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

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

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

Date: April 24 - 25, 2024

Location: OBSERVATION AND PUBLIC COMMENT IN PERSON:
California Department of Consumer Affairs
1625 North Market Blvd., First Floor Hearing Room
Sacramento, CA 95834

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
Trevor Chandler, Public Member, Treasurer
Renee Barker, PharmD, Licensee Member
Jeff Hughes, Public Member
Kartikeya "KK" Jha, Licensee Member
Jason "J." Newell, MSW, Public Member
Satinder Sandhu, PharmD, Licensee Member
Maria Serpa, PharmD, Licensee Member
Nicole Thibeau, PharmD, Licensee Member
Jason Weisz, Public Member

Board Members Not Present:
Indira Cameron-Banks, Public Member
Jose De La Paz, Public Member

Staff Present:
Anne Sodergren, Executive Officer
Julie Ansel, Assistant Executive Officer
Corinne Gartner, DCA Staff Counsel
Shelley Ganaway, DCA Staff Counsel
Jennifer Robbins, DCA Regulations Counsel
Debbie Damoth, Executive Specialist Manager
Sara Jurrens, Public Information Officer (4/25/24 only)

April 24, 2024

I. Call to Order, Establishment of Quorum, and General Announcements (Including Possible Notifications, Actions, and Disclosures Pursuant to Government Code section 11123.2(j))

President Oh called the Board meeting to order at approximately 1:00 p.m. President Oh welcomed to the Board public members Jeff Hughes and Jason "J." Newell and licensee member Dr. Satinder Sandhu. Dr. 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.

Roll call was taken. The following Board members were physically present in Sacramento: Jessi Crowley, Licensee Member; Trevor Chandler, Public Member; Renee Barker, Licensee Member; Jeff Hughes, Public Member; J. Newell, Public Member; Satinder Sandhu, Licensee Member; Maria Serpa, Licensee Member; and Seung Oh, Licensee Member. KK Jha, Licensee Member, and Nicole Thibeau, Licensee Member, participated via WebEx. Members Jha and Thibeau each disclosed that no persons over 18 years old were present in the room with them as they participated in the meeting remotely via WebEx. A quorum was established.

President Oh reminded members participating via WebEx to remain visible with cameras on throughout the open session of the meeting. Dr. Oh advised if members needed to temporarily turn off their camera due to challenges with internet connectivity, they must announce the reason for their nonappearance when the camera was turned off.

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

President Oh announced the Board would accept public comment for items not on the agenda and provided instructions on how the public could provide comment.

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 civil engineer and pain patient advocate asked when the subject of thresholds and the injunctive relief state attorneys general have put in place

with the three major distributors of controlled substances would be discussed, and at which committee it would be discussed.

Enforcement and Compounding Committee Chairperson Serpa stated it would be on a future agenda for the Enforcement and Compounding Committee.

The Board also heard a comment requesting that the Board establish a commission for those injured by the COVID-19 vaccine.

III. Election of Board Officers

President Oh advised as included in the Board of Pharmacy Board Member Procedure Manual, officers shall serve a one-year term, effective June 1, and may be re-elected for consecutive terms.

President Oh thanked the Board for the opportunity to serve as president. Dr. Oh also thanked Vice President Jessi Crowley and Treasurer Trevor Chandler for their service.

President Oh then opened the nominations for the office of president.

Nomination for President: Seung Oh

Nominated by: Jessica Crowley

Dr. Oh accepted the nomination.

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

Support: 10 Oppose: 0 Abstain: 0 Not Present: 3

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

Dr. Oh was re-elected as president.

President Oh next accepted nominations for the office of vice president.

Nomination for Vice President: Jessi Crowley

Nominated by: Seung Oh

Dr. Crowley accepted the nomination.

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

Support: 10 Oppose: 0 Abstain: 0 Not Present: 3

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

Dr. Crowley was re-elected as vice president.

President Oh then accepted nominations for the office of treasurer.

Nomination for Treasurer: Trevor Chandler

Nominated by: Seung Oh

Mr. Chandler accepted the nomination.

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

Support: 10 Oppose: 0 Abstain: 0 Not Present: 3

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

Mr. Chandler was re-elected as treasurer.

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

President Oh reminded those present that the Board recognizes pharmacists that have been licensed for 40 or more years by posting the information on the Board's website and providing pharmacists with a certificate.

President Oh invited pharmacists licensed for 40 years or more to identify themselves and be recognized by the Board. 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.

V. Approval of Board Meeting Minutes

Dr. Oh referenced the draft minutes from the February 8, 2024 Board meeting.

Members were provided an opportunity to comment.

Member Serpa requested her comment on page 26 of 50 be changed to read: "Member Serpa commented there was another accreditation method of school-based training that she personally found issues with as many of those groups are not ASHP accredited programs but are community college based or private for-profit institutions."

Motion: Approve the February 8, 2024 Board meeting minutes as presented in the meeting materials with the correction noted by Dr. Serpa

M/S: Serpa/Crowley

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

Support: 9 Oppose: 0 Abstain: 1 Not Present: 3

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

VI. Presentation by Erin Hager, Diversion Investigator, Drug Enforcement Administration, regarding Electronic Prescription Fraud

President Oh advised the presentation was postponed due to a last minute conflict.

VII. Report by the California Department of Consumer Affairs

President Oh introduced and welcomed Judie Bucciarelli, Staff Services Manager with the Department of Consumer Affairs (DCA), to provide an update from the Department.

Ms. Bucciarelli welcomed new Board Members Jeff Hughes, J. Newell, and Satinder Sandhu to the Board. Ms. Bucciarelli thanked all Board members for their continued service and dedication to the consumers of California.

Ms. Bucciarelli next reported that DCA would host an in-person meet and greet with Agency Secretary Tomiquia Moss and executive leaders on April 30, 2024, to serve as an opportunity to meet the new secretary and hear her vision for Agency and the Department. Invitations have been sent to DCA executive officers. If any members of the Board have questions for Secretary Moss, they are encouraged to submit them to their executive officer.

Ms. Bucciarelli then shared an important update regarding federal Title IV funding. A new U.S. Department of Education (DOE) regulation that goes into effect on July 1, 2024, would impact students of boards or bureaus that approve nondegree school programs leading to licensure. Currently, schools can offer programs that exceed a state's minimum hour requirements, and they can still offer their students federal financial aid. Starting July 1, 2024, this will change. The US DOE regulation limits the program length to 100 percent of the state's minimum requirements, making the minimum requirement the maximum. As a result, noncompliant programs will not be eligible for federal Title IV funding after July 1, 2024. The program length must be equal to the state's minimum hour requirements and there can no longer be any deviations, or the entire program will lose federal financial aid. As of April 9, 2024, the US DOE issued a notice that allows for the delay in enforcement and implementation of the 100 percent requirements for Title IV until January 1, 2025. DCA will continue to work with the U.S. DOE, California Legislature, and executive officers on this important issue.

Ms. Bucciarelli next advised that DCA's Diversity, Equity, and Inclusion (DEI) Steering Committee held its last meeting on April 5, 2024. The committee discussed DEI actions, priorities, and language access. Ms. Bucciarelli reminded members that DCA's Learning Management System had many DEI-related training courses available to Board members.

Ms. Bucciarelli then reported that DCA's Office of Public Affairs staff would participate in two Facebook Live events hosted by the Consulate of Mexico

during its Financial Education Week. Staff will present "Get to Know DCA" in Spanish and share a broad overview of consumer and licensing resources. The first event is with the Consulate of Mexico in Sacramento, and the second event will be with the Consulate of Mexico in Fresno. Ms. Bucciarelli added DCA would be developing workforce development outreach opportunities for all the boards and bureaus to participate.

Ms. Bucciarelli then reported that DCA's Division of Investigation (DOI) updated the Complaint Prioritization and Referral Guidelines for Healing Arts Boards in March 2024. The new guidelines were in effect and should be used to evaluate complaint referrals. Ms. Bucciarelli noted referral guidelines for non-healing arts boards/bureaus were in development.

Ms. Bucciarelli concluded by thanking Board members and executive officers who helped DCA achieve compliance with the annual Form 700 reporting period.

Members were provided an opportunity to comment on Ms. Bucciarelli's report; however, no comments were made.

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

VIII. Discussion and Possible Action related to Proposed Amendment to California Code of Regulations, Title 16, Section 1749 Related to Fees

President Oh advised that the proposed action related to proposed regulation, title 16, California Code of Regulations (CCR), section 1749, related to fees, was included in the meeting materials. Following the Board's action in December 2023 to initiate a rulemaking to update the Board's fee regulations, staff prepared the necessary rulemaking documents and submitted the rulemaking package to the DCA for review. Through its review, DCA has suggested that the Board rescind its December 2023 motion and instead facilitate regulation changes through two separate actions. Specifically, where the Board has determined that the fee should align with the predetermined amount established in the statute effective January 1, 2025, it was recommended that the executive officer, through delegated authority, pursue a Section 100 rulemaking. As noted in the materials, a Section 100 rulemaking is a change without regulatory effect. The Board will simultaneously pursue a rulemaking to amend section 1749(c) related to pharmacy technician fees. Dr. Oh indicated being comfortable with the recommendations offered by DCA.

Members were provided the opportunity to comment.

Mr. Chandler provided some background for new members on the fee audit that led to the statutory fee changes.

Dr. Serpa asked how decreases in fees would impact the Board's fund condition and reserve which was currently below the one year requirement. Ms. Sodergren provided the language was consistent with the policy that the Board established in December 2023, noting the fund condition was very fluid and the language reflects the decrease in pharmacy technician fees.

Dr. Crowley asked if there was a need for other regulatory changes for licenses other than pharmacy technician licenses. Ms. Sodergren provided the fee updates applicable to other license types would be completed through the Section 100 rulemaking through the delegated authority in the law.

Motion: Rescind the December 13, 2023 motion related to the amendment to Title 16, CCR Section 1749 in its entirety, regarding all fees, as discussed. Approve the proposed regulation text for CCR section 1749 specifically regarding the pharmacy technician applications, renewals, and delinquency fees 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(c) as noticed.

Department of Consumer Affairs
Title 16. Pharmacy

Proposed Regulatory Language

Fee Schedule – Pharmacy Technician Fees

Legend: Added text is indicated with underline. Deleted texts is indicated with strikethrough.

Amend 16 CCR § 1749(c) Fee Schedule as follows:

§ 1749 – Fee Schedule
The application, renewal, penalties, and other fees, unless otherwise specified, are hereby fixed as follows:

…

(c) The fee for the issuance of a pharmacy technician license is one hundred twenty dollars ($120) ~~one hundred ninety-five dollars ($195)~~. The fee for the biennial renewal of a pharmacy technician license is one hundred fifty dollars ($150) ~~one hundred ninety five dollars ($195)~~. The penalty for failure to renew is seventy-five dollars ($75). ~~ninety-seven dollars and fifty cents ($97.50)~~.
…

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

M/S: Chandler/Crowley

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

Support: 10 Oppose: 0 Abstain: 0 Not Present: 3

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

IX. Discussion and Possible Action Related to Proposed Regulations, Title 16, California Code of Regulations, Section 1760, Related to Disciplinary Guidelines, Including Review of Comments Received During the 45-Day Comment Period

President Oh advised that next for the Board's consideration was proposed changes to section 1760. Dr. Oh provided that no written comments were received during the 45-day comment period; however, as indicated in the meeting materials, staff were recommending two additional changes. Dr. Oh explained that the cover memo in the meeting materials detailed the two areas: a proposed change to optional term 23 related to the pharmacists recovery program, and a proposed change to optional term 24 related to drug and alcohol testing. Dr. Oh stated he was comfortable with the additional staff recommended changes.

Members were provided the opportunity to comment.

Dr. Crowley asked why the document had a January 2022 revision date. Ms. Sodergren provided staff could work with counsel to make a nonsubstantive update to the revision date.

Motion: Accept the Board staff recommended change and notice the regulation text and disciplinary guidelines for a 15-day public comment period. Additionally, should no adverse comments be received, authorize the executive officer to take all steps necessary to adopt the proposed regulation at Sections 1760 and the Disciplinary Guidelines, incorporated by reference, and complete the rulemaking process. Finally, delegate to the executive officer the authority to make technical or nonsubstantive changes as may be required by the Control agencies to complete the rulemaking file.

DEPARTMENT OF CONSUMER AFFAIRS
Title 16. Board of Pharmacy

PROPOSED REGULATORY LANGUAGE
Disciplinary Guidelines

Legend: **Added text is indicated with an underline.**
Deleted text is indicated by strikeout.

Amend section 1760 of Article 8 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1760. Disciplinary Guidelines.

In reaching a decision on a disciplinary action under the Administrative Procedure Act (Government Code sections 11400, et seq.) the ~~b~~ Board shall consider the disciplinary guidelines entitled "Disciplinary Guidelines" (Rev. ~~2/2017~~ 1/2022), which are hereby incorporated by reference.

Deviation from these guidelines and orders, including the standard terms of probation, is appropriate where the ~~b~~ Board, in its sole discretion, determines that the facts of the particular case warrant such a deviation--the presence of mitigating factors; the age of the case; evidentiary problems.

Note: Authority cited: Sections 315, 315.2, 315.4, and 4005, Business and Professions Code; and Section 11400.20, Government Code. Reference: Sections 315, 315.2, 315.4, and 4300-4313, Business and Professions Code; and Sections 11400.20 and 11425.50(e), Government Code.

M/S: Thibeau/Crowley

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

Support: 10 Oppose: 0 Abstain: 0 Not Present: 3

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

X. Closed Session Matters

Open session concluded at approximately 1:41 p.m. The Board entered closed session at approximately 1:52 p.m. Member Weisz arrived at approximately 2:16 p.m. Closed session ended at 5:32 p.m.

XI. Reconvene in Open Session to Adjourn for the Day

The Board reconvened into open session and adjourned the meeting for the day at approximately 5:33 p.m.

April 25, 2024

President Oh called the second day of the Board meeting to order at approximately 9:00 a.m. Dr. 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.

Roll call was taken. The following Board members were physically present in Sacramento: Jessi Crowley, Licensee Member; Trevor Chandler, Public Member; Renee Barker, Licensee Member; Jeff Hughes, Public Member; J. Newell, Public Member; Satinder Sandhu, Licensee Member; Maria Serpa, Licensee Member; Jason Weisz, Public Member; and Seung Oh, Licensee Member. KK Jha, Licensee Member, and Nicole Thibeau, Licensee Member, participated via WebEx. Members Jha and Thibeau each disclosed that no persons over 18 years old were present in the room with them as they participated in the meeting remotely via WebEx. A quorum was established.

President Oh reminded members participating via WebEx to remain visible with cameras on throughout the open session of the meeting. Dr. Oh advised if members needed to temporarily turn off their camera due to challenges with internet connectivity, they must announce the reason for their nonappearance when the camera was turned off.

XII. Enforcement and Compounding Committee

Chairperson Serpa provided the Board with a summary of the Committee's efforts at the April 11, 2024 meeting. Dr. Serpa thanked fellow members Vice-Chair Barker, Ms. Cameron-Banks, Dr. Oh, and Dr. Thibeau.

a. Presentation by the National Association of State Boards of Pharmacy on Drug Shortages including Discussion on the National Landscape

   Dr. Serpa recalled the Board received a request during public comment for items not on the agenda for the Board to agendize a discussion on drug

shortages, which was referred to the Enforcement and Compounding Committee for discussion. During the April 2024 meeting, the Committee received a presentation from Andrew Funk, Pharm D., Member Relations and Government Affairs Director with the National Association of State Boards of Pharmacy (NABP). The slides from Dr. Funk's presentation are included in the meeting materials. Dr. Serpa encouraged Board members and members of the public that were unable to attend the meeting to view the webcast to learn more about the issue.

Dr. Serpa reported that as part of Dr. Funk's presentation, members learned about a committee hearing being conducted by the federal House Committee on Oversight and Accountability on April 11, 2024, which would include an examination of the FDA's response to drug shortages. Dr. Serpa was hopeful that staff will be monitoring for any actions taken at the federal level that could be shared.

The Committee discussed their experiences with drug shortages, noting the complexity of the issue and that shortages span a variety of different types of medications. Additional information about the Committee's discussion and public comment received is included in the meeting materials.

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

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

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

A civil engineer and pain patient advocate noted Dr. Funk's presentation was good but didn't discuss the very real impact of the nationwide settlement with the three major distributors of controlled substances to pharmacies. The commenter added this was an additional contributor to shortages of FDA approved pain medications. The commenter was aware of the negative impact of the DEA's ever shrinking controlled substance production quotas on the supply to pharmacies of FDA approved pain medications. The commenter urged the Board to engage in the critical issue contributing to the ongoing shortages on pharmacy shelves.

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

b. Proposed Changes to ADDS Self-Assessment Rulemaking and Form, As Requested by the Office of Administrative Law

Dr. Serpa advised that, as included in the meeting materials, 16 CCR section 1715.1 established the requirement for the pharmacist-in-charge (PIC) of each automated drug delivery system (ADDS), to complete a self-assessment form evaluating the pharmacy's compliance with state and federal law. The self-assessment form is incorporated by reference in the section. As a result, when updates to the form are required to reflect changes in the law, the Board must undertake the rulemaking process.

Dr. Serpa noted that in January 2022, the Board voted to initiate a rulemaking to update the self-assessment form. At the end of the rulemaking process, the Office of Administrative Law (OAL) identified issues with the form that could not be resolved within the limited timeframe provided. As such, the rulemaking was withdrawn.

Dr. Serpa presented for the Board's consideration an updated version of the self-assessment form that included the previous changes approved by the Board, as well as the changes required by OAL, along with a few additional minor changes to reflect changes in pharmacy law that have occurred since the Board initiated the prior rulemaking in 2022. An example of a recent change is in the Note for hospital pharmacies. Specifically, the change is the last sentence of the paragraph that states "attach a list of all unlicensed ADDS, their locations and hours of operation," which was new language.

Dr. Serpa reported that the meeting materials detailed all changes being proposed, noting that while the form appears to indicate that a significant number of changes have been made, the vast majority of the changes were approved previously by the Board in 2022. Dr. Serpa further noted that an example of a change requested by OAL was on the first page in the Note for hospital pharmacies. The prior version approved by the Board referenced operating an ADDS pursuant to BPC section 4427.2. At the request of OAL, "ADDS" has been replaced with "AUDS." Similar changes were made throughout, replacing "ADDS" with "AUDS" where OAL deemed it appropriate.

Dr. Serpa noted that during the meeting, a member of the public had requested that the Board release the information received from the OAL detailing the changes, and that the memo from OAL was included in the meeting materials.

Dr. Serpa reported that at its April meeting, the Committee reviewed the changes and noted agreement, and was offering a recommendation to initiate a rulemaking.

Committee Recommendation: Recommend initiation of a rulemaking to amend California Code of Regulations, title 16, section 1715.1 consistent with the Committee's discussion and self-assessment form 17M-112, incorporated by reference. Authorize the executive officer to further refine the language consistent with the Committee's discussion and OAL's recommendations and to make any nonsubstantive changes prior to presenting the proposed rulemaking to the Board.

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

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

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

A member of the public thanked the Board for including the OAL memo in the meeting materials.

Support: 11 Oppose: 0 Abstain: 0 Not Present: 2

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

c. Compounding Activities by IV Hydration Clinics

Dr. Serpa advised that the meeting materials included relevant sections of federal law that establish the conditions under which compounded human drug products are exempt from three sections of the federal Food, Drug and Cosmetic Act. Dr. Serpa stated that the meeting materials also provided some background information on the issue of IV hydration clinics, including information about warnings released by the FDA involving instances of drug products being compounded under insanitary conditions. The materials highlighted that many of the warnings stem from compounding occurring in sites that are not regulated by the Board, including IV hydration clinics.

Dr. Serpa further explained that IV hydration clinics appear to be operating in many settings, including beauty salons, mobile vans, and gymnasiums, and some appear to lack appropriate oversight, use inappropriate equipment, and/or have improper storage, placing patients at risk. Examples of this practice are found in media and advertising offering IV hydration in the workplace, home, or hotels. These issues are occurring across the nation, including in California.

Dr. Serpa reported that Board staff have observed inspections in some IV hydrations clinics and report witnessing alarming practices placing consumers at risk. Staff also report challenges with conducting investigations because even basic patient information, administration information, *etc*. are not maintained and/or provided to the Board. Given the risk to patients, and

the documented harm, this issue was brought before the Committee to consider the issue and determine if there were any actions the Board should take to protect patients.

Dr. Serpa reported that the Committee discussed a number of policy questions at its April meeting. The meeting materials provided a summary of the discussion and public comments received. Dr. Serpa believed it was important to emphasize the Committee members agreed that given the Board's statutory mandate and the need to protect consumers, the Board must take some action. Members generally agreed it may be appropriate for the Board to secure additional cease and desist authority if there were instances of unsafe compounding that were not currently addressed under the Board's existing authority. Members also noted the need to ensure patients are educated about potential safety concerns, without creating fear for patients that may need IV hydration treatment for an underlying medical condition. It was determined that education would be appropriate as well as development of a policy statement. At its next meeting, the Committee will consider a draft policy statement that can be used to memorialize the Board's position. Further, the Committee suggested that the Communication and Public Education Committee develop consumer-facing educational materials highlighting some of the potential dangers of receiving IV products from unlicensed facilities or personnel as well as appropriate sources for IV products.

Chairperson Weisz of the Communication and Public Education Committee was agreeable to work on the project within the Committee.

Members were provided the opportunity to comment.

Mr. Chandler noted that at its April meeting, the Licensing Committee discussed the issue of pharmacy technicians compounding outside of pharmacies, including in IV hydration clinics and oncology infusion clinics, and that the Committee is concerned that the same compounding standards required in pharmacies were not being applied in these settings, making it potentially unsafe for patients.

Dr. Barker added both pharmacy technicians and people who are not trained in sterile compounding were doing the compounding in these settings, noting that this is a safety risk that patients may not be aware of.

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

Dr. Serpa reported she would be working with staff to develop a potential policy statement for consideration at the Committee's July 2024 meeting. This issue may also be appropriate for inclusion in the Board's upcoming sunset report.

d. Updates to Frequently Asked Questions Related to Assembly Bill 1286

Dr. Serpa recalled that given the comprehensive nature of AB 1286 (Haney, Chapter 470, Statutes of 2023), the Committee had determined that development of frequently asked questions (FAQs) was appropriate. The FAQs were considered during the February 2024 Board meeting. The Board approved the FAQs at that time but suggested that a few additional items related to minimum staffing may be appropriate.

Dr. Serpa stated that the meeting materials included a copy of the updated FAQs. The proposed changes to the FAQs were in questions 8 and 9 and were reflected with underlined text.

Committee Recommendation: Recommend approval of the additional FAQs related to Assembly Bill 1286.

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

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

Members were provided the opportunity to provide comment.

Dr. Crowley stated that SB 1442 still applies outside of the hours listed in the updated FAQs, and this is a source of confusion for licensees. Dr. Crowley wondered if the FAQs could address this and provide additional clarification.

Dr. Oh commented that additional questions could be added to the FAQs over time.

Dr. Sandhu asked if, in general, the Board tracked questions that were asked as a possible source for future FAQs. Ms. Sodergren provided questions come

to the Board from different sources (*e.g.*, inspectors, written comments, staff, *etc.*) from which FAQs are derived.

Support: 11 Oppose: 0 Abstain: 0 Not Present: 2

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

e. Enforcement Statistics

Dr. Serpa reported that the meeting materials included a summary of enforcement statistics for the first nine months of the fiscal year. The Board received 2,453 complaints and closed 2,174 investigations. As of March 1, 2024, the Board had 1,566 field investigations pending. The materials provide a breakdown of the average timeframe for the various stages of the field investigation process.

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

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

XIII. Licensing Committee

Chairperson Oh provided a report on the Licensing Committee's work at its April 10, 2024 meeting and thanked fellow Committee members Mr. Chandler, Dr. Barker, Dr. Crowley, and Mr. Weisz.

a. Presentations Regarding Pharmacy Technician Certification Programs

Dr. Oh recalled that as part of the Committee's January 2024 meeting, the Committee discussed pharmacy technician training programs, including employer-based training programs. At that time, members discussed what appeared to be great variability in the quality of employer-based programs and suggested perhaps the need for greater oversight of such training programs.

Also during the January meeting, the Committee discussed work being performed by the DCA Office of Professional Examination Services (OPES), which was performing an occupational analysis for the Board for the pharmacy technician licensure program. It was noted that the results of this analysis may help inform the Committee in its assessment of training program requirements moving forward. During this prior discussion, members suggested it would be helpful to learn more about pharmacy technician certification programs and accreditation requirements.

Dr. Oh reported that, to that end, during the April 2024 Licensing Committee meeting, the Committee received presentations from representatives of the Pharmacy Technician Certification Board (PTCB) and National Healthcareers Association (NHA). The meeting materials provided summary information from both of the presentations as well as the presentation slides. Dr. Oh reported the presentations were educational and no action by the Committee was taken.

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

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

b. Presentation by the American Society of Health-System Pharmacists Regarding Technician Training Program Accreditation

Dr. Oh referenced meeting materials detailing several relevant sections of pharmacy law including CCR, title 16, section 1793.6, which specifies that a pharmacy technician training program approved by the Board for purposes of licensure as a pharmacy technician includes a training program that is accredited by the American Society of Health-System Pharmacists (ASHP). At the January 2024 meeting, the Licensing Committee requested hearing a presentation on the pharmacy technician accreditation program.

Dr. Oh reported that during the April 2024 Licensing Committee meeting, members received a presentation from a representative from ASHP. A summary of the presentation and the presentation slides were included in the meeting materials. Dr. Oh advised this agenda item was for educational purposes and the Committee did not act on the information received.

Members were provided the opportunity to comment.

Dr. Serpa shared her personal experience with pharmacy technicians trained under ASHP accredited programs.

Dr. Oh added that the Committee also discussed limitations in the law regarding the types of training programs that allow for experience as a pharmacy technician trainee as a result of the statutory definition of the term in BPC section 4038. There was a general consensus among members that expansion of the pharmacy technician trainee definition may be appropriate and the Committee would consider draft language at its July 2024 meeting.

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

c. Survey Results Received Related to Pharmacist to Pharmacy Technician Ratio

Dr. Oh reported that one area the Board continually receives comments about was the issue of the pharmacist to pharmacy technician ratio. The meeting materials detailed the current law related to ratios. Dr. Oh noted that the pharmacist to pharmacy technician ratio was a very complicated issue with a variety of opinions on the topic, but that it was incumbent upon the Board to determine if the current ratio established in the statute or its regulation was appropriate for consumer protection, or if changes were appropriate.

Dr. Oh recalled that at the February 2024 Board meeting, the Board approved a survey for release to solicit feedback from California licensed pharmacists on the issue. He thanked the OPES for their collaboration on both the survey design as well as more recently for their assistance with evaluating some of the survey results.

Dr. Oh referenced meeting materials that included the data provided to the Licensing Committee during its April meeting. He also noted that later in today's meeting, as part of the Legislation and Regulation Committee report, the Board would be considering SB 1365, a measure that, as

introduced, would increase the pharmacist to pharmacy technician ratio to 1:6 in many pharmacy settings, including community pharmacies.

Returning to the survey results, Dr. Oh highlighted that the Board received over 5,100 survey responses, which shows that pharmacists are very concerned about the issue. Dr. Oh thanked the survey participants and added it was so important for the Board to understand their opinions on this very important issue, as it directly impacts licensees' ability to safely provide quality care to California patients. Dr. Oh added that not all of the survey respondents were California licensed pharmacists currently practicing in California. As a result, for purposes of the responses discussed during the Committee meeting, a little over 4,500 responses were analyzed.

Dr. Oh noted that general demographic data suggested that about 35 percent of the respondents to the survey identified as serving as a PIC and about 88 percent of survey respondents indicated that they currently supervise a pharmacy technician. Approximately 15 percent of respondents indicated that they did not supervise other pharmacy personnel. Based on the categories of number groupings for additional personnel that the respondent supervised, the highest response rate was between 5-10 other personnel, which was slightly higher than the response rate of pharmacists suggesting they do not supervise other pharmacy personnel. Dr. Oh highlighted this because it showed there were significant variances in the current scope of supervision required of pharmacists, adding that the Board must be mindful of this when considering if changes were appropriate for the pharmacist to pharmacy technician ratio.

Dr. Oh believed the two most critical questions were if it was believed the ratio was appropriate in two settings, institutional and noninstitutional. He continued by reminding members that the ratio for the institutional setting is determined by the Board via regulation whereas the statute establishes the ratio generally for the noninstitutional setting.

When posed the question if the individual believed that the current pharmacist to pharmacy technician ratio in the institutional setting was appropriate, over 50 percent of respondents indicated that the current 1:2 ratio *was* appropriate. Dr. Oh added that while he was not sure the Board was ready to foreclose the decision to update the current ratio via the regulation process for the institutional pharmacy setting, the survey results appear to suggest that the current ratio remains appropriate.

When asked the same question about the current ratio in the noninstitutional setting, the data suggested great variability among

respondents. The most frequent response suggests that the ratio of 1:2 was appropriate, followed by responses indicating that the current 1:1 ratio was appropriate.

Dr. Oh added that when taking a closer look at this question specifically, the data suggested that respondents identified as in a management or administrative position, 83.7 percent responded that the current 1:1 ratio in the noninstitutional setting was NOT appropriate. When asked to select the appropriate ratio for the noninstitutional setting, a ratio of 1:2 received the highest response rate, about 38 percent, followed by 1:3, about 27 percent, with about 22 percent indicating the ratio should be established by the PIC.

Ms. Sodergren announced Member Jha was disconnected from the meeting at 9:42 a.m.

Dr. Oh explained that the data suggested that respondents that identified as serving as a PIC in a noninstitutional setting, 82.6 percent indicated that the current 1:1 ratio in the noninstitutional setting was NOT appropriate. When asked to select the appropriate ratio for the noninstitutional setting, a ratio of 1:2 received the highest response rate, about 41.8 percent, followed by 1:3, about 26.1 percent, with about 20.1 percent indicating the ratio should be established by the PIC.

Dr. Oh highlighted this specific data as he thought it was indicative that while sometimes public comment suggested that the Board should be significantly changing or eliminating the ratio, even pharmacists in management or administrative positions, or those serving as a PIC, seem to disagree.

Dr. Oh reported that at the Licensing Committee meeting, members requested that staff provide more information about the number of survey respondents who were not in a management position or serving as a PIC and their belief on the current 1:1 ratio.

Dr. Oh further reported that, as suggested by the meeting materials, public comment received during the meeting varied greatly, with some suggesting the Board's survey results were consistent with results from workgroup meetings convened by the California Pharmacists Association (CPhA), and others suggesting that broad expansion of the pharmacist to pharmacy technician ratio was appropriate. Public comment also suggested that the Board should also consider establishing an overall cap on the number of individuals that can work in the pharmacy.

The Committee did not take action on this item, but indicated the issue should be raised as part of the upcoming sunset review.

Members were provided the opportunity to comment.

Dr. Barker commented that while public comment has suggested that the Board look at ratios in other states, that's not always informative because it's often not an apples-to-apples comparison.

Dr. Sandhu thought the survey was very helpful and confirmed what he has been hearing anecdotally, i.e., that many pharmacists would like to have a higher ratio. Dr. Sandhu asked if California was the only state with a 1:1 ratio. Dr. Oh noted California has very specific duties that pharmacy technicians perform, and this must be considered when comparing to other states' ratios.

Member Jha was reconnected to the meeting at approximately 9:45 a.m.

Dr. Sandhu asked how many states had no ratio. Ms. Sodergren provided California had a 1:1 ratio for licensed pharmacy technicians but had no ratio for unlicensed staff. Mr. Jha added according to his records there were 21 states with no ratio. Mr. Jha noted California had an unlimited ratio for the clerk typists. Dr. Serpa added some states have no licensure requirements for pharmacy technicians with no education or training requirements.

Dr. Serpa noted there were more pharmacy technician roles in the institutional settings that makes a ratio of 1:2 very difficult to maintain. Dr. Serpa indicated in the future being interested in having more discussions on institutional settings and educating the Licensing Committee and Board about what was so different about institutional settings. Dr. Serpa understood the current discussion was mostly about noninstitutional settings.

Dr. Oh discussed the possibility of parsing out the two settings and the different considerations that apply to each, and having a separate discussion at Licensing Committee in the future before sunset.

Dr. Crowley commented how the data opened her mind in some respects but there was a need to further evaluate the data.

Mr. Chandler noted the helpfulness of the survey and was interested in also getting feedback on the ratio issue from pharmacy technicians. He further noted that the survey seems to show support for a 1:2 or 1:3 ratio in the community setting.

Mr. Weisz commented that in the noninstitutional setting, 1:2 and 1:3 ranked the highest but added most respondents were management. He looked forward to hearing back form nonmanagement pharmacists.

Dr. Sandhu clarified the survey was to all pharmacists including both management and nonmanagement pharmacists. Ms. Sodergren agreed, noting the responses from nonmanagement pharmacists still need to be validated by OPES.

Mr. Hughes commented in support of matching the needs of the pharmacists as expressed in the survey responses with the protection of the public and looked forward to receiving additional data.

Dr. Thibeau commented in support of a hybrid approach to set a maximum with a caveat that it was at the discretion of the PIC. Dr. Oh agreed and was hopeful it could be added to the sunset report. Dr. Sandhu and Dr. Crowley also agreed, adding the pharmacist should be able to reject the additional pharmacy technician.

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

A representative of CCPC commented in appreciation of the survey completed by the Board. The representative noted according to her data there were 26 states without a ratio. The representative spoke in support of discussions to increase the ratio and reduce the bottlenecks caused by the current 1:1 ratio.

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

A representative of CPhA thanked the Board for the survey and was looking forward to seeing further subgroup analysis after validation. The representative noted SB 1365 was recently amended to 1:4 ratio.

A representative of CCAP commented in appreciation that Dr. Serpa brought up the fact that there needs to be a separate meeting for institutional care, including skill nursing facilities. There are some instances where pharmacies serving institutional settings can't use the 1:2 ratio and this needs to be changed.

A representative for UFCW WSC commented in appreciation of the survey and was looking forward to future discussions and a further breakdown of the data. The commenter emphasized that discussions of changing the

ratio can't just look at numbers, but also have to include what other protections pharmacists need. UFCW supports giving the pharmacists the discretion and authority to scale back if an increase of ratio would lead to a decrease in safety for patients. The representative also cautioned about second pharmacists being laid off if the ratio is increased. The representative noted the survey results supported a ratio of 1:2 over 1:4. The representative thought it was an appropriate discussion for sunset review process.

A pharmacist from San Francisco noted the practice of pharmacy was evolving and expanding in scope, need to be mindful of the previous comments about second pharmacists. The commenter also cautioned against setting a maximum number of staff as many things should be considered such as technology and remote pharmacists.

Another commenter was concerned with increasing the pharmacy technician ratio as pharmacists are already overworked and increasing the ratio would increase the work by increasing the number of people who had to be supervised. The commenter asked for the ratios to protect the pharmacists.

A pharmacist representative of Kaiser Permanente commented on the discussion about whether the PIC or pharmacist on duty should have the ability to designate the number of pharmacy technicians they can effectively supervise. If the Board goes that route, the representative encouraged doing it in a way that supports the pharmacy being able to effectively develop staff schedules being developed and suggested looking at the clerk regulation, 16 CCR section 1793.3(c), might be instructive.

Members were provided the opportunity to comment having heard public comment.

Dr. Crowley noted as the Committee continues the discussion about expanding pharmacists' duties and providing more clinical services, it was useful to highlight how beneficial it can be to have a second pharmacist in the store in a community setting, so that one pharmacist can focus on verification while the other pharmacist provides consultation, specialty injections, *etc*. She noted from the ISMP presentation, medication errors consistently stay the same regardless of volume, indicating that more support doesn't necessarily mean there will be fewer errors. Dr. Crowley also expressed concern that pharmacists don't fully grasp the liability associated with supervising more pharmacy technicians, adding that it was essential to ensure that, as the discussion on the ratio issue continues, pharmacists understand that supervision comes with responsibility.

Mr. Weisz followed up on the comment of the Kaiser representative and asked how pharmacies schedule in the real world.

Dr. Crowley commented that if a pharmacist was not comfortable with an increase of pharmacy technicians working in the pharmacy, the additional pharmacy technicians can work as a clerk which would help scheduling issues.

Mr. Newell appreciated the survey and noted without having information on errors, and if they tend to increase when the ratio is increased, some of the data needed to make a decision was missing.

Dr. Oh commented in support for the Board to secure the regulatory authority to change the ratio. He added this would add flexibility for the future.

The Board took a break from 10:18 a.m. to 10:33 a.m. Following the break, the following Board members were physically present in Sacramento: Jessi Crowley, Licensee Member; Trevor Chandler, Public Member; Renee Barker, Licensee Member; Jeff Hughes, Public Member; J. Newell, Public Member; Satinder Sandhu, Licensee Member; Maria Serpa, Licensee Member; Jason Weisz, Public Member; and Seung Oh, Licensee Member. KK Jha, Licensee Member, and Nicole Thibeau, Licensee Member, were present via WebEx. A quorum was established.

d. Implementation of Senate Bill 339 (Wiener, Chapter 1, Statutes of 2024) Related to HIV Preexposure Prophylaxis (PrEP) and Postexposure prophylaxis (PEP), including Draft Emergency Regulations and Possible Action to Initiate an Emergency Rulemaking and a Regular Rulemaking to Amend California Code of Regulations, Title 16, Section 1747

Dr. Oh referenced meeting materials including background information and the relevant law and reported that in response to recently enacted legislation, the Board must pursue emergency regulations to implement the expanded provisions for pharmacist-furnished HIV preexposure prophylaxis (PrEP). He added, with the recent passage of Assembly Bill 317 (Weber, Chapter 322, Statutes of 2023) related to reimbursement, he was hopeful that some of the barriers to implementation that have previously been identified, including for pharmacist-furnished care such as PrEP and PEP, have been addressed to allow access for patients with commercial health plans.

Dr. Oh thanked the experts with the Office of AIDS and the California Department of Health Care Services, pharmacist-experts that have provided input as well as the Medical Board Director and Medical Board

President for their consultation and review of the proposed emergency and permanent regulations. The language included in the meeting materials incorporates the feedback from many individuals. Dr. Oh was informed the Medical Board had no concerns or edits to the language.

Dr. Oh added that as emergency regulations were not something the Board generally pursues, Jennifer Robbins, DCA regulation counsel, was available to assist with any questions.

Dr. Oh reminded members and the public to be mindful during the discussion that pharmacists are routinely providing healthcare in a very prescriptive manner because of specificity provided in the law. As healthcare professionals, he believed it was appropriate to start empowering pharmacists to rely on their professional judgement when providing patient care and cautioned not to be overly prescriptive on the proposed regulation language. The Committee considered the language and believed it was appropriate. The meeting materials included the Committee's recommendation that serves as the motion.

Committee Recommendation: As an emergency exists by law, recommend initiation of an emergency rulemaking to amend California Code of Regulations, Title 16, section 1747 as proposed and a regular rulemaking to make the regulation amendments permanent. Authorize the executive officer to further refine the language consistent with the committee's discussion and to make any nonsubstantive changes prior to presenting the proposed emergency and regular rulemakings to the Board.

DEPARTMENT OF CONSUMER AFFAIRS
TITLE 16. PHARMACY

PROPOSED EMERGENCY REGULATORY LANGUAGE
HIV Preexposure Prophylaxis

Legend:	Added text is indicated with an underline. Deleted text is indicated by ~~strikeout~~.

Amend section 1747 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1747. Independent HIV Preexposure and Postexposure Prophylaxis Furnishing.

(a) Prior to independently initiating and furnishing HIV preexposure and/or postexposure prophylaxis to a patient pursuant to Business and Professions Code sections 4052.02 and 4052.03, a pharmacist shall successfully complete a training program approved by the board, provided by a

provider accredited by an approved accreditation agency, or as part of an equivalent curriculum-based training program completed from a recognized school of pharmacy. The training program shall satisfy the following criteria:
(1) Each training program shall be specific to the use of HIV preexposure and postexposure prophylaxis, and include at least 1.5 hours of instruction covering, at a minimum, the following areas:
(A) HIV preexposure and postexposure prophylaxis pharmacology.
(B) Requirements for independently initiating and furnishing HIV preexposure and postexposure prophylaxis contained in Business and Professions Code sections 4052.02 and 4052.03.
(C) Patient counseling information and appropriate counseling techniques, including at least, counseling on sexually transmitted diseases and sexual health.
(D) Patient referral resources and supplemental resources for pharmacists.
(E) Financial assistance programs for preexposure and postexposure prophylaxis, including the Office of AIDS' PrEP Assistance Program (PrEP-AP).
(F) Clinical eligibility recommendations provided in the federal Centers for Disease Control and Prevention (CDC) guidelines defined in Business and Professions Code sections 4052.02(c) and 4052.03(c).
(2) The training program shall require the passing of an assessment based on the criteria of (a)(1) with a score of 70% or higher to receive documentation of successful completion of the training program.
(b) A pharmacist who independently initiates or furnishes HIV preexposure and/or postexposure prophylaxis pursuant to Business and Professions Code sections 4052.02 and 4052.03 shall maintain documentation of their successful completion of the training program for a period of four (4) years. Training obtained as part of an equivalent curriculum-based training program, as identified in (a), can be documented by written certification from the registrar or training director of the educational institution or program from which the licensee graduated stating that the training is included within the institution's curriculum required for graduation at the time the pharmacist graduated, or within the coursework that was completed by the pharmacist. Documentation <u>of training</u> maintained pursuant to this subdivision must be made available upon request of the board.
<u>(c) For the purposes of this section, documentation of preexposure prophylaxis furnished and services provided shall be maintained in patient records, in the record system maintained by the pharmacy, for a minimum of three years from the date when the preexposure prophylaxis was furnished. Such records shall be made available upon request of the Board, consistent with the provisions of Business and Professions Code sections 4081 and 4105.</u>

NOTE: Authority cited: Sections 4005, 4052.02 and 4052.03, Business and Professions Code. Reference cited: Sections 4052, 4052.02, ~~and~~ 4052.03, 4081 and 4105, Business and Professions Code; and Section 120972, Health and Safety Code.

Members were provided the opportunity to comment.

Mr. Chandler commented in support noting Senator Weiner was a champion of the bill. He added this action was in tandem with the continuing education update regarding care to the LGBTQ community seen as past agenda items. Mr. Chandler added he was from San Francisco where they were fortunate to have robust HIV/AIDS prevention services as well as a robust representation of the LGBTQ community but that was not the case throughout the state especially in rural areas. Expanding the universe so that pharmacists can provide PrEP and PEP was important especially for those in the LGBTQ community who were looking to protect themselves. Mr. Chandler was in support of this measure and expansion of HIV/AIDS prevention because every infection now was preventable.

Dr. Crowley highlighted that the Committee's discussion about record retention requirements needed to be part of a larger discussion moving forward. She thought consideration of increasing the length of time that records were retained needed to be discussed.

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 representative of Mission Wellness Pharmacy commented that they recently participated in a stakeholder call with community pharmacists trying to implement PrEP and PEP. The representative noted the training requirements in the regulation were very specific and potentially foreclosed pharmacists from taking training programs outside of the California specific PrEP and PEP training.

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

Mr. Chandler asked if the training had to be California specific because of the specifics of SB 339 making sure time limits for prescription were known. Ms. Sodergren agreed and provided that, as presented, the motion contains two parts, an emergency regulation and a full rulemaking. The

Board could determine to move forward with the emergency rulemaking as proposed, and then as part of the full rulemaking, the Board could direct staff to address and research the training component.

Counsel Robbins provided an overview of the emergency regulation process and the regular rulemaking process.

Support: 11 Oppose: 0 Abstain: 0 Not Present: 2

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

e. Possible Amendment to California Code of Regulations, Title 16, Section 1713, Related to the Use of Automated Drug Delivery Systems

Dr. Oh referenced meeting materials detailing the relevant laws including Business and Professions Code (BPC) section 4427.6, which provides specific requirements for the use of automated patient dispensing systems (APDS) and specifically, subdivision (f) provides that all prescribed drugs and devices dispensed to a patient from an APDS shall be accompanied by a consultation conducted by a pharmacist licensed by the Board via a telecommunications link that has two-way audio and video. This requirement became effective in 2019 as part of Senate Bill 1447 (Hernandez, Chapter 666, Statutes of 2018).

Dr. Oh continued that also related is CCR, title 16, section 1713, specifically subdivision (d), which provides authority for a pharmacy to use an APDS to deliver medications to a patient under specified conditions. One condition is that an immediate consultation with a pharmacist be provided upon the request of the patient either in-person or via telephone. Section 1713 was amended in 2019, to make some conforming changes based on the provisions of SB 1447; however, the

proposed changes to the regulation text at that time did not differentiate the technology requirements consistent with the statutory requirements. This has led to some confusion among stakeholders about when two-way audio and video was required, consistent with BPC section 4427.6 and the regulation. To provide clarity to the regulated public, it was recommended that the Board amend section 1713(d) to be more specific to licensees and consolidate both technology requirements in a single location to allow for ease of use and ensure a common understanding of the two legal requirements. Dr. Oh reported that after discussion, the Committee noted agreement with the staff recommendation and proposed language.

Committee Recommendation: Recommend initiation of a rulemaking to amend California Code of Regulations, title 16, section 1713 consistent with the committee's discussion. Authorize the executive officer to further refine the language consistent with the committee's discussion and to make any nonsubstantive changes prior to presenting the proposed rulemaking to the Board.

Department of Consumer Affairs
Title 16. Pharmacy

Proposed Regulatory Language
Automated Patient Dispensing Systems Consultation

Legend: Added text is indicated with an underline.
Deleted text is indicated as ~~strikeout~~

Amendment to § 1713 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1713. Receipt and Delivery of Prescriptions and Prescription Medications Must be To or From Licensed Pharmacy.

(a) Except as otherwise provided in this Division, no licensee shall participate in any arrangement or agreement, whereby prescriptions, or prescription medications, may be left at, picked up from, accepted by, or delivered to any place not licensed as a retail pharmacy.
(b) A licensee may pick up prescriptions at the office or home of the prescriber or pick up or deliver prescriptions or prescription medications at the office of or a residence designated by the patient or at the hospital, institution, medical office or clinic at which the patient receives health care services. In addition, the Board may, in its sole discretion, waive application of subdivision (a) for good cause shown.
(c) A patient or the patient's agent may deposit a prescription in a secure container that is at the same address as the licensed pharmacy premises.

The pharmacy shall be responsible for the security and confidentiality of the prescriptions deposited in the container.
(d) A pharmacy may use an automated patient dispensing system (APDS) to deliver prescription medications to patients provided:
(1) A pharmacist has determined that each patient using the APDS meets inclusion criteria for use of the APDS established by the pharmacy prior to delivery of prescription medication to that patient.
(2) The APDS has a means to identify each patient and only release that patient's prescription medications to the patient or patient's agent.
(3) A patient shall receive consultation by a pharmacist from an APDS for the first time the prescribed drug is dispensed, as specified in Business and Professions Code section 4427.6 via a telecommunications link that has two-way audio and video. Further, ~~The~~ the pharmacy is able to provide~~s~~ an immediate consultation with a pharmacist, either in-person or via telephone, upon the request of a patient.
(4) Any incident involving the APDS where a complaint, delivery error, or omission has occurred shall be reviewed as part of the pharmacy's quality assurance program mandated by Business and Professions Code section 4125.
(e) Any pharmacy making use of an APDS shall maintain, and on an annual basis review, written policies and procedures providing for:
(1) Maintaining the security of the APDS and the dangerous drugs within the APDS.
(2) Determining and applying inclusion criteria regarding which medications are appropriate for placement in the APDS and for which patients, including when consultation is needed.
(3) Ensuring that patients are aware that consultation with a pharmacist is available for any prescription medication, including for those delivered via the APDS.
(4) Describing the assignment of responsibilities to, and training of, pharmacy personnel regarding the maintenance and filing procedures for the APDS.
(5) Orienting participating patients on use of the APDS, notifying patients when expected prescription medications are not available in the APDS, and ensuring that patient use of the APDS does not interfere with delivery of prescription medications.
(6) Ensuring the delivery of medications to patients in the event the APDS is disabled or malfunctions.
(f) Written policies and procedures shall be maintained at least three years beyond the last use of an APDS.

Credits

NOTE: Authority cited: Sections 4005, 4075 and 4114, Business and Professions Code. Reference: Sections 4005, 4017.3, 4052, 4116, 4117, 4427, 4427.1, 4427.2, 4427.3, 4427.4, 4427.5, 4427.6, 4427.7 and 4427.8, Business and Professions Code.

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

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

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

Support: 11 Oppose: 0 Abstain: 0 Not Present: 2

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

f. Proposal to Establish Authority to Waive the Renewal Fee Requirement for Pharmacists Licensed over 50 Years

Dr. Oh recalled that following a request from the public, the Board referred this item to the Licensing Committee for consideration. Dr. Oh referenced background information included in the meeting materials and summarized public comment suggesting that the Board consider development of a step-down licensure process for pharmacists getting ready to retire. It was suggested through public comment that the Board consider the approach used by Nevada. As included in the meeting materials, a pharmacist that has been registered with Nevada for at least 50 years was not required to pay renewal fees after that time.

Dr. Oh reported that based on the number of pharmacists that have currently been licensed for over 50 years in California, such a change could result in an annual loss of revenue to the Board of about $250,000.

Dr. Oh further reported that during the Committee's discussion, members requested staff conduct additional research for further consideration at a future meeting. As the Committee believes this may be an appropriate issue to include in the Board's sunset report, Dr. Oh indicated this item would be included for discussion at a future Licensing Committee meeting.

Members were provided the opportunity to comment.

Dr. Serpa shared her personal experience with Nevada's step-down licensure process. She was able to stop paying renewal fees on her Nevada license and although this meant she couldn't be a practicing pharmacist in Nevada, she could "restart" her license within five years without being required to take any tests. She indicated she would just need to pay the renewal fee and have the required continuing education. Dr. Serpa clarified that she was not licensed in Nevada to practice and the Committee discussed practicing without paying the renewal fee.

Members confirmed this would apply to those licensed for over 50 years and spoke in favor of Nevada's model, noting it would help in times of emergency. Members also spoke about the need to ensure that the burden of replacing missing revenue from fee waivers didn't fall on younger practicing pharmacists. Members pondered the logistics of turning off and on the license if this option was selected.

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

g. Compounding by Pharmacy Technicians Outside of Pharmacies

Dr. Oh advised that as requested by the Enforcement and Compounding Committee, the Licensing Committee discussed the requirements for licensure for a pharmacy technician. By definition, pharmacy technicians work in a pharmacy under the direct supervision and control of a pharmacist. Dr. Oh referenced meeting materials highlighting USP General Chapter 797, which provides the minimum requirements that apply to all persons who prepare compounded sterile preparations and all places where sterile preparations are compounded. This includes pharmacists and pharmacy technicians compounding in all places, including those areas outside of a pharmacy. Dr. Oh also recalled that federal law, Section 503A of the Food Drug and Cosmetic Act, made clear that

authority to compound a drug preparation was in part predicated on compliance with USP compounding chapters.

Dr. Oh reported that during the Committee meeting, the Committee considered a number of policy questions in its assessment of this issue. The meeting materials provide summary information on the Committee's discussion. Dr. Oh highlighted that members of the Committee believed the Board should begin conducting inspections at some of these unlicensed locations to gain a better understanding of compounding practices that were occurring at such sites. Members also generally spoke in support of the Board establishing a notification requirement to ensure the Board was aware of locations where pharmacy technicians may be compounding outside of a Board-licensed facility, but did not reach consensus if the requirement should be placed on the pharmacy technician or the unlicensed location. Members also agreed that the development of educational materials was appropriate.

The Committee noted that compounding practices in some unlicensed sites was an urgent patient safety issue. A summary of the public comments received was also included in the meeting materials.

Dr. Oh indicated the Committee did not take action on this item but the discussion would be included as an issue in the sunset review process.

Members were provided the opportunity to comment.

Dr. Crowley recalled the Committee's discussion including starting inspections, the survey, and not wanting to create a situation where pharmacy technicians were being surveyed and admitting they were practicing pharmacy without supervision. She recalled discussing the pharmacy technician's liability being a possible point of discussion as the pharmacy technician role expands over time.

Dr. Serpa expressed concern about pharmacy technicians compounding in locations that were not licensed pharmacies. She noted it was better than having someone with no pharmacy background providing those services, but acknowledged it was a form of independent practice that was worrisome. Dr. Serpa commented pharmacy technicians need to know they are not considered pharmacy technicians outside of a pharmacy and that their pharmacy technician license could be in jeopardy.

Dr. Serpa also expressed concern about a pharmacist supervising pharmacy technicians in a location not licensed by the Board. She noted

this may have implications for both the pharmacy tech's license as well as the pharmacist's license.

Mr. Chandler was surprised to hear this was happening at IV hydration clinics and other types of clinics where the pharmacy technicians were being sought out to be the "expert" at the site. He spoke in support of further investigation and action by the Board in this area.

Mr. Jha expressed concern about pharmacy technicians compounding in an oncology clinic without a supervising pharmacist, and supported finding out more information about the places this was happening. Dr. Oh indicated this was what the Committee and Board were trying to discern.

Dr. Barker explained that in order to protect the product and the consumer you have to look not just at manipulation of the drug product, but also at the environment in which the compounding is occurring.

Dr. Crowley added in addition to concerns about sterility, there was also a concern about worker safety given that we're talking about manipulation of hazardous materials.

The discussion continued, with members commenting on issues including the Board's jurisdiction and its consumer protection mandate, pharmacist/pharmacy technician liability, and workplace safety.

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.

Dr. Oh concluded by noting that this issue was appropriate for inclusion in the Board's sunset report. He further stated that given the Board's discussion it was appropriate to request that over the next few months Board staff conduct a few inspections at some of these unlicensed locations where pharmacy technicians were performing compounding and report back findings. Depending on the staff resources, Dr. Oh intended to continue the discussion at a future Licensing Committee meeting.

h. Presentations on Central Fill Pharmacy Models

Dr. Oh noted that strategic objective 1.2 calls 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. Consistent with this strategic objective, the Committee scheduled discussion on central fill pharmacies.

Dr. Oh advised that the Committee previously considered a number of policy questions. Following consideration of the various policy questions, the Committee determined it was appropriate to update its regulations to remove some of the ambiguity in the law. Dr. Oh reminded participants the Committee previously received public comment suggesting 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. DCA regulation counsel previously confirmed that the Board cannot interpret regulations through an FAQ or the newsletter and it must be done through regulation.

Dr. Oh reported during the January 2024 meeting, the Committee discussed draft regulations. The Committee and stakeholders had robust discussions around several provisions contained in the draft regulations, including on topics such as final product verification, the use of technology in central fill pharmacies, and concerns that the proposed regulations would disrupt central fill operations that already exist. Ultimately, the Committee determined that the proposed text was not ready for consideration by the Board. The Committee received several offers from individuals interested in providing presentations to the Committee on central fill models currently in use.

Dr. Oh continued that during the April 2024 Licensing Committee meeting, members received presentations from Albertsons and Walgreens. The presentations were very informative; however, neither model was operational in California. Summary information was provided in the meeting materials along with the presentation slides. Following the presentations, members noted that they did not believe they had sufficient information to continue evaluation of current central fill models. During the July 2024 Licensing Committee meeting, members will receive additional information, including information from field staff on central fill models that were currently operational in California.

Members were provided the opportunity to comment.

Dr. Crowley noted in the previous meeting public comment had expressed concern about changing the regulation language because doing so would disrupt patients' access to medication in California. As a result, she was surprised to hear that neither company that presented to the Committee at its April meeting actually had widespread central fill

operations in California. Dr. Crowley was looking forward to receiving more information from those who operate in California.

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

A representative of Walgreens thanked the Board for the opportunity to present to the Committee and indicated she was available for questions if needed.

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

A pharmacist representative of Kaiser Permanente commented they sent a letter to the Licensing Committee. The representative clarified that Kaiser Permanente did not operate a central fill pharmacy in California. Accordingly, Kaiser's comments were based on what they think would help in the future. Regarding the draft regulatory language, the representative encouraged the Committee and Board to not include a requirement that a pharmacist working in the originating pharmacy must provide final verification, as this would require manual documentation and reduce economies of scale benefits. He also asked the Committee and Board to opine on technology-assisted product verification.

Members were provided the opportunity to comment.

Dr. Crowley made a point of correction noting that Albertsons has around 10 pharmacies in California that utilize central fill.

i. Licensure and other Requirements for Nonresident Pharmacies

Dr. Oh began the discussion of this item by noting his concern about the Board's inability to regulate nonresident pharmacies, including mail order pharmacies. Nonresident pharmacies can create unique challenges for patients. The Board has reviewed previous investigations that resulted in discipline stemming from these challenges and placing patients at risk. Over the last two years, the Board has referred 11 nonresident pharmacies to the Office of the Attorney General for formal discipline and issued 39 citations. In addition, the Board took disciplinary action on 12 nonresident pharmacies. The underlying violations vary in egregiousness and include extremely serious causes of action including clearly excessive furnishing of controlled substances.

Dr. Oh reminded participants there was currently no requirement for pharmacists working in nonresident pharmacies, that are providing

services to California patients, to be licensed in California. Additionally, the Board previously voted and will be pursuing a statutory change to require the PIC of a nonresident pharmacy to be licensed in California.

During its April 2024 Licensing Committee meeting, members continued discussion of this issue. The meeting materials summarized the Committee's discussion and public comments. Dr. Oh highlighted that the Committee believed the Board should be conducting inspections of nonresident pharmacies. Members also noted some concern with changes made in some other jurisdictions that allow for reciprocity with Canadian pharmacists.

Members were provided the opportunity to comment.

Dr. Sandhu asked if nonresident pharmacies have to agree to follow all of the rules and regulations of the state it is shipping to. He thought it would be very complicated to get all of the pharmacists working in other facilities to be licensed in California, adding it could disrupt the supply to consumers in California.

Dr. Serpa added nonresident pharmacy was a license category for pharmacies outside of California shipping into California. Dr. Serpa noted the Enforcement and Compounding Committee was grappling with the issue as well, noting that currently the Board was very close to meeting the inspection goal for pharmacies in California being inspected once every four years and that she was surprised to hear there was no such goal for nonresident pharmacies. Dr. Serpa spoke in support of an inspection goal for nonresident pharmacies.

Dr. Oh hoped the Board could secure statutory authority for mandatory periodic nonresident pharmacy inspections.

Counsel Gartner clarified for the Board that there is a Board precedential decision that discusses nonresident pharmacies and gives some sense of the Board's authority and jurisdiction over them.

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 representative from Kaiser Permanente commented that many states that license nonresident pharmacies require a recent inspection report from their resident state or third-party.

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

j. Proposed Amendments to Pharmacy Law to Transition to a More Robust Standard of Care Model for Some Pharmacist-Provided Patient Care Services

Dr. Oh referenced meeting materials describing relevant laws and regulations generally detailing the scope of practice for pharmacists. Dr. Oh then recalled that as required by the Board's last sunset review, the Board was required to evaluate if moving to a standard of care enforcement model was feasible and appropriate for the regulation of pharmacy.

Dr. Oh reported that through an ad hoc committee, the Board dove into the issue and ultimately concluded that the Board's current hybrid approach to the regulation of the practice of pharmacy was appropriate. At that time, the Board noted that based on information received, California patients would benefit from pharmacists gaining additional authority to provide some patient care services consistent with their respective education, training, and experience; however, any such change would require legislation.

Dr. Oh continued that during the April 2024 Licensing Committee meeting, members initiated discussion of potential statutory language that could facilitate such a transition, noting that the draft statutory language was included in the meeting materials. Dr. Oh noted this was a starting place to initiate the discussion and summarized the concepts in the proposal:

1. Would expand provisions for pharmacists to perform CLIA waived tests, beyond those currently allowed in BPC section 4052.4.
2. Would allow a pharmacist to perform a therapeutic interchange under specified conditions.
3. Would establish authority for pharmacists to furnish FDA approved or authorized medication that is preventative or does not require a diagnosis under specified conditions.
4. Would expand upon pharmacists' current authority to administer biologics and would allow a pharmacist to furnish an FDA approved or authorized noncontrolled medication for the treatment of minor, nonchronic health conditions or for which a CLIA waived test provides diagnosis, and the treatment is limited in duration.
5. Would expand current authority for pharmacists to complete missing information on a noncontrolled medication if there is evidence to support the change.

6. Would expand authority for pharmacists to substitute medications that are generally considered interchangeable (*i.e.*, if insurance will only cover one medication but an interchangeable medication was prescribed.)
7. Would allow for medication therapy management and adjust treatments to manage chronic conditions diagnosed by a prescriber to optimize drug therapy (*i.e.*, adjusting medication dosing in response to laboratory results such as for warfarin, or medication to better control diabetes.)

Dr. Oh noted that he realized that for some, this proposal may seem too expansive and to others it may not go far enough. As indicated in the meeting materials, the Committee received public comments generally supportive of the language. Members highlighted that while the language appeared to be removing authority, that is not the case, rather the Board was simplifying the language.

Dr. Oh reported some members of the Committee and members of the public indicated that they believed the language was too expansive and may be open to interpretation. It was also noted that pharmacists in some work environments may not have sufficient autonomy to use their professional judgement to take care of patients. As this was the first discussion, the Committee will review the language again after receiving direction from the Board.

Members were provided the opportunity to comment.

Dr. Serpa expressed excitement over the language, noting that it resulted from the long process through the ad hoc committee. Dr. Serpa asked the Committee to discuss and refine several items: 4052(a)(12) – expand upon what is meant by "drug therapy related tests"; 4052(a)(16) – include that the vaccinations be suggested or advised by the ACIP; and the concept of therapeutic interchange, as the issue of therapeutic interchange with dosage forms was always fraught with concerns, worries, and discussion.

Dr. Crowley expressed significant concerns with the language as presented, noting that she thought it was too broad of an expansion. Some areas made sense to her, like expanding CLIA waived tests. However, establishing an authority to furnish medication that was considered "preventative" seemed too expansive as "preventative" was up to interpretation. Other areas that were too expansive included substituting medication without reaching out to a physician's office, specifically in chain retail settings. Dr. Crowley noted some of the items would be appropriate in a clinic setting (*e.g.*, ambulatory care setting) where the pharmacist can see the labs, whereas in a retail chain setting

the information was often missing or incomplete. Dr. Crowley recalled from the workforce committee survey, 95 percent of the chain community pharmacists reported that their employer required expanded services including immunizations and 78 percent of the chain community pharmacists felt they didn't have enough time to properly screen prior to immunizations which was a basic expanded service that has been done for some time. Dr. Crowley had concerns about the impact of authorizing additional pharmacist-provided patient care services requiring more focus and time, and was interested in finding out if pharmacists would actually feel comfortable providing the additional expanded services.

Dr. Oh commented that he hoped pharmacists feel they have the power and autonomy to use their professional judgment and not provide services when they feel they don't have the experience or training to competently do so. Dr. Oh noted the draft statutory proposal would be a mechanism to empower pharmacists to take care of their patients when they can.

Dr. Thibeau was excited to see the proposed statutory changes after having participated on the ad hoc committees. The straightforward changes like completing missing information on a prescription when you know what it is supposed to be, without having to go to a provider, will help patients. Dr. Thibeau noted the biggest barrier to any of the expansions has been payment. She provided the example of the data coming from the original PrEP bill SB 159 (Weiner, Chapter 532, Statutes of 2019) that services weren't being offered or expanded because the providers can't get paid for their services. Other parts of the pharmacy community need to be advocating for payment to make it happen now that there is authorization for the services to be done. She noted this would be really helpful for independent pharmacies to expand services and help their community.

Dr. Sandhu commented from the safety perspective, pharmacists should be confident in their skills, have the proper training, and not feel forced to provide expanded services. Dr. Sandhu liked the standard of care model because it provided a lot of opportunities that benefit the patient; for example, if a medication needs to be changed and the physician doesn't have to be contacted so that treatment is not delayed. Dr. Sandhu recommended thinking about concerns carefully, but this shouldn't stop the proposal from moving forward. He said it was a positive move for the profession and the consumers of California, especially rural areas and health care deserts.

Mr. Newell asked if this gives the pharmacist at the point of sale the power to make a change to the medication, how does that information get

back to the prescriber. Dr. Oh responded that it depended on the pharmacy. Mr. Newell noted reservations about giving pharmacists this authority without a system in place to ensure that the pharmacist has all of the patient's records and that the prescriber is notified about the change. Dr. Oh added notification was important and would hope the pharmacist would only proceed with making a change if they feel they have enough information and the patient will benefit from the change (*e.g.*, changing insulin from one brand that is not accepted by insurance to another brand that is accepted by insurance).

The discussion continued, with members further commenting on the need for a mechanism to ensure that medication changes are relayed back to the prescriber. Members also discussed reimbursement issues, collaborative practice agreements, and whether the pharmacist would then be considered the prescriber if they made a change to the patient's medication regimen.

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 from CPhA commented in support of and appreciation for the draft statutory proposal and noted CPhA looked forward to the discussion moving forward. CPhA was reconvening their subject matter expert groups to review the proposed language. The representative encouraged the Board to keep lab tests broad as there may be some tests that are not laboratory based that may affect decisions on medication use. The representative thought the preventative care language was taken from other states using the standard of care model where there has been past success. Regarding continuity of care, the representative agreed the intent was not to remove the primary prescriber, noting communication was important. Regarding payment, the representative noted it would potentially be addressed through AB 317 (Weber, Chapter 322, Statutes of 2023).

A pharmacist representative with Kaiser Permanente thanked the Committee and Board for the fantastic proposal provided. The representative was appreciative of language clarifying a prescription furnished by a pharmacist was a valid prescription under the definition of a prescription and recommended taking the same approach with definitions in the Health and Safety Code. The representative encouraged the Board to recognize that some of the new authorities in BPC section 4052 (*e.g.*, therapeutic substitution, pharmacist furnishing certain

preventative medications, *etc.*) could also be done under a collaborative practice agreement. The representative didn't want to see the collaborative practice option being removed.

A representative of CSHP commented in appreciation of the Board's efforts in transitioning to a standard of care model. For those with concerns that not all pharmacists were equally qualified, the representative commented that this is part of being a professional. Not all professionals are equally competent in all areas of specialty, and are obligated to decline the request to perform services outside of their specialty.

A representative of UFCW WSC thought the Board had a great discussion around the consumer concerns that could arise with transitioning to a standard of care model. The representative agreed with Dr. Crowley and Mr. Newell regarding making sure the primary care physician was informed of changing medications at the pharmacy. The commenter also noted that as this discussion continues, the Board needed to be mindful of different pharmacy settings, as this model would be different in a clinical setting than in a retail pharmacy setting. The representative further noted that the corporate practice prohibition doesn't apply to pharmacy, and pharmacists in retail settings often face pressures from corporate management that might make it hard to implement a standard of care model in that setting. The representative thought the medication error reporting system needed to be in place before the model is changed so that tracking of errors was monitored.

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

k. Licensing Statistics

Dr. Oh referenced licensing statistics for the first nine months of the fiscal year included in the meeting materials. The Board has issued 9,223 licenses during this time period including over 1,300 pharmacist licenses, over 3,600 pharmacy technician licenses, and over 1,000 pharmacist intern licenses.

Dr. Oh drew attention to the processing time for individual licenses, which as of April 1, 2024, was at or below 15 days for both initial applications and to process deficiency items, and further noted that unfortunately some site application processing times remained beyond the 30-day processing times due in part to loss of staff including a manager. The Committee would continue to monitor the progress made by staff. Dr. Oh understood that one position was recently filled and anticipated that as vacant

positions continue to be filled, improvement will be seen again with site licensing timeframes.

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

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

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

The Board took a lunch break from 12:15 p.m. to 1:00 p.m. Roll call was taken. The following Board members were physically present in Sacramento: Jessi Crowley, Licensee Member; Jeff Hughes, Public Member; J. Newell, Public Member; Satinder Sandhu, Licensee Member; Maria Serpa, Licensee Member; Jason Weisz, Public Member; and Seung Oh, Licensee Member. KK Jha, Licensee Member, and Nicole Thibeau, Licensee Member, participated via WebEx. A quorum was established.

XIV. Legislation and Regulation Committee

Chairperson Crowley provided a summary of the Committee's efforts at the April 11, 2024, meeting. Dr. Crowley thanked fellow members, Vice-Chair De La Paz, Mr. Chandler, Mr. Jha, Dr. Serpa, and Dr. Thibeau.

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

Dr. Crowley advised the last day for policy committees to consider a bill with fiscals was April 26, 2024. The last day for policy committees to hear bills without a fiscal was May 3, 2024. Dr. Crowley noted some of the measures have changed since the release of the meeting materials and she would be highlighting those measures.

Dr. Crowley reported there were some measures with a Board position already established by President Oh under his delegated authority. In addition, the Committee was offering recommended positions on a number of measures. Where recommendations were offered, the Committee recommendation would serve as the motion.

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

1. Assembly Bill 82 (Weber, 2022) Dietary Supplements for Weight Loss and Over-the-Counter Diet Pills

   Dr. Crowley advised AB 82 would prohibit a retail establishment from selling dietary supplements for weight loss or over-the-counter diet pills to any person under 18 years of age without a prescription. The measure would also require the California Department of Public Health (CDPH) to develop a notice for distribution and posting describing some of the possible side effects of taking such products and will require CDPH to consult with the FDA and other stakeholders to determine which dietary supplements for weight loss and OTC diet pills will be subject to the section and established an effective date of July 1, 2024.

   Dr. Crowley noted a potential increase in establishments seeking licensure as a pharmacy and staff were not recommending a position on the measure. Dr. Crowley believed this may be an appropriate measure to monitor and didn't believe a position was necessary. The Committee did not believe a position was necessary on this measure. Dr. Crowley noted as the chair of the Committee, she could continue to monitor with staff and bring the measure back to the Committee and Board if deemed appropriate.

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

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

2. Assembly Bill 1842 (Reyes, 2024) Health Care Coverage: Medication-Assisted Treatment

   Dr. Crowley advised AB 1842 would prohibit a health care service plan or health insurer from requiring prior authorization or step therapy for a naloxone or other opioid antagonist approved by the FDA or a buprenorphine or long-acting injectable naltrexone for detoxification or maintenance treatment of a substance use disorder.

   Dr. Crowley referenced meeting materials that noted the Committee was recommending that the Board establish a support position. Dr. Crowley added the Board had a long history of supporting measures that facilitate better access to naloxone and other medication-assisted treatments.

Member Barker returned to the meeting at 1:04 p.m.

Committee Recommendation: Establish a support position.

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

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

Support: 9 Oppose: 0 Abstain: 1 Not Present: 3

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

3. Assembly Bill 1902 (Alanis, 2024) Prescription Drug Labels: Accessibility

Dr. Crowley reported AB 1902 would require pharmacies to provide translated directions for use on prescription labels under specified conditions and further would require a pharmacy to provide a person, at no additional cost, an accessible prescription label that among other conditions, was appropriate to the disability and language of the person making the request through the use of audible, large print, Braille, or translated labels. As amended this measure would not apply if the dispenser was a veterinarian. The Committee agreed that the policy goal of the measure was laudable, but it was unclear if the measure could be implemented in its current form.

Dr. Crowley noted as indicated in the meeting materials, the Committee did not believe a position was appropriate. Similar to AB 82, Dr. Crowley

would continue to monitor the measure with staff and bring the measure back for consideration.

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

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

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

A representative of CSHP urged a position of support if amended, applauding the efforts to increase accessibility for sight-impaired persons, but expressing concern about the requirement being added at no cost to the consumer.

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

4. Assembly Bill 2115 (Haney, 2024) Controlled Substances

Dr. Crowley advised as amended AB 2115 would authorize a nonprofit or free clinic to dispense a schedule II controlled substance for the purpose of relieving acute withdrawal symptoms while arrangements are being made for referral for treatment. The measure would also make changes to narcotic treatment programs. The measure was heard in the Assembly Health Committee on April 23, 2024.

Dr. Crowley reported that through his delegated authority, President Oh recently established a support position and offered technical amendments. Dr. Crowley understood the author's office intended to accept the Board's technical amendments. The Committee agreed with the position established by President Oh. A summary of the public comment received was included in the meeting materials.

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

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

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

A representative of CSHP commented with concerns about the wording of the bill. Specifically, the commenter stated that a clinic wasn't a person and thus can't prescribe.

Dr. Crowley agreed with the concerns raised but noted the importance of the measure.

Motion: Formalize support position.

M/S: Oh/Crowley

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

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

Support: 9 Oppose: 0 Abstain: 1 Not Present: 3

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

5. Assembly Bill 2169 (Bauer-Kahan, 2024) Prescription Drug Coverage: Dose Adjustments

Dr. Crowley advised AB 2169 would allow a health care professional to request authority to adjust the dose or frequency of a drug to meet specific medical needs of the enrollee without prior authorization under specified conditions, including that the dose has not been adjusted more than two times without prior authorization. This measure was heard in Assembly Appropriations Committee on April 24, 2024. Dr. Crowley

reported the Committee was recommending the Board establish a support position on the measure.

Members were provided the opportunity to comment.

Dr. Oh thought that this would help alleviate the overuse of prior authorizations for patients. Dr. Crowley agreed.

Committee Recommendation: Establish a support position.

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 CSHP spoke in support of the Committee's recommendation of a support position.

Support: 9 Oppose: 0 Abstain: 1 Not Present: 3

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

6. Assembly Bill 2269 (Flora, 2024) Board Membership Qualifications: Public Members

Dr. Crowley advised AB 2269 would reduce the prohibition of a public member of any board from having a specified relationship (employer, contractual relationship, *etc.*) with a licensee of that board within three years (currently five years) of the public member's appointment. This

measure passed out of Assembly Appropriations Committee and was ordered to the consent calendar.

The Committee did not believe a position is necessary on this measure.

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

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

7. Assembly Bill 2271 (Ortega, 2024) Coverage for Naloxone Hydrochloride

Dr. Crowley advised AB 2271 was amended on April 18, 2024, and did not need to be discussed.

8. Assembly Bill 2445 (Wallis, 2024) Prescriptions: Personal use Pharmaceutical Disposal System

Dr. Crowley advised staff reported AB 2445 was not moving.

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

Dr. Crowley advised AB 3063 was similar to AB 782 from last year. Dr. Crowley recalled the Board initially established an Oppose Unless Amended (OUA) position in the hopes the Board could work with the author's office to discuss implementation challenges that some pharmacies indicated they would experience as a means to facilitate the policy goal of the measure without creating conflict with state and federal law and national standards. Regrettably that did not occur.

Dr. Crowley advised the primary difference between the two measures was that AB 3063 included a sunset date, meaning that conflict would only exist until January 1, 2030. Inclusion of the sunset date did not address the Board's concerns. Dr. Crowley noted President Oh established an OUA position pursuant to his delegated authority, which she believed was consistent with the actions of the Board from last year. The Committee agreed with the OUA position established. Dr. Crowley added Board staff have a meeting scheduled with the author's office to discuss the conflicts with federal law and to determine what amendments may address the Board's concerns while meeting the policy goals of the author.

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

Motion: Formalize oppose unless amended position.

M/S: Oh/Crowley

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 Flavor Rx urged the Board to support the bill.

A representative of CSHP spoke in support of AB 3063.

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

Dr. Serpa noted this has been an ongoing discussion at Board and committee meetings in recent years. Dr. Serpa added USP 795 specifically addresses flavoring and has guidance regarding adding flavoring. The Board's stance has consistently been to provide education to Board licensees on how to provide flavoring following the documentation requirements. Dr. Serpa added the Board was not "anti-flavoring" and noted no additional licensure or certification was required.

Support: 9 Oppose: 0 Abstain: 1 Not Present: 3

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

10. Assembly Bill 3146 (Essayli, 2024) Healing Arts: Sex-Reassignment

Dr. Crowley advised AB 3146 in its current form would establish that it is the intent of the Legislature to enact legislation prohibiting a health care provider from providing sex-reassignment prescriptions or procedures to a patient under 18 years of age. Meeting materials noted that the author's office indicated that amendments would be forthcoming; however, as of April 9, 2024, the amendments were not yet in print. The author's office advised staff of their intention to amend the language to include some of the provisions of the "Protect Kids" ballot initiative.

Dr. Crowley noted that although it appeared that the measure was not moving, during the Committee meeting, members expressed significant concerns with the measure's language and the policy goal of the measure. Members noted that the ballot initiative was very transphobic. Given the concerns of the members, the Committee was recommending that the Board establish an Oppose position.

Dr. Crowley highlighted that the status of the measure had not changed, and the measure was not referred to a legislative committee. With the policy deadline fast approaching, she didn't believe this measure would move this year.

Committee Recommendation: Establish an oppose position.

Members were provided the opportunity to comment.

Dr. Thibeau commented it was unusual to take a position without the language in place but noted it was important to take a position on this bill because of the transphobic nature of the measure and the "Protect Kids" act that it was coming from. Dr. Thibeau noted the name of the bill included transphobic language. Dr. Thibeau noted it was important to understand outcomes would be better in gender-affirming care at a younger age and if they had to wait until 18 years of age, they would not have as good of outcomes as they would have if they were able to start care earlier. Dr. Thibeau thought it was dangerous to allow the Legislature to ban a medical treatment that the medical community recognizes. Dr. Thibeau thought there were so many issues with the measure that while it was unusual to take an oppose position at this time, it was important to do so as a Board.

Dr. Crowley agreed.

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

Support: 9 Oppose: 0 Abstain: 1 Not Present: 3

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

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

Dr. Crowley advised SB 966 was recently amended quite significantly on April 18, 2024. As amended, the measure would establish the regulation of pharmacy benefit managers (PBMs) but would place the regulation under the jurisdiction of the Department of Insurance. As indicated in the meeting materials, the measure as introduced would have placed the regulation of PBMs within the Board's jurisdiction. Dr. Crowley highlighted President Oh, through his delegated authority, established a support position on the measure, which was consistent with the Board's prior policy on the regulation of PBMs by the Board. Dr. Crowley added given this change, she thought it was appropriate to discuss if the Board's current position remains appropriate or if perhaps it may be appropriate to move to a neutral position on the measure given the change.

Members were provided the opportunity to comment.

Dr. Thibeau still supported the measure as PBMs were still a huge problem for patients and thought oversight was needed regardless of whether it was the Board of Pharmacy or Department of Insurance. Dr. Crowley agreed. Dr. Oh thought it was a great effort to bring care to patients who have to be at the will of these businesses.

Motion: Formalize support position.

M/S: Oh/Crowley

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 CCAP commented in support of the position.

A representative of CPhA commented even with the recent amendments this bill impacts consumers receiving pharmacy services and encouraged the Board to vote for the motion.

Support: 8 Oppose: 0 Abstain: 2 Not Present: 3

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

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

Dr. Crowley advised SB 1067 would require the Board to develop a process to expedite the licensure process for an applicant that demonstrates that they intend to practice in a medically underserved area or serve a medically underserved population. The measure was heard in Senate Appropriations Committee on April 22, 2024.

Dr. Crowley recalled discussions at the Committee meeting that while she appreciated the policy goal of the measure it was written quite broadly.

Dr. Crowley was concerned about the potential impact to individuals seeking licensure as pharmacists, pharmacy technicians, etc., and the potential impact on application processing times if the Board was required to expedite the applications for those serving in a medically underserved area. Dr. Crowley was fearful that prioritizing applications for specific populations of applicants is going to create a barrier to licensure for others.

Dr. Crowley reported the Committee was not recommending the Board take a position on the measure. The Committee did believe it may be appropriate to request additional resources to ensure reprioritization of applications did not result in extended licensing delays for other applicants.

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

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

13. Senate Bill 1365 (Glazer, 2024) Pharmacy Technicians

Dr. Crowley advised as introduced, SB 1365 would update the pharmacist to pharmacy technician ratio to 1:6, from the current 1:1. The status of the measure indicated that it was recently amended from 1:6 to 1:4 and recently passed out of the Senate Business, Professions and Economic Development Committee on April 15, 2024. Given the change, Dr. Crowley thought it was appropriate to discuss if the Board's current position remained appropriate or if it may be appropriate to move to a neutral position.

Dr. Crowley noted the Licensing Committee received the results from the Board's recent survey on the current ratio. She thought the survey results could potentially support an increase in the ratio in the community pharmacy setting to a 1:2 if a pharmacist retains the ability to decline to supervise more than one technician consistent with the current provisions of the law. The Committee had significant discussion about the appropriate position to establish, oppose or oppose unless amended. The vote was not unanimous, but the majority determined an oppose position was appropriate given that the Board did not have a specific amendment to offer.

Committee Recommendation: Establish an oppose position.

Members were provided the opportunity to comment. An extended discussion ensued, with some members expressing support for an OUA or neutral position, and others suggesting that an oppose position was appropriate. Members raised issues including engagement with the author's office on the bill, what specific feedback the Board might want to provide to the author at this time, and how different positions might be perceived (*i.e.*, does an oppose position indicate to others that the Board doesn't even want to engage in a discussion of the ratio issue). Some members expressed disappointment that this measure was being brought forward now by others, as it made the discussion seem rushed or premature, especially given that the Board has recently discussed taking a more comprehensive and thoughtful approach to the ratio issue as part of its upcoming sunset review, and has begun taking actions (including the recent survey) to help inform this approach. Members also discussed the potential merits of moving the ratio out of statute and giving the Board the authority to set the ratio applicable to different pharmacy settings by regulation.

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 CCAP advised that the later in the legislative process the Board waits to provide comment, the harder it will be for the Board to make an impact. The representative had been in communication with the author's office and confirmed it applied to all community pharmacies.

A representative of UFCW WSC supported an oppose position even with the reduction to 1:4, noting that UFCW had over 100 member pharmacists writing in to oppose the 1:4 ratio. The representative encouraged engaging with the author's office to inform them of the work the Board was doing with ad hoc committees and surveys. The representative noted pharmacists should have the ability to provide their feedback and comments at future meetings. The representative noted other discussions that needed to happen including PIC/pharmacist authority to decline to supervise additional pharmacy technicians, *etc.*

A representative of CSHP commented that CSHP recommends Board staff work with the author's office to arrive at a number or ratio that was more consistent with the results of the Board's survey . The representative recommended mirroring the tech-check-tech regulation where certain services are required if the ratio was increased.

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

Dr. Crowley added wanting to further review the survey data, see the data out of AB 1286, and see the medication error reporting implemented.

Support: 5 Oppose: 4 Abstain: 1 Not Present: 3

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

Dr. Oh commented he voted yes in the spirit of the discussion that the Board will engage with the author with amendments the Board believes were necessary including possibly pharmacist authority to refuse additional pharmacy technicians and possibly Board regulatory authority. Dr. Serpa thought it would be easier and cleaner if the Board could have the regulatory authority. Dr. Crowley agreed. Dr. Thibeau asked for clarification from the author's office that they do or do not intend to include the pharmacy technicians who were not performing pharmacy technician duties (*e.g.*, clerks) in the ratio. Dr. Crowley recommended not comparing ratios of autonomous practitioners (*e.g.*, nurse practitioners, *etc.*) with the pharmacist technician ratio.

14. Senate Bill 1468 (Ochoa Bogh and Roth, 2024) Department of Consumer Affairs

Dr. Crowley advised SB 1468 would allow a practitioner who was not specifically registered to conduct a narcotic treatment program to dispense not more than a 3-day supply of narcotic drugs under specified conditions.

Committee Recommendation: Establish a support position.

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

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

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

A pharmacist commented that the bill requires the dissemination of information about the change in federal law.

Support: 9 Oppose: 0 Abstain: 1 Not Present: 3

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

b. Proposed Regulation Related to the Use of Digital Signatures

Dr. Crowley referenced meeting materials detailing the relevant laws related to the use of digital signatures. In April 2023, the Board approved a policy statement related to the acceptance of digital signatures. To fully implement the policy statement, regulations were necessary. Meeting materials included proposed regulation language for consideration. As included in the meeting materials, the Committee was recommending that the Board initiate a rulemaking consistent with the language presented.

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

Committee Recommendation: Recommend initiation of a rulemaking to adopt California Code of Regulations, title 16, section 1700 as proposed. Authorize the executive officer to further refine the language consistent with the committee's discussion and to make any nonsubstantive changes prior to presenting the proposed rulemaking to the Board.

DEPARTMENT OF CONSUMER AFFAIRS
TITLE 16. PHARMACY

PROPOSED REGULATORY LANGUAGE

Digital Signatures

Legend: Added text is indicated with an underline.

Adopt section 1700 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1700. Digital Signatures.

Consistent with the authority established in Government Code section 16.5, in any written communication, application, or other document in which a signature is required or used, the Board shall accept digital signatures that meet the requirements set forth in the California Code of Regulations, Title 2, section 22003(a).

Note: Authority cite: Section 16.5, Government Code. Reference cited: Section 16.5, Government Code.

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

Support: 9 Oppose: 0 Abstain: 1 Not Present: 3

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

c. Draft Frequently Asked Questions related to Cultural Competency Continuing Education

Dr. Crowley referenced meeting materials detailing the relevant sections of the law. Dr. Crowley added staff have experienced an increase in the number of calls from pharmacy technicians who were, for the first time, responsible for earning continuing education as part of the renewal process. To assist licensees in understanding the requirements, staff have developed FAQs that could be made available on the Board's website to serve as a resource for licensees. Following consideration, members of the Committee determined that the proposed FAQs were appropriate and were offering a recommendation to approve the FAQs.

Members were provided the opportunity to comment. Members agreed the FAQs would be helpful.

Committee Recommendation: Recommend approval of the draft FAQs related to continuing education for pharmacy technicians.

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

Support: 10 Oppose: 0 Abstain: 0 Not Present: 3

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

d. Board-Adopted Regulations Approved by the Office of Administrative Law
   1. Proposed Regulation to Amend Title 16 CCR section 1706.6 Related to the Military Spouse Temporary License
   2. Proposed Regulation to Amend Title 16 CCR section 1707.6 Related to the Notice to Consumer

e. Board-Adopted Regulations Undergoing Final Review by the Department of Consumer Affairs, or Business, Consumer Services and Housing Agency
   1. Proposed Regulation to Amend Title 16 CCR section 1732.5 and Add section 1732.8 Related to Continuing Education

f. Board-Adopted Regulations - Staff Drafting Final Rulemaking Documents
   1. Proposed Regulation to Amend Title 16 CCR section 1746.3 Related to Opioid Antagonist

g. Board-Approved Regulations Undergoing Pre-Notice Review by the Department of Consumer Affairs, or Business, Consumer Services and Housing Agency
   1. Proposed Regulation to Add Title 16 CCR sections 1750 and 1750.1 Related to Outsourcing Facilities
   2. Proposed Regulation to Add Title 16 CCR section 1746.6 Related to Medication Assisted Treatment Protocol
   3. Proposed Regulation to Amend Title 16 CCR sections 1735 et seq, Add sections 1736 et seq, 1737 et seq, and 1738 et seq, and Repeal sections 1751 et seq Related to Compounded Drug Preparations
   4. Proposed Regulation to Amend Title 16 CCR section 1708.2 Related to Discontinuance of Business
   5. Proposed Regulation to Amend Title 16 CCR section 1749 Related to the Fee Schedule
   6. Proposed Regulation to Amend Title 16 CCR section 1711 Related to Quality Assurance

7. Proposed Regulation to Amend Title 16 CCR section 1793.65 Related to Pharmacy Technicians

h. Board-Approved Regulations – Board Staff Drafting Initial Rulemaking 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

Dr. Crowley advised all items included in the regulations portion of the report were for information only. The Board had several regulations in various stages of promulgation. The Board's Notice to Consumer regulation was recently approved by the Office of Administrative Law. The regulations become effective July 1, 2024. The updated notice will be mailed in June to all licensed pharmacies.

Dr. Crowley advised that the 45-day comment period for the Board's proposed compounding regulations started April 19, 2024, and would close June 3, 2024. A regulation hearing was scheduled for June 18, 2024. All the required documents including the Notice, Initial State of Reasons, Proposed Text, and the Board's requested format for submitting comments were available on the Board's website under pending regulations.

Dr. Crowley reported staff was working on drafting final rulemaking documents to regulations that have been adopted by the Board. There were several regulations in the pre-review stage including the Board's fee regulation. Dr. Crowley advised the Board's fee regulation would be brought to the Board for consideration and action based on a recent recommendation from the DCA.

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

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

XV. Organizational Development Committee

Dr. Oh referenced meeting materials including updated information on the Board's budget for the current fiscal year which began July 1, 2023. The Board's authorized expenditures were anticipated to be about $34.1 million. The largest expenditures included personnel, pro rata, enforcement, and facilities.

Dr. Oh reported the Board's fund condition indicated that it was projected that the Board fund would slowly decrease; however, at a slower rate than was provided in the Board's fee audit. According to the report provided by the DCA, the Board's fund currently has 6 months of reserve. Dr. Oh reminded all under the provisions of BPC section 4400(p), the Board shall seek to maintain a reserve equal to approximately one year's operating expenditures.

Dr. Oh advised that Board member attendance and mail vote information was also included in the meeting materials. Dr. Oh thanked the members for their time and commitment to protecting California consumers.

Dr. Oh continued the Board currently had five vacant staff positions with ongoing recruitments. Dr. Oh indicated he received 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 next provided that the Board's procedure manual served as a resource guide for members and referenced meeting materials indicating staff were recommending updates to the manual. Dr. Oh noted meeting materials included the recommended changes reflected in track changes. Dr. Oh reviewed the proposed changes and believed they were appropriate.

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

Motion: Recommend approval of the updated Board Procedure Manual as presented.

M/S: Crowley/Baker

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

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

Support: 10 Oppose: 0 Abstain: 0 Not Present: 3

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

Finally, Dr. Oh referenced meeting materials that contain the remaining meeting dates for 2024, noting that September 12, 2024, may be a full Board meeting. Dr. Oh hoped to have 2025 meeting dates available at the July 2024 Board meeting.

XVI. Executive Officer Report

Ms. Sodergren provided the CPJE/NAPLEX statistics were included in the meeting materials with general trending information and noted the footnote for the NAPLEX statistics.

Ms. Sodergren thanked Board staff Sara Jurrens and Victor Perez who worked hard on the special *The Script* edition regarding the implementation of AB 1286.

Ms. Sodergren reminded participants of the anticipated change to the CURES System – ASAP 4.2B effective August 1, 2024, noting information on the change was posted on the Board's website.

Members of the Board were provided the opportunity to comment.

Dr. Crowley asked what the (E) meant for the NAPLEX statistics. Ms. Sodergren provided those NAPLEX scores were received outside of the content outline.

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

XVII. Closed Session Matters

The Board ended open session at 2:21p.m. and went into closed session at 2:30 p.m. The Board ended closed session at 4:02 p.m.

XVIII. Reconvene in Open Session to Adjourn for the Day

The Board reconvened into open session and adjourned the meeting at 4:03 p.m.