



California State Board of Pharmacy
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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor



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

Date: September 23, 2021

Location: Teleconference Public Board Meeting
Note: Pursuant to the provisions of Governor Gavin Newsom's Executive Order N-08-21, dated June 11, 2021, neither a public location nor teleconference locations are provided.

Board Members

Present:

Seung Oh, Licensee Member, President
Maria Serpa, Licensee Member, Vice President
Jignesh Patel, Licensee Member,
Jose De La Paz, Public Member
Lavanza Butler, Licensee Member
Shirley Kim, Public Member
Ricardo Sanchez, Public Member
Nicole Thibeau, Licensee Member
Jason Weisz, Public Member
Debbie Veale, Licensee Member

Staff Present:

Anne Sodergren, Executive Officer
Eileen Smiley, DCA Staff Counsel
Sheila Tatayon, DCA Staff Counsel
Debbie Damoth, Administration Manager

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

The meeting was called to order at 9:00 a.m. President Oh reminded everyone that the meeting was being conducted consistent with the provisions of Governor Gavin Newsom's Executive Order N-8-21. Provisions for providing public comment throughout the meeting were reviewed.

DCA staff provided instructions for providing public comment throughout the meeting.

President Oh advised those participating in the teleconference the Board would convene in closed session after deliberating on the open session items, except adjournment.

Roll call was taken. Board Members present included Maria Serpa, Jignesh Patel, Lavanza Butler, Jose De La Paz, Shirley Kim, Ricardo Sanchez, Nicole Thibeau, Debbie Veale, Jason Weisz, and Seung Oh. A quorum was established.

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

During the meeting members of the public were provided the opportunity to provide public comment on items not on the agenda; however, no public comments were made.

III. Discussion and Consideration of Adoption of Board Approved Regulation, Title 16 California Code of Regulations Section 1709 Related to Ownership, Management & Control of Business Entities, including Consideration of Public Comments Received during the 45-day comment period.

President Oh referenced the meeting materials for the regulation and commented in appreciation of the detailed responses to the comments received along with the relevant statutory provisions. Dr. Oh noted the history clarified the regulation language was developed with expertise from an attorney from the Business and Tax Section of the Office of the Attorney General.

President Oh acknowledged all had the opportunity to review the meeting materials including the comments received and staff recommendations. Dr. Oh advised Ms. Tatayon and Ms. Smiley were presented to answer any legal questions on the language, comments received, and staff recommendations developed in response to comments.

President Oh stated after reviewing the comments, he agreed with the recommendations of staff. Members were provided the opportunity to provide comment; however, no comments were made.

Motion: Accept the Board staff recommended comment responses and adopt the regulation language as noticed for 45-day comment on July 23, 2021. Additionally, 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.

To Amend Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

Legend: Insertions are Underlined; Deletions are Stricken

§1709. Names of Owners and Pharmacist In Charge Ownership, Management, and Control of Pharmacies and Other Regulated Business Entities.

- (a) Each permit license issued by the board to operate a pharmacy shall reflect show the name and address of the pharmacy, the form of ownership, (individual, partnership or corporation) and the pharmacist-in-charge. Each pharmacy shall, in its initial application and on the annual renewal form, report the name of the pharmacist-in-charge, the names of all owners, and the names of the corporate officers (if a corporation). Any changes in the pharmacist-in-charge, or the owners, or corporate officers shall be reported to the Board within 30 days of the change.
- (b)(1) Any transfer, in a single transaction or in a series of transactions, of 10 percent or more of the beneficial interest in a business entity licensed by the board to a person or entity who did not hold a beneficial interest at the time the original permit license was issued, shall require written notification to the board within 30 days of the transfer.
- (2) Any transfer of the management or control over a business entity licensed by the board to a person or entity who did not have management or control over the license at the time the original license was issued, shall require written notification to the board within 30 days of the transfer.
- (c) A license issued by the board shall not be transferred from one owner to another. The following shall constitute a change of ownership transfer of permit and shall require a new application for a change of ownership licensure:
- (1) any transfer of a beneficial interest in a business entity licensed by the board, in a single transaction or in a series of transactions, to any person or entity, which transfer results in the transferee's holding 50% or more of the beneficial interest in that license. The new owner shall apply to the board for licensure in advance of the proposed transaction taking place.
- (d) If any beneficial interest of a business entity licensed by the board is held in trust, the applicant, licensee, or any person with management or control of the business entity shall do the following:
- (1) In addition to the requirements in subdivision (a), as part of their application and renewal, report the name of any other person in any position with management or control of the business entity;

- (2) As part of the application, disclose the full name of the trust, and provide to the board a complete copy of, and any amendments to, the trust document. A trust document and any related amendments shall be considered confidential financial documents by the board;
- (3) As part of annual renewal, provide to the board a complete copy of any amendments to the trust document made after submission of the original application;
- (4) Include in the application and annual renewal the name, address, phone number, and any email address for each grantor, settlor, trustee, and/or trust protector, as applicable;
- (5) Include in the application and annual renewal the name, address, phone number, and any email address for each named beneficiary of the trust who is age 18 or older. Where the beneficiary is under age 18, the guardian of the beneficiary(ies) shall be identified; and
- (6) Notify the board in writing within 30 days of all the following:
- (A) A change in trustee, protector or any other person with management or control of the business entity;
 - (B) Any change in the beneficiaries of the trust, where the beneficiary is age 18 or older. Where the beneficiary is under age 18, the guardian of the beneficiary(ies) shall be identified;
 - (C) The revocation of the trust;
 - (D) The dissolution of the trust;
 - (E) Any amendment to the trust since the original application; and
 - (F) Any change in the character of the trust, including, but not limited to, the trust changing from revocable to irrevocable.
- (e) An application may be denied, or a license may be suspended or revoked, based on the failure of any individual required to be disclosed to the board to qualify pursuant to the provisions of sections 4302, 4307, or 4308 of the Business and Professions Code.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4035, 4037, 4058, 4101, 4110, 4111, 4112, 4113, 4120, 4124, 4130, 4131, 4133, 4141, 4149, 4160, 4161, 4196, 4201, 4205, 4207, 4302, 4304, 4305, 4307, 4308, and 4330, Business and Professions Code.

M/S: Veale/Sanchez

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

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

Board Member	Vote
Butler	Support
De La Paz	Support
Kim	Support
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Thibreau	Support
Veale	Support
Weisz	Support

IV. Agenda Item IV. Requests to Waive Pharmacy Law Provisions Consistent with Authority of Business and Professions Code section 4062

- a. Consideration of Policy Granting President Discretion to Waive Provisions of Pharmacy Law

President Oh advised members it may be appropriate to consider the current delegation to the Board President to determine if changes are appropriate. Dr. Oh noted he believed the Board has been very thoughtful and deliberate in response to the COVID-19 pandemic and ability to respond quickly to the dynamic nature of the emergency in large part has been through the delegated authority. He advised the meeting materials include the two separate provisions for delegation and noted the delegated authority of the President to extend an existing waiver expired on August 31, 2021; the authority for the President to approve a new waiver remains.

Dr. Oh referenced information in the materials for the Board's consideration which included an alternative approach to the delegation that would provide the Board President the authority to approve or extend waivers through June 30, 2022, or until 90 days following the declared disaster, whichever is sooner.

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

Motion: Delegate authority to the Board President to approve or extend pharmacy law waivers as appropriate based on current conditions

through June 31, 2022, or until 90 days following the declared disaster, whichever is sooner.

M/S: Veale/Butler

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

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

Board Member	Vote
Butler	Support
De La Paz	Support
Kim	Support
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Thibreau	Support
Veale	Support
Weisz	Support

b. Consideration of Mass Vaccination Site Waiver

President Oh advised members that the mass vaccination site waiver was used to facilitate the significant COVID-19 vaccination effort in California and was set to expire on October 16, 2021, unless extended. Dr. Oh advised that staff confirmed with California Department of Public Health (CDPH) the waiver is still needed and with the recent expansion of approval of boosters to additional populations, it may become more necessary in various regions throughout California.

President Oh referred to the recommendation in the meeting materials to delegate to the Board President the authority to extend the mass vaccination site waiver at their discretion after consultation with the CDPH.

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

Motion: Delegate authority to the Board President to extend the pharmacy law waiver for mass vaccination sites at the President's discretion after consultation with the CDPH.

M/S: Veale/Patel

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

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

Board Member	Vote
Butler	Support
De La Paz	Support
Kim	Support
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Thibreau	Support
Veale	Support
Weisz	Support

c. Consideration of Site-Specific Waiver for California Department of Public Health Alternate Care Site Facility – Sacramento, HPE 57779

President Oh indicated that the waiver for CDPH Alternate Care Site Facility, HPE 57779 was to reinstate a temporary hospital license issued to CDPH. Dr. Oh referenced information in the meeting materials that included the license history, background information, and a recommendation to delegate to the Board President the authority to extend the temporary license as the President's discretion after consultation with the CDPH.

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

Motion: Extend the waiver through the end of the year and if additional extension is necessary, delegate to the Board President the authority to extend the waiver at their discretion after consultation with the CDPH.

M/S: Serpa/De La Paz

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

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

Board Member	Vote
Butler	Support
De La Paz	Support
Kim	Support
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Thibreau	Support
Veale	Support
Weisz	Support

V. Discussion and Consideration of Request from University of California, Irvine School of Pharmacy and Pharmaceutical Sciences, for Board Recognition Pursuant to Title 16, California Code of Regulations Section 1719

President Oh noted that the Board received a request to recognize the University of California, Irvine, (UCI) for purposes of issuing intern licenses to students enrolled in their program. Dr. Oh noted as included in the meeting materials, UCI received pre-candidate status from ACPE; however, candidate status cannot be achieved until the school produces its first class of graduates. He stated absent board approval, students will be unable to progress through their education.

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

Motion: Grant Board recognition to University of California, Irvine, School of Pharmacy and Pharmaceutical Sciences, for purposes of issuing intern licenses.

M/S: Butler/Patel

Members of the public were provided the opportunity to provide comment.

Jan Hirsh, founding Dean of University of California, Irvine, School of Pharmacy and Pharmaceutical Sciences, commented she was available for questions.

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

Board Member	Vote
Butler	Support
De La Paz	Support
Kim	Support
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Thibreau	Support
Veale	Support
Weisz	Support

VI. Strategic Planning Session

President Oh referenced meeting materials that included the draft objectives that could serve as a starting point for discussion. Dr. Oh recommended as the Board discussed the various committees of the Board, the focus should be on the intent of each item and ensure a common understanding, but allow some flexibility to finalize language later, especially during the goal development. He believed this approach would ensure the Board completed its session and indicated that as President he would be agreeable to finalize language with staff after approval prior to publication.

- a. Strategic Planning Overview and Discussion and Consideration of Results of Environment Scan Survey

President Oh introduced Trisha St. Clair and Sarah Irani as Strategic Business Analysts and Facilitators with SOLID Planning to guide the Board through the process. Ms. St. Clair reviewed the role of the facilitators and reviewed ground rules.

- b. Strategic Planning Action Items

- i. Discussion and Consideration of Board's Mission, Vision, and Values

Ms. St. Clair reviewed the definitions and purpose of the mission, vision, and value statements. She stated the mission and environmental analysis indicate where the Board is now; the vision notes where the Board is going in the future; and goals and objectives provide how the Board will get to the vision.

Ms. St. Clair reviewed the strategic planning roadmap indicating the preliminary meeting and environmental scan had been completed. She noted the meeting today served as the planning session. Next steps would be to create and finalize the plan with action planning.

Ms. St. Clair defined the SWOT analysis as the review of internal strengths and weaknesses as well as external opportunities and threats. She also reviewed the environmental scan completed in 2016 versus 2021 and indicated there was over an 800 percent increase in the number of responses received.

Ms. St. Clair reviewed the Board's mission statement, vision statement, and values. She stated that objectives should be specific, measurable, action oriented, realistic, and time based. Ms. St. Clair advised that the executive officer and staff would be responsible for implementing the strategic plan and ensuring strategic objectives are completed.

Members did not make changes to the Board's current mission statement, vision statement and values.

ii. Discussion and Consideration of Board's Strategic Goals

Ms. St. Clair reviewed each committees' goal prior to the committee's respective objective discussion.

iii. Discussion and Consideration of Strategic Goal Objectives

President Oh explained he and Executive Officer Sodergren reviewed the environmental scan and drafted objectives for consideration as a place to start the discussions around strategic goal objectives.

Licensing Committee

Members reviewed the goal and discussed the draft objectives for the Licensing Committee.

Motion: Approve the objectives as displayed and delegate to the Board President and Board staff to make any nonsubstantive changes to the language.

- 1.1 Evaluate, and change if appropriate, legal requirements for authorized duties that can occur outside of a pharmacy to reflect the dynamic nature of the pharmacy profession.
- 1.2 Consider and pursue necessary changes in the law regarding various pharmacy practice settings to ensure variances in the practice are appropriate.

- 1.3 Explore, and pursue changes in law as appropriate, authorized duties of a pharmacy technician and potential expansion based on other jurisdictions to expand authorized duties.
- 1.4 Determine if application requirements for a pharmacist-in-charge (PIC) are appropriate to ensure sufficient knowledge, skills, and abilities for individuals seeking to serve as a PIC.
- 1.5 Engage with Cal/OSHA on pharmacy working conditions to ensure sufficient resources and conditions exist to facilitate safe patient care.
- 1.6 Consider results, and change laws as appropriate, regarding the Office of Professional Examination Services audit of the California Multi-State Jurisprudence Pharmacy Examination and pharmacy law requirements to ensure exams are relevant.
- 1.7 Decrease licensing processing times to improve customer service and support applicants and licensees.
- 1.8 Streamline the licensing process to improve efficiency and staff performance.
- 1.9 Migrate the entire licensing process online to promote timeliness, reduce staff workload, and provide better customer service.

M/S: Sanchez/Veale

Members of the public were provided the opportunity to provide comment; however, there were no

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

Board Member	Vote
Butler	Support
De La Paz	Support
Kim	Support
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Thibeau	Support
Veale	Support
Weisz	Support

The Board took a break from 10:25 a.m. to 10:40 a.m. Roll call was taken after the break. Members present included Maria Serpa, Jignesh Patel, Lavanza Butler, Jose De La Paz, Shirley Kim, Ricardo Sanchez, Nicole Thibeau, Jason Weisz, Debbie Veale, and Seung Oh. Quorum was established.

Enforcement and Compounding Committee

Members reviewed the goal and discussed the draft objectives for the Enforcement and Compounding Committee.

- Motion:** Approve the objectives as displayed and delegate to the Board President and Board staff to make any nonsubstantive changes to the language.
- 2.1 Evaluate, and take necessary actions, regarding the causes and effects of medication errors to reduce errors.
 - 2.2 Analyze enforcement outcomes to identify trends to educate licensees of common violations and improve patient outcomes.
 - 2.3 Complete routine inspections of all licensed pharmacies at least every 4 years to proactively assess pharmacy operations and educate licensees.
 - 2.4 Determine and reduce barriers to timely case resolution to improve consumer protection.
 - 2.5 Assess, and pursue where appropriate, further use of a Standard of Care Model to protect consumers.

- 2.6 Establish greater consistency in how inspectors interpret the law and carry out inspections to improve compliance, support licensees, and further patient care.
- 2.7 Write a Budget Change Proposal to increase the number of enforcement staff to ensure more regular inspections and investigations, and to improve case processing times.
- 2.8 Educate licensees clearly about enforcement responsibilities to improve compliance and build relationships.
- 2.9 Assess the pharmacist involvement in medication handling at locations not regulated by the Board of Pharmacy to increase patient safety and standardize care.
- 2.10 Evaluate if regulations align with Federal regulations and standards governing the practice of compounding and pursue changes if appropriate, to ensure patient safety and assist licensees with standards.

M/S: Oh/Patel

Members of the public were provided the opportunity to provide comments. Members heard comments encouraging prioritizing inspection of pharmacies that have not been inspected in years; improving communication; and using the current regulatory process to ensure that pharmacists working outside of a pharmacy are still under the purview of the Board.

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

Board Member	Vote
Butler	Support
De La Paz	Support
Kim	Support
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Thibreau	Support
Veale	Support
Weisz	Support

The Board took a break from 12:02 p.m. – 1:03 p.m. Roll call was taken after the break. Members present included Maria Serpa, Jignesh Patel, Lavanza Butler, Jose De La Paz, Shirley Kim, Ricardo Sanchez, Debbie Veale, Jason Weisz, Nicole Thibeau, Debbie Veale, and Seung Oh. Quorum was established.

Legislation and Regulation Committee

Members reviewed the objectives and discussed the draft objectives for the Legislation and Regulation Committee.

Motion: Approve the goals as displayed and delegate to the Board President and Board staff to make any nonsubstantive changes to the language.

- 3.1 Consider, and advocate for necessary changes, regarding recognition for provider status for pharmacists to improve patient access.
- 3.2 Review, and update if necessary, existing regulations and statutes, to keep pharmacy law and its regulations current and inclusive for all.
- 3.3 Evaluate, and if appropriate, advocate, regarding barriers to patient care driven by outside entities, e.g., Pharmacy Benefit Manager practices and Drug Manufacturers, to remove barriers to prescription and (specialty) medications.
- 3.4 Identify opportunities to leverage pharmacist knowledge, skills, abilities, and accessibility to create appropriate access points to care to improve public health.
- 3.5 Support legislation that increases scope of practice for pharmacists and pharmacy technicians to increase access and improve health outcomes for the public.
- 3.6 Promote legislation that ensures pharmacists are adequately provided with qualified resources to promote working conditions that minimize errors and improve health outcomes for the public.

M/S: Butler/De La Paz

Members of the public were provided the opportunity to provide comments. Members heard comments in support the Board advocating as it is appropriate for the Board especially when unlicensed entities are practicing pharmacy

without a license; removing barriers for prescriptions and specialty medications; including all practicing settings; and removing barriers preventing pharmacists from being health care providers.

Support: 9

Oppose: 0

Abstain: 1

Not Present: 0

Board Member	Vote
Butler	Support
De La Paz	Support
Kim	Support
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Thibreau	Support
Veale	Support
Weisz	Abstain

Communication and Public Education

Members reviewed the goal and discussed the draft objectives for the Communication and Public Education Committee.

- Motion:** Approve the objectives as displayed and delegate to the Board President and Board staff to make any nonsubstantive changes to the language.
- 4.1 Develop a consumer education campaign to educate consumers about the Board and the importance of pharmacy services.
 - 4.2 Reevaluate, and update if necessary, educational materials related to pharmacy law to assist licensees in operating in compliance.
 - 4.3 Promote the self-assessment process to educate licensees about the importance of the tool.
 - 4.4 Create an educational program through the colleges of Pharmacy and a required training prior to obtaining an intern license to ensure an understanding of the Board and its consumer protection mandate.

- 4.5 To educate about the profession, enhance consumer protection, and give the Board a bigger presence.
- 4.6 Create more webinars to post on the website to disseminate basic information.
- 4.7 Improve communication to licensees by personalizing it and decreasing verbiage to encourage licensee engagement.
- 4.8 Research creating a recognition program for pharmacists to help build relationships between public, licensees, and the Board.

M/S: Sanchez/Butler

Members of the public were provided the opportunity to provide comments. Members heard comments in support of working with the schools of pharmacy in California.

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

Board Member	Vote
Butler	Support
De La Paz	Support
Kim	Support
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Thibeau	Support
Veale	Support
Weisz	Support

e. Organizational Development

Members reviewed the goal and discussed the draft objectives for the Organizational Development Committee.

Motion: Approve the objectives as displayed and delegate to the Board President and Board staff to make any nonsubstantive changes to the language.

- 5.1 Secure the necessary resources to fulfill the Board's strategic goals to meet the Board's Vision.
- 5.2 Develop a formal onboarding program for new members to ensure new members are prepared.
- 5.3 Promote staff training and development to ensure staff retention and a positive work environment.
- 5.4 Continue Business Modernization activities to determine technology needs.
- 5.5 Develop staff through training and setting clear expectations to increase staff retention and support staff.
- 5.6 Improve public and licensee access to staff to provide better customer service and support licensees.

M/S: Butler/Sanchez

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

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

Board Member	Vote
Butler	Support
De La Paz	Support
Kim	Support
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Thibreau	Support
Veale	Support
Weisz	Support

The Board agreed to have the Strategic Plan for five years.

VII. Closed Session Matters

The Board recessed into closed session at approximately 2:45 p.m. The Board went into closed session at approximately 3:00 p.m.

VIII. Adjourn

The Board adjourned after closed session at approximately 4:00 p.m.