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



LEGISLATION AND REGULATION COMMITTEE MEETING MINUTES

- DATE: July 18, 2022
- LOCATION: Pursuant to the provisions of Government Code section 11133, neither a public location nor teleconference locations are provided.
- COMMITTEE MEMBERS PRESENT: Jessi Crowley Licensee Member Chair Jose De La Paz, Public Member Vice Chair Seung Oh, Licensee Member Maria Serpa, Licensee Member Nicole Thibeau, Licensee Member
- STAFF MEMBERS PRESENT:Anne Sodergren, Executive Officer
Eileen Smiley, DCA Staff Counsel
Lori Martinez, Senior Admin and Policy Manager
Debbie Damoth, Executive Manager Specialist

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

Chairperson Crowley called the meeting to order at 1:02 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. Members present included: Seung Oh, Licensee Member; Maria Serpa, Licensee Member; Nicole Thibeau, Licensee Member; and Jessi Crowley; 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 comments for items not on the agenda.

Members heard comments from a pharmacist requesting the Board to support a

Legislation and Regulation Committee Minutes – July 18, 2022 Page 1 of 14 bill to modify Business and Professions Code (BPC) section 4111 to allow for pharmacist owners to participate in collaborative practices due to a conflict because of the passage of AB 1533.

Members were surveyed to add agenda items to future agendas; no members provided future agenda items.

III. Approval of April 26, 2022, Committee Meeting Minutes

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

- **Motion:** Approve the April 26, 2022, Legislation and Regulation Committee meeting minutes as presented.
- M/S: Oh/Serpa

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

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

Board Member	Vote
Crowley	Yes
De La Paz	Not Present
Oh	Yes
Serpa	Yes
Thibeau	Yes

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

Chairperson Crowley advised as legislation is very dynamic and there had been changes to some measures since the release of the meeting materials where changes have been identified, changes would be highlighted. Dr. Crowley noted recommendations voted on would be considered by the Board on at the July 2022 Board Meeting. Dr. Crowley noted there were other measures previously considered by the Committee and Board that were not moving and not included for discussion. These measures included:

• Assembly Bill 2055 which would have transitioned the CURES operations to the Board.

- Assembly Bill 2265 which would have required opioids to be dispensed in lockable vials.
- Assembly Bill 2948 which would have required the Board to advise a complainant of the outcome of an investigation within 60 days of closure.
- Senate Bill 958 which was the Medication and Patient Safety Act of 2022, related to brown bagging and white bagging.
- Senate Bill 1031 which would have reduced the renewal fee for an inactive license.
- Senate Bill 1379 which was the Board's remote processing proposal.

1. <u>Assembly Bill 852 (Wood) Health Care Practitioners: Electronic Prescriptions: Nurse</u> <u>Practitioner Scope of Practice: Practice without Standardized Procedures</u>

Chairperson Crowley advised AB 852 has not previously been considered by the Committee or Board as it initially related solely to nurse practitioners. As amended this measure would make changes to the e-prescribing requirements. As included in the meeting materials, some of the provisions included in the measure are Board-sponsored. The measure would require the Board to maintain a list of health care practitioners that are exempt from the requirements. Dr. Crowley noted it appeared staff believe this could be facilitated through an online registry which would not involve significant resources. Dr. Crowley noted agreement with staff's recommendation to establish a support position.

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

Motion: Support

M/S: Serpa/Oh

Members of the public were provided the opportunity to provide comments. Members heard comments from a pharmacist and a Kaiser representative concerned with the lead time provided and requesting modification to similar federal rulings.

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

Board Member	Vote		
Crowley	Yes		
De La Paz	Not Present		
Oh	Yes		
Serpa	Yes		
Thibeau	Yes		

2. Assembly Bill 1328 (Irwin) Clinical Laboratory Technology and Pharmacists

Chairperson Crowley provided his measure would amend several provisions of the BPC to expand the authority for pharmacists to perform CLIA-waived tests either approved or authorized by the FDA upon patient request or hospital authorization provided that there is a valid and respective CLIA certificate of waiver and laboratory license, with some exceptions. The measure would amend Pharmacy Law to declare that pharmacy practice is a patient and public health-oriented health service that is continually evolving to include more sophisticated and comprehensive patient care and public health activities. Dr. Crowley noted there have been no changes to the measure, and it appears there are no updates available on its status. The Board previously established a support position. Dr. Crowley spoke in agreement with the Board's current support position.

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

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

3. <u>Assembly Bill 1662 (Gipson) Licensing Boards: Disqualification from Licensure:</u> <u>Criminal Conviction</u>

Chairperson Crowley advised AB 1662 would allow a prospective applicant to request a preapplication determination based on information provided by the prospective applicant regarding their criminal conviction. It would also require the Board to determine if the prospective applicant could be disqualified from licensure based upon the information submitted with the request.

Chairperson Crowley noted the measure was amended April 27 and would establish authority for the Board to assess a fee of not more that \$50 to perform the workload required. The Board would be required to provide a summary of the criteria used by the Board, the process for an applicant to request a copy of their conviction history, and notification of the right to appeal the Board's decision. Chairperson Crowley provided the Board initially sought a Support, if amended position as the policy goal of the measure appear to align with the Board's policy in this area. Board staff indicated that the Board would need to promulgate regulations should this measure be enacted. Dr. Crowley advised the measure was scheduled to be heard in Senate Appropriations on August 1, 2022. Dr. Crowley agreed with staff's recommendation to maintain and Support, if amended, position and request that the author's office consider the Board's prior amendments including that the outcome of a preapplication determination is a point in time outcome.

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

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

4. Assembly Bill 1733 (Quirk) State Bodies: Open Meetings

Chairperson Crowley advised AB 1733 would expand authority for the Board to convene meetings held entirely by teleconference under specified conditions which are detailed in the report. Dr. Crowley noted regrettably the hearing on this measure was postponed by the Committee. The Board established a Support, if amended position during the April Board Meeting.

Chairperson Crowley noted the data provided in the meeting materials demonstrates that remote meetings expand access to participation in meetings, including by individuals who may not otherwise be available to participate because of health, cost, or other barriers. This transition back to in person meetings indicated that members of the public largely prefer to continue to participate via WebEx.

Chairperson Crowley advised the Board was able to resume full teleconference meetings for an additional year because of temporary changes to the Government Code. Dr. Crowley noted as these changes are temporary, she believed it was appropriate to continue to support efforts to make the changes permanent. Dr. Crowley suggested the Board consider having a discussion at a later meeting on how to return to awarding CE credits to individuals participating remotely. Member De La Paz arrived at 1:26 p.m.

Members were provided the opportunity to provide comment. Members spoke in support and agreed in finding a way to allow for continuing education and agreed the measure supports equity and accessibility.

Members of the public were provided the opportunity to provide comment. Members heard comments from a pharmacist and CCAP representative supporting participation for all Californians and encouraged Board Members being required to participate in person as well as allowing for public participation for quality of input, relationships, and trust.

5. <u>Assembly Bill 2194 (Ward) Pharmacists and Technicians; Continuing Education:</u> <u>Cultural Competency</u>

Chairperson Crowley provided AB 2194 would require that at least one of the 30 hours of required continuing education (CE) for pharmacists include participation in a cultural competency course, as defined. The bill would also prohibit the Board from renewing a pharmacist or pharmacy technician license unless the applicant submits proof to the Board of completion of at least one hour of participation in a cultural competency course. Dr. Crowley noted the intent of the bill was to help ensure that pharmacies through the pharmacists and pharmacy technicians are providing culturally competent care to members of the LGBTQ+ community. Dr. Crowley advised the bill is co-sponsored by the California Pharmacists Association (CPhA) and Equality California.

Chairperson Crowley noted at the April meeting, the Board established a Support, if amended position, requesting a delayed implementation to allow licensees time to complete the required coursework and to confirm that an audit-based approach for compliance would be consistent with the provisions. Dr. Crowley stated her understanding that the author's office has confirmed that an audit-based approach for compliance is appropriate and will be amending the measure to delay implementation.

Chairperson Crowley stated support for the measure as it is an important first step in opening doors for education in this area, but wish it was a bit more inclusive of other marginalized communities. Dr. Crowley noted with such a diverse population California pharmacists may differ in the cultural competency training that would best help them serve their specific patients. For example, a pharmacist with multiple deaf or hard of hearing patients would potentially benefit from a CE on serving patients with disabilities, health literacy, or utilization of ASL interpreters in pharmacies. Dr. Crowley noted other marginalized communities that need better care include, but are not limited to, undocumented residents, patients who speak English as a second language, patients with poor literacy, and residents with poor social determinants of health. Dr. Crowley stated the measure highlights an important issue for the Board and agreed with the staff recommendation to maintain a Support, if amended position and monitor for amendments to be incorporated. Dr. Crowley noted it appeared appropriate to schedule discussion on how the Board can promote education on other marginalized communities and perhaps development of a policy statement in the area.

Members were provided the opportunity to provide comment. Members spoke in support as well as expanding to additional marginalized groups and intersectionality. Members were in support of having the Communication and Public Education Committee develop a policy statement.

Ms. Sodergren noted as a potential agenda item for the Communication and Public Education Committee to review and see if the development of a policy statement. Ms. Sodergren noted at the October Enforcement and Compounding Committee Meeting implementation of recently enacted legislation is discussed or a policy statement could be developed if the measure is not passed.

Members of the public were provided the opportunity to provide comment. Members heard comments from a UFCW Western States Council representative and a member of the public agreeing with members that it is a good first step that needs to be expanded to additional marginalized communities and intersectionality.

6. <u>Senate Bill 731 (Durazo) Criminal Records: Relief</u>

Chairperson Crowley reported the measure was recently amended and would expand automatic relief to include arrests for felonies punishable by state prison as well as expand automatic conviction relief to certain felonies under specified conditions. Dr. Crowley noted that serious and violent felonies, and felonies requiring sex registration are excluded. Dr. Crowley reported the Board previously established an Oppose, unless amended, position. Chairperson Crowley stated while the intention is appreciated and the measure may be seeking to remedy some injustices and racial disparities, specifically regarding a disproportionate number or arrests among Black and Latino Californians, Dr. Crowley struggled with the implementation approach. Dr. Crowley noted the measure takes away discretion for the Board to make a decision consistent with the Board's mandate. Dr. Crowley stated there may be some felony drug offenses for example that the Board should be able to consider as part of its licensing decision. Dr. Crowley continued and provided an example that there is a spectrum on drug related offenses and believed the Board should have the discretion to make a decision on the appropriate outcome for an individual with previous felonies, which may differ for an individual with marijuana convictions versus an individual that manufactured methamphetamine that is now seeking licensure. For reasons stated, Dr. Crowley stated support for the Board's current Oppose, unless amended position.

Members were provided the opportunity to provide comment. Member De La Paz shared the concern of Dr. Crowley and spoke in support of Oppose, unless amended position.

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

7. Senate Bill 872 (Dodd) Pharmacies: Mobile Units

Chairperson Crowley advised Senate Bill 872 was amended on June 15 noting the policy goal remains the same to provide for the use of mobile units to bring pharmacy services to Californian's that may not otherwise have access and added the approach offered was now different. Dr. Crowley continued rather than licensure, the approach now was to allow for the use of the mobile unit as an extension of the pharmacy. Dr. Crowley added the provisions continue to be limited to city or county to operate a mobile unit to provide prescription medications within its jurisdiction to individuals without a fixed address, individuals living in county-owned or city-and-county-owned housing facilities, and individuals enrolled in Medi-Cal plans operated by the local jurisdiction or health department.

Chairperson Crowley continued with the amendments, she believed the Board's previous issues surrounding the operational requirements were addressed as all relevant provisions of pharmacy law would be required. Dr. Crowley noted should the measure be enacted, it may be helpful for the Board to issue FAQs or

other education materials detailing out how some of the provisions of pharmacy law are applicable to the use of the mobile unit. Dr. Crowley believed discussion on implementation of legislation usually occurs under the Enforcement and Compounding Committee. Dr. Crowley requested the Enforcement and Compounding Committee consider development of educational materials in its discussion later this fall if the measure is enacted.

Chairperson Crowley stated support for the measure and its capacity to expand access to communities. Dr. Crowley agreed with staff's recommendation to change the Board's position to support.

Members were provided the opportunity to comment. Member Serpa recommended FAQ be sent to the Communication and Public Education Committee. Member Thibeau spoke in support and noted it was a good first step but may not go far enough.

Motion: Support

M/S: Thibeau/De La Paz

Serpa

Thibeau

Members of the public were provided the opportunity to comment. A pharmacist spoke in support and suggested the issue should stay with the Enforcement and Compounding Committee.

Support:	5	Oppose: (0	Abstain: 0	I	Not Present:	0
	Γ	Board Member		Vote			
		Crowley	Yes				
		De La Paz	Yes				
		Oh	Yes				

Yes

Yes

8. <u>Assembly Bill 988 (Hueso): Compassionate Access to Medical Cannabis Act or</u> <u>Ryan's Law</u>

Chairperson Crowley advised Senate Bill 988 was also amended since the Board's last discussion. Dr. Crowley reported last year Senate Bill 988 established provisions for a terminally ill patient within a hospital to access their medicinal cannabis. Late amendments to the measure created conflicts with several provisions of state and federal law. Dr. Crowley advised the amendments appear consistent with the language of the letter published in the Senate Journal, wherein the author's office conveyed the intentions of the measure. Dr. Crowley noted although the approach now offered in the measure is different from the prior version, Dr. Crowley believed the measure still remedies the conflicts created in last year's legislation and agreed with staff's recommendation that the Board's current position remains appropriate.

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

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

9. <u>Senate Bill 1237 (Newman) Licenses: Military Services</u>

Chairperson Crowley advised Senate Bill 1237 would expand the provisions for a fee waiver for a member of the military "called to active duty," and the term active duty would have the same meaning as "active duty" as defined in federal law. Dr. Crowley noted the measure will be considered by the Assembly Appropriations Committee on August 3 and the Board established a support position in April that Dr. Crowley believed was still appropriate.

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

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

10. Senate Bill 1259 (Laird) Pharmacists: Furnishing Opioid Antagonists

Chairperson Crowley stated Senate Bill 1259 had not previously been considered by the Board as it originally related to retail installment contracts. However, as amended this measure would expand authority for pharmacists, and allow pharmacists to furnish any opioid antagonist approved by the FDA under specified conditions. Dr. Crowley noted if enacted, the Board will need to promulgate regulations in coordination with other specified agencies including the Medical Board, California Society of Addiction Medicine, and the California Pharmacists Association. Dr. Crowley added given the Board's long history of supporting access to live saving medications including naloxone, Dr. Crowley agreed with staff recommendation to establish a support position.

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

Motion: Support

M/S: Thibeau/Serpa

Members of the public were provided the opportunity to comment. Members heard comments from a representative from UCSF Western States Council stated they do not have a position since the bill was amended and recommended labor unions be added for consultation to get members feedback for the implementation process.

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

Board Member	Vote		
Crowley	Yes		
De La Paz	Yes		
Oh	Yes		
Serpa	Yes		
Thibeau	Yes		

11. <u>Senate Bill 1346 (Becker) Surplus Medication Collection and Distribution</u>

Chairperson Crowley advised Senate Bill 1346 would expand provisions for redistribution of unused donated medications and noted the measure had been amended since the last discussion after which the Board established an Oppose, unless amended position. Dr. Crowley noted amendments expand the entities authorized to donate medications to redistribution programs and limit expansion of specified provisions for redistribution programs to specified counties and place a sunset date on the county programs. Dr. Crowley noted that the Board will be required to submit a legislative report.

Chairperson Crowley shared all the patient safety concerns previously raised by the Board as well as the broad civil and criminal immunity provisions. Dr. Crowley agreed with staff's recommendation to maintain an Oppose unless amended position as the Board's requested amendments are not yet incorporated into the measure.

Chairperson Crowley noted should the measure pass, Dr. Crowley suggested that staff, as part of its evaluation and assessment of these programs, pay special attention to IV and infused medication if they are allowed to be redistributed under a county program. Dr. Crowley suggested that if the measure is passed, that the Board receive annual updates on the program and any issues that arrive. Members were provided the opportunity to comment. Ms. Sodergren clarified a motion was not need if the Committee was maintaining the current Oppose unless amended position.

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

V. <u>Board Adopted Regulations Under Final Review by the Office of the Administrative</u> Law

- 1. Proposed Regulation to Amend Title 16, CCR Section 1715.65 Related to Inventory Reconciliation
- 2. Proposed Regulation to Amend Title 16, CCR Section 1708.1 Related to the Temporary Closure of Facilities

VI. <u>Discussion and Consideration of Board Adopted Regulations Undergoing Final</u> <u>Review by the Department of Consumer Affairs or Business, Consumer Services and</u> <u>Housing Agency</u>

- 1. Proposed Regulations to Amend Title 16, CCR Section 1715 to Update Self-Assessment Forms 17M-13 and 17M-14
- 2. Proposed Regulation to Amend Title 16, CCR Section 1784 to Update the Wholesale/3PL Self-Assessment Form 17M-26
- 3. Proposed Regulations to Amend Title 16, CCR Section 1793.5 Related to Pharmacy Technician Application, Section 1793.6 Related to the Pharmacy Technician Training Requirements, and Section 1793.65 Related to the Pharmacy Technician Certification Programs

VII. <u>Discussion and Consideration of Board Approved Regulations Undergoing Pre-</u> <u>Notice Review by the Department of Consumer Affairs or Business, Consumer</u> <u>Services and Housing Agency</u>

- 1. Proposed Regulation to Amend Title 16 CCR Section 1707.6 Related to the Notice to Consumers
- 2. Proposed Regulation to Amend Title 16, CCR Section 1709.1, Related to the Designation of Pharmacist-in-Charge
- 3. Proposed Regulation to Amend Title 16, CCR Section 1715.1 Related to the ADDS Self-Assessment Form 17M-112
- 4. Proposed Regulation to Amend Title 16, CCR Section 1760 Related to the Disciplinary Guidelines

Chairperson Crowley advised the regulation items were for information only. Dr. Crowley noted as detailed in the meeting materials, the Board has several regulations in various stages of promulgation. Dr. Crowley noted that the Board has two regulations undergoing final review by the Office of Administrative Law, including one related to Temporary Closures. The Board had three undergoing final review by DCA or Business, Consumer Services and Housing Agency. Dr. Crowley noted it appeared that the regulation related to Pharmacy Technicians will need to be considered by the Board during the Board Meeting.

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

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

VIII. Discussion and Consideration of Committee's Strategic Plan Goals

Chairperson Crowley advised the Board's strategic plan includes six strategic objectives for our committee. The meeting materials detail both the objectives and status if action has been undertaken. Dr. Crowley stated belief that all the strategic objectives are still appropriate and appreciated members comments.

- 3.1 Consider, and advocate for necessary changes, regarding recognition for provider status for pharmacists to improve patient access.
- 3.2 Review, and update if necessary, existing regulations and statutes, to keep pharmacy law and its regulations current and inclusive for all. Status: As part of promulgation process, Board transition to gender neutral language, including changes in the Board's Disciplinary Guidelines and various self-assessment regulations.
- 3.3 Evaluate, and if appropriate, advocate, regarding barriers to patient care driven by outside entities, e.g. pharmacy benefit manager practices and drug manufacturers, to remove barriers to prescription and (specialty) medications.

Status: Board establishes a support position on Senate Bill 958, Medication and Patient Safety Act of 2022.

- 3.4 Identify opportunities to leverage pharmacist knowledge, skills, abilities, and accessibility to create appropriate access points to care to improve health outcomes for the public.
- 3.5 Support legislation that increases scope of practice for pharmacists and pharmacy technicians to increase access and improve health outcomes for the public.

Status: Board supports Assembly Bill 1328, Clinical Laboratory Technology

and Pharmacists.

3.6 Promote legislation that ensures pharmacists are adequately provided with qualified resources to promote working conditions that minimize errors and improve health outcomes for the public. Status: The Board established a support position on Senate Bill 362, Chain Community Pharmacies: Quotas, and following enactment releases information for pharmacy personnel on how to file a complaint with the Board.

Members were provided the opportunity to comment. Member De La Paz stated the goals are still relevant and recommended no changes.

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

IX. <u>Future Committee Meeting Dates</u>

Chairperson Crowley advised the next Committee meeting date was April 26, 2023.

X. <u>Adjournment</u>

Chairperson Crowley adjourned the meeting at 2:02 p.m.