembly Bill 1902 (Alanis) Prescription Drug Labels: Accessibility

AB 1902 would require pharmacies to provide translated directions for use on prescription labels under specified conditions and further would require a pharmacy to provide a person, at no additional cost, an accessible prescription label that among other conditions, was appropriate to the disability and language of the person making the request through the use of audible, large print, Braille, or translated labels. As amended this measure would not apply if the dispenser was a veterinarian. The Board previously considered this measure and determined a position was not appropriate. As shared during the April 2024 Committee Meeting, the policy goals of the measure were laudable. The measure enjoyed broad support. According to the recent Senate Floor analysis, the measure had no opposition on file. Dr. Crowley recommended the Board continue to monitor this legislation.

Members were provided the opportunity to comment. Members agreed to watch closely as the language was not clear of impact to pharmacies. Members agreed with the intent but expressed concern with logistics of implementation.

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

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

d. Assembly Bill 2115 (Haney) Controlled Substances

Dr. Crowley advised as amended AB 2115 would authorize a nonprofit or fee clinic to dispense a schedule II controlled substance for the purpose of relieving acute withdrawal symptoms while arrangements were being made for referral for treatment. The measure would also make changes to narcotic treatment programs. The measure was recently scheduled for hearing during the Assembly Business and Professions Committee hearing on April 16, 2024.

Dr. Crowley added the Board had a support position on the measure. The measure was amended twice since the Committee's last review in part to clarify the measure and address concerns from other stakeholders engaged in the process. Amendments included a requirement for a clinic,

when applicable, to establish policies and procedures in specified areas as related to clinic dispensing of narcotic drugs consistent with the authorities being established. Dr. Crowley believed the Board's support position remained appropriate and didn't recommend any action.

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

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

Members of the public via WebEx were provided the opportunity to provide comments.

A member of the public asked if the bill could be used by inpatient hospitals dispensing up to a 72-hour supply of methadone to patients who were going to be discharged and starting in a methadone treatment program after discharge.

Members were provided the opportunity to comment; however, no comments were made. Dr. Crowley advise staff would discuss with counsel to address the question.

e. Assembly Bill 2169 (Bauer-Kahan) Prescription Drug Coverage: Dose Adjustments

Dr. Crowley noted AB 2169 would authorize a health care professional to request authority to adjust the dose or frequency of a drug to meet specific medical needs of the enrollee without prior authorization under specified conditions, including that the dose had not been adjusted more than two times without prior authorization. Dr. Crowley reminded the Board had a support position on the measure and added the measure had not been amended since the Committee's last consideration. The measure was scheduled to be considered during the August 5, 2024 Senate Appropriations Committee.

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

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

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

f. Assembly Bill 3063 (McKinnor) Pharmacies: Compounding

Dr. Crowley advised AB 3063 was similar to AB 782 last year. Dr. Crowley reminded the Board 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. Dr. Crowley noted regrettably that did not occur adding the primary difference between the two measures was the AB 3063 included a sunset date, meaning that conflict would only exist until January 1, 2030. Dr. Crowley added as previously discussed, inclusion of the sunset date did not address the Board's concerns. The Board ratified the oppose unless amended position established by President Oh as part of the April 2024 Board Meeting.

Dr. Crowley advised 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; however, regrettably those amendments were not accepted. Dr. Crowley believed a change to an oppose position was appropriate.

Dr. Crowley noted there was published research that demonstrated 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 (1)." Dr. Crowley added such a conclusion reinforces the importance of compliance with the national standards, most notably provisions for establishing beyond-use dates.

Members were provided the opportunity to comment. Members were disappointed to hear the author didn't take minor suggested amendments that would help licensees and encouraged changing the position to oppose.

Motion: Recommend to the Board to change to an oppose position.

M/S: Serpa/Thibeau

Members of the public located in Sacramento or participating via WebEx were provided the opportunity to provide comments; however, no comments were provided.

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

Board Member	Vote
Chandler	Not Present
Crowley	Support
Jha	Support
Serpa	Support
Thibeau	Support

g. Senate Bill 954, (Manjivar, 2024) Sexual Health

Dr. Crowley advised SB 954 had not been previously considered by the Committee or Board as it was identified as a potential measure for consideration after the April 2024 Committee Meeting. She recommended the measure be included on the agenda not because of policy concerns but to ensure the Board and members of the regulated public were aware of pending provisions in the Health and Safety Code that pharmacies may not routinely monitor for changes. Dr. Crowley continued under the provisions of the measure, pharmacies would be prohibited from refusing to furnish nonprescription contraception to a person based solely on age. Dr. Crowley agreed with the policy of the measure and didn't believe the Board needed to engage in the legislation. Dr. Crowley believed it would be appropriate to include this measure in any educational materials released related to changes in pharmacy law.

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

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

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

h. Senate Bill 966 (Wiener) Pharmacy Benefits

Dr. Crowley advised as amended, Senate Bill 966 would establish the regulation of Pharmacy Benefits Managers (PBM) within the Department of Insurance. She recalled the initial version of the measure would have placed the regulation of BPMs within the Board's purview. The measure was most recently amended July 3, 2024 and was referred to the Assembly Appropriations Committee. Dr. Crowley added the Board had a support position on the measure. She believed the Board's current support position remained appropriate.

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

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

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

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

Dr. Crowley advised SB 1067 would require the Board to develop a process to expedite the licensure process for an applicant that demonstrated they intend to practice in a medically underserved area or serve a medically underserved population. When previously considering this measure, the Board did not establish a position. As policy in California continues to seek to expedite certain types of applications, other applicants experience delays based to the priority that must be placed on certain applications. Dr. Crowley still believed the Board didn't need to establish a position on the measure. The measure had been amended since we previously considered it. As amended, the measure includes a sunset date of January 1, 2029.

Members were provided the opportunity to comment. Members discussed concerns related to a definition of "underserved" and issues related to backlogs and delays for other applicants.

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

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

j. Senate Bill 1089 (Smallwood-Cuevas) Addressing Food Injustice: Notice of Grocery and Pharmacy Closures

Dr. Crowley advised the Committee and Board did not previously discuss this measure as it was not identified in advance of notice requirements. 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. Dr. Crowley reported 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. Dr. Crowley noted that the amendment sought was consistent with the Board's policy in this area where the Board was seeking amendment to regulations to require such notification. Dr. Crowley 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. Dr. Crowley believed given the change, it was appropriate to change the Board's position to support.

Members were provided the opportunity to comment. Counsel provided clarification the measure was related to permanent closure.

Motion: Recommend changing the Board's position to support.

M/S: Thibeau/Serpa

Members of the public located in Sacramento or participating via WebEx were provided the opportunity to provide comments; however, no comments were provided.

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

Board Member	Vote
Chandler	Not Present
Crowley	Support
Jha	Support
Serpa	Support
Thibeau	Support

k. Senate Bill 1365 (Glazer) Pharmacy Technicians

Dr. Crowley reported as originally introduced SB 1365 would update the pharmacist to pharmacy technician ratio to 1:6, from the current ratio in

place of 1:1 or 1:2. The measure was amended April 24, 2024 to update the pharmacist to pharmacy technician ratio to 1:4 from the current ratio in place. Dr. Crowley recalled during the April 2024 Committee Meeting and April 2024 Board Meeting, members expressed concern with the measure and after considerable discussion determined it appropriate to establish an oppose position on the measure. Dr. Crowley advised the measure was held in the Senate Appropriations Committee on the suspense file and would not be moving forward. Dr. Crowley determined it was appropriate to include this measure on the agenda to ensure all interested parties were aware of the outcome. Dr. Crowley advised no action was required.

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

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

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

l. Senate Bill 1468 (Ochoa Bogh and Roth) Department of Consumer Affairs

Dr. Crowley advised SB 1468 would allow a practitioner who was not specifically registered to conduct a narcotic treatment program to dispense not more than a 3-day supply of narcotic drugs under specified conditions. Similar to the AB 2115, the Board established a support position on this measure. The measure was amended since the Board previously considered the measure to include a provision that states that the provisions do not apply the Veterinary Medical Board.

c. The Committee heard comments from a member of the public noting the measure didn't provide guidance if it was permissible for an inpatient hospital pharmacy to provide methadone under the three-day rule. A pharmacist commented providing his personal account of experience working on the measure.

m. House Resolution 58 (Jackson) Reliable and Safe Access to Care

Dr. Crowley recalled both Committees and the Board have received a number of public comments requesting that the Board take action to address the issue of drug shortages. Dr. Crowley believed generally speaking drug shortages were outside of the scope of the Board's purview. She requested House Resolution 58 be included on the agenda

to ensure the Board and interested parties were aware of the House resolution that made a number of legislative finding related to access to ADHD medication and that the state Assembly urged the California Health and Human Services Agency to hold pharmaceutical companies and others accountable for actions to address the current ADHD medication shortages and to meet with the US Department of Health and Human Services and DEA regarding modifications of any insufficiently justified quotas.

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

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

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

V. Discussion and Consideration of Board Regulations

Chairperson Crowley advised all items included in the regulations portion of the report were for information only. The Board had several regulations in various stages of promulgation. Dr. Crowley reported the Board had two regulations undergoing post-adoption review by the Office of Administrative Law including the Board's continuing education regulations and Board's section 100 updates to the Board's fee schedule that includes all fees except fees related to pharmacy technicians. The regulations related to pharmacy technicians were undergoing pre-notice review along with several other proposed rulemakings. Dr. Crowley noted the compounding regulations comment period recently closed and would be discussed during the Board meeting.

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

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

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

VI. Discussion and Consideration of Committee's Strategic Goals

Dr. Crowley reported the Legislation and Regulation Committee had six strategic

objectives and referenced meeting materials included updates to the respective objectives over the past year. She noted the updates highlighted the work of the Board in its policy making efforts to protect California consumers. Dr. Crowley added there was one objective for which there were no status updates included, which was for strategic goal 3.1 related to advocating for provider status. While there were no specific updates to provider status, she noted the passage of AB 317 provides for reimbursements under specified conditions, which was related to the policy goal of provider status. Dr. Crowley believed the objectives remained appropriate and didn't believe any changes were appropriate.

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

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

Members of the public participating via WebEx were provided the opportunity to provide comments. A pharmacist requested clarification on the first strategic goal regarding provider status and was reminded of the Board's jurisdiction was within California.

VII. Future Committee Meeting Dates

Chairperson Crowley advised the next Committee meeting date was scheduled for April 10, 2025 and encouraged participants to watch the Board's website for updates.

VIII. Adjournment

Chairperson Crowley adjourned the meeting at 3:02 p.m.