



California State Board of Pharmacy

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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

**STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
PUBLIC BOARD MEETING
MINUTES**

DATE: March 27, 2018

LOCATION: Embassy Suites LAX South – Imperial Ballroom
1440 E. Imperial Ave.
El Segundo, CA 90245

**BOARD MEMBERS
PRESENT:** Amy Gutierrez, Licensee Member, President
Victor Law, Licensee Member, Vice President
Ryan Brooks, Public Member
Lavanza Butler, Licensee Member
Amjad Khan, Public Member
Gregory Lippe, Public Member
Ricardo Sanchez, Public Member
Albert Wong, Licensee Member

**BOARD MEMBERS
NOT PRESENT:** Allen Schaad, Licensee Member
Valerie Muñoz, Public Member
Stanley Weisser, Licensee Member
Deborah Veale, Licensee Member

**STAFF
PRESENT:** Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Laura Freedman, DCA Staff Counsel
Kelsey Pruden, DCA Staff Counsel
Laura Hendricks, Staff Analyst
Kevin Schettig, Deputy Attorney General
Lisa Miller, Deputy Attorney General

Tuesday, March 27, 2018

Call to Order

8:37 a.m.

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

President Gutierrez called the meeting to order at 8:37 a.m.

Board members present: Lavanza Butler, Victor Law, Amy Gutierrez, Ricardo Sanchez, Ryan Brooks, Amjad Khan Gregory Lippe, and Albert Wong.

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

Pharmacist Richard Fond offered to assist the board in educating licensees on the dangers of opioid addiction by providing testimony on his personal experiences and the experiences of his family members. The board thanked him for his testimony.

III. Discussion and Consideration of Board Approval of Training Program for a Designated Representative-Reverse Distributor

President Gutierrez reported that with the enactment of SB 752 the board is required to issue a license to individuals who qualify for a designated representative-reverse distributor license. She noted that the Designated Representative-Reverse Distributor application was made available on the board's website March 1, 2018.

President Gutierrez explained that one of the licensing requirements specified in BPC section 4053.2(b)(3)(A) requires an individual to complete a training program approved by the board. The board has not yet approved a training program.

Ms. Herold reported that board staff received a request from SkillsPlus Inc. to provide an approved designated representative-reverse distributor training program. The program content has been reviewed by Supervising Inspector Janice Dang, PharmD., who has determined that it meets the criteria established in BPC section 4053.2. Ms. Herold also stated that Skills Plus Inc. currently offers a training program for individuals to qualify to become licensed as a designated representative and a designated representative-3PL.

Ms. Herold noted that due to proprietary concerns, the actual content of the training program was reviewed by Dr. Dang and could not be provided in the public meeting materials. However, a document provided by SkillsPlus Inc. that lists the laws and regulations covered in its designated representative-reverse distributor program was provided in the materials for the board's review.

Ms. Herold stated that the program consists of approximately 7.25 hours of training and includes a final examination of approximately 90-100 questions.

Ms. Herold explained that upon board approval, SkillsPlus Inc. could offer the training program immediately. She also noted that at least one individual is waiting to enroll in a board-approved program to qualify for a designated representative-reverse distributor license.

Bob Shaw, president of Medical Waste services, expressed concern that the training program is too extensive and covers items related to pharmacy that a reverse distributor would not need to know in order to complete his or her job. Ms. Herold responded that designated representatives have an important role in the pharmaceutical supply chain and

are responsible for the tracking and destruction of highly priced and often diverted pharmaceutical drugs.

Pharmacist Holly Strom noted that one of the regulation code sections is listed incorrectly on the training program content outline provided by SkillsPlus Inc. The board commented that this was likely a typo and asked that Supervising Inspector Janice Dang review all of the code sections to ensure they are correct.

Motion: Direct a supervising inspector to review the training program outline to ensure that the code sections are correct. Upon verification that the code sections are correctly listed, approve the designated representative-reverse distributor training program offered by SkillsPlus Inc. for a period of five years and require SkillsPlus Inc. to submit annual updates regarding the content of the training plan to be reviewed by a Supervising Inspector.

M/S: Lippe/Sanchez

Support: 8 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks	x			
Butler	x			
Gutierrez	x			
Khan	x			
Law	x			
Lippe	x			
Munoz				x
Sanchez	x			
Schaad				x
Veale				x
Weisser				x
Wong	x			

IV. Discussion and Consideration of Proposed Regulations to Amend Title 16, California Code of Regulations, Section 1746.3, Related to the Naloxone Fact Sheet

President Gutierrez explained that California Code of Regulations (CCR) Title 16, section 1746.3 specifies the protocol requirements for pharmacists furnishing naloxone hydrochloride. Included in this regulation is the requirement for a board-approved fact sheet that the pharmacist is required to give the patient upon furnishing naloxone hydrochloride.

President Gutierrez reported that the board currently has a pending regulation that will provide the board's executive officer the authority to approve alternate fact sheets that contain the same content as the board's required fact sheet but are formatted or presented in a different manner.

President Gutierrez explained that during DCA pre-review, concerns were raised that the language require alternative fact sheets to contain the same content as the board-approved

fact sheet. Additionally, there was a concern the regulation language does not address fact sheets in other languages.

President Gutierrez explained that provided in the meeting materials (and below) is language that includes amendments from DCA legal to address the concerns. **Note:** For ease of reading, changes made to the approved language are shown by ~~double strikethrough~~ for deleted language and double underline for added language.

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(6) Fact Sheet: The pharmacist shall provide the recipient a copy of the current naloxone fact sheet approved by the Board of Pharmacy ~~or substantially similar a~~ fact sheet approved by the executive officer. The executive officer may only approve a fact sheet that has all the elements and information that is contained in the current board-approved fact sheet. ~~This~~ The board-approved fact sheet shall be made available on the Board of Pharmacy's website in alternate languages for patients whose primary language is not English. Fact sheets in alternate languages must be the current naloxone fact sheet approved by the Board of Pharmacy.

...

Ms. Herold clarified that any patients who need translation services must be provided with the translated fact sheet provided by the board, not an alternative factsheet using translations developed by the pharmacy.

There were no comments from the public.

Motion: Approve the proposed modification to CCR Title 16, section 1746.3 as provided below and initiate the formal rulemaking process. Further, delegate to the executive officer the authority to make any nonsubstantive changes and clarifying changes consistent with the board's policy direction upon recommendations of the control agencies.

...

(6) Fact Sheet: The pharmacist shall provide the recipient a copy of the current naloxone fact sheet approved by the Board of Pharmacy ~~or substantially similar a~~ fact sheet approved by the executive officer. The executive officer may only approve a fact sheet that has all the elements and information that is contained in the current board-approved fact sheet. ~~This~~ The board-approved fact sheet shall be made available on the Board of Pharmacy's website in alternate languages for patients whose primary language is not English. Fact sheets in alternate languages must be the current naloxone fact sheet approved by the Board of Pharmacy.

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M/S: Law/Butler

Support: 8 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks	x			
Butler	x			

Gutierrez	x			
Khan	x			
Law	x			
Lippe	x			
Munoz				x
Sanchez	x			
Schaad				x
Veale				x
Weisser				x
Wong	x			

V. Discussion and Consideration of Draft Frequently Asked Questions Relating to Inventory Reconciliation Reports of Controlled Substances (Title 16, California Code of Regulations, Section 1715.65)

President Gutierrez explained that Title 16, California Code of Regulations (CCR) section 1715.65 requires that every pharmacy, and every clinic licensed under sections 4180 or 4190 of the Business and Professions Code, shall perform periodic inventory and inventory reconciliation functions to detect and prevent the loss of controlled substances.

President Gutierrez reported that the regulation was approved by OAL on January 25, 2018, and the effective date is April 1, 2018. She stated that since the adoption of the regulation the executive officer and board inspectors have received numerous questions from licensees regarding the new requirements for controlled substance inventory. In order to provide additional guidance to the regulated public, board staff worked with the DCA counsel to draft FAQ's which will be made available on the board's website and in a future publication of *The Script*.

The board reviewed the FAQ's provided in the board meeting materials.

President Gutierrez stated that the FAQ listed below is confusing because it says that no quarterly reconciliation report is required for an ADDS in an inpatient hospital. However, the first bullet point says that the transfer of stock to an ADDS would be reflected in the pharmacy's reconciliation report.

Q: Does an inpatient hospital pharmacy or any pharmacy that services onsite or offsite automated drug delivery systems (ADDS) have to complete an inventory reconciliation report for Schedule-II controlled substances contained within the ADDS?

A: No, there is no quarterly reconciliation report required for an ADDS machine that is operated by a pharmacy. However, the regulation (in subsection (h)) requires that such pharmacies:

- Account for all controlled substances (not just Schedule-II drugs) stored in or removed from the ADDS. **The pharmacy's transfer of stock to an ADDS would, however, be reflected as a disposition in the pharmacy's reconciliation report.**
- Limit access to the ADDS to authorized facility staff.
- Perform ongoing evaluations of discrepancies or unusual access to controlled substances stored in the ADDS.

- Report all controlled substances losses from an ADDS to the board.

Ms. Herold stated that she would work with DCA legal to amend the FAQ to clarify the requirement.

Mr. Lippe stated that the board should consider amending its regulation to require pharmacies to maintain the inventory reconciliation reports for longer than three years because it often takes longer than three years to disciplinary cases to be completed. The board asked that this discussion be placed on the agenda of a future Enforcement Committee meeting.

Members of the public thanked the board for creating the FAQ's.

Members of the public asked that the board reconsider allowing perpetual inventory to fulfil the requirements of the regulation. Ms. Herold stated that the difficulty is that all pharmacies have a slightly different way of completing a perpetual inventory.

It was also requested that the board clarify the definition of "readily retrievable." Ms. Herold agreed to work with DCA legal to further clarify this term.

A representative from Kaiser asked if the board could include information on the differences between the state and federal controlled substance schedules in the FAQ's. Ms. Herold responded that board staff would work to compile this information and provide it on the board's website.

A representative from CPhA asked if the board would be allowing pharmacies a window of time to come into compliance with the regulation. Ms. Herold explained that typically when a new regulation is passed the board's inspectors spend the first six months educating pharmacies and helping them to get in compliance. She added that after the first six months they would expect to see pharmacies taking actual steps to complete the inventory, for example having the policies and procedures created.

Ms. Herold stated that these FAQ's would be updated as the regulation is implemented and board staff sees areas where licensees need further clarification on the requirements. The board asked that when the FAQ's are posted the include a note informing licensees that they will be updated on an ongoing basis.

Motion: Direct staff to update the FAQ's relating to inventory reconciliation reports of controlled substances (Title 16, California Code of Regulations, Section 1715.65) based on the board's discussion and post the FAQs on the board's website and publish them in the next issue of *The Script*.

M/S: Lippe/Law

Support: 8 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks	x			

Butler	x			
Gutierrez	x			
Khan	x			
Law	x			
Lippe	x			
Munoz				x
Sanchez	x			
Schaad				x
Veale				x
Weisser				x
Wong	x			

VI. Discussion and Consideration of Proposed Regulations to Amend Title 16, California Code of Regulations, Section 1793.5, Related to the Pharmacy Technician Application; Section 1793.6, Related to the Pharmacy Technician Training Requirements; and Section 1793.65, Related to the Pharmacy Technician Certification Programs

Ms. Herold reported that this regulation updates the board’s pharmacy technician application that is incorporated by reference in CCR section 1793.5. The regulation also updates the requirements for pharmacy technician training courses specified by the board. In addition, this regulation proposes to add CCR section 1793.65 to specify pharmacy technician certification programs approved by the board.

Ms. Herold explained that since 1793.5, 1793.6 and 1793.65 all relate to pharmacy technicians, staff is recommending that the changes to the sections be handled as one regulation. The board agreed with this recommendation.

The board reviewed the draft language as provided in the board meeting materials.

Ms. Herold noted that the language in § 1793.5 should be amended to remove the date of “10/2016” because the board did not release the application in 2016. The board agreed with her recommendation.

Ms. Herold also recommended changing § 1793.65 to extend the date that the programs are valid until December 31, 2021, to allow time to complete the regulation process. The board agreed with this recommendation.

There were no comments from the public.

Motion: Approve the proposed modifications to amend CCR Title 16, section 1793.5 and 1793.6 and add section 1793.65 as provided below and initiate the formal rulemaking process. Further, delegate to the executive officer the authority to make any nonsubstantive changes and clarifying changes consistent with the board’s policy direction upon recommendations of the control agencies.

Proposal to 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. ~~10/15~~ ~~10/2016~~ 3/2018)), 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.

(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 ~~144, 163.5, 4005, 4007, 4038, 4115, and 4202, 4207 and 4400~~, Business and Professions Code. Reference: Sections 144, 144.5, 163.5, 4005, 4007, 4038, 4115, 4202, 4207, 4400 and 4402 and ~~4400~~, Business and Professions Code; and Section 11105, Penal Code.

Proposal to 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 A)~~ (1 A) Knowledge and understanding of different pharmacy practice settings.

~~(2 B)~~ (2 B) 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.

~~(3 C)~~ (3 C) 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 ~~D~~) Knowledge of and the ability to carry out calculations required for common dosage determination, employing both the metric and apothecary systems.

(5 ~~E~~) Knowledge and understanding of the identification of drugs, drug dosages, routes of administration, dosage forms and storage requirements.

(6 ~~F~~) Knowledge of and ability to perform the manipulative and record-keeping functions involved in and related to dispensing prescriptions.

(7 ~~G~~) 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 and counsel applicants to the program about the negative impact to securing licensure if the background check reveals criminal history.

(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.

(C) Require students to be at least 18 years of age prior to the beginning of instruction.

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

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

Proposal to add §1793.65 of 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 following pharmacy technician certification programs offered by ~~until January 1, 2021~~:

(1) The Pharmacy Technician Certification Board, and

(2) The National Healthcareer Association's Examination for the Certification of Pharmacy Technicians Program.

(b) Approval of these programs is valid through December 31, 2021.

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

Reference: Business and Professions Code Sections ~~4005~~, 4038 and 4202.

M/S: Lippe/Brooks

Support: 8 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
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Brooks	x			
Butler	x			
Gutierrez	x			
Khan	x			
Law	x			
Lippe	x			
Munoz				x
Sanchez	x			
Schaad				x
Veale				x
Weisser				x
Wong	x			

The board recessed for a break at 9:40 a.m. and resumed at 9:57 a.m.

VII. Petitions for Reinstatement of Licensure or Other Reduction of Penalty

Administrative Law Judge Carla Garrett presided over the following petitions for reduction of penalties.

- Yumon Kwock, RPH 28573
- James Blair, RPH 30343

The board recessed for a break at 11:05 a.m. and resumed at 11:15 a.m.

- Douglas Austin, RPH 40244
- Keith Chung, RPH 50486

The board recessed for a break at 12:30p.m. and resumed at 12:41 p.m.

- Angela Forcucci, RPH 49860
- Charles Walker, RPH 32316

VIII. Closed Session

The board recessed into closed session at 1:30 p.m.

IX. Reconvene Open Session

The board reconvened to open session at 4:50 p.m.

President Gutierrez adjourned the meeting at 4:51 p.m.