Attachment XII

a. November 1-2, 2023 Board Meeting Draft Minutes



California State Board of Pharmacy 2720 Gateway Oaks Drive, Suite 100 Sacramento, CA 95833 Phone: (916) 518-3100 Fax: (916) 574-8618 www.pharmacy.ca.gov



California State Board of Pharmacy Department of Consumer Affairs DRAFT Public Board Meeting Minutes

Date: November 1-2, 2023

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

Board of Pharmacy staff members were present at the observation and public comment location.

PUBLIC PARTICIPATION AND COMMENT FROM A REMOTE LOCATION: WebEx

Board Members

Present:Seung Oh, PharmD, Licensee Member, President
Jessica Crowley, PharmD, Licensee Member, Vice President
Renee Barker, PharmD, Licensee Member
Indira Cameron-Banks, Public Member
Jose De La Paz, Public Member (joined on 11/1/23 at 2:59pm)
Kartikeya "KK" Jha, Licensee Member
Jignesh Patel, Licensee Member (11/2/23 only)
Maria Serpa, PharmD, Licensee Member
Nicole Thibeau, PharmD, Licensee Member
Jason Weisz, Public Member

Board Members Not Present: Trevor C

- **Not Present:** Trevor Chandler, Public Member, Treasurer
- Staff Present: Anne Sodergren, Executive Officer Julie Ansel, Assistant Executive Officer Corinne Gartner, DCA Counsel Rebecca Bon, DCA Counsel Debbie Damoth, Executive Specialist Manager

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November 1, 2023

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

President Oh called the Board meeting to order at approximately 1:02 p.m. President Oh reminded all individuals present that the Board is a consumer protection agency charged with administering and enforcing Pharmacy Law. Where protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount.

President Oh advised all individuals the meeting was being conducted via WebEx and in person. Dr. Oh advised that participants watching the webcast could only observe the meeting. Dr. Oh noted anyone interested in participating in the meeting must join the WebEx using the instructions posted on the Board's website. Department of Consumer Affairs' staff provided general instructions for participating in the meeting via WebEx or phone.

Roll call was taken. The following members were present via WebEx: Jessi Crowley, Licensee Member; Renee Barker, Licensee Member; Indira Cameron-Banks, Public Member; KK Jha, Licensee Member; Maria Serpa, Licensee Member; Nicole Thibeau, Licensee Member; Jason Weisz, Public Member; and Seung Oh, 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 with an opportunity to provide comment for items not on the agenda or agenda items for a future meeting.

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

Public comment was received via WebEx.

The Board heard several comments from specialty pharmacists thanking the Board for taking all comments regarding remote processing by specialty pharmacists into consideration. Comments noted that the proposed amendments to Business and Professions Code (BPC) section 4071.1 were clear, thorough, and inclusive.

A member of the public requested that the Board call an emergency meeting to discuss product contamination in COVID-19 vaccinations.

A retired pharmacist requested the Board review the retired pharmacist licensure status and proposed an interim period of suspended license status like Nevada with five years to allow the pharmacist to return to active status or a stepdown license category. A member of the public commented to advocate for those injured by the COVID-19 vaccines and suggested a committee be formed to review and investigate the error reports.

The executive director of the California Orthopedic Association wanted to make the Board aware that patients were having a difficult time gaining access to narcotic medication for post-surgical pain management. The commenter noted typically this was experienced in December when pharmacies were reaching their maximum allocation but this year was more severe and starting earlier. The commenter cited complaints in the Santa Cruz and Riverside areas in California and added physicians in the community needed recommendations from the Board for how to handle this shortage of common narcotic pain medications for post-surgical patients.

Members were provided an opportunity to comment.

Member Serpa requested to add an item to a future agenda to learn about the wholesale process to determine the ordering levels by pharmacists. Dr. Serpa expressed concern about limits and access. President Oh agreed, wanted to narrow down the topic, and inquired how to handle the issue. Dr. Serpa suggested adding a fact-finding agenda item with Enforcement and Compounding Committee. Member Thibeau was experiencing this issue beyond narcotics and including the transgender community (e.g., testosterone, etc.), noting the issue has worsened over the past year. Dr. Oh asked to add another issue of drug shortages. Member Jha wanted to hear what set of timelines manufactures had to increase the quotas for limitations of controlled substances for the pharmacy as it didn't seem to be set.

Members Oh, Thibeau, and Crowley thought the in-between licensure category for pharmacists nearing retirement who would like to pause their license for a period of time would be an appropriate item for the Licensing Committee.

President Oh indicated he would work with the executive officer on the suggested agenda items.

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

President Oh reminded members that several years ago, the Board changed its recognition program for pharmacists and currently recognizes pharmacists that have been licensed for 40 or more years. Dr. Oh noted that the information was posted on the Board's website and pharmacists were provided with a certificate.

President Oh noted that prior to transitioning to remote meetings, the Board routinely provided an opportunity for pharmacists licensed for 40 years to attend a Board meeting and be recognized by the Board. Dr. Oh continued that although the Board has returned to remote meetings, the Board would still like to provide an opportunity for pharmacists that have been licensed in California for 40 years to receive recognition.

California State Board of Pharmacy DRAFT Board Meeting Minutes – November 1-2, 2023 Page 3 of 42 Pharmacist Vicky Ferraresi was recognized as having served as a licensed pharmacist for over 40 years. Dr. Ferraresi was the first pharmacist to be recognized as having served as a licensed pharmacist for over 40 years via WebEx.

President Oh thanked and congratulated Dr. Ferraresi and all pharmacists who have been licensed for over 40-years, and thanked all staff who work in pharmacy serving the consumers of California.

IV. Approval of Board Meeting Minutes

a. August 30, 2023 Board Meeting

President Oh referenced the draft minutes from the August 30, 2023 Board meeting.

Members were provided with an opportunity to comment.

- **Motion:** Approve the August 30, 2023 Board meeting minutes as presented in the meeting materials.
- M/S: Crowley/Thibeau

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

Support: 8 Oppose: 0 Abstain: 0 Not Present: 3

Board Member	Vote
Barker	Support
Cameron-Banks	Support
Chandler	Not Present
Crowley	Support
De La Paz	Not Present
Jha	Support
Oh	Support
Patel	Not Present
Serpa	Support
Thibeau	Support
Weisz	Support

b. September 12, 2023 Board Meeting

President Oh referenced the draft minutes from the September 12, 2023 Board meeting.

California State Board of Pharmacy DRAFT Board Meeting Minutes – November 1-2, 2023 Page 4 of 42 Members were provided with an opportunity to comment.

- Motion: Approve the September 12, 2023 Board meeting minutes as presented in the meeting materials.
- M/S: Thibeau/Crowley

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

Board Member	Vote
Barker	Support
Cameron-Banks	Support
Chandler	Not Present
Crowley	Support
De La Paz	Not Present
Jha	Support
Oh	Support
Patel	Not Present
Serpa	Support
Thibeau	Support
Weisz	Support

Support: 8 Oppose: 0 Abstain: 0 Not Present: 3

V. Presentation on "Pharmacist Sexual & Reproductive Health Services in California: Recent Research Findings"

President Oh recalled the Board received a presentation on research underway on pharmacist-furnished HIV prevention and reproductive health services in California at the October 2022 Board meeting. Dr. Oh welcomed Betty Dong, Loriann DeMartini, and Sally Rafie to present the findings from this very important research.

Dr. DeMartini introduced the presenters as Dr. Betty Dong and Dr. Sally Rafie. Dr. DeMartini reviewed the study participants.

Dr. Betty Dong reviewed the pharmacists' authorities to provide HIV PrEP and PEP provided by SB 159. Dr. Dong reviewed the survey results for the PrEP and PEP provisions, attitudes, barriers to PrEP and PEP provisions, conclusions of the study, recommendations to increase SB 159 implementation and steps for implementation.

Dr. Sally Rafie reviewed the history of available pharmacist authorities to provide contraception and barriers for providing hormonal contraception. Dr. Rafie reviewed

the pharmacists' attitudes and understanding of providing access to hormonal birth control, including emergency contraception as well as steps for implementation.

Dr. Sally Rafie reviewed the history and authorities for pharmacists being involved in medication abortion as well as pharmacists' attitudes and understandings of their ability to prescribe abortion medication. Dr. Rafie reviewed the steps for implementation and recommendations.

Members were provided the opportunity to comment on the presentation.

President Oh commented it was a very important topic and noted two issues that stood out to him: pharmacists don't feel they have time and payment parity.

Member Crowley agreed the presentation was consistent with what she had heard in terms of reimbursement and barriers to providing these services. Dr. Crowley inquired with regard to medication abortion if the presenters had heard of an increase in pharmacies providing the medication now that there was a REMS allowance this year. Dr. Rafie responded prior to the REMS change, it was prohibited and with the COVID-19 pandemic there was an emergency allowance where mail order pharmacies could dispense the drug to assist the clinics. With the change to telehealth, pharmacists were now becoming certified and dispensing it.

Member Thibeau indicated PEP and PrEP was a huge issue in the LGBTQ community and was glad to hear it was being taken on. Dr. Thibeau provided SB 339 was extended to a 2-year bill with significant changes at the request of drug manufacturers and asked if there were any barriers being presented by the drug manufacturers. Dr. De Martini advised the amendments came in late and the author pulled it as it would undo the work of SB 159 and were hoping there would be some movement to address some of the significant concerns.

Members of the public were then provided the opportunity to comment on this agenda item in Sacramento; however, no comments were made.

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

A representative of CPhA commented highlighting the differences in the community and independent pharmacy settings similar to the Board's workplace survey. CPhA was looking forward to working on the mifepristone project and that SB 339 would be a priority in the upcoming year.

A pharmacist commented to offer assistance to the health care professionals who did the study. The commenter noted SB 493 deliberately used the word furnished instead of prescribed whereas the presentation used the words interchangeably. The commenter noted the differences in the definition. A pharmacist representative of Kaiser encouraged the Board to clean up the definition of prescription in BPC sections 4040 and 4052 that specifies the conditions under which the prescription issued by a pharmacist is a valid prescription. The representative noted this could be a barrier.

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

Dr. De Martini commented hoping to help increase access to care. Dr. Rafie commented it had been seven years since drafting the hormonal contraception protocol and it was time to update it.

The Board took a break from 2:28 p.m. to 2:35 p.m. Roll call was taken. The following members were present via WebEx: Jessi Crowley, Licensee Member; Renee Barker, Licensee Member; KK Jha, Licensee Member; Maria Serpa, Licensee Member; Nicole Thibeau, Licensee Member; Jason Weisz, Public Member; and Seung Oh, Licensee Member. A quorum was established.

Member Cameron-Banks arrived after roll call was taken.

VI. Enforcement and Compounding Committee Report

Chairperson Serpa provided the Board a summary of the Committee's efforts at the July 18, 2023 and October 19, 2023 meetings. Dr. Serpa thanked fellow Committee Members Vice-Chair Renee Barker, Indira Cameron-Banks, Seung Oh, and Jignesh Patel.

a. Presentation on the Disciplinary Case Process by the Office of the Attorney General

Chairperson Serpa reported as part of the actions undertaken by the Board to meet its consumer protection mandate, the Board may refer a completed investigation to the Office of the Attorney General in instances where the investigation identifies egregious violations that warrant removal or restriction of the license. A review of the annual statistics revealed that the Board referred 259 matters to the Attorney General last fiscal year, which was about eight percent of all closed investigations. The data also revealed that 218 disciplinary matters were closed with outcomes including 59 revocations, 74 licenses placed on probation, 67 licenses being surrendered, and the public reproval of 20 licenses.

Dr. Serpa reported that during the July 2023 meeting the Committee received a presentation from Kristina Jarvis and Nicole Trama, Deputy Attorneys General that serve as liaisons to the Board on the disciplinary case process. Dr. Serpa noted that the presentation was excellent and covered several aspects of the process which ensure due process for licensees. She also suggested members review the presentation, which is posted on the Board's website as part of the

livestream recording of the July 2023 meeting. Following the presentation, members received public comment from one individual suggesting that the Board should resume its discussion on the use of prefiling conferences.

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

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

b. Presentation on the Board's Inspection Program

Chairperson Serpa reported strategic objective 2.3 of the Board's strategic plan calls for completion of routine inspections of all licensed pharmacies at least every four years to proactively assess pharmacy operations and educate licensees. Dr. Serpa reported the Committee receives an annual presentation providing summary information detailing accomplishments towards this objective. The annual presentation in July was a very informative presentation from Board Assistant Executive Officer Julie Ansel. Dr. Serpa was pleased to see the progress being made to achieve the strategic objective and was hopeful that it may be achieved by next year's presentation and ongoing. Dr. Serpa noted appreciation for all of the efforts of field staff to perform these inspections as this workload was established and performed within existing resources. The Committee asked staff during the meeting about the potential incorporation of routine inspections for nonresident pharmacies and was advised that to date staff have focused on achieving the strategic objective for resident pharmacies.

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

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

c. Presentation on the Board's Citation and Fine Program

Chairperson Serpa reported consistent with strategic objective 2.2, on an annual basis the Committee also receives a presentation on the citation and fine program that includes information on common violations. This year's presentation was made in July by the Board's Executive Officer Anne Sodergren. Information shared during the annual presentation was also included in the Board's newsletter providing education to licensees. Dr. Serpa reported about 33 percent of all investigations completed by the Board result in the issuance of a citation. Dr. Serpa shared providing this statistic provides valuable information to licensees on areas of operations that can result in citations. The data

California State Board of Pharmacy DRAFT Board Meeting Minutes – November 1-2, 2023 Page 8 of 42 presented during the meeting included information on the number of citations issued under the Board's new authority as included in BPC section 4317.5(a)&(b). The presentation slides were included in the meeting materials.

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

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

d. Presentation on Quality Assurance (QA) Reports Received Pursuant to California Code of Regulations Section 1711(f) Related to the Use of Automated Drug Delivery Systems (ADDS)

Chairperson Serpa advised the Board is required to submit a report to the Legislature on the regulation of automated drug delivery systems as part of the upcoming sunset evaluation process. To ensure the Committee had sufficient time for discussion and input in advance of the report deadline, staff presented information and members were provided with an opportunity to provide feedback. Dr. Serpa reported the presentation was comprehensive and served as a great starting point for the Board's assessment. Dr. Serpa noted it was the Committee's first opportunity to review the ADDS program. Dr. Serpa will be working with staff on other elements that should be considered for inclusion in the report. Dr. Serpa shared concern about what appears to be a lack of reporting by some hospitals using unlicensed ADDS and requested that staff determine if there were additional means the Board could use to remind hospitals of the reporting requirements, either through incorporation of the requirement on the renewal form or some other means.

Public comment received suggested that following submission of the report to the Legislature, the Board should consider updating its regulations to remove the requirement for QA reports stemming from the use of automated drug delivery devices to be reported to the Board.

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

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

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

A pharmacist representative from Kaiser suggested sunsetting the ADDS error reporting requirement after the ADDS report was submitted to the Legislature,

California State Board of Pharmacy DRAFT Board Meeting Minutes – November 1-2, 2023 Page 9 of 42 noting with the passage of AB 1286, which requires community pharmacies to report medication errors, it would be prudent for the Board to revisit this requirement.

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

e. Enrolled or Recently Signed Legislation Impacting the Practice of Pharmacy

Chairperson Serpa confirmed members received the written comments received, specifically, three comments were received regarding AB 782 and one set of comments on AB 1286.

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

Dr. Serpa recalled the Board established a support position for AB 663, which expands provisions for the use of a mobile unit that were 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, such mobile units will have the ability to carry controlled substances approved by the FDA for treatment of opioid use disorder.

The Committee agreed with staff's recommended implementation activities, including updating the Frequently Asked Questions (FAQs) related to this program, highlighting the changes in the Board's Pharmacy Law Changes webinar, and inclusion of the information in a future issue of *The Script*.

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

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

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

A pharmacist suggested including in the FAQs on how to handle the address requirement when a patient doesn't have an address.

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

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ii. Assembly Bill 782 (Lackey, 2023)

Dr. Serpa reported the governor vetoed this measure, which would have exempted from the definition of compounding, the adding of a flavoring agent. Accordingly, the measure wasn't discussed at the Committee's October meeting.

Dr. Serpa noted that some written comments received prior to the Board meeting may indicate that a specific compounding license was necessary to provide flavoring. Dr. Serpa clarified that no special pharmacy license was required to add flavoring. Dr. Serpa noted some of the written comments may be more related to regulation activities of the Board.

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

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

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

Dr. Serpa reported the Board's patient safety measure, AB 1286, was signed by the governor. The Committee agreed with the implementation activities identified by staff, including development of FAQs that cover the various provisions within the measure. Dr. Serpa believed the piece that requires the most discussion and education was related to the process to be used by the Board to approve an entity to receive the medication error reports. Dr. Serpa noted that until the Board approves such an entity, medication error reporting would not begin. Dr. Serpa reminded members that prior discussions have involved the Board using a single entity for the medication error reporting to allow for aggregation of the information.

Dr. Serpa advised staff would be arranging presentations from various organizations that could potentially be considered by the Board as an entity responsible for receiving and evaluating medication errors. The Board should also release an alert regarding the effective date of the medication error reporting requirement.

Dr. Serpa reported the Committee also agreed that updates to the selfassessment form and the Board's pharmacy law webinar were appropriate as was an article in a future issue of *The Script*. Dr. Serpa reported that at the October meeting, a member of the public commented that the Board must promulgate a regulation to approve an entity to receive the medication error reports; however, counsel clarified that selection of such an entity would most likely be done through the state contracting process and not through regulations.

Dr. Serpa further reported that, prior to the Board meeting, the Board received a comment in writing requesting an enforcement delay with respect to the measure's requirement that chain community pharmacies be staffed at all times with at least one clerk or pharmacy technician fully dedicated to performing pharmacy-related services. The commenter noted that their organization and the industry in general is already experiencing a stressed job market.

Member Jose De La Paz joined the meeting at approximately 2:59 p.m.

Members were provided the opportunity to comment.

Member Thibeau commented it was reasonable to have a delay in enforcement as the measure was meant to help pharmacists with their staffing.

Member Crowley agreed with Member Thibeau and thought a six-month delay was reasonable.

President Oh agreed in general and noted in the past with SB 362 and 1442 there have been blatant disregard for provisions. Dr. Oh noted every decision warrants its own investigation based on circumstances. Dr. Oh was supportive of providing flexibility provided the organizations were committed in improving patient care but would not tolerate blatant disregard. Dr. Oh advised with a formal delay, it may establish a feeling that the Board won't watch for this.

Member Thibeau recommended keeping the implementation date but allow for a six-month delay in enforcement.

Member Serpa commented that, historically, the Board focuses on education with new laws. The Board still reviews it, looks into it and efforts to achieve compliance are factored into decisions.

President Oh recommended a policy statement similar to the policy statement regarding USP implementation.

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

California State Board of Pharmacy DRAFT Board Meeting Minutes – November 1-2, 2023 Page 12 of 42 Members of the public participating from WebEx were provided the opportunity to comment.

A representative from CCPC flagged a concern for the ability of members to comply with minimum staffing. The representative was told there were delays in the processing of pharmacy technician applications of approximately 90-120 days with the Board that will have an impact on workforce issues and compliance. The representative agreed that an enforcement delay or policy statement would be helpful and suggested holding a stakeholder meeting regarding medication error reporting.

A pharmacist agreed with the need for a delay but didn't encourage an open-ended delay. The pharmacist reviewed the options available to inspectors for enforcing compliance.

A pharmacist representative from Kaiser reiterated their belief that the regulation process was needed to secure the designation of a third party for medication error reporting in addition to the state contracting process.

A representative from Albertsons/Safeway thanked the Board for consideration of their comment letter and committed to compliance as soon as possible.

A medication safety officer commented on the requirement to report medication errors and noted many pharmacies may already be reporting to PSOs. The commenter requested a carve out for those reporting to PSOs.

Dr. Serpa recommended staff take all issues into consideration when evaluating compliance with AB 1286 and also spend time working with the organizations on a case by case basis. Dr. Oh agreed.

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

Dr. Serpa reported this measure authorizes, until January 1, 2025, a pharmacist to furnish COVID-19 oral therapeutics. This measure had an urgency clause and became effective immediately upon the governor's signature. The Committee agreed that the implementation activities identified by staff were appropriate.

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

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

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

Dr. 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 24-hours 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 AB 1557, 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. The Committee agreed with the implementation activities identified by staff in the meeting materials. Dr. Serpa noted the Licensing Committee continues its discussion about the potential to further expand provisions for remote processing, including as part of its meeting in October 2023.

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

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

vi. <u>Senate Bill 345 (Skinner, Chapter 260, Statutes of 2023)</u>

Dr. Serpa advised Senate Bill 345 was supported by the Board. The measure will prohibit a healing arts board from denying an application for a license or imposing discipline upon a licensee or a health care practitioner based on a civil judgment, criminal conviction, or disciplinary action in another state, if that action would have been lawful if provided in California. The Committee agreed that 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* as well as coordination with the Office of the Attorney General as appropriate.

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

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

A pharmacist commented the Board may need to review how this bill and its provisions impacts of the current unprofessional conduct statute.

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

vii. <u>Senate Bill 816 (Roth, Chapter 723, Statutes of 2023)</u>

Dr. Serpa reminded members Senate Bill 816 was sponsored by the Board and recasts the Board's fee schedule consistent with the findings of the independent fee audit. As the effective date for the new fees will be January 1, 2025, the Board should have sufficient time to update its regulation language in California Code of Regulations (CCR), title 16, section 1749 to ensure consistency between the statute and related regulation. The Committee requested that staff begin development of the regulation text for consideration by the Board in the near future to ensure the regulations are in effect at the same time as the statutory changes. The Committee agreed with staff comments that education on the changes was appropriate. Updates to applications and renewal applications and forms will also be required.

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

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

f. Proposed Revisions to Frequently Asked Questions Related to Inventory Reconciliation Regulations

Chairperson Serpa recalled the Board had 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 has proven to be very dynamic, when changes in the law occur, updates to the FAQs may be necessary. Effective January 1, 2023, the Board's inventory reconciliation requirements were updated; however, the FAQs released had not yet been updated to incorporate the new requirements. Meeting materials included a copy of the draft updated version of the FAQs that incorporate clarification offered by DCA counsel. Dr. Serpa noted the track changes were lost in the transition to pdf. Dr. Serpa highlighted that during the Committee meeting, members requested that the FAQs be formatted to an outline format. The requested FAQ formatting changes were not made based on feedback from

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counsel and concerns that such a format may cause users of the document to misinterpret the alphabetical listing.

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

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

Dr. Serpa requested that staff work to post the updated FAQs.

g. Proposed Revisions to Frequently Asked Questions Related to Pharmaceutical and Sharps Waste Stewardship Programs

Chairperson Serpa advised that the meeting materials provided background on the stewardship programs. Dr. Serpa provided a high-level summary, noting 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. Although CalRecycle is 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. 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. The meeting materials included a copy of the proposed updated version of the FAQs with changes highlighted. Dr. Serpa reviewed the proposed changes as being in question one and question three as well as adding two additional questions, numbers 17 and 18. Dr. Serpa noted that the Committee agreed with the proposed changes.

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

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

h. Enforcement Statistics

Chairperson Serpa referenced meeting materials that contained enforcement statistics for the first quarter of the fiscal year. The Board received 765 complaints

California State Board of Pharmacy DRAFT Board Meeting Minutes – November 1-2, 2023 Page 16 of 42 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. As of October 1, 2023, the Board had 1,396 field investigations pending. The meeting materials provided 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 made.

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

VII. Closed Session Matters

The Board ended open session at 3:33 p.m. and went into closed session at 3:38 p.m.

VIII. Reconvene in Open Session to Adjourn for the Day

The Board ended closed session at 4:50 p.m., reconvened into open session, and adjourned the meeting at 4:51 p.m.

November 2, 2023

President Oh called the second day of the Board meeting to order at approximately 9:00 a.m. President Oh reminded all individuals present that the Board is a consumer protection agency charged with administering and enforcing Pharmacy Law. Where protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount.

President Oh advised all individuals the meeting was being conducted via WebEx and in person. Dr. Oh advised that participants watching the webcast could only observe the meeting. Dr. Oh noted anyone interested in participating in the meeting must join the WebEx using the instructions posted on the Board's website. Department of Consumer Affairs' staff provided general instructions for participating in the meeting via WebEx or phone.

Roll call was taken. The following members were present via WebEx: Jessi Crowley, Licensee Member; Renee Barker, Licensee Member; Indira Cameron-Banks, Public Member; Jose De La Paz, Public Member; KK Jha, Licensee Member; Jig Patel, Licensee Member; Maria Serpa, Licensee Member; Nicole Thibeau, Licensee Member; Jason Weisz, Public Member; and Seung Oh, Licensee Member. A quorum was established.

IX. Update from the Department of Consumer Affairs

President Oh introduced Judie Bucciarelli with DCA. Ms. Bucciarelli thanked all Board members for their service and dedication in protecting the consumers of California. Ms. Bucciarelli reported California Business, Consumer Services and Housing Agency Secretary Lourdes M. Castro Ramírez was appointed by Mayor Karen Bass to the Chief of Housing and Homelessness for Los Angeles County effective November 2, 2023. DCA is grateful for her leadership and wishes her the best in her new role.

Ms. Bucciarelli next provided an update on the Department's DEI efforts including continued support of boards and bureaus in expanding culturally competent communications and promoting the importance of meeting the needs of all California consumers, licensees, and applicants. Ms. Bucciarelli reported DCA's Deputy Director of Communications recently met with the Consulate of Mexico in San Francisco to share information and resources about DCA and hear about areas of interest to the Consulate. DCA offered partnership for future in-person and online events and to share available consumer resources.

The DEI Steering Committee was proud to highlight the work of the Board of Vocational Nursing and Psychiatric Technicians. DCA's Tribal Liaison and DEI Steering Committee Chair Yeaphana LaMarr recently introduced the executive officer for the Board of Vocational Nursing and Psychiatric Technicians to Chief Executive Officer Britta Guerrero, executive officer of the Sacramento Native American Health Clinic, to discuss the possibility of tribal health clinics serving as locations for vocational nursing students needing clinical hours for licensure as well as strategies to encourage members of California's tribal communities to consider becoming a health care provider. Future discussions to include consortiums of tribal health providers such as the Consortium for Urban Indian Health and the California Rural Indian Health Boards are in the planning stages. The DEI Steering Committee will continue to learn about and showcase DCA's board and bureau DEI activities.

Ms. Bucciarelli noted DCA Counsel Corinne Gartner would be providing an update on SB 544 later in the meeting. Ms. Bucciarelli reminded members of the mandatory Board member training, specifically sexual harassment prevention training by December 31, 2023.

Ms. Bucciarelli reported with the approval of SB 447, travel restrictions to states that have adopted discriminatory anti-LGBTQ+ laws ended and was replaced with a new public awareness project that will consult with community leaders to promote California's values of acceptance and inclusion of the LGBTQ+ community.

Ms. Bucciarelli provided an update to the Board on the Department's Our Promise Giving at Work Campaign and DCA Turkey Drive.

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

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

X. Presentation on Implementation of the Drug Supply Chain Security Act and National Association of Boards of Pharmacy (NABP) Efforts

President Oh welcomed Josh Bolin, Associate Executive Director, Government Affairs and Innovations with the National Association of Boards of Pharmacy (NABP), who also provided a presentation as part of the October 2022 Board meeting.

Mr. Bolin provided a summary of major Drug Supply Chain Security Act (DSCSA) milestones, noting that the supply chain was not ready for the original implementation date of November 2023. Mr. Bolin reviewed product complaints linked to licensed secondary distributors and significant illicit counterfeiting scheme of HIV drugs throughout the country. Mr. Bolin provided the FDA "Stabilization Period" for one year which was not a delay but a chance to increase adoption and stability but also a delay in FDA enforcement.

Mr. Bolin reviewed dispenser DSCSA responsibilities currently existing, NABP inspection observations, dispenser requirements, product tracing processes, suspect/illegitimate product investigation process requirements, and distributor and solution provider support for dispensers. Mr. Bolin discussed next steps for pharmacies including establishing detailed policies and procedures as well as how to document training staff proving DSCSA requirements were being followed.

Mr. Bolin provided an overview of the United States prescription drug supply chain noting that it is decentralized which requires each trading partner to store their own sterilized data; send and/or receive serialized data via electronic and interoperable means; and respond to requests from federal and state regulators and trading partners as part of investigations into suspect and illegitimate products. Mr. Bolin highlighted the problem because the supply chain is decentralized and tools are needed to achieve interoperability noting there was no single directory to connect the prescription drug supply chain.

Mr. Bolin reviewed the product inquiries through Pulse by NABP as well as the history of development. Mr. Bolin provided an overview of Pulse's digital directory and integration platform including how Pulse supports the supply chain. Mr. Bolin presented what state boards of pharmacy can do to prepare and provided a glossary of commonly used terms and references for DSCSA.

Members were provided the opportunity to comment.

President Oh asked about increases in drug shortages and if there was a DSCSA correlation. Mr. Bolin advised FDA's decision to not move forward with enforcement helped because if there was full enforcement of DSCSA, the drug shortage situation would be worse. Mr. Bolin had not heard that DSCSA requirements were leading to

California State Board of Pharmacy DRAFT Board Meeting Minutes – November 1-2, 2023 Page 19 of 42 drug shortages. Dr. Oh noted national wholesaler standards was a concern of the Board and as well as the ceiling where the Board provided written comment to the FDA. Mr. Bolin applauded the Board for providing comment as 18 states also provided comments. Mr. Bolin thought the FDA has heard from states that there needs to be clarity about the floors and ceilings. Mr. Bolin didn't believe the FDA was focused on the administrative process and thought there would be flexibility as well as time.

President Oh asked about Pulse. Mr. Bolin noted that NABP viewed Pulse as building a set of tools for state boards as well as the dispenser community, which may not be able to purchase a solution so providing the tool at no cost was important.

Member Jha wasn't clear about the inter-pharmacy transfers and where the liability lies or if repackagers were treated as manufacturers or separate status. Mr. Bolin replied DSCSA defines limited parties including manufactures, repackagers wholesalers, third-party logistics providers and dispensers (including pharmacies and other dispensing locations). Repackagers were regulated under DSCSA. Regarding inter-pharmacy transfer, Mr. Bolin provided DSCSA was a change of ownership law and was not a physical movement of product law. Mr. Bolin noted a change of ownership triggers DSCSA and requires there to be documentation that the transaction occurred. A transfer from pharmacy to pharmacy or hospital pharmacy to hospital pharmacy under common ownership was not considered a transaction in DSCSA. If a pharmacy sells a product to another pharmacy where there is no common ownership, there are also exemptions that allow the transfer to meet a specific patient need. Mr. Jha asked if that changed the pharmacy status for the transfer. Mr. Bolin answered if a transfer was done between two pharmacies under common ownership and control, the pharmacy is not acting as a wholesaler. If a pharmacy is selling to another pharmacy not under common ownership for non-specific patient needs that becomes a wholesale distribution.

Member Barker asked about the outreach done by NABP for the smaller pharmacy community about Pulse and tools available. Mr. Bolin explained NABP was working on messaging, promotion, collaboration with organizations that represent smaller pharmacy community as well as providing presentations at state pharmacy associations, trade shows and working with boards to provide communication to the smaller pharmacy community.

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

The Board took a break from 10:04 a.m. to 10:15 a.m. Roll call was taken. The following members were present via WebEx: Jessi Crowley, Licensee Member; Renee Barker, Licensee Member; Indira Cameron-Banks, Public Member; Jose De La Paz, Public Member; KK Jha, Licensee Member; Jig Patel, Licensee Member; Maria Serpa, Licensee Member; Nicole Thibeau, Licensee Member; Jason Weisz, Public Member; and Seung Oh, Licensee Member. A quorum was established.

XI. Presentation on Senate Bill 544 (Laird, Chapter 216, Statutes of 2023) Bagley-Keene Open Meeting Act: Teleconferencing, and Consideration of Potential Changes to Board Member Procedure Manual

President Oh introduced and welcomed DCA Counsel Corinne Gartner to provide a presentation on the upcoming changes established in Senate Bill 544.

DCA Counsel Gartner provided a summary and overview of some of the additional teleconference meeting options and flexibilities added to the Bagley-Keene Open Meeting Act by SB 544 effective January 1, 2024. Ms. Gartner provided a note and disclaimer for the presentation.

Counsel Gartner reviewed the new option for all state bodies (Government Code section 11123.2). Ms. Gartner also reviewed the new option for advisory bodies (Government Code section 11123.5). Ms. Gartner reminded members that in-person, single-location meetings and traditional teleconference meetings were also still options.

Members were provided the opportunity to ask questions and comment.

Member Thibeau asked if one method was required to be selected or if it could change meeting to meeting. Ms. Gartner provided the statute allows for all except for options available only to the advisory committee. Dr. Thibeau asked about the disclosure for disability and that personal medical information had to be provided but wondered what needed to be disclosed. Ms. Gartner explained the statute's requirements and it would have to be what the member was comfortable disclosing.

President Oh thanked Ms. Gartner for the presentation. Dr. Oh thanked all members for their dedication to the Board, noting the Board was a very active board working diligently to protect consumers, with policy related work being done in numerous public committee and board meetings each year. Dr. Oh noted the dedication demonstrated by the members was commendable.

President Oh noted the changes in Senate Bill 544, although temporary, have the potential to ease some of the constraints some may face at times to participate in meetings. Dr. Oh was hopeful that the questions detailed in the meeting materials, would allow the Board to thoughtfully consider if an interim policy on the best means by which to convene meetings during this period should be developed. Dr. Oh highlighted some of the challenges with COVID-19 required the Board to pivot some operations to allow for continuation of services and meetings. The Board learned through this process that the Board and members of the public were very adept at convening meetings via WebEx. Dr. Oh noted the level of participation from members of the public has significantly increased with the transition to WebEx meetings.

Policy Question #1: Section 2 of SB 544 provides authority for advisory committee meetings to be held via teleconference, with members participating remotely from private, non-public locations, as long as there is at least one publicly-accessible site with a staff member present. Under this model, members of the public would have the option of participating via WebEx or in person at the publicly-accessible site. All the Board's standing committees that are subject to the Act (Communication and Public Education, Enforcement and Compounding, Legislation and Regulation, and Licensing) are advisory committees. Should the Board transition meetings of these committees to teleconference meetings until January 1, 2026?

President Oh posed the question should the Board transition all meetings of committees to teleconference until January 1, 2026, noting committees were considered advisory bodies under section 11123.5. Dr. Oh believed such transition was appropriate and would reduce costs for the Board and members of the public by allowing for full participation via WebEx. Dr. Oh noted that as required by the statute, Board staff would be present at a public location.

Members were provided the opportunity to comment.

Members Weisz and Patel were interested in seeking a motion to transition to remote committee meetings.

Member De La Paz was in favor of moving to remote committee meetings to assist in establishing quorum and increasing inclusivity.

Policy Question #2 - Section 1 of SB 544 provides authority for some members of the Board to participate remotely from a private, non-public location if a quorum of the Board is physically present at a single publicly-accessible location. Should the Board transition to this meeting option until January 1, 2026? Staff note that the Business and Professions Code provision requiring the Board to conduct at least one meeting annually in southern California remains in place.

President Oh asked if the Board should transition to a Board meeting model that allows for some members to participate remotely from a private, non-public location if a quorum of the Board is present at a single publicly-accessible location. Dr. Oh believed the transition was appropriate and would allow for equal participation for members, including members that could not otherwise participate because of the need to travel or attend in person.

Members were provided the opportunity to comment.

Members discussed operational functionality of this question, posing examples of getting a member getting a cold before a meeting and could they still count toward the quorum if they participated remotely. Ms. Gartner stated that if the requirements of the Government Code section 11123.2(j) (2) were met, it could be possible.

Member Thibeau highly advocated for the option and disclosed being chronically ill being left with mobility issues. This would allow for her continued participation with the Board.

President Oh preferred having a majority of people in one room and a few members who cannot travel participate remotely.

Members discussed options and suggested confirmation of attendance for the calendar year. Ms. Gartner reiterated that there was now an option to have a quorum of seven members in one location and have other members, above a quorum, participate from private non-disclosed remote locations. Ms. Gartner clarified that adverse weather conditions were not included as a reason that would allow a member attending and participating from a remote location to count toward the quorum.

Policy Question #3 – Business and Professions Code section 4309 establishes the provisions for petitioning the Board for reinstatement or modification of penalty, including modification or termination of probation, and provides flexibility for petitions to be heard by the full Board sitting with an administrative law judge (ALJ), a committee of the Board sitting with an ALJ, or by an ALJ sitting alone. Currently the Board conducts petition hearings as a full Board. In light of the statutory flexibility provided, should the Board transition to having a committee of the Board, rather than the full Board, consider petitions? Such an approach would allow for members to participate from remote locations in the same manner as petition decisions, however, and would mean that decisions issued by the ALJ following the petition hearing would be subject to review by the Board in the same manner as any other proposed decision on a disciplinary matter.

President Oh explained the three means by which the Board may conduct hearings for petitions for reinstatement or modification of penalties. The Board's current practice was to conduct such hearings as a full Board, however, when a quorum of the Board was not present, a committee of the Board may conduct the hearing. Dr. Oh believed the committee process used by the Board worked well and provided all members an opportunity to participate in the decision making through the mail vote process. Dr. Oh was in favor of conducting hearings through a committee of the Board. Dr. Oh clarified a committee would consist of six or less members with final decisions voted on via mail vote process.

Members were provided the opportunity to comment.

Member Crowley was in favor of changing to petitions being heard by committee.

Members Serpa, Patel, Barker, and Weisz were in favor of meeting as the full Board with the option of a committee if a quorum was not obtained. Dr. Serpa appreciated having remote access for public members even though the law did not require it. Mr.

California State Board of Pharmacy DRAFT Board Meeting Minutes – November 1-2, 2023 Page 23 of 42 Weisz did not want a committee to delay response time for the petitioners because the mail vote process was used.

There was consensus on transitioning committee meetings to teleconference format as authorized by Government Code section 11123.5, as operative January 1, 2024, and using the hybrid Board meeting model under new Government Code section 11123.2 to allow some members to participate from a private non-public location where a quorum of the Board is physically present in one location for all Board meetings. However, there was no consensus on how to handle petitioner hearings, and the Board continued to discuss options between using a committee or Board meeting for petitioner hearings.

- Motion: In light of the flexibility provided by Business and Professions Code section 4309, and the temporary authorities established in Senate Bill 544, the Board supports the following:
 - 1. As of January 1, 2024, all committee meetings will be convened via teleconference consistent with the provisions established in section 2 of SB 544.
 - 2. As of January 1, 2024, all Board meetings will be convened via teleconference consistent with the provisions established in section 1 of SB 544.

M/S: Weisz/Patel

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.

The Board heard comments in support of allowing WebEx public comment and continuing remote meetings.

President Oh confirmed the Board will continue to have WebEx and re-read the motion: In light of the flexibility provided by Business and Professions Code section 4309, and the temporary authorities established in Senate Bill 544, the Board supports the following: As of January 1, 2024, all committee meetings will be convened via teleconference consistent with the provisions established in section 2 of SB 544. As of January 1, 2024, all Board meetings will be convened via teleconference consistent with the provisions established in section 2 of SB 544. As of January 1, 2024, all Board meetings will be convened via teleconference consistent with the provisions 1 of SB 544.

Support: 10 Oppose: 0 Abstain: 0 Not Present: 1

Board Member	Vote
Barker	Support
Cameron-Banks	Support
Chandler	Not Present
Crowley	Support
De La Paz	Support
Jha	Support
Oh	Support
Patel	Support
Serpa	Support
Thibeau	Support
Weisz	Support

Member Crowley asked if the petitioners had to be present in person for petition hearings. Dr. Oh noted the petitioner would have the option to be remote or in person.

Motion: In light of the flexibility provided by Business and Professions Code section 4309, and the temporary authorities established in Senate Bill 544, the Board supports the following: Hearings convened for purposes of considering petitions for reinstatement or modification of penalty will be heard by a committee of the Board.

M/S: Weisz/Crowley

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

Board Member	Vote
Barker	Support
Cameron-Banks	Support
Chandler	Not Present
Crowley	Support
De La Paz	Support
Jha	Support
Oh	Support
Patel	Support
Serpa	No
Thibeau	Support
Weisz	Support

Support: 9 Oppose: 1 Abstain: 0 Not Present: 1

Member Serpa asked if records would be sent out to members before the hearing and if members could watch if not on the committee.

President Oh would work with staff and counsel to make any necessary updates to the Board's procedure manual to reflect the Board's position on these matters. Once updates were made, members will receive an electronic copy of the updated manual.

XII. Organizational Development Committee Report

President Oh provided a report for the Organizational Development Committee for information only.

Dr. Oh reported the fiscal year ended June 30, 2023, and final budget figures were reflected in the meeting materials. The Board's authorized budget for last fiscal year was about \$32.6 million. The Board received about \$36.9 million in revenue during the fiscal year and estimates it has expended about \$31.3 million. Meeting materials provide breakdowns in both expenditures and revenue received and the first report of the new fiscal year which began July 1. It is anticipated that the Board's authorized budget for this fiscal year will be about \$32.9 million. Meeting materials contain budget charts of the first two months of the current fiscal year. The Board's fund condition indicated that it was projected that the Board's fee audit. According to the report provided by DCA, the Board's fund currently has 6.2 months is reserve. As a reminder, under the provisions of BPC section 4400(p), the Board shall seek to maintain a reserve equal to approximately one year's operating expenditures.

President Oh further reported that member attendance and mail vote information was included in the meeting materials. Dr. Oh was grateful to everyone for their time and commitment to protecting California consumers.

President Oh reported the Board currently had 14 vacant staff positions with recruitments ongoing. Dr. Oh receives regular updates on recruitments as part of weekly meetings with the Executive Officer and monthly as part of the Organizational Development Committee meetings. Dr. Oh noted there were two vacant public member positions on the Board.

President Oh reported meeting dates for 2024 were included in meeting materials and referenced a few changes to the schedule. Dr. Oh would work with the Board and staff to schedule committee meetings for petitioners and would also try to do one day Board meetings in 2024.

Members were provided the opportunity to comment; 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.

The Board took a break from 11:37 a.m. to 11:45 a.m. Roll call was taken. The following members were present via WebEx: Jessi Crowley, Licensee Member; Renee Barker, Licensee Member; Jose De La Paz, Public Member; KK Jha, Licensee Member; Jig Patel, Licensee Member; Maria Serpa, Licensee Member; Nicole Thibeau, Licensee Member; Jason Weisz, Public Member; and Seung Oh, Licensee Member. A quorum was established.

XIII. Licensing Committee Report

Chairperson Oh provided a report on the Licensing Committee, thanking fellow Committee members: Jig Patel, Indira Cameron-Banks, Trevor Chandler, Jessica Crowley, and Jason Weisz.

a. Provisions for Remote Processing

Chairperson Oh recalled that to facilitate physical distancing early in the COVID-19 pandemic, the Board approved a waiver to extend the provisions for remote processing. The waiver was based on the Board's authority in BPC section 4062 and was limited in duration.

Dr. Oh reported during the July 2023 Committee meeting, the Committee reached consensus on fundamental policy questions that could guide the path forward on provisions for remote processing. Following significant discussion at the October 2023 Licensing Committee meeting, the Committee is now offering a recommendation for the Board to sponsor legislation.

Dr. Oh provided an overview of the legislative proposal, which would provide the Board with the authority to waive both provisions of Pharmacy Law and regulation to allow for research and study into new and innovative methods for drug handling under specified conditions. Dr. Oh believed this was appropriate to ensure the Board had means to allow for research into the use of technology; for example, under the auspices of an accredited school of pharmacy. The approach would allow for evaluation of changes in a controlled, research driven environment, and allow future decisions of the Board to be made based on data.

In addition, the proposed legislative language provided the Board with explicit authority to adopt regulations to establish provisions for remote processing beyond those currently allowed. Establishing explicit authority for the Board to promulgate regulations in this area would allow the Board to respond more nimbly to conditions as they change and to respond to findings of research through a public rulemaking process. The language also included a proposed definition of remote processing.

Dr. Oh noted that for some members of the Committee and some members of the public, the proposed language didn't go far enough, and for others the proposed language went too far. If the Board agreed with the compromise language being proposed, Board staff would work to identify an author for the measure. Dr. Oh recommended that should the Board agree with the Licensing Committee recommendation, the Board should begin development of regulations while the legislation was going through the process to hopefully ensure regulations were ready for promulgation should the legislation be successful.

Members were provided the opportunity to comment.

Member Serpa asked if the definition of "remote processing" included in subdivision (f) was only applied to subdivision (f). Ms. Sodergren provided that, as drafted, the definition would apply only to subdivision (f), but this was a policy decision for the Board. Dr. Serpa asked if the Board was comfortable that the schools of pharmacy studies could include technology that includes the dispensing, counseling, and verification. Ms. Sodergren provided subdivision (e) was written broadly so that Board members could have greater flexibility to make a decision.

Member Cameron-Banks returned to the meeting at 10:50 a.m.

President Oh clarified that subdivision (e) was for the research of remote processing while subdivision (f) was for the purposes of the regulation, remote processing was being defined. Ms. Sodergren agreed with Dr. Oh's clarification.

Dr. Serpa wanted to be prepared for applications of waivers of technology companies that partner with a school of pharmacy to look at technology dispensing medications and potentially bypassing pharmacists. Dr. Oh asked if the definition could be expanded to subdivisions (e) and (f) to address Dr. Serpa's concerns. Ms. Sodergren noted "drug handling" might need to be narrowed down rather than pulling in the definition that was being added to (f). Dr. Serpa preferred it to be a little narrower.

Member Jha encouraged the Board to be cautious but also to embrace and facilitate technology.

Chairperson Oh advised it took six to seven committee meetings to develop this language and encouraged proceeding with the committee motion.

California State Board of Pharmacy DRAFT Board Meeting Minutes – November 1-2, 2023 Page 28 of 42 Member Barker offered changing "drug handling" to "medication management" to allow for more flexibility.

Committee Recommendation (Motion):

Recommend to the Board sponsorship of a statutory proposal as discussed by the Committee. Update the language to include a definition of remote processing and authorize the Committee Chair to finalize the language to present to the Board.

Section 4071.1 of the Business and Professions Code is amended to read:

4071.1.

(a) A prescriber, a prescriber's authorized agent, or a pharmacist may electronically enter a prescription or an order, as defined in Section 4019, into a pharmacy's or hospital's computer from any location outside of the pharmacy or hospital with the permission of the pharmacy or hospital. For purposes of this section, a "prescriber's authorized agent" is a person licensed or registered under Division 2 (commencing with Section 500).

(b) This section does not reduce the existing authority of other hospital personnel to enter medication orders or prescription orders into a hospital's computer.

(c) A dangerous drug or dangerous device shall not be dispensed pursuant to a prescription that has been electronically entered into a pharmacy's computer without the prior approval of a pharmacist.

(d) (1) A pharmacist located and licensed in the state may, on behalf of a health care facility licensed pursuant to Chapter 2 (commencing with Section 1250) of Division 2 of the Health and Safety Code, from a location outside of the facility, verify medication chart orders for appropriateness before administration consistent with federal requirements, as established in the health care facility's policies and procedures.

(2) (A) A health care facility shall maintain a record of a pharmacist's verification of medication chart orders pursuant to this subdivision.

(B) A record maintained pursuant to subparagraph (A) shall meet the same requirements as those described in Sections 4081 and 4105.

(e) In order to enable any accredited school of pharmacy recognized by the Board to experiment with new and innovative methods for drug handling, or to develop new and better methods or concepts involving the ethical practice of pharmacy, the Board may waive the application of provisions of Pharmacy Law and its regulations applicable to remote processing of prescriptions, if the Dean of said school has filed with the Board an experimental plan or program which specifies the particular provisions to be waived, and which has been approved by the Board.

(f) The Board may adopt regulations that establish provisions for remote processing of prescriptions. At a minimum, remote processing of prescriptions may only be performed by a California licensed pharmacist, from a location within California. The regulations shall include provisions for security to protect health information, recordkeeping requirements and autonomy for the pharmacist-in-charge to determine when such processing is allowed. For purposes of this subdivision, "remote processing of prescriptions" includes, but is not limited to, order entry, other data entry, performing prospective drug utilization review, interpreting clinical data, insurance processing, performing therapeutic interventions, providing drug information services, authorizing release of medication for administration, and patient consultation. For purposes of this subdivision, "remote processing of prescriptions" shall not include final product verification or the dispensing of a drug.

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

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

The Board heard comments from specialty pharmacists, pharmacists, and representatives from CPhA, CCPC, and Kaiser agreeing with the language as drafted to keep subdivisions (e) and (f) separate. CCPC shared comments indicating the proposal should be expanded to pharmacists outside of California.

The Board also heard comments from members of the public concerned with the broadness of the proposed language.

Members were provided the opportunity to comment after having received public comment. Dr. Serpa expressed interest in removing the words "for drug handling" while Dr. Crowley thought it sounded odd. Member Weisz indicated he would abstain from the vote but shared having voting to bring the measure to the Board.

Board Member	Vote
Barker	Yes
Cameron-Banks	Yes
Chandler	Not Present
Crowley	No
De La Paz	Yes
Jha	Abstain
Oh	Yes
Patel	Yes
Serpa	Yes
Thibeau	Yes
Weisz	Abstain

Support: 7 Oppose: 1 Abstain: 2 Not Present: 1

b. Pharmacist to Pharmacy Technician Ratio

Chairperson Oh reported that strategic objective 1.3 related to the exploration and pursuit of changes in law appropriate for the authorized duties of a pharmacy technician. The Licensing Committee convened listening sessions and solicited feedback from licensees regarding potential changes. The results of these efforts were incorporated in Assembly Bill 1286, which the governor signed. Dr. Oh noted this was an important first step but believed additional changes were appropriate.

Dr. Oh reported one area the Board continually receives comments on, was the issue of the pharmacist to pharmacy technician ratio. Current pharmacy law was reflected in the meeting materials related to ratios as well as several policy questions considered by the Licensing Committee and a summary of the committee's discussion including public comment. Dr. Oh explained while the subject was complex, it was incumbent upon the Board to determine if the current ratio established in the statute was appropriate for consumer protection, or if changes were appropriate. Dr. Oh reported the Licensing Committee did not reach consensus on this topic and requested that staff develop a draft survey for committee members to consider at a future meeting.

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 of CPhA commented AB 1286 needs to have a year of implementation first and agreed that conducting the survey was prudent. CPhA offered assistance with stakeholder discussions.

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

c. Pharmacist Provided CLIA Waived Tests, Including Potential Expansion of Authorized Tests

Chairperson Oh recalled the Board sponsored SB 409 in 2021 to expand access to pharmacist-provided CLIA waived tests. The legislation established the general types of tests that pharmacists could provide under specified conditions, but left open the potential for additional expansion of authority. This item was discussed by the Licensing Committee to determine if, in the interest of public safety, the Board should consider expanding pharmacist authority to other tests. Dr. Oh reported the Licensing Committee received comments both

in support of and opposed to expanding authority. Comments in support of such expansion noted that one area that may be appropriate was woman's health. Dr. Oh advised that as the Committee chair, he would be working with staff on next steps.

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

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

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

A representative of CPhA agreed with using the regulatory process and added it was premature to bring another legislative action regarding this topic. The representative encouraged allowing licensees to petition the Board to add a test where was a demonstrated demand and need.

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

d. Central Fill Pharmacies, Including Title 16, California Code of Regulations Section 1707.4

Chairperson Oh advised that strategic objective 1.2 called for the Committee and Board to consider and pursue necessary changes in the law regarding various pharmacy practice settings to ensure variances in the practice were appropriate. Dr. Oh reported the Licensing Committee conducted a discussion on central fill pharmacies and considered a number of policy questions included in the meeting materials. The Committee determined it was appropriate to update its regulations to remove some of the ambiguity in the law. During the Licensing Committee meeting, members of the public suggested that the Board could convey its policy through a means other than through rulemaking, suggesting that The Script may be an appropriate means by which to convey the information. Since the meeting, DCA regulation counsel confirmed that the Board cannot interpret regulations through an FAQ or the newsletter; rather, this must be done through regulation. Dr. Oh also reported public comment suggested that the title of the regulation may be not considered part of the law. DCA regulation counsel confirmed that the regulation title was considered part of the regulation text and could not be updated without going through the rulemaking process. As the Licensing Committee chair, Dr. Oh would be working with staff to draft proposed changes to the regulation text for consideration at the January 2024 Licensing Committee meeting.

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

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

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

A pharmacist representative from Kaiser commented the current regulations were working well and didn't need changes. The representative requested confirmation that the Board won't be changing policy decided in 2005.

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

e. Board's Regulation of Mail Order Pharmacies

Chairperson Oh reported the Licensing Committee began evaluation of mail order pharmacies. Dr. Oh believed there was consensus among members in the need to better regulate nonresident pharmacies and concern that the Board does not currently inspect such facilities. The Committee suggested that the issue of out of state inspections should be raised as a new issue as part of the Board's sunset report.

Members were provided the opportunity to comment.

Member Serpa thanked the committee for discussing inspections of nonresident pharmacies and looked forward to seeing metrics.

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

f. Licensing Statistics

Chairperson Oh referred to meeting materials including licensing statistics for the first quarter of the new fiscal year, 2023/24. The Board issued 2,445 licenses to individuals; 182 site licenses; and 96 temporary licenses. Dr. Oh congratulated all of those individuals who received a license during the first quarter, including new graduates of pharmacy schools and those entering pharmacy school. Dr. Oh reported a review of processing times showed improvement in several areas. Dr. Oh pointed out the report reflected the oldest application of each application type so that members understood the Board's average processing time was shorter than what was reported. Dr. Oh also noted that, as projected, with staff vacancies being filled and onboarding being completed, processing times in

California State Board of Pharmacy DRAFT Board Meeting Minutes – November 1-2, 2023 Page 33 of 42 several areas of operations had improved. The Licensing Committee will continue to monitor the progress made by staff. Dr. Oh thanked licensing staff who have demonstrated great commitment to applicants during this time, many of whom are taking time away from family and friends working overtime to address these backlogs.

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

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

XIV. Legislation and Regulation Committee Report

Chairperson Crowley reported on items under the purview of the Legislation and Regulation Committee. Dr. Crowley thanked fellow committee members for their hard work including Jose De La Paz, Trevor Chandler, KK Jha, Maria Serpa and Nicole Thibeau. During the July 2023 meeting, the committee reviewed several measures. With the legislative year over, Dr. Crowley reported on the final outcomes for measures. Action was not required by the Board at this time. Dr. Crowley noted there were some measures previously considered by the Committee and Board that were not included. Generally, this was because the measure was either no longer impacting the practice of pharmacy or was not moving. These measures included Assembly Bill 602, which was amended to address false advertising of pregnancy-related services; Assembly Bill 1619, which was related to pharmacist disclosures of cannabis interactions; Senate Bill 524 related to pharmacists furnishing specified prescription medications based on CLIA waived tests; and Senate Bill 826 related to criminal history information were not moving this year.

A. Pending Legislation Impacting the Practice of Pharmacy, the Board's Jurisdiction, or Board Operations

1. Assembly Bill 317 (Weber, Chapter 322, Statutes of 2023) Pharmacist Service Coverage

Assembly Bill 317 will require a health care service plan and specified disability insurers that offer coverage for a service that is within the scope of practice of a pharmacist to pay or reimburse the cost of services performed by a pharmacy at an in-network or out-of-network pharmacy as specified. The Licensing Committee received public comment from pharmacists detailing barriers to patient care stemming from a lack of reimbursement. The measure was sponsored by the California Pharmacy Association and National Community Pharmacists Association. The Board established a support position. This measure was approved by the governor on October 7,

California State Board of Pharmacy DRAFT Board Meeting Minutes – November 1-2, 2023 Page 34 of 42 2023.

2. <u>Assembly Bill 663 (Haney, Chapter 539, Statutes of 2023) Pharmacy: Mobile</u> <u>Units</u>

Assembly Bill 663 will allow a mobile unit deployed as an extension of a county owned pharmacy to carry controlled substances approved by the FDA for the treatment of opioid use disorder under specified conditions. This measure followed up on last year's provisions which created the initial authority of the use of a mobile unit as an extension of a county owned pharmacy. The Board established a support position. The measure was approved by the governor on October 8, 2023.

3. Assembly Bill 782 (Lackey, 2023) Pharmacies: Compounding

Assembly Bill 782 would have amended BPC section 4126.8 to exempt from the definition of compounding, the adding of a flavoring agent to enhance palatability. The Board had an oppose unless amended position on the measure. The measure was vetoed by the governor on October 8, 2023.

4. Assembly Bill 913 (Petrie-Norris, 2023) Pharmacy Benefit Managers

Assembly Bill 913 would require the Board to license and regulate pharmacy benefits managers as specified. It would require the Board to promulgate necessary regulations and prepare a report to the Legislature on or before August 1, 2025, and annually thereafter. The measure would address inequities that currently exist in pharmacy reimbursement models. As was previously announced, the measure has been become a two-year bill. The Board has a support position on the bill.

5. <u>Assembly Bill 1060 (Ortega, 2023) Health Care Coverage: Naloxone</u> <u>Hydrochloride</u>

Assembly Bill 1060 would have made legislative findings regarding naloxone hydrochloride as a medicine that can counter overdose effects when administered timely to reduce opioid overdose deaths. The measure would have also prohibited health care service plans, health insurance plans, and Medi-Cal from imposing a cost-sharing requirement, including a copayment or deductible, for coverage provided and would require the plan to cover the costs of prescription or nonprescription naloxone hydrochloride. The Board had a support position on the measure. The governor vetoed the measure on October 7, 2023.

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

Assembly Bill 1286 was the Board's patient medication safety bill which was

signed by the governor on October 8, 2023. The measure was amended several times to address concerns from the opposition. The basic tenets of the measure remain present although some different approaches are now in place. Dr. Crowley was excited about the Board's measure and believed it has the potential to significantly reduce medication errors and improve patient care.

7. <u>Assembly Bill 1341 (Berman, Chapter 276, Statutes of 2023) Public Health:</u> <u>COVID-19 Testing and Dispensing Sites: Oral Therapeutics</u>

Assembly Bill 1341 established temporary authority, for a pharmacist to furnish COVID-19 therapeutics until January 1, 2025, under specified conditions. Pharmacists have been performing these functions under a waiver issued by DCA as well as provisions of the PREP Act. The measure was signed by the governor on September 30, 2023. The Board had a support position on this measure.

8. <u>Assembly Bill 1557 (Flora, Chapter 141, Statutes of 2023) Pharmacy:</u> <u>Electronic Prescriptions</u>

Assembly Bill 1557 was also a board-sponsored measure that was signed by the governor on September 1, 2023. The measure makes permanent authority for a California licensed pharmacist to perform medication chart order reviews from a remote location within California on behalf of California licensed health care facilities licensed under Health and Safety Code section 1250 under specified conditions.

9. <u>Senate Bill 339 (Weiner, 2023) HIV Preexposure Prophylaxis and Postexposure</u> <u>Prophylaxis</u>

Senate Bill 339 would authorize a pharmacist to furnish up to a 90-day course of PrEP or beyond, under specified conditions. It would require the Board to adopt emergency regulations by July 1, 2024. Further, it would require health plans and health insurers to cover PrEP and PEP including medications furnished and tests ordered by pharmacists as specified. The bill addresses some of the challenges discussed during the Licensing Committee's recent post-implementation discussion on pharmacist-provided PrEP and PEP. Further, it updates the law to allow for flexibility in treatment by removing the specified type of PrEP authorized to be furnished and provides a means by which a pharmacist can continue to provide care beyond the 90-days under specified conditions, including that a patient receives testing and follow-up care consistent with the CDC guidelines. The Board has a support position on the measure. The measure was placed on the inactive file late in the legislative year. Dr. Crowley was hopeful that discussion will continue and that the measure will be reconsidered early in the year.

10.<u>Senate Bill 345 (Skinner, Chapter 260, Statutes of 2023) Health Care Services:</u> Legally Protected Health Care Services

Senate Bill 345 will prohibit a healing arts board from suspending, revoking, or denying a license of a person based solely because the licensee provided legally protected activity as defined. Legally protected activities include the exercise of rights related to reproductive health care services or genderaffirming health care services. The Board had a support position on the measure. The governor approved the measure September 27, 2023.

11. <u>Senate Bill 427 (Portantino, 2023) Health care coverage: Antiretroviral Drugs,</u> <u>Devices, and Products</u>

Senate Bill 427 would prohibit prior authorization or step therapy for medications approved for the prevention of AIDS/HIV under specified conditions. The measure would allow for prior authorization or step therapy if at least one therapeutically equivalent version was covered without prior authorization or step therapy. The measure was placed on the inactive file late in the legislative year. The Board originally established a support if amended position but was later changed to a support position following amendments that strengthened health care coverage protections. Staff will monitor the measure next year and bring the matter back to the Committee and Board for further consideration as appropriate.

12. <u>Senate Bill 544 (Laird, Chapter 216, Statutes of 2023) Bagley-Keene Open</u> <u>Meetings Act: Teleconferencing</u>

Senate Bill 544 created temporary authority for remote Board Meetings under specified conditions. The Board had a support position on the measure.

13. <u>Senate Bill 816 (Roth, Chapter 723, Statutes of 2023)</u> Professions and <u>Vocations</u>

Senate Bill 816 included the Board's fee proposal to recast the Board's fees consistent with the independent fee analysis performed. Some fees will be reduced, some will remain the same, and others will be raised. The governor signed the measure on October 10, 2023.

14. Senate Bill 873 (Bradford, 2023) Prescription Drugs: Cost Sharing

Senate Bill 873 would require the cost sharing savings of a prescription drug, based on rebates received, to be calculated at the point of sale as specified, by requiring the health care service plan or insurer to provide the information to the dispensing pharmacy. The measure was held in Senate Appropriations Committee.

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15. <u>Senate Bill 887 (Senate Business, Professions, and Economic Development</u> <u>Committee, Chapter 723, Statutes of 2023) Consumer Affairs</u>

Senate Bill 887 was an omnibus measure that included a Board-sponsored provision to change the deadline for the Board to submit its legislative report on the use of automated drug delivery systems to coincide with the Board's sunset process. The measure also included provisions for several other programs with the Department of Consumer Affairs. The measure was approved by the governor October 8, 2023.

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

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

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

The Board heard a comment on AB 1341 that it was a dangerous for pharmacists to be in the position of prescribing emergency use authorization products.

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

b. Board-Adopted Regulations Undergoing Final Review by the Office of Administrative Law

- 1. Proposed Regulation to Amend Title 16 CCR section 1707.6 Related to the Notice to Consumer
- 2. Proposed Regulation to Amend Title 16 CCR section 1706.6 Related to the Military Spouse Temporary License

c. Board-Adopted Regulations Undergoing Final Review by the Department of Consumer Affairs, or Business, Consumer Services and Housing Agency

1. Proposed Regulation to Add Title 16 CCR section 1715.1 Related to the ADDS Self-Assessment

d. Board-Approved Regulations Undergoing Pre-Notice Review by the Department of Consumer Affairs, or Business, Consumer Services and Housing Agency

- 1. Proposed Regulation to Amend Title 16 CCR section 1709.1 Related to the Designation of Pharmacist-in-Charge
- 2. Proposed Regulation to Add Title 16 CCR sections 1750 and 1750.1 Related to Outsourcing Facilities
- 3. Proposed Regulation to Amend Title 16 CCR section 1746.3 Related to Opioid Antagonist

- 4. Proposed Regulation to Add Title 16 CCR section 1746.6 Related to Medication Assisted Treatment Protocol
- 5. Proposed Regulation to Amend Title 16 CCR section 1760 Related to Disciplinary Guidelines
- 6. Proposed Regulation to Amend Title 16 CCR section 1732.5 and Add section 1732.8 Related to Continuing Education
- 7. Proposed Regulation to Amend Title 16 CCR sections 1735 and 1751 Related to Compounding
- 8. Proposed Regulation to Amend Title 16 CCR section 1708.2 Related to Discontinuance of Business

e. Board-Approved Regulations – Board Staff Drafting Initial Rulemaking Documents

- 1. Proposed Regulation to Amend Title 16 CCR section 1711 Related to Quality Assurance
- f. Board-Authorized Section 100 Board Staff Drafting Section 100 Documents
 - 1. Proposed Regulation to Amend Title 16 CCR sections 1715 and 1784 Related to the Community Pharmacy, Hospital Pharmacy, and Dangerous Drug Distributor Self-Assessment Forms

Chairperson Crowley advised all of the items included in the regulations portion of the report were for information only. The Board had two regulations undergoing final review by the Office of Administrative Law, including the proposed updates to the Board's Notice to Consumers Poster. The Board also had one regulation undergoing final review by the Department of Consumer Affairs. The Board had eight proposed regulations undergoing pre-notice review by the Department of Business, Consumer Services and Housing Agency. Staff were working on preparing the initial rulemaking documents for the proposed changes to the Board's quality assurance regulations as well as updates to the self-assessment forms that will be updated through the Section 100 streamlined regulation process.

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

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

XV. Communication and Public Education Committee Report

Chairperson Weisz provided a summary of the Committee's efforts at the July 2023 meeting. Mr. Weisz thanked fellow members, Vice-Chair Nicole Thibeau, Renee Barker, Jose De La Paz, and KK Jha.

a. Update to Website

The Board will be updating its website to a new template for state agencies. The vision for the new model is to create a seamless digital experience for Californians accessing the services they need. The meeting materials provided an overview of the template and requirements. Mr. Weisz had an opportunity to review the updated webpage template that will be used, including highlighting upcoming meeting dates, an item the Committee had discussed. Members of the Committee have volunteered to serve as resources to the staff during the development process as questions arise.

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

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

b. Update on Communication and Public Education Activities by Staff

The Script was released prior to the Board meeting and included a range of topics including the most common violations that result in the issuance of a citation and fine and the top corrections ordered during inspections.

The Committee identified three education campaigns, the first of which is focused on naloxone. The Board is in the process of updating its regulations regarding pharmacist provided naloxone in response to changes in statute. Board staff recommend that educational materials be updated to reflect the changes in the requirements and a campaign be developed to support the release of the new requirements and educational materials.

Staff was recommending that the public awareness campaign related to treating pharmacy staff with courtesy be incorporated in with the campaign related to the revised notice to consumers poster. The messaging would focus on the importance of speaking with pharmacists as well as messaging about pharmacy personnel and the importance of services they provide.

The Committee previously also requested an educational campaign on the Institute for Safe Medication Practices (ISMP). The Board's website has been updated to include a link to the ISMP homepage. Further, as part of the education campaign, information will be included in the next issue of *The Script*.

Mr. Weisz concluded his report by highlighting the outreach efforts undertaken by staff, including a number of presentations provided to the various schools of pharmacy.

California State Board of Pharmacy DRAFT Board Meeting Minutes – November 1-2, 2023 Page 40 of 42 Members were provided the opportunity to comment; however, no comments were made.

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

XVI. Executive Officer Report

Executive Officer Sodergren provided her report.

a. Annual Review of Sunset Report Activities

Ms. Sodergren advised the Sunset review process was an opportunity for the oversight committees of the Legislature to learn about the Board's efforts to fulfill its consumer protection mandate. Compilation of the report was a large undertaking. To monitor progress, the Board requested annual reporting on efforts. Included in the meeting materials was updated information on anticipated areas for reporting in the Board's Sunset report. This data will also help inform trends. It is recommended that over the coming year as committees are conducting their policy discussions, they work to identify issues that are appropriate to raise as part of the sunset review process.

b. Biannual Report of the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE) and the North American Pharmacist Licensure Examination (NAPLEX)

Ms. Sodergren reported the semi-annual statistics for the CPJE and NAPLEX were not yet available and were anticipated to be available the week following the Board meeting. Upon completion the information will be sent to members and posted on the website and the information will also be provided to the deans for the various California schools of pharmacy.

c. FDA Announcement: Drug Supply Chain Security Act Compliance Policies Establish 1-year Stabilization Period for Implementing Electronic Systems

Ms. Sodergren advised the FDA has released a guidance document conveying a 1-year stabilization period for DSCSA provisions. Ms. Sodergren highlighted in addition to having a staff member participating at the national level, the Board has been providing general education and promoting resources available to assist licensees in facilitation through the mandatory CE pharmacy law webinar. It was also discussed during presentations and information provided at association meetings. Field staff were also providing general education as part of the inspection process as well. d. Drug Enforcement Agency (DEA) Announcement: Revised Regulation Allows DEA Registered Pharmacies to Transfer Electronic Prescriptions at a Patient's Request

Ms. Sodergren announced this agenda item was for awareness that the DEA published its final revised regulations allowing DEA registered pharmacists to transfer electronic prescriptions at a patient's request.

e. Update on Business Modernization Activities

Ms. Sodergren reported business modernization was the process the Board must undertake to determine what, if any, changes are appropriate to systems used by the Board to support licensing and enforcement related activities. The process included a number of activities. The Board reached another milestone in the business modernization process by defining the functional requirements necessary for the system. Ms. Sodergren was looking forward to learning about next steps and continue the partnership with DCA on this process.

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

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

President Oh advised the next meeting of the Board was scheduled for December 13, 2023, and encouraged participants to monitor the Board's website for meeting details.

XVII. Adjournment

The Board adjourned the meeting at 1:09 p.m.

Attachment XII

b. December 13, 2023 Board Meeting Draft Minutes



California State Board of Pharmacy 2720 Gateway Oaks Drive, Suite 100 Sacramento, CA 95833 Phone: (916) 518-3100 Fax: (916) 574-8618 www.pharmacy.ca.gov



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I	California State Board of Pharmacy Department of Consumer Affairs DRAFT Public Board Meeting Minutes
Date:	December 13, 2023
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.
Board Members	PUBLIC PARTICIPATION AND COMMENT FROM A REMOTE LOCATION: WebEx
Present:	Seung Oh, PharmD, Licensee Member, President Jessica Crowley, PharmD, Licensee Member, Vice President Trevor Chandler, Public Member, Treasurer Renee Barker, PharmD, Licensee Member Indira Cameron-Banks, Public Member (joined at 11:55 a.m.) Jose De La Paz, Public Member Kartikeya "KK" Jha, Licensee Member Maria Serpa, PharmD, Licensee Member Nicole Thibeau, PharmD, Licensee Member
Board Members Not Present:	Jignesh Patel, Licensee Member Jason Weisz, Public Member
Staff Present:	Anne Sodergren, Executive Officer Julie Ansel, Assistant Executive Officer Corinne Gartner, DCA Staff Counsel Jennifer Robbins, DCA Regulations Counsel Debbie Damoth, Executive Specialist Manager

December 13, 2023

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

California State Board of Pharmacy DRAFT Board Meeting Minutes – December 13, 2023 Page 1 of 26 President Oh called the Board meeting to order at approximately 9:00 a.m.

President Oh reminded all individuals present that the Board is a consumer protection agency charged with administering and enforcing Pharmacy Law. Where protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount.

President Oh advised all individuals the meeting was being conducted via WebEx. Dr. Oh advised participants watching the webcast they could only observe the meeting. Dr. Oh noted anyone interested in participating in the meeting must join the WebEx meeting using the instructions posted on the Board's website. Department of Consumer Affairs' staff provided general instructions for participating in the meeting via WebEx or phone.

Roll call was taken. The following Board members were present via WebEx: Jessi Crowley, Licensee Member; Trevor Chandler, Public Member; Renee Barker, Licensee Member; Jose De La Paz, Public Member; KK Jha, Licensee Member; Maria Serpa, Licensee Member; Nicole Thibeau, Licensee Member; and Seung Oh, 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 with an opportunity to provide comment for items not on the agenda or agenda items for a future meeting.

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

A pharmacist commented wanting to ensure the Board was enforcing AB 1286 and shared their experiences with working conditions.

An owner of a pharmacy commented on issues arising with closing pharmacies and an influx of patients to the surrounding pharmacies. The patients are being turned away by local chain pharmacies and coming to the independent pharmacies. The commenter noted the impact of access to consumers with large chains closing and other chains turning away consumers. The commenter thought the issue was a reimbursement issue.

Member Chandler requested a future agenda item to better understand reimbursement issues by PBMs and explore any potential authority the Board has in this regard. Ms. Sodergren will work with President Oh and suggested the Board may want to have a presentation provided on the new legislation that passed and speaks to reimbursements. President Oh noted awareness and concern of the situation. Dr. Oh expressed concern about helping in this area and noted the many limitations.

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

California State Board of Pharmacy DRAFT Board Meeting Minutes – December 13, 2023 Page 2 of 26 A member of the public commented to advocate for those injured or killed by COVID-19 vaccines.

A specialty pharmacist thanked the Board for expanding the remote processing definition in November 2023 and requested how the public would be informed if an author was secured.

The Board heard a comment requesting a future agenda item to discuss a need for advance notice to consumers when there were closures of pharmacies.

A member of the public commented concerning the safety of COVID-19 vaccines.

A representative of CSHP requested an FAQ on medication flavoring.

A comment was received requesting the Board discuss the intern-pharmacist ratio.

Members were then provided an opportunity to comment.

Members discussed the possible agenda items presented to the Board. The Board was interested in discussing the issues of closures of pharmacies and access to controlled substances on a future agenda. Specifically, if a pharmacy closes, does the allocation of the access to controlled substances increase in the surrounding areas to accommodate for the increase of patients to surrounding pharmacies. The Board also expressed an interest to explore the pharmacy deserts created by pharmacy closures. The Board realized it would be an educational opportunity. President Oh and Executive Officer Sodergren were working on the issue with state agencies.

The Board also expressed a desire to have a discussion on drug shortages. President Oh advised staff were working on this topic as a future agenda item.

President Oh asked Chairperson Serpa of the Enforcement and Compounding Committee about the request for FAQs on flavoring. Dr. Serpa advised USP has FAQs on flavoring.

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

President Oh reminded members that several years ago, the Board changed its recognition program for pharmacists and currently recognizes pharmacists that have been licensed for 40 or more years. Dr. Oh noted the information was posted on the Board's website and pharmacists were provided with a certificate.

President Oh noted prior to transitioning to remote meetings, the Board routinely provided an opportunity for pharmacists licensed for 40 years to attend a Board

California State Board of Pharmacy DRAFT Board Meeting Minutes – December 13, 2023 Page 3 of 26 meeting and be recognized by the Board. Dr. Oh continued although the Board has returned to remote meetings, the Board would like to provide an opportunity for the Board to recognize pharmacists that have been licensed in California for 40 years.

There were no pharmacists identifying themselves to be recognized for 40 years of service as a pharmacist. President Oh thanked and congratulated pharmacists who had been licensed as a pharmacist for over 40-years. Dr. Oh thanked all pharmacy staff who worked in pharmacy serving the consumers of California.

IV. Discussion and Possible Action Related to Proposed Regulations, Title 16, California Code of Regulations, section 1707.6, Related to Notice to Consumers, Including Changes Requested by the Office of Administrative Law

President Oh recalled in April 2023, following a 45-day comment period, the Board voted to adopt regulation text to amend California Code of Regulations, title 16, section 1707.6 related to the Board's Notice to Consumers poster. Following adoption by the Board, the final rulemaking package was submitted to the Office of Administrative Law (OAL) as required by the Administrative Procedure Act. During the review by OAL issues were identified. OAL requested three amendments to the regulation text to ensure compliance with the Administrative Procedure Act.

President Oh reported that the draft regulation text included in the meeting materials reflected the changes requested by OAL. The modified text was reflected in double underline and double strikethrough. Dr. Oh considered the information and agreed with the staff recommendations, noting that if the Board agreed and voted to further amend the proposed regulation text, the Board would initiate a 15-day comment period, providing licensees with an opportunity to provide comments on these additional changes to the proposed regulation text.

Members were provided an opportunity to comment.

Members expressed concerns about the suggested language noting the implication of the language that pharmacists have a duty to fill prescriptions. With the closure of many chain pharmacies coupled with the decision of chain pharmacies to not carry certain medication as well as drug shortages, there was additional concern of implication that the pharmacist was required to find the medication. Ms. Sodergren noted to change the language would require a change in Business and Professions Code (BPC) section 733. As originally noticed, the proposed language would have cross referenced BPC section 733, but the Board was advised by OAL that the Board could not take that approach and must include the specific statutory language.

DCA Regulations Counsel Robbins agreed with Ms. Sodergren and stated the language was to ensure there were no roadblocks put in place by pharmacists in line with statutory language rather to insist that pharmacists have to somehow provide a

> California State Board of Pharmacy DRAFT Board Meeting Minutes – December 13, 2023 Page 4 of 26

way to provide alternatives. Ms. Robbins stated the language would not be used to require that of pharmacists.

Members discussed the implications of the language but identified it was the same language as included on the current Notice to Consumers poster. Members agreed that in the future the Board should look at the statutory language in BPC section 733 and consider updating it.

Motion: Approve the amended regulation text and initiate a 15-day comment period. Additionally, if no adverse comments are received during the 15day comment period, authorize the executive officer to take all steps necessary to complete the rulemaking and adopt the proposed regulations at Section 1707.6 as noticed. Further, delegate to the executive officer the authority to make technical or non-substantive changes as may be required by the Control agencies to complete the rulemaking file.

Title 16. Board of Pharmacy Modified Text

Proposed Text: <u>Underline</u> is text that will be added. Strikethrough is text that will be deleted.

Modified Text: <u>Double Underline</u> is text that will be added. Double Strikethrough is text that will be deleted.

Amend Section 1707.6 to Title 16 of the California Code of Regulations, to read as follows:

§ 1707.6. Notice to Consumers.

(a) In every pharmacy there shall be prominently posted, in a place conspicuous to and readable by a prescription drug consumer, a notice containing the text in subdivision (b). Every pharmacy shall post a notice containing the text in subsection (b) and shall place the notice in a conspicuous place, physically accessible to a prescription drug consumer (consumer) so that the consumer can easily read the notice, and use the QR code displayed on the notice to obtain language translation of the notice. Such notice shall be posted at all locations where a consumer receives medication. Each pharmacy shall use the standardized poster-sized notice provided or made available by the board, unless the pharmacy has received prior approval of another format or display methodology from the board. The board may delegate authority to a committee or to the Executive Officer to give the approval. As an alternative to a printed notice, the pharmacy may also or instead display the notice on a video screen located in a place conspicuous to and readable by prescription drug consumers, so long as: (1) The video screen is at least 24 inches, measured diagonally; (2) The pharmacy utilizes the video image notice provided by the board; (3) The text of the notice remains on the screen for a

California State Board of Pharmacy DRAFT Board Meeting Minutes – December 13, 2023 Page 5 of 26 minimum of 60 seconds; and (4) <u>The video screen utilizes QR code</u> <u>technology for the consumer to access translation of the notice, with sufficient</u> <u>display time for consumers to access the QR code; and (5)</u> No more than five minutes elapses between displays of any notice on the screen, as measured between the time that a one-screen notice or the final screen of a multiscreen notice ceases to display and the time that the first or only page of that notice re-displays. The pharmacy may seek approval of another format or display methodology from the board. The board may delegate authority to a committee or to the Executive Officer to give the approval.

(b) The notice <u>must also include a QR code that assists limited-English-proficient</u> individuals and informs consumers that the QR code may be used to obtain a translation of the notice. Consumers must be able to use the QR code to obtain translation of the notice in the top 16 languages spoken by limited-<u>English-proficient individuals in California, as determined by the U.S.</u> <u>Department of Health and Human Services, Office for Civil Rights, and the</u> <u>California Department of Health Care Services.</u> Arabic, Armenian, Chinese, <u>English, Farsi, Hindi, Hmong, Japanese, Korean, Khmer / Cambodian,</u> <u>Punjabi, Russian, Spanish, Tagalog, Thai, and Vietnamese. It shall contain</u> the following text:

NOTICE TO CONSUMERS KNOW YOUR RIGHTS

California law requires a pharmacist to speak with you <u>upon your request</u>, every time you get a new prescription, <u>and every time you get a new</u> <u>prescription dosage form</u>, <u>strength</u>, <u>or written directions</u>.

You have the right to ask for and receive from any pharmacy prescription drug labels in 12-point font.

Interpreter services are available to you upon request at no cost.

TALK TO THE EXPERT – SPEAK WITH YOUR PHARMACIST

Before <u>you leave the pharmacy, CHECK</u>: taking your medicine, be sure you know: the name of the medicine and what it does; how and when to take it, for how long, and what to do if you miss a dose; possible side effects and what you should do if they occur; whether the new medicine will work safely with other medicines or supplements; and what foods, drinks, or activities should be avoided while taking the medicine. Ask the pharmacist if you have any questions.

- The patient name on the label is correct;
- The medication matches the description on the label;
- The name of the medicine and what it does;
- How and when to take the medication, for how long, and what to do if you miss a dose;
- Possible side effects and what you should do if they occur;
- Whether the medication will work safely with other medicines or supplements; and
- What foods, drinks, or activities should be avoided while taking the medicine.

California State Board of Pharmacy DRAFT Board Meeting Minutes – December 13, 2023 Page 6 of 26 <u>The address and contact information for consumers to send any complaints</u> about the pharmacy:

California State Board of Pharmacy 2720 Gateway Oaks Drive, Suite 100 Sacramento, CA 95833 (916) 518-3100 www.pharmacy.ca.gov.

<u>This pharmacy must provide any medicine or device legally prescribed for</u> <u>you, unless it is not covered by your insurance; you are unable to pay the cost</u> <u>of the drug or device a copayment; or the pharmacist determines doing so</u> <u>would be against the law or potentially harmful to the patient's health. If a</u> <u>medicine or device is not immediately available, the pharmacy will work with</u> <u>you to help you get your medicine or device in a timely manner.</u>

You may ask this pharmacy for information on drug pricing and use of generic drugs.

(c) Every pharmacy, in a place conspicuous to and readable by a prescription drug consumer, at or adjacent to each counter in the pharmacy where dangerous drugs are dispensed or furnished, shall post or provide a notice containing the following text:

Point to your language. Interpreter services will be provided to you upon request at no cost.

This text shall be repeated in <u>Arabic, Armenian, Chinese, English, Farsi, Hindi,</u> <u>Hmong, Japanese, Korean, Khmer / Cambodian, Punjabi, Russian, Spanish,</u> <u>Tagalog, Thai, and Vietnamese.</u><u>the top 16 languages spoken by limited-English-</u> proficient individuals in California, as determined by the U.S. Department of <u>Health and Human Services, Office for Civil Rights, and the California</u> <u>Department of Health Care Services.</u>

This text shall be repeated in at least the following languages: Arabic, Armenian, Cambodian, Cantonese, Farsi, Hmong, Korean, Mandarin, Russian, Spanish, Tagalog, and Vietnamese.

Each pharmacy shall use the standardized notice provided or made available by the board, unless the pharmacy has received prior approval of another format or display methodology from the board. The board may delegate authority to a committee or to the Executive Officer to give the approval.

The pharmacy may post this notice in paper form or on a video screen if the posted notice or video screen is positioned so that a consumer can easily point to and touch the statement identifying the language in which he or she requests they request assistance. Otherwise, the notice shall be made available on a flyer or handout clearly visible from and kept within easy reach of each counter in the pharmacy where dangerous drugs are dispensed or furnished, available at all

California State Board of Pharmacy DRAFT Board Meeting Minutes – December 13, 2023 Page 7 of 26 hours that the pharmacy is open. The flyer or handout shall be at least 8 1/2 inches by 11 inches.

(d) As an alternative to posting the notice from subdivision (b) in a conspicuous place, pharmacies may instead provide the notice on a patients' written receipt. Every pharmacy shall either post or provide on the patient's written receipt a statement describing patients' rights per Business and Professions Code sections 733 and 4122.

Note: Authority cited: Sections 4005 and 4122, Business and Professions Code. Reference: Sections 733, 4005, 4076.5 and 4122, Business and Professions Code.

M/S: Chandler/Thibeau

Members of the public were provided the opportunity to comment in Sacramento. A member of the public expressed concern with the vagueness of the term "timely manner."

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

A pharmacist recommended rejection of the OAL's proposed language and removal of the reference as the legislative intent was not being considered.

The Board heard a comment that this was retail focused without taking into consideration inpatient pharmacy or home health care pharmacy. The commenter requested an FAQ.

Members were provided an opportunity to comment.

President Oh advised there would be a 15-day comment period if approved by the Board.

Support: 8 Oppose: 0 Abstain: 0 Not Present: 3

Board Member	Vote
Barker	Yes
Cameron-Banks	Not Present
Chandler	Yes
Crowley	Yes
De La Paz	Yes
Jha	Yes
Oh	Yes
Patel	Not Present
Serpa	Yes
Thibeau	Yes
Weisz	Not Present

The Board took a break from 10:00 a.m. to 10:15 a.m. Roll call was taken. The following Board members were present via WebEx: Jessi Crowley, Licensee Member; Trevor Chandler, Public Member; Renee Barker, Licensee Member; Jose De La Paz, Public Member; KK Jha, Licensee Member; Maria Serpa, Licensee Member; Nicole Thibeau, Licensee Member; and Seung Oh, Licensee Member. A quorum was established.

V. Update, Discussion and Possible Action Related to Proposed Regulations, Title 16, California Code of Regulations, section 1706.6, Related to Temporary License for Military Spouses

President Oh reminder the Board that as part of the July 2023 Board meeting, the Board adopted the regulation text defining the provisions for military spouses and partners to obtain a temporary license. The OAL asked for several edits. The recommended changes were reflected in the meeting materials. Language recommended to be deleted is shown by bold italic double strikethrough and added language is reflected using bold italic wavy underline. Dr. Oh reviewed the language and was comfortable with the recommended changes. If the Board agreed and voted to further amend the language, the Board would initiate a 15-day comment period, providing interested parties with an opportunity to provide comments on these additional changes to the proposed regulation text.

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

Motion: Approve the amended regulation text and initiate a 15-day comment period. Additionally, if no adverse comments are received during the 15day comment period, authorize the executive officer to take all steps necessary to complete the rulemaking and adopt the proposed regulations at Section 1706.6 as noticed. Further, delegate to the executive officer the authority to make technical or non-substantive changes as may be required by the Control agencies to complete the rulemaking file.

<u>Title 16. Board of Pharmacy</u> <u>Second Modified Text</u>

Proposed changes made to the current regulation language are shown by double strikethrough for deleted language and <u>double underline</u> for added language.

Additional proposed changes made to the current regulation language are shown by **bold italic double strikethrough** for deleted language and **bold italic wavy underline** for added language.

Add section 1706.6 to Article 1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1706.6. Temporary Licenses for Military Spouses/Domestic Partners

- (a) Definitions: For the purposes of this section, the following definitions shall apply:
 - (1) "Disciplined" means that the applicant's license was placed on probation, revoked, suspended, reproved, censured, reprimanded, restricted, limited, or conditioned.
 - (2) "Jurisdiction" shall mean a California or another state's licensing board or agency, any agency of the federal government, or another territory of the United States.
 - (3) "Disciplinary proceeding" shall mean any proceeding or investigation under the authority of the licensing jurisdiction pursuant to which a licensee may be disciplined.
 - (4) "Good standing" shall mean that the applicant has not been disciplined, is not the subject of an unresolved complaint or review procedure and is not the subject of any unresolved disciplinary proceeding.
 - (5) "Original licensing jurisdiction" shall mean the entity that issued a license to the applicant authorizing the applicant to practice within the same scope for which the applicant seeks a temporary license from the Board.
 - (6) "License" shall mean a license of the same type that the applicant is applying for, or comparable authority to practice in another state, district, or territory of the United States.
- (b) An applicant for a temporary pharmacist, advanced practice pharmacist, pharmacy technician, designated representative, designated representativereverse distributor, designated representative-3PL, or a designated paramedic temporary license pursuant to section 115.6 of the Business and Professions Code ("Code") shall submit a completed application to the Board and meet all of the requirements of this section and section 115.6 of the Code

to be eligible for a temporary license. A completed application shall provide the following information:

- (1) The applicant's identifying and contact information:
 - (A) Applicant's full legal name ((Last Name) (First Name) (Middle Name) and, *for if applicable*, (Suffix)),
 - (B) Other name(s) applicant has used or has been known by,
 - (C) Applicant's address of record (The address of record may be a post office box number or other alternate address.).
 - (D) Applicant's physical address, if different than the applicant's address of record,
 - (E) Applicant's email address,
 - (F) Applicant's telephone number,
 - (G) Applicant's Social Security Number or Individual Taxpayer Identification Number, and,
 - (H) Applicant's birthdate (month, day, and year).
- (2) The applicant shall indicate that the applicant is married to, or in a domestic partnership or other legal union with, an active-duty member of the Armed Forces of the United States who is assigned to a duty station in California under official active-duty military orders and shall provide the following documentation with the application:
 - (A) Certificate of marriage or certified declaration/registration of domestic partnership filed with the California Secretary of State or other documentary evidence of legal union with an active-duty member of the Armed Forces, and,
 - (B) A copy of the military orders establishing their spouse or partner's duty station in California.
- (3) The applicant shall disclose whether the applicant holds a current, active, and unrestricted license of the same type of license that the applicant is applying for, or comparable authority to practice in another state, district, or territory of the United States, and provide written verification from the applicant's original licensing jurisdiction that the applicant's license or other comparable authority ("license") is in good standing in under that jurisdiction. The verification shall include all of the following:
 - (A) the full legal name of the applicant and any other name(s) the applicant has used or has been known by,
 - (B) the license type and number issued to the applicant by the original licensing jurisdiction, and relevant law(s) and regulation(s) under which the license was issued,
 - (C) the name and location of the licensing agency,
 - (D) the issuance and expiration date of the license, and,
 - (E) information showing that the applicant's license is currently in good standing.
- (4) The applicant shall disclose whether the applicant has committed an act any jurisdiction that would have constituted grounds for denial, suspension, or revocation of the license pursuant to Sections 141, 480, or 490 of the Code, or Sections 4300, 4301, or 4311 of the Code, or section 1762 of this Division. For applicants for a temporary pharmacist license, those applicants shall also disclose whether the

California State Board of Pharmacy DRAFT Board Meeting Minutes – December 13, 2023 Page 11 of 26 applicant has committed an act in any jurisdiction that would have constituted grounds for denial, suspension, or revocation of the license pursuant to Sections 4305 or 4306.5 of the Code.

- (4) The applicant shall attest that the applicant meets all of the requirements for temporary licensure as set forth in Business and Professions Code Section 115.6 (c)(1) through (5), including that the applicant has not committed an act in any jurisdiction that would have constituted grounds for denial, suspension, or revocation of the license under the Business and Professions Code or this division at the time the act was committed and that the applicant is aware that a violation of this paragraph may be grounds for the denial or revocation of a temporary license issued by the Board of Pharmacy.
- (5) The applicant shall also attest that disclose whether the applicant has not been disciplined by a licensing entity in another jurisdiction or not the subject of an unresolved complaint, review procedure, or disciplinary proceeding conducted by a licensing entity in another jurisdiction.
- (6) The applicant shall submit fingerprints for use by and accessible to the <u>Board in conducting criminal history information record checks through the</u> <u>California Department of Justice.</u>
- (7) For applicants for a temporary pharmacist license, the applicant has successfully completed the California Practice Standards and Jurisprudence Examination (CPJE).
- (8) The applicant shall sign a statement attesting to the fact that the applicant meets all the requirements for the temporary license, and that the information submitted in the application is accurate, to the best of the applicant's knowledge.
- (c) In addition to the above requirements, and prior to submission of the application specified in subsection (b), applicants for a temporary pharmacist license must successfully complete the Board's law and ethics examination designated as the California Practice Standards and Jurisprudence Examination (CPJE) for Pharmacists set forth in Section 4200 of the Code, which tests the applicant's knowledge and proficiency in state and federal laws and provisions of safe patient care_₹ and the items set forth in Section 4200.2 and 4200.3 (d) of the Code.
- (d) Upon issuance of a temporary license in accordance with Section 115.6(a) of the Code, the Board shall provide written notice to the applicant of the following:
 - (1) That the temporary license is nonrenewable;
 - (2) <u>That the license expires 12 months after issuance, upon issuance or denial of a standard license, upon issuance or denial of a license by endorsement</u>, or upon issuance or denial of an expedited license pursuant to Section 115.5 of the Code, whichever occurs first; and,
 - (3) Any holder of a temporary license desiring to continue their licensure or to practice in California after expiration of their temporary license shall apply for and obtain a standard pharmacist, advanced practice pharmacist,

California State Board of Pharmacy DRAFT Board Meeting Minutes – December 13, 2023 Page 12 of 26 pharmacy technician, designated representative, designated representative-reverse distributor, designated representative-3PL, or a designated paramedic license, as applicable, in accordance with Sections 4200, 4202, 4210, 4053, 4053.1, 4053.2, and 4202.5 of the Code. Authority: Sections 115.6 and 4005, Business and Professions Code. Reference: Sections 30, 31, 115.6, 141, 480, 490, <u>4026.5,</u> 4200, 4300, 4301, 4301.5, 4305, 4306.5, and 4311, Business and Professions Code.

M/S: Chandler/De La Paz

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 through WebEx; however, no comments were made.

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

Board Member	Vote
Barker	Yes
Cameron-Banks	Not Present
Chandler	Yes
Crowley	Yes
De La Paz	Yes
Jha	Yes
Oh	Yes
Patel	Not Present
Serpa	Yes
Thibeau	Yes
Weisz	Not Present

Support: 8 Oppose: 0 Abstain: 0 Not Present: 3

VI. Discussion and Possible Action to Amend Title 16, California Code of Regulations, section 1749, Related to Fees

President Oh advised the draft language to update the Board's fee schedule consistent the changes to the statute was included in the meeting materials. Dr. Oh noted that with the exception of the pharmacy technician renewal fee, all other fees would be established at the pre-set levels. At Dr. Oh's request, the pharmacy technician renewal fee was recommended to be set at \$150 while the pre-set level in

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the statute was \$180 dollars. This would reduce the Board's projected revenue by about \$900,000 annually. Dr. Oh reported that he had been monitoring the Board's revenue and believed that even with this reduction, the Board's fund will slowly restore to the statutory level of a 12-month reserve. Dr. Oh was comfortable with the language and believed it is important for the Board to initiate the rulemaking process early, to ensure the regulation text can become effective January 1, 2025, aligning with the statutory implementation of the new fee structure.

Members were provided an opportunity to comment.

Member Serpa requested confirmation that the fee for pharmacy technicians would be lower than the current amount, \$195. President Oh confirmed this was true. Dr. Oh noted that the proposal to lower the fee for techs was in response to the pharmacy technician shortage.

Motion: Approve the proposal regulation text for CCR section 1749 as proposed, direct staff to submit the text to the Director of the Department of Consumer Affairs and the Business, Consumer Services, and Housing Agency for review and if no adverse comments are received, authorize the executive officer to take all steps necessary to initiate the rulemaking process, make any nonsubstantive changes to the package, and set the matter for hearing if requested. If no adverse comments are received during the 45-day comment period and no hearing is requested, authorize the executive officer to take all necessary steps to complete the rulemaking and adopt the proposed regulations at section 1749 as noticed.

Proposal to Amend 16 CCR § 1749 Fee Schedule as follows:

The application, renewal, penalties, and other fees, unless otherwise specified, are hereby fixed as follows:

(a) The fee for the issuance of any pharmacy license, including a remote dispensing site pharmacy license, is seven hundred fifty dollars (\$750) five hundred seventy dollars (\$570). The fee for the annual renewal of any pharmacy license, including a remote dispensing site pharmacy license, is one thousand twenty-five dollars (\$1,025) nine hundred and thirty dollars (\$930). The penalty for failure to renew is one hundred fifty dollars (\$150).

(b) The fee for the issuance of any temporary pharmacy license is <u>one</u> <u>thousand six hundred dollars (\$1,600)</u> three hundred twenty-five dollars (\$325).

California State Board of Pharmacy DRAFT Board Meeting Minutes – December 13, 2023 Page 14 of 26 (c) The fee for the issuance of a pharmacy technician license is <u>one</u> <u>hundred twenty dollars (\$120)</u> one hundred ninety five dollars (\$195). The fee for the biennial renewal of a pharmacy technician license is <u>one</u> <u>hundred fifty dollars (\$150)</u> one hundred ninety-five dollars (\$195). The penalty for failure to renew is <u>seventy-five dollars (\$75)</u>. ninety seven dollars and fifty cents (\$97.50).

(d) The application fee for examination as a pharmacist is <u>two hundred</u> <u>sixty dollars (\$260)</u> two hundred eighty-five dollars (\$285).

(e) The fee for regrading an examination is one hundred fifteen dollars (\$115).

(f) (1) The fee for the issuance of an original pharmacist license is <u>one</u> <u>hundred ninety-five dollars (\$195)</u> two hundred and fifteen dollars (\$215).
(2) The application fee for an advanced practice pharmacist license is three hundred dollars (\$300). If granted, there is no fee for the initial license issued, which will expire at the same time the pharmacist license expires.

(g)(1) The fee for the biennial renewal of a pharmacist license is <u>four</u> <u>hundred fifty dollars (\$450)</u> five hundred five dollars (\$505). The penalty fee for failure to renew is one hundred fifty dollars (\$150).

(2) The fee for the biennial renewal of an advanced practice pharmacist license is three hundred dollars (\$300). The penalty fee for failure to renew is one hundred fifty dollars (\$150). The fees in this paragraph are in addition to the fees required to renew the pharmacist's license as specified in paragraph 1.

(h) The fee for the issuance of a wholesaler or third-party logistics provider license is <u>one thousand dollars (\$1,000)</u> eight hundred twenty dollars (\$820). The fee for the annual renewal of a wholesaler or third-party logistics provider license is <u>one thousand dollars (\$1,000)</u> eight hundred twenty dollars (\$820). The penalty for failure to renew is one hundred fifty dollars (\$150). The fee for a temporary wholesaler or third-party logistics provider license is seven hundred fifteen dollars (\$715).

(i) The fee for the issuance of a hypodermic license is <u>five hundred fifty</u> <u>dollars (\$550)</u> two hundred forty dollars (\$240). The fee for the annual renewal of a hypodermic needle license is <u>four hundred dollars (\$400)</u> two <u>hundred eighty dollars (\$280)</u>. The penalty for failure to renew is <u>one</u> <u>hundred fifty dollars (\$150)</u> one hundred forty dollars (\$140). (j) The fee for the issuance of a designated representative license pursuant to Section 4053 of the Business and Professions Code, a designated representative-3PL license pursuant to Section 4053.1 of the Business and Professions Code, or a designated representative-reverse distributor license pursuant to Section 4053.2 of the Business and Professions Code, is <u>three hundred forty-five dollars (\$345)</u> two hundred ten dollars (\$210). The fee for the annual renewal of a license as a designated representative, designated representative-3PL, or a designated representative-reverse distributor is <u>three hundred eighty-eight</u> <u>dollars (\$388)</u> three hundred dollars (\$300). The penalty for failure to renew is one hundred fifty dollars (\$150).

(k) The application fee for a license as a nonresident wholesaler or nonresident third-party logistics provider is <u>one thousand dollars (\$1,000)</u> eight hundred twenty dollars (\$820). The fee for the annual renewal of a nonresident wholesaler or nonresident third-party logistics provider is <u>one</u> <u>thousand dollars (\$1,000)</u> eight hundred twenty dollars (\$820). The penalty for failure to renew is one hundred fifty dollars (\$150). The fee for a nonresident wholesaler or nonresident third-party logistics provider temporary license is seven hundred fifteen dollars (\$715).

(1) The fee for an intern pharmacist license is <u>one hundred seventy-five</u> <u>dollars (\$175)</u> two hundred thirty dollars (\$230). The fee for transfer of intern hours or verification of licensure to another state is <u>one hundred twenty</u> <u>dollars (\$120)</u> thirty dollars (\$30).

(m) The fee for the reissuance of any license, or renewal thereof, which must be reissued because of change in the information <u>on a premises</u> license, other than name change, is <u>three hundred ninety-five dollars</u> (\$395) one hundred thirty dollars (\$130).

(n) The fee for the reissuance of any license that has been lost or destroyed or reissued due to a name change is seventy-five dollars (\$75) forty-five dollars (\$45). The fee for processing an application to change a name or correct an address on a premises is two hundred six dollars (\$206). The fee for the processing of an application to change a pharmacist-in-charge, designated representative-in-charge, or responsible, manager on a premises license record is two hundred fifty dollars (\$250).

(o) The fee for evaluation of continuing education courses for accreditation is forty dollars (\$40) for each hour of accreditation requested.

(p) The fee for the issuance of a clinic license is <u>six hundred twenty dollars</u> (<u>\$620</u>) five hundred seventy dollars (<u>\$570</u>). The fee for the annual renewal of a clinic license is <u>four hundred dollars</u> (<u>\$400</u>) three hundred sixty dollars (<u>\$360</u>). The penalty for failure to renew is one hundred fifty dollars (\$150).

(q) The fee for the issuance of a nongovernmental license to compound sterile drug preparations or a hospital satellite compounding pharmacy license is three thousand eight hundred seventy-five dollars (\$3,875) two thousand three hundred five dollars (\$2,305). The fee for the annual renewal of a nongovernmental-license to compound sterile drug preparations or a hospital satellite compounding pharmacy license is four thousand eighty-five dollars (\$4,085) one thousand eight hundred fifty five dollars (\$1,855). The penalty for failure to renew a nongovernmental-license to compound sterile drug preparations or a hospital satellite compounding pharmacy license is one hundred fifty dollars (\$150). The fee for a nongovernmental temporary license to compound sterile drug preparations or a hospital satellite compounding pharmacy temporary license is <u>one thousand sixty-five dollars (\$1,065)</u> seven hundred fifteen dollars (\$715).

(r) The fee for the issuance of a nonresident sterile compounding pharmacy <u>license</u> is <u>eight thousand five hundred dollars (\$8,500)</u> three thousand three hundred thirty-five dollars (\$3,335). The fee for the annual renewal of nonresident sterile compounding pharmacy license is <u>eight</u> <u>thousand five hundred dollars (\$8,500)</u> three thousand one hundred <u>eighty dollars (\$3,180)</u>. The penalty for failure to renew is one hundred fifty dollars (\$150). The fee for a temporary nonresident sterile compounding pharmacy license is <u>one thousand five hundred dollars (\$1,500)</u> seven hundred fifteen dollars (\$715).

(s) The fee for the issuance of a license as a designated representative for a veterinary food-animal drug retailer is <u>three hundred forty-five dollars</u> (\$345) two hundred ten dollars (\$210). The fee for the annual renewal of a license as a designated representative for a veterinary food-animal drug retailer is <u>three hundred eighty-eight dollars</u> (\$388) three hundred dollars (\$300). The penalty for failure to renew is one hundred fifty dollars (\$150).

(†) The fee for a veterinary food-animal drug retailer license is six hundred ten dollars (\$610). The application fee for the annual renewal for a veterinary food-animal drug retailer is four hundred sixty dollars (\$460). The fee for a veterinary food-animal drug retailer temporary license is <u>five</u> <u>hundred twenty dollars (\$520)</u> two hundred and fifty dollars (\$250). The penalty for failure to renew is one hundred fifty dollars (\$150). (u) The fee for the issuance of a retired pharmacist license is fifty dollars (\$50)shall be forty-five dollars (\$45).

(v) The fee for the issuance of a centralized hospital packaging pharmacy license is <u>three thousand eight hundred fifteen dollars (\$3,815)</u> one thousand one hundred fifty dollars (\$1,150). The fee for the annual renewal of a centralized hospital packaging pharmacy license is <u>two</u> thousand nine hundred twelve dollars (\$2,912) one thousand one hundred twenty five dollars (\$1,125). The penalty for failure to renew is one hundred fifty dollars (\$150).

(w) The fee for the issuance of an outsourcing facility license is <u>twenty-five</u> <u>thousand dollars (\$25,000)</u> three thousand one hundred eighty dollars (\$3,180). The fee for the annual renewal of an outsourcing facility is <u>twenty-five dollars (\$25,000)</u> one thousand eight hundred fifty-five dollars (\$1,855). The penalty for failure to renew is one hundred fifty dollars (\$150). The fee for an outsourcing facility temporary license is <u>four thousand</u> <u>dollars (\$4,000)</u> seven hundred fifteen dollars (\$715).

(x) The fee for the issuance of a nonresident outsourcing facility license is twenty-eight thousand five hundred dollars (\$28,500) three thousand three hundred thirty-five dollars (\$3,335). The fee for the annual renewal of a nonresident outsourcing facility is twenty-eight thousand five hundred dollars (\$28,500) three thousand one hundred eighty dollars (\$3,180). The penalty for failure to renew is one hundred fifty dollars (\$150). The fee for a nonresident outsourcing facility temporary license is four thousand dollars (\$4,000) seven hundred fifteen dollars (\$715).

(y) The fee for the issuance of a correctional clinic license that is not owned by the state is <u>six hundred twenty dollars (\$620)</u> five hundred seventy dollars (\$570). The annual renewal application fee for a correctional clinic license is <u>four hundred dollars (\$400)</u> three hundred sixty dollars (\$360). The penalty for failure to renew is one hundred fifty dollars (\$150).

(z) The application and initial license fee for operation of an EMSADDS is <u>one hundred fifty dollars (\$150)</u> one hundred dollars (\$100). The application fee for the annual renewal of an EMSADDS is <u>two hundred</u> <u>dollars (\$200)</u> one hundred dollars (\$100). The penalty for failure to renew is <u>one hundred dollars (\$100)</u> thirty-five dollars (\$35). The application and renewal fee for a licensed wholesaler that is also an emergency medical services provider agency is eight hundred ten dollars (\$810).

(aa) The application fee of a co-location clinic license is seven hundred fifty dollars (\$750).

California State Board of Pharmacy DRAFT Board Meeting Minutes – December 13, 2023 Page 18 of 26 (<u>aa</u>ab) The application and initial license fee for a designated paramedic license is <u>three hundred fifty dollars (\$350)</u> one hundred and forty dollars (\$140). The application fee for the biennial renewal of a designated paramedic license is <u>two hundred dollars (\$200)</u> one hundred forty dollars (\$140). The penalty for failure to renew a designated paramedic license is <u>one hundred dollars (\$100)</u> sixty five dollars (\$65).

(ab) The application and initial license fee for a remote dispensing site pharmacy application is one thousand seven hundred thirty dollars (\$1,730). The fee for the annual renewal for a remote dispensing site pharmacy license is one thousand twenty-five dollars (\$1,025). The penalty for failure to renew a remote dispensing site pharmacy license is one hundred fifty dollars (\$150). The fee for the issuance of any temporary remote dispensing site pharmacy license is <u>eight hundred ninety dollars</u> (\$890).

(ac) The fee for the issuance of an ADDS license to a correctional clinic is five hundred dollars (\$500). The fee for the annual renewal of an ADDS license issued to a correctional clinic is four hundred dollars (\$400). The penalty for failure to renew is one hundred fifty dollars (\$150).

(ad) The fee for the issuance of an ADDS license to all entities other than correctional clinics is five hundred twenty-five dollars (\$525). The fee for the annual renewal of an ADDS license, issued to entities other than correctional clinics, is four hundred fifty-three dollars (\$453). The penalty for failure to renew is one hundred fifty dollars (\$150).

<u>(ae)</u> The fee for the issuance of a nonresident pharmacy license <u>is two</u> thousand four hundred twenty-seven dollars (\$2,427). The fee for the annual renewal of a nonresident pharmacy license is <u>one thousand</u> twenty-five dollars (\$1,025). The penalty for failure to renew is one hundred fifty dollars (\$150). The fee for the issuance of a temporary nonresident pharmacy license is <u>two thousand dollars (\$2,000)</u>.

Authority cited: Sections 4005 and 4400, Business and Professions Code. Reference: Sections 163.5, 4005, 4044.3, 4053, 4053.1, 4110, 4112, 4119.01, <u>4119.11</u>, 4120, 4127.1, 4127.15, 4127.2, 4128.2, 4129.1, 4129.2, 4129.8, 4130, 4160, 4161, 4180, <u>4180.5</u>, 4187, 4190, 4196, 4200, 4202, 4202.5, 4203, 4208, 4210, 4304, 4400, 4401 and 4403, Business and Professions Code.

M/S: Thibeau/De La Paz

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 through WebEx; however, no comments were made.

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

Board Member	Vote
Barker	Yes
Cameron-Banks	Not Present
Chandler	Yes
Crowley	Yes
De La Paz	Yes
Jha	Yes
Oh	Yes
Patel	Not Present
Serpa	Yes
Thibeau	Yes
Weisz	Not Present

Support: 8 Oppose: 0 Abstain: 0 Not Present: 3

VII. Discussion of Implementation of Requirements of AB 2194 (Ward, Chapter 958, Statutes of 2022) Related to Continuing Education and Cultural Competency

President Oh recalled the California Pharmacists Association (CPhA) co-sponsored Assembly Bill 2194, which requires pharmacists and pharmacy technicians to have one hour of continuing education in cultural competency as defined in the legislation. Following passage of the measure, the CPhA began working with experts to develop a training program. Dr. Oh welcomed Dr. Rajan Vaidya, PharmD, and Dr. Tam Phan, PharmD, AAHIVP, to provide a presentation to the Board on the CPhA training program.

Dr. Vaidya provided an overview of the AB 2194: Cultural Competency Training, entitled Caring for All: The Pharmacy Professionals' Role in LGBTQ+ Health and Equity, that would be delivered by subject matter experts including Dr. Tam Phan, PharmD, AAHIVP; Dr. Jay Holloway, PharmD, AAHIVP; and Dr. Cheryl Wisseh, PharmD, MPH, BCACP. Dr. Vaidya reviewed the statutory requirements for cultural competency training: (1) The course focuses on patients who identify as lesbian, gay, bisexual, transgender, gender nonconforming, or queer, or who question their sexual orientation or gender identity and expression. (2) The course is approved from an accreditation agency approved by the board. (3) The course covers recognized health disparities

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faced by Black, Indigenous, and people of color. (4) The course contains elements demonstrating how sexual identity is directly impacted through intersectionality.

Dr. Pham reviewed the learning objectives of the CPhA course, as follows: define at least 10 commonly used terms related to the LGBTQ+ population; describe at least three primary disparities experienced by the LGBTQ+ community; explain the concept of intersectionality and how it impacts the experiences of Black, Indigenous, and other LGBTQ+ people of color; list three ways in which pharmacy practice can be made more affirming for LGBTQ+ individuals; and identify three key resources that pharmacy professionals can use to support affirming environments for LGBTQ+ individuals.

Dr. Pham then reviewed the contents each Module: Module 1 – Commonly used terminology in LGBTQ+ health; Module 2 – LGBTQ+ disparities using the Minority Stress Model; Module 3 – Intersectionality and how identities can affect LGBTQ+ persons; and Module 4 – Recommendations on how to create an affirming pharmacy practice.

Dr. Vaidya provided the availability of the training, with on-demand virtual training available at <u>www.cpha.com/cct</u>; presented live at CPhA's Western Pharmacy Exchange April 18-21, 2024; and future live offerings based on demand. Dr. Viadya concluded by stating that the training was developed both for pharmacists and pharmacy technicians, and that it's being made available for free on CPhA's website.

Members were provided the opportunity to comment.

Members expressed excitement about the training and commented on the thoroughness and depth of the training.

Dr. Vaidya added that the training would be updated annually.

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

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

A pharmacist complimented CPhA on getting AB 2194 passed and developing this training program.

A pharmacist and representative of CSHP complimented CPhA and inquired if the course would need to be taken once or during each renewal period.

A pharmacy technician commented as a member of the LGBTQ+ community in support of the training.

Dr. Vaidya thanked the Board for allowing to presentation.

California State Board of Pharmacy DRAFT Board Meeting Minutes – December 13, 2023 Page 21 of 26 Members asked if a subscriber alert could be sent out. The Board discussed that any such alert would not be an endorsement of this specific training course, but rather a courtesy notice to licensees about the availability of the course. Members also asked if the Board needed to approve the training. Ms. Sodergren commented Board approval was not required but the course needed to meet the statutory and regulatory requirements.

VIII. Discussion of Implementation of Requirements of AB 2194 (Ward, Chapter 958, Statutes of 2022) Related to Continuing Education and Cultural Competency

President Oh advised that as part of the activities required by the Board to implement AB 2194, the Board must develop regulations regarding the new CE requirement. The regulation text was necessary to provide clarity to pharmacists and pharmacy technicians about the requirements and specifically for pharmacy technicians, to implement the provisions for an inactive license consistent with provisions of the general BPC sections detailed in the meeting materials. Dr. Oh advised the pre-notice review of the proposed regulations was recently completed, and it was anticipated that the 45-day public comment period will begin on December 15, 2023. Given the required public comment periods established in the Government Code, the proposed regulations will not be effective by the end of January 2024.

President Oh noted that this item was placed on the agenda at the request of Board staff, to allow members an opportunity to provide feedback to staff on the implementation of the measure until such time as the regulations were effective. Dr. Oh noted no formal action was required by the Board.

President Oh referenced the meeting materials, which highlighted two specific issues noted by staff. Dr. Oh agreed with both recommendations offered and the overall sentiment to focus on achieving compliance with these new requirements during this transition period and affording licensees the opportunity to demonstrate compliance. Dr. Oh sought input from Board members with the implementation plan.

Members were provided the opportunity to comment. Members were agreeable to the policies presented in the meetings materials.

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

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

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

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IX. Discussion of Draft Policy Statement Related to Implementation of Assembly Bill 1286 (Haney, Chapter 470, Statutes of 2023)

President Oh referenced meeting materials containing a draft statement prepared by staff describing the Board's policy related to implementation of AB 1286. During previous public discussion on implementation activities related to AB 1286, the Board agreed that an alert should be released to licensees regarding implementation on the medication error reporting requirements. Dr. Oh believed the draft statement appropriately incorporates the Board's discussion at the previous Board meeting.

Dr. Oh noted that application processing times fluctuate. Dr. Oh requested an update on the status of processing times for pharmacy technician applications. The oldest pharmacy technician applications to be processed were received November 13 and the oldest deficiency mail to process was received on December 6.

Members were provided an opportunity to comment and expressed support for the draft statement as written. Member Crowley asked about the selection process for the entity to receive medication error reports. President Oh advised that this will be discussed at the Enforcement and Compounding Committee, and then will come to the full Board for approval. Ms. Sodergren added that the state contracting process will be used.

Motion: Approve the policy statement as drafted.

Draft Statement Re: Assembly Bill 1286 Implementation The California State Board of Pharmacy provides licensees and interested stakeholders with the following information on its policy relating to implementation of provisions contained within Assembly Bill 1286 (Haney, Chapter 470, Statutes of 2023).

Assembly Bill 1286 establishes a requirement for the reporting of medication errors that occur in the outpatient setting to an entity approved by the Board under specified conditions. The Enforcement and Compounding Committee will begin its evaluation of entities in the coming months. During this intervening period, reporting of such errors is not required nor will it be retroactive. It is anticipated that reporting of such errors will only be expected after approval of such an entity with an appropriate transition period for implementation. Interested stakeholders are encouraged to participate in relevant public meetings.

California State Board of Pharmacy DRAFT Board Meeting Minutes – December 13, 2023 Page 23 of 26 Assembly Bill 1286 also establishes a self-assessment process for surgical clinics. Development of the self-assessment form will be undertaken by the Enforcement and Compounding Committee. Upon development and approval of the self-assessment form, the Board will advise licensees and make the form available on its website. During this intervening period, completion of the self-assessment form requirement will be delayed. Interested stakeholders are encouraged to participate in relevant public meetings.

Several additional provisions contained in Assembly Bill 1286 become effective January 1, 2024. The Board encourages licensees to begin taking the necessary steps for compliance immediately. The Board recognizes that despite good faith efforts, there may be delays in achieving compliance by January 1, 2024. During the implementation period, the Board will consider actions taken to secure compliance when areas of non-compliance are identified through the inspection or investigation process. The Board encourages licensees to maintain documentation of actions taken to achieve compliance and to present such information to the Board upon request. November 20, 2023

M/S: Crowley/Thibeau

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

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

A representative of CCPC appreciated the policy statement as compliance by the effective date would be difficult. With regard to AB 1286 implementation for technicians being trained to provide vaccines, the representative asked if there could be an extension for the training requirement.

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

Support: 8 Oppose: 0 Abstain: 0 Not Present: 3

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Board Member	Vote
Barker	Yes
Cameron-Banks	Not Present
Chandler	Yes
Crowley	Yes
De La Paz	Yes
Jha	Yes
Oh	Yes
Patel	Not Present
Serpa	Yes
Thibeau	Yes
Weisz	Not Present

The Board took a break from 10:58 a.m. to 11:05 a.m. Roll call was taken. The following Board members were present via WebEx: Jessi Crowley, Licensee Member; Trevor Chandler, Public Member; Renee Barker, Licensee Member; Jose De La Paz, Public Member; KK Jha, Licensee Member; Maria Serpa, Licensee Member; Nicole Thibeau, Licensee Member; and Seung Oh, Licensee Member. A quorum was established.

X. Petitions for Reinstatement of Licensure, Early Termination of Probation, or Other Modification of Penalty

Administrative Law Judge Sean Gavin presided over the first two hearings.

a. Nouri Nourani, RPH 58760

Member Cameron-Banks joined the meeting at 11:55 a.m.

b. Purva Patel, RPH 65038

Administrative Law Judge Heather Rowan presided over the remaining hearings.

c. Christine Low-Blunt, RPH 47198

The Board took a break from 12:58 p.m. to 2:00 p.m. Roll call was taken. The following Board members were present via WebEx: Jessi Crowley, Licensee Member; Trevor Chandler, Public Member; Renee Barker, Licensee Member; Indira Cameron-Banks, Public Member; KK Jha, Licensee Member; Maria Serpa, Licensee Member; Nicole Thibeau, Licensee Member; and Seung Oh, Licensee Member. A quorum was established.

d. Randy K. Ouellette, RPH 84113

California State Board of Pharmacy DRAFT Board Meeting Minutes – December 13, 2023 Page 25 of 26 The Board took a break from 2:48 p.m. to 2:55 p.m. Roll call was taken. The following Board members were present: Jessi Crowley, Licensee Member; Trevor Chandler, Public Member; Renee Barker, Licensee Member; KK Jha, Licensee Member; Maria Serpa, Licensee Member; Nicole Thibeau, Licensee Member; and Seung Oh, Licensee Member. A quorum was established.

e. Michael Maravich, RPH 48738

Member Chandler stepped away from the meeting at 3:04 p.m. and returned at 3:08 p.m.

Member De La Paz returned to the meeting at 3:18 p.m.

Member Cameron-Banks returned to the meeting at approximately 3:35 p.m.

XI. Closed Session

Open session concluded at approximately 3:44 p.m. The Board entered closed session at approximately 3:50 p.m. and ended closed session at 4:59 p.m.

XII. Reconvene in Open Session to Adjourn for the Day

The Board reconvened into open session and adjourned the meeting at approximately 5:00 p.m.