

California State Board of Pharmacy 2720 Gateway Oaks Drive, Suite 100

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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: December 4, 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 (via WebEx)

Trevor Chandler, Public Member, Treasurer Renee Barker, PharmD, Licensee Member

Jeff Hughes, Public Member

Jason "J." Newell, MSW, Public Member Satinder Sandhu, PharmD, Licensee Member Maria Serpa, PharmD, Licensee Member

Nicole Thibeau, PharmD, Licensee Member (via

WebEx)

Board Members

Not Present: Indira Cameron-Banks, Public Member

Kartikeya "KK" Jha, RPh, Licensee Member

Jason Weisz, Public Member

Staff Present: Anne Sodergren, Executive Officer

Julie Ansel, Deputy Executive Officer Corinne Gartner, DCA Staff Counsel Shelley Ganaway, DCA Staff Counsel

Jennifer Robbins, DCA Regulations Counsel Sara Jurrens, Public Information Officer

Debbie Damoth, Executive Specialist Manager

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December 4, 2024

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 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: Trevor Chandler, Public Member; Renee Barker, PharmD, Licensee Member; Jeff Hughes, Public Member; J. Newell, MSW, Public Member; Satinder Sandhu, PharmD, Licensee Member; Maria Serpa, PharmD, Licensee Member; and Seung Oh, PharmD, Licensee Member. Jessi Crowley, PharmD, Licensee Member, and Nicole Thibeau, PharmD, Licensee Member, participated via WebEx. Dr. Crowley and Dr. 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.

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

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

Public comment was received requesting an investigation into and full halt of the administration of the COVID vaccines in pharmacies. The commenter asked the Board to investigate if pharmacies are trained and compliant in filing vaccine adverse event reports into VAERS and also requested a future agenda item to review how many adverse event reports have been filed and what course of action was taken by the pharmacies.

A member of the public commented that properly dosed ivermectin could treat COVID and expressed concern that the COVID vaccine is disproportionately harming and killing people of color.

A pharmacist thanked the Board for the newsletter article pointing out pharmacies that go past 30 days without a pharmacist-in-charge (PIC) and

requested a follow up article indicating which pharmacies are lacking PICs past 30 days.

A representative of Cardinal Health commented about Business and Professions Code (BPC) section 4071.1 related to shared services and remote work and suggested there should be a waiver process to allow for remote work for emergency situations (e.g., strikes, natural disaster, etc.) and future workforce shortage.

A pharmacist suggested there be a new PIC requirement to attend at least one Board of Pharmacy meeting as part of being a PIC. Additionally, the commenter suggested Board staff provide a one hour training course for all PICs.

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

A civil engineer and patient pain advocate requested the Board of Pharmacy work with the Medical Board of California to brief the California Attorney General on the impact of the opioid settlement injunctive relief on consumers.

A representative from the Alliance for Pharmacy Compounding commented regarding the Board's proposed compounding regulations.

A representative from CPhA commented about the Sunset Review item related to payor practices that negatively impact patient care from the November 2024 Board meeting. Related to implementation of AB 1114, which authorizes Medi-Cal reimbursement for pharmacist-provided clinical services, (e.g., HIV PEP and PrEP, naloxone, nicotine replacement therapy, self-administered hormonal contraception, etc.) there continue to be significant inconsistencies among the 24 Medi-Cal contracted managed care organizations (MCOs). CPhA urged the Board to include mandatory MCO reporting in the Sunset Review.

A pharmacist representative of Kaiser Permanente recommended agendizing discussion on the HIPAA final rule to support reproductive health care privacy that takes effects December 23, 2024. The rule was intended to strengthen privacy protections and may require Board representatives to sign an attestation in the future.

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

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

President Oh reminded those present that the Board recognizes pharmacists who 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. Pharmacist Mark Raus was recognized for 40 years of service as a pharmacist. President Oh thanked and congratulated Dr. Raus for his service as a pharmacist. Dr. Oh thanked all pharmacists who worked in pharmacy serving the consumers of California.

IV. Review and Approval of Draft Sunset Report, Including Sections 1-9 and Appendices

President Oh noted that the Board has completed significant work to identify areas to raise as part of the Board's Sunset Report to the Legislature. Dr. Oh stated that he believed the work undertaken was notable and he was proud of the Board's efforts. He reminded those present that as part of the November 2024 Board meeting, the Board approved the New Issues portion of the Board's Sunset Report, and added that today the Board would consider the remainder of the draft report, sections 1-9 and related appendices. Dr. Oh thanked staff for their work on the extensive report.

Dr. Oh provided members the opportunity to provide comments.

Dr. Crowley commented on the continuing education (CE) failure rates and was curious if any failure rates included cultural competency failure rates. She thought it would be appropriate to add a statement about compliance with implementation on the measurement of cultural competency given the diversity, equity, and inclusion initiative.

Mr. Chandler inquired about the fund condition and budget sections. Ms. Sodergren stated that she would confirm the most current budget would be included and add language to explain the disparity in assessed versus collected fines. Mr. Chandler also asked questions to clarify his understanding of some of the Board's business modernization activities as well as staffing issues and challenges.

Dr. Barker commented that the report accurately outlines the amount of work completed by the Board on behalf of consumers.

Dr. Sandhu requested additional trending information on complaints. Ms. Sodergren added some of the complaints received include non-jurisdictional complaints.

Dr. Serpa appreciated the discussion on CE and thought it would be good for the Board to discuss how to improve understanding of CE requirements. She also expressed concern that the attestation CE requirements may be checked off without having been actually completed. She recommended adding a forcing function (e.g., additional checkboxes) for required CEs.

Dr. Thibeau was very impressed by the report and found the format easy to read. She noted that the report repeatedly made clear the effects that COVID had on the Board and its processes.

Dr. Oh stated he reviewed the report and was in support of the information provided. He appreciated the trending information in Licensing and Enforcement and Compounding as well as the significant policy work undertaken by the Board to protect California consumers.

Motion: Approve the draft Sunset Report Sections 1-9, including its

appendices and attachments not previously approved by the Board, and further, delegate to the Board President to finalize the report, appendices, and attachments consistent

with the Board's policy discussions.

M/S: Oh/Chandler

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

A representative of CVS Health commented about the impact of reduced intern applications, increased pharmacy technician duties and ratio and recommended the Board expand more the pharmacy technician authorized duties. He was concerned with the number of pharmacies closing and recommended taking a new look at telepharmacy for urban and suburban areas in addition to rural areas. He also encouraged the Board to leverage technology to anticipate pharmacist shortage.

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

Members heard comments from pharmacists, a pharmacist representative from Kaiser Permanente, and a pharmacy technician. Comments received encouraged the Board to continue to evaluate whether the MPJE is an appropriate exam; expressed agreement with the recommendation to repeal BPC section 4427.8 and urged the Board to eliminate the separate ADDS

medication error reporting requirement; requested that the Board publish data on pharmacy deserts; expressed support for expanding pharmacy technician duties; and suggested that the Board consider requiring licensees to use the NABP CE Monitor as a way of ensuring required CE is completed.

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

Dr. Serpa noted the Board's previous discussion on the MPJE was significant and extensive. She noted that the Office of Professional Examination Services (OPES) of the Department of Consumer Affairs had determined that the MPJE's methodology didn't meet California's statutory requirements.

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

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

V. Discussion and Possible Action Related to Proposed Amendment to California Code of Regulations, Title 16, Section 1793.65 Related to Pharmacy Technician Certification Programs

Dr. Oh reminded those present that the changes being proposed to California Code of Regulations, title 16, section 1793.65 would extend the sunset date of the pharmacy technician certification programs approved by the Board. Dr. Oh recalled that the Board has contracted with the Office of Professional Examination Services to conduct the necessary audits of both certification programs to confirm compliance with legal requirements, and that as the audits were still underway, extension of the sunset date was necessary to ensure the Board has sufficient time to receive and consider the audit results.

Dr. Oh referenced the meeting materials, noting that the comment period on the proposed regulations ended October 7, 2024 and no comments were received. He added that as the Board's original motion did not delegate authority for the executive officer to adopt the changes if no negative comments were received, this issue was agendized to allow the Board to consider the matter and adopt the amended regulation text.

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

Motion:

Adopt the regulation text as noticed on August 23, 2024, and authorize the executive officer to take all steps necessary to complete the rulemaking. Further, delegate to the executive officer the authority to make technical or non-substantive changes as may be required by the Control agencies to complete the rulemaking file.

Department of Consumer Affairs Title 16. Board of Pharmacy

Proposed Regulation Text Pharmacy Technician Certification Programs

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

Amend section 1793.65 to Article 11 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

- § 1793.65. Pharmacy Technician Certification Programs Approved by the Board.
- (a) Pursuant to Business and Professions Code section 4202(a)(4), the <u>bB</u>oard approves the pharmacy technician certification program offered by:
 - (1) The Pharmacy Technician Certification Board, and
 - (2) The National Healthcareer Association.
- (b) Approval of these programs is valid through December 31, 2024. June 30, 2026.

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M/S: Chandler/Sandhu

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

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

A pharmacist requested the effective date of the regulation.

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

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

VI. Discussion and Possible Action Related to Proposed Amendment to California Code of Regulations, Title 16, Section 1747 Related to Independent HIV Preexposure Prophylaxis Furnishing – Permanent Regulations, Including Review of Comments Received During the 45-Day Comment Period

Dr. Oh recalled that following enactment of Senate Bill 339 (Wiener, Chapter 1, Statutes of 2024), the Board adopted emergency regulations that became effective August 14, 2024, updating the Board's regulations establishing the training program requirements consistent with the statutory provisions for pharmacist-furnished HIV Preexposure and Postexposure Prophylaxis (HIV PrEP

and PEP). Dr. Oh referenced the meeting materials that included a brief background on the rulemaking, the comments received during the 45-day comment period, and staff recommended responses to the comments received. Dr. Oh stated that he had reviewed the staff recommendations and agreed with them. He noted that while he appreciated commenters suggesting changes to the language to allow for additional training programs, he also agreed with staff that an approved training program needs to address California specific legal requirements that may not be included in CDC training programs. He further noted that the Board's regulations establish minimum requirements, and that nothing would prevent a pharmacist from completing additional training, including training offered by the CDC.

Dr. Oh continued that should the Board be successful in securing a transition to a more robust standard of care model, this would remove some current restrictions for pharmacist-furnished HIV PrEP and PEP, which could then allow the Board to remove the requirement for this section of regulation. Dr. Oh also reminded those present that members approved the Board's updated HIV PrEP and PEP training course at the November 6-7, 2024 Board meeting.

Members were provided the opportunity to comment.

A member asked why a submitted comment was outside the scope of the regulation. Counsel Robbins explained the regulation is about training program requirements for furnishing HIV PrEP and PEP and document requirements and does not address which specific drugs can be administered. A member provided additional information about barriers to care related to PrEP and PEP.

Motion:

Accept the Board staff's recommended comment responses, adopt the regulation text as noticed on September 20, 2024, and authorize the executive officer to take all steps necessary to complete the rulemaking. Further, delegate to the executive officer the authority to make technical or non-substantive changes as may be required by the Control agencies to complete the rulemaking file.

Department of Consumer Affairs **Title 16. Pharmacy**

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PROPOSED REGULATORY LANGUAGE Independent HIV Preexposure Prophylaxis Furnishing

Legend: Added text is indicated with an <u>underline</u>.

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 bBoard, 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

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- 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 curriculumbased 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 araduated, or within the coursework that was completed by the pharmacist. Documentation of training maintained pursuant to this subdivision must be made available upon request of the bBoard.
- (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.

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

M/S: Thibeau/Chandler

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

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

A representative of CPhA and a pharmacist provided additional information regarding long-acting injectables and commented on logistical barriers to providing long-acting injectables for Medicare patients.

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

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

The Board took a break from 10:32 a.m. to 10:45 a.m. Roll call was taken. The following Board members were physically present in Sacramento: Trevor Chandler, Public Member; Renee Barker, PharmD, Licensee Member; Jeff

Hughes, Public Member; J. Newell, MSW, Public Member; Satinder Sandhu, PharmD, Licensee Member; Maria Serpa, PharmD, Licensee Member; and Seung Oh, PharmD, Licensee Member. Jessi Crowley, PharmD, Licensee Member, and Nicole Thibeau, PharmD, Licensee Member, participated via WebEx.

VII. Discussion and Consideration of Board-Provided Pharmacist-in-Charge Overview and Responsibility Training Course, Consistent with California Code of Regulations, Title 16, Section 1709.1

Dr. Oh advised that, consistent with the recent changes to California Code of Regulations, title 16, section 1709.1 related to PIC requirements in January 2022, the Board approved proposed regulation text to amend section 1709.1. At the November 2024 Board meeting, the Board adopted the final regulation text. To ensure the Board's training program was available in advance of the effective date of the regulation requirements, the proposed training program was before the Board today for review. Dr. Oh thanked Supervising Inspector Ngondara for his efforts to develop this training program. Dr. Oh stated that he had reviewed the materials and believed the training program was appropriate and consistent with the direction of the Board.

Members were provided the opportunity to comment.

Members discussed including a slide that covered when and how often PICs are required to complete the training, and noted that all pharmacists, not just PICs, can take the training and obtain CE credit. A member also noted that 16 CCR section 1715.65 subsections (c) and (d) regarding inventory reconciliation should be included.

Motion: Approve the draft Pharmacist-in-Charge Overview and

Responsibility training course consistent with the Board's

discussion.

M/S: Serpa/Barker

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

A pharmacist expressed concerned for ensuring new PICs actually take the class; suggested that the Board explore creating a pharmacy technician-in-charge; and inquired about whether the Board is discussing the use of AI in pharmacy.

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

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

Members discussed whether the training requirement applied to existing PICs or only new/incoming PICs. Counsel Gartner confirmed a PIC shall complete the Board-provided PIC training within two years prior to the date of application to be PIC. Members also discussed adding slides reminding about the requirement to sign up to receive subscriber alerts and providing links to additional resources such as the lawbook, *The Script*, and FAQs.

Executive Officer Sodergren offered post-implementation review of the regulation as an agenda for the Licensing Committee in a year as well as preparing a PIC toolbox on the Board's website with links to resources.

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

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

VIII. Closed Session Matters

Open session concluded at approximately 11:03 a.m. The Board convened in closed session at approximately 11:21 a.m. and ended closed session at 12:53 p.m.

IX. Reconvene in Open Session to Adjourn for the Day

The Board reconvened into open session and adjourned the meeting at 12:53 p.m.