

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



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

Date: March 18, 2021, 2020

Location: Teleconference Public Board Meeting Note: Pursuant to the provisions of Governor Gavin Newsom's Executive Order N-25-20, dated March 17, 2020, neither a public location nor teleconference locations are provided.

Board Members

Present:	Gregory Lippe, Public Member, President Debbie Veale, Licensee Member, Vice President Maria Serpa, Licensee Member, Treasurer Lavanza Butler, Licensee Member Seung Oh, Licensee Member Shirley Kim, Public Member Jignesh Patel, Licensee Member Ricardo Sanchez, Public Member Jason Weisz, Public Member Albert Wong, Licensee Member
Staff Present:	Anne Sodergren, Executive Officer Lyle Matthews, Assistant Executive Officer MaryJo Tobola, Senior Enforcement Manager

Eileen Smiley, DCA Staff Counsel Sheila Tatayon, DCA Staff Counsel

Debbie Damoth, Administration Manager

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

The meeting was called to order at 9:04 a.m. As part of the opening announcements, President Lippe reminded everyone that the meeting was being conducted consistent with the provisions of Governor Gavin Newsom's Executive Order N-29-20.

Provisions for providing public comment throughout the meeting were reviewed.

President Lippe 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: Debbie Veale, Lavanza Butler, Jason Weisz, Ricardo Sanchez, Seung Oh, Shirley Kim, Albert Wong, Jignesh Patel, Maria Serpa and Greg Lippe. 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.

Danny Martinez, California Pharmacists Association, requested that the Board Enforcement and Compounding Committee to discuss methylcobalamin at the next meeting.

Enforcement and Compounding Chairperson Serpa noted that the issue of API is an ongoing agenda item and will be discussed.

III. Discussion and Consideration of Adoption of Board Approved Regulation, Title 16 CCR Section 1747, Related to HIV Preexposure and Postexposure Prophylaxis Furnishing, (Any comments, if timely received, to be reviewed by the Board.)

President Lippe referenced the meeting materials, and noted that at the January 2020 Board meeting, the Board approved the regulation language to establish, on a permanent basis, the criteria for training programs that a pharmacist must complete prior to independently initiating or furnishing preexposure and postexposure prophylaxis.

The comment period for this regulation ended on March 15, 2021. One comment was received during the comment period, which indicated support for the Board's regulation.

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

Motion: Adopt the regulatory language as noticed on January 29, 2021, and delegate to the executive officer the authority to make technical or non-substantive changes as may be required by Control agencies to complete the rulemaking file.

§ 1747. Independent HIV Preexposure and Postexposure Prophylaxis Furnishing.

California State Board of Pharmacy Board Meeting Minutes – March 18, 2021 Page 2 of 10 (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, or 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. <u>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</u>

California State Board of Pharmacy Board Meeting Minutes – March 18, 2021 Page 3 of 10 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 maintained pursuant to this subdivision must be made available upon request of the board.

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

M/S: Veale/Oh

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

Steve Gray noted the regulation is very important and spoke in support of the regulation.

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

Board Member	Vote
Butler	Support
Kim	Support
Lippe	Support
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Veale	Support
Weisz	Support
Wong	Support

IV. Discussion and Consideration of Board Approved Text to Initiate Rulemaking Related to the Pharmacy Technician Application, Pharmacy Technician Training Requirements and Pharmacy Technician Certification Programs

President Lippe provided an overview of the agenda topic. Mr. Lippe provided a summary of each of the recommended changes including:

The recommended language in section 1793.5 would update the revisions date of the application.

The recommended language in section 1793.6 (c)(2)(A) would recast the criminal background check requirement to more closely align with licensure requirements while ensuring informed consent to the student.

California State Board of Pharmacy Board Meeting Minutes – March 18, 2021 Page 4 of 10 The recommended language in section 1793.6(c)(2)(B) would recast the drug screening requirement to include a mandatory advisement to an applicant about the possibility the individual may be required to undergo a drug screen and the potential impact if the drug screen returns a positive result.

The recommended language in section1793.6(c)(2)(C) would align the age requirement for enrollment in practical experience with a similar age requirement for pharmacist licensure.

The recommended language change in section 1793.65(b) would extend the validity period of the accepted certification programs to December 2024.

Members were provided the opportunity to comment on the item.

Motion: Approve the recommended amended language and continue with the rulemaking process. 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.

Amend §1793.5 of Article 11 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1793.5. Pharmacy Technician Application.

The "Pharmacy Technician Application" (Form 17A-5 (Rev. <u>10/157/20202/2021</u>)), incorporated by reference herein, required by this section is available from the Board of Pharmacy upon request.

- (a) Each application for a pharmacy technician license shall include:
 - (1) Information sufficient to identify the applicant.
 - (2) A description of the applicant's qualifications and supporting documentation for those qualifications.
 - (3) A criminal background check that will require submission of fingerprints in a manner specified by the board and the fee authorized in Penal Code section 11105(e).
 - (4) A sealed, original Self-Query from the National Practitioner Data Bank (NPDB) dated no earlier than 60 days of the date an application is submitted to the board.
- (b) The applicant shall sign the application under penalty of perjury and shall submit it to the Board of Pharmacy.

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- (c) The board shall notify the applicant within 30 days if an application is deficient; and what is needed to correct the deficiency. Once the application is complete, and upon completion of any investigation conducted pursuant to section 4207 of the Business and Professions Code, the board will notify the applicant within 60 days of a license decision.
- (d) Before expiration of a pharmacy technician license, a pharmacy technician must renew that license by payment of the fee specified in subdivision (r) of section 4400 of the Business and Professions Code.

Note: Authority cited: Sections 163.5, <u>114.5, 115.4, 115.5,</u> 4005, 4007, 4038, 4115, <u>and</u> 4202, 4207 and 4400, Business and Professions Code. Reference: Sections <u>144, 144.5,</u> 163.5, 4005, 4007, 4038, 4115, 4202, 4207, <u>4400 and</u> 4402 and 4400, Business and Professions Code; and Section 11105, Penal Code.

Amend §1793.6 of Article 11 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1793.6. Training Courses Specified by the Board.

A course of training that meets the requirements of Business and Professions Code section 4202(a)(2) is:

- (a) Any pharmacy technician training program accredited by the American Society of Health-System Pharmacists,
- (b) Any pharmacy technician training program provided by a branch of the federal armed services for which the applicant possesses a certificate of completion, or
- (c)(1) Any other course that provides a training period of at least 240 hours of instruction covering at least the following:
 - (1<u>A</u>) Knowledge and understanding of different pharmacy practice settings.
 - (2<u>B</u>) Knowledge and understanding of the duties and responsibilities of a pharmacy technician in relationship to other pharmacy personnel and knowledge of standards and ethics, laws and regulations governing the practice of pharmacy.
 - (<u>3C</u>) Knowledge and ability to identify and employ pharmaceutical and medical terms, abbreviations and symbols commonly used in prescribing, dispensing and record keeping of medications.
 - (4<u>D</u>) Knowledge of and the ability to carry out calculations required for common dosage determination, employing both the metric and apothecary systems.

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- (<u>5E</u>) Knowledge and understanding of the identification of drugs, drug dosages, routes of administration, dosage forms and storage requirements.
- (6<u>F</u>) Knowledge of and ability to perform the manipulative and record-keeping functions involved in and related to dispensing prescriptions.
- (7<u>G</u>) Knowledge of and ability to perform procedures and techniques relating to manufacturing, packaging, and labeling of drug products.
- (2) In addition to the content of coursework specified in subdivision (c)(1), the course of training must also satisfy all of the following:
 - (A) Prior to admission to the course of training, an administrator or instructor must conduct a criminal background check of and counsel applicants to the program about the negative impact to securing licensure if the background check reveals criminal history. Prior to enrolling in any classes or admission into the course of training, an administrator or instructor shall conduct a criminal background check on the applicant that is consistent with the criminal background check required for a pharmacy technician license per Business and Professions Code section 4202(c). If the criminal background check reveals the applicant has committed acts that would constitute grounds for denial of licensure, the administrator or instructor shall counsel applicants about the negative impact to securing licensure.
 - (B) Administer at least one drug screening to each student to evaluate use of illicit drugs or use of drugs without a prescription. The results of any screen shall be considered as part of the evaluation criteria to determine (1) acceptance into the course of training, or (2) appropriateness for continuation in the course of training. An administrator or instructor shall counsel students about the negative impact of a positive drug screen on eligibility for licensure. Prior to enrollment in any classes or admission into the course of training includes practical training at a pharmacy which may require the applicant to undergo drug screening for illicit drug use. As administrator or instructor shall counsel applicants about the negative impact of a positive drug screen, including eligibility to continue the course of training and eligibility for licensure.
 - (C) Require students to be at least 18 years of age prior to the beginning of instruction. Require students to be at least 18 years of age prior to enrolling in any course work involving practical training, such as an externship or any other training equivalent to pharmacy technician trainee placement as defined by Business and Professions Code section 4038. 4115, 4115, and 4115.5

(D) Require a final examination that demonstrates students' understanding and ability to perform or apply each subject area identified in subdivision (1) above.

Authority cited: Sections 4005, 4007, 4038, 4115, and 4202, Business and Professions Code. Reference: Sections 4005, 4007, 4038, 4115, 4115.5, and 4202, Business and Professions Code.

Add §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 board 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, 2021 2024.

Note: Authority cited: Sections 4005 and 4202, Business and Professions Code. Reference: Sections 4038 and 4202, Business and Professions Code.

M/S: Serpa/Butler

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

Leona Dombroske, Santa Ana Community College, commented on items B and C of the language identifying operational concerns and indicating a background check cannot be operationalized.

Member Veale reiterated the policy the Board is trying to solve and required the onus be provided prior to enrollment.

Member Wong requested that when students sign up that the students are provided a notice. Ms. Tatayon noted that the regulation is to ensure the programs fully inform applicants of potential adverse impact at the beginning of the program.

Member Serpa suggested that development of educational materials be referred to the Communication and Public Education Committee while allowing the regulations to move forward as is.

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Steven Gray, CSHP, spoke in support of the regulation as written and noted that the regulation is needed and indicated the Board has done an excellent job in drafting the requirements.

Ms. Tatayon clarified the obligation to counsel applicants about the negative impact to securing licensure could be met by pointing them to the pharmacy law. She noted the pharmacy law does indicate a background check is required and that if criminal conduct is revealed, a license may not be issued. She clarified the requirement is not to the specificity that Ms. Dombroske expressed concern.

Ms. Dombroske noted that comments from counsel clarified the obligation on the program.

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

Board Member	Vote
Butler	Support
Kim	Support
Lippe	Support
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Veale	Support
Weisz	Support
Wong	Support

The meeting recessed from 9:47 a.m. – 9:57 a.m. Following the recess, a roll call was again taken. Members present: Lavanza Butler, Jignesh Patel, Seung Oh, Jason Weisz, Maria Serpa, Albert Wong, Debbie Veale, Ricardo Sanchez . A quorum was established.

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

Administrative Law Judge Coren Wong presided over the following petition hearings:

- a. Jane Young Ju Ha, RPH 56562
- b. Cesar Cabrera, RPH 42719
- c. Daniel Oh, RPH 75995
- d. Ahmad Nabhan, RPH 41

California State Board of Pharmacy Board Meeting Minutes – March 18, 2021 Page 9 of 10 The meeting was in recess from 10:10 a.m. to 10:20 a.m. to address technology challenges. Upon returning from recess, roll call was taken with the following members present: Lavanza Butler, Seung Oh, Jignesh Patel, Maria Serpa, Jason Weisz, Albert Wong, Debbie Veale, Ricardo Sanchez. A quorum was established.

The meeting was in recess from 11:40 a.m. to 12:20 p.m. Upon returning from recess, roll call was taken with the following members present: Ricardo Sanchez, Seung Oh, Jignesh Patel, Jason Weisz, Debbie Veale, Maria Serpa, Greg Lippe, and Albert Wong. A quorum was established.

The meeting was in recess from 12:52 p.m. to 12:59 p.m. Upon returning from recess, roll call was taken with the following members present: Lavanza Butler, Seung Oh, Jignesh Patel, Maria Serpa, Jason Weisz, Debbie Veale, Albert Wong, Ricardo Sanchez, and Greg Lippe. A quorum was established.

The meeting was in recess from 1:16 p.m. to 1:26 p.m. Upon returning from recess, roll call was taken with the following members present: Lavanza Butler, Seung Oh, Jignesh Patel, Maria Serpa, Debbie Veale, Albert Wong, Ricardo Sanchez, and Greg Lippe. A quorum was established. Jason Weisz was not present at the time of roll call but joined shortly thereafter.

V. Closed Session Matters

The Board recessed into closed session at approximately 2:06 p.m.

VI. Reconvene Open Session

The Board adjourned after closed session at approximately 3:40 p.m.