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
Public Board Meeting Minutes
January 29-30, 2020

DATES: January 29-30, 2020

LOCATION: Embassy Suites by Hilton Los Angeles - Glendale
800 North Central Avenue
Glendale, CA 91203

BOARD MEMBERS PRESENT: Gregory Lippe, Public Member, President
Debbie Veale, Licensee Member, Vice President
Allen Schaad, Licensee Member, Treasurer
Shirley Kim, Public Member
Ricardo Sanchez, Public Member
Maria Serpa, Licensee Member
Ryan Brooks, Public Member
Albert Wong, Licensee Member
Lavanza Butler, Licensee Member

BOARD MEMBERS NOT PRESENT: Valerie Muñoz, Public Member

STAFF PRESENT: Anne Sodergren, Executive Officer
Norine Marks, DCA Counsel
Ryan Greenlaw, DCA Counsel
Steve Pyun, Deputy Attorney General
Jennifer Niklas, Senior Administrative and Policy Manager
MaryJo Tobola, Senior Enforcement Manager
Bob Dávila, Public Information Officer

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

President Gregory Lippe opened the meeting at 3:09 p.m.

President Lippe explained that the Board's strategic plan creates standing Committees through which the Board establishes its goals and organizes its activities. Each Committee is comprised of public and licensee members. The Committee structure provides an important venue for ensuring staff and members share information in crafting and implementing objectives. These meetings also provide an opportunity for stakeholder involvement and public comment is encouraged. Following Committee meetings, the chairs from each of the respective Committees provide reports to the full Board as part of Board meetings. Committee recommendations on policy decisions are referred to the full Board as the final decision maker. President Lippe stated that as indicated on the agenda, during this meeting the Board will receive reports from the chairperson of several of the Board's Committees.

President Lippe took roll call. Board Members Present: Allen Schaad, Gregory Lippe, Lavanza Butler, Ryan Brooks, Ricardo Sanchez, Debbie Veale, Shirley Kim, Maria Serpa and Albert Wong. Quorum was established.

II. Update from the Department of Consumer Affairs (taken out of order)

Kimberly Kirchmeyer, Director of the Department of Consumer Affairs (Department), provided an update from the Department. Ms. Kirchmeyer stated that her initial focus as the recently appointed director will be client services and satisfaction, working smarter together, data, transparency, and action.

Processing regulations is a major focus within the Department in order for boards to implement statutes. Ms. Kirchmeyer noted that regulation processing for the Department is a major issue related to the Board of Pharmacy, which has a number of packages at various stages in the regulation process. Additional areas of focus for Ms. Kirchmeyer will be obtaining Fi$Cal reports for the Department, reducing the timeframe to perform investigations at the Division of Investigations (internal within the Department), working on Americans with Disabilities Act (ADA) compliance issues, and ensuring legislation is implemented by the boards and bureaus within the Department.

Ms. Kirchmeyer stated she held her first Quarterly Director's meeting in December with all the boards and bureaus. She stated her goal is to meet with each board individually to discuss their goals and issues. However, she acknowledged the number of executive team vacancies within the Department, and once those are filled, she will schedule the meetings with the boards.

The Department's Legal office has created a new Regulations Unit to assist in the Department's rulemaking process. The current priority for this new unit is the implementation of Assembly Bill (AB) 2138 and the development of a data tracking system that will track all regulation submissions and progresses within the Department. Ms. Kirchmeyer thanked Ms. Sodergren and the Board for their assistance with the piloting of the data tracking system.

The Board was advised that the Department is also in the testing phase of a new budget and expenditure reporting system which will allow staff to run monthly reports of expenditures which can be compared against budgets.

Ms. Kirchmeyer offered the Department's support to the Board during its upcoming Sunset Report hearings.

Ms. Kirchmeyer provided members with information on the schedule for mandatory 2020 Board Member Orientation Trainings, including March 25, 2020 in Sacramento, June in Southern California, and October in Sacramento. Ms. Kirchmeyer reminded the Board that the Sexual Harassment Prevention Training was due last year for all Board and staff members and that the Statement of Economic Interests Form 700 filings are due by April 1, 2020.

Finally, Ms. Kirchmeyer shared information regarding the Department's Organizational Improvement Office (OIO) in the hopes that the Board will utilize their services. This office provides the Department's programs with change management services, business process mapping, and information technology system requirement documentation. Ms. Kirchmeyer noted that the OIO also offers collaborative consulting on process reengineering that maximizes utilization of existing resources, improves productivity, and increases work product quality.

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

Danny Martinez, on behalf of California Pharmacists Association (CPhA) read the statement below from CPhA's Director of Pharmacy Practice and Policy Rajan Vaidya requesting the applications for the CPJE examination are processed in a timely manner and requests adequate testing availability during the June and July exam dates. CPhA also requested additional testing dates in September 2020 to accommodate those entering the profession.

Dear President Lippe,

Recently, the CA Board of Pharmacy release the remainder of California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE) dates for 2020. CPhA appreciates the Board's work in ensuring availability of future dates with ample time for candidates to plan and schedule for the CPJE.

As the 2020 cohort of PharmD graduates are preparing for the start of their careers with staff pharmacist, post-graduate residency and fellowship positions. The current allotment of examination dates presents some challenges. Given the timeline of the 2019 CPJE issue, there were many instances of pharmacists not being able to meet their contractual obligations of being licensed by specific fall deadlines thus unable to deliver the care to their patients.

Previous experience with the Board's protocol for processing pharmacists' applications, which are based on the batch of applications received from pharmacy programs, and notifying the National Association of Boards of Pharmacy (NABP) to release the Authorization to Test (ATT) which allow pharmacists to schedule examination dates has ranges from late-June to mid-July. The release of ATTs at this time would result in the earliest 2020 PharmD graduates would be eligible to sit for the CPJE the July examination block, with majority of the examinees being able to test in the August schedule block.

As far as the availability of exam results, on average, it takes 30 days after candidates take the CPJE for the Board to mail their scores. If the same process continues to be followed, those taking the exam in July would receive their results in August with pharmacists' licenses being approved and release by September at best.

In addition, if a candidate does not pass the CPJE during this time, the Board's procedure for applicant to retake the CPJE calls for 30 days to process the application. Based on this information, candidates will not have an opportunity to re-test and me either employer contracts or national residency standards to be licensed within 90 days of their start date.

CPhA respectfully requests the Board ensures that applications for examinations are processed in a timely manner to facilitate the earlier June and July exam dates and for adequate testing center availability during these higher demand dates for candidates. We would also respectfully request for additional examination dates be made available in September 2020 to allow for reasonable testing availability and licensure opportunities for pharmacists entering the profession to practice in California.

Sandra Levee, speaking on behalf of the people, discussed the future of sterile compounding. She urged the Board to take into consideration limiting any access to sterile compounding products. Ms.

Levee also urged the Board to carefully consider legislation that would limit the ability of pharmacies that produce both sterile and non-sterile compounded products that would negatively limit their care and would have a negative effect on the quality of life for those using such products.

Jill Simonian requested to provide a presentation to the Board on Cannabidiol (CBD), therapeutics, and current regulations across the nation.

Mark Chew, pharmacist for Orange County EMS, stated there may be conflicting regulations between the Food and Drug Administration (FDA) and the Centers for Disease Control (CDC) on the practice of pharmacists crushing products for use in the event of an emergency.

IV. Approval Board Meeting Minutes

a. November 5-6, 2019, Minutes

The Board decided to vote on both the November and December 2019 minutes at one time.

b. December 13, 2019, Minutes

President Lippe stated a number of non-substantive changes were made to the November 2019 Board meeting minutes since they were originally sent for review. No Board members had any comments or concerns with the changes made.

Motion: Approve the November 5-6, 2019, Board meeting minutes with the non-substantive changes as noted, and approve the December 13, 2019 Board meeting minutes.

M/S: Veale/Brooks

Support: 9 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks	Support			
Butler	Support			
Kim	Support			
Lippe	Support			
Muñoz				Not Present
Sanchez	Support			
Schaad	Support			
Serpa	Support			
Veale	Support			
Wong	Support			

V. Recognition and Celebration of Pharmacists Licensed in California for 40 Years and other Recognitions

The Board recognized Helen Mizrahie-Johan for 51 years of service as a pharmacist.

VI. Organizational Development Committee

a. Budget Update/Report

As chair of the Organizational Development Committee, President Lippe stated the fiscal year-end figures are not yet available for Fiscal Years 2017/18 and 2018/19. He reported that the Board's authorized expenditures for the current fiscal year are about $26 million, about an 11 percent increase from the prior year. He also noted that preliminary revenue details indicated that the Board has received over $13 million thus far and has expended about $10.5 million.

President Lippe stated that the Board's fund condition reports a gradual increase in its months in reserve with the new fees taking effect April 1, 2020.

The Board heard public comment from past Board of Pharmacy Presidents, Stan Goldenberg and Raffi Simonian, congratulating Ms. Sodergren on her appointment as the Executive Officer of the Board.

b. Board Member Attendance Information

President Lippe noted the meeting materials included a summary of Board member attendance for the first six months of the fiscal year. He thanked the members for their commitment to the Board and its mission.

c. Personnel Update

President Lippe noted that information on vacant positions was included in the chair report. With the permanent appointment of the Executive Officer, President Lippe stated that he expected recruitment for the Assistant Executive Officer position to happen quickly.

d. Board and Committee Calendar for 2020

President Lippe presented the schedule of meeting dates for the remainder of the calendar year. He noted that some meeting dates have changed to accommodate the schedule of Board members and ensure quorum. Mr. Lippe reported that the next meeting is scheduled for March 12, 2020, at Keck Graduate Institute School of Pharmacy.

Note: additional changes to the schedule include the May meeting, which is now schedule for May 6-7, 2020; and the petitioner meetings are now scheduled for June 18, 2020, September 17, 2020, and December 3, 2020.

VII. Licensing Committee

a. Discussion and Consideration of Implementation of Recently Enacted Legislation -- SB 159 (Weiner, Chapter 532, Statutes of 2019) Related to HIV Preexposure and Postexposure Prophylaxis, including Possible Adoption of Emergency Regulations and Initiation of Regular Rulemaking Related to Development of Training Program

Chairperson Veale provided a brief overview of SB 159 which establishes the authority for a pharmacist to furnish preexposure prophylaxis (PrEP) and postexposure prophylaxis (PEP) in specified

amounts under specified conditions, including that the pharmacist has determined the patient meets the clinical criteria consistent with federal guidelines. The legislation provides that prior to a pharmacist furnishing PrEP and PEP, a pharmacist must complete a training program approved by the Board, in consultation with the Medical Board of California. Additionally, the statute identifies specific areas that must be covered in the training program including information about financial assistance programs and CDC guidelines.

Chairperson Veale stated the Licensing Committee remains focused on the intent of the bill, to reduce barriers to access the medications for PrEP and PEP and is working to ensure the regulations themselves do not create barriers.

Chairperson Veale reported that during the November 2019 Licensing Committee meeting members heard a large range of public comments regarding the length of the training program and what topics should be covered. The Committee determined that a second meeting was needed to receive additional information from stakeholders.

Chairperson Veale reported that at the second Committee meeting, public comment on the length of the training ranged from one to four hours. Based on the public comment and a letter submitted by CSHP, the Committee determined the necessary elements of a training program could be achieved in 1.5 hours. Additionally, the Committee determined that the two content areas that must be included as part of the training (per the statutory requirements) are information on financial assistance programs for PrEP and PEP and the clinical eligibility recommendations provided in the CDC guidelines as referenced in the statute.

Chairperson Veale stated that, as a result of the background materials, written and oral stakeholder comments, the Committee reached the following conclusions:

1. A single training program should be developed that encompasses PrEP and PEP.
2. The training program should be a minimum of 1.5 hours. Other training programs related to HIV PrEP and PEP have been evaluated and the training duration has been consistent with 1.5 to 2 hours.
3. The Board should accept a training program that satisfies the required elements if the training provider is Board approved or approved by ACPE. Ensuring that a variety and flexibility of trainings can be made available.
4. The training program must include, at a minimum, all of the elements detailed in the attached proposal including:

    - Preexposure and postexposure prophylaxis pharmacology.
    - Legal requirements contained in BPC sections 4052.02 and 4052.03.
    - Patient counseling information and techniques, including counseling on sexually transmitted diseases and sexual health.
    - Patient referral and supplemental resources.
    - Clinical eligibility requirements.

5. Pharmacists must maintain documentation of completion of the training program for at least four years.

6. An approved training course must include an assessment of the individual's knowledge and that a passing score of 70% or higher is appropriate.

Chairperson Veale reported that the Committee voted to update the regulation text as discussed during its meeting. The Committee also recommend the Board's adoption of the proposed emergency regulations and delegating to the Interim Executive Officer the authority to make changes consistent with the policy. Below is the draft regulation language based on the Committee's discussion.

Proposal to Add Section 1747 to Title 16 of the California Code of Regulations, to read as follows:

§ 1747. Independent HIV Preexposure and Postexposure Prophylaxis Furnishing.

(a) Prior to independently initiating and furnishing HIV preexposure and/or postexposure prophylaxis to a patient pursuant to Business and Professions Code sections 4052.02 and 4052.03, a pharmacist shall successfully complete a training program approved by the board or provided by a provider accredited by an approved accreditation agency. To be approved or accredited, the 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:

(1) Preexposure and postexposure prophylaxis pharmacology.

(2) Requirements for independently initiating and furnishing preexposure and postexposure prophylaxis contained in Business and Professions Code sections 4052.02 and 4052.03.

(3) Patient counseling information and appropriate counseling techniques, including at least, counseling on sexually transmitted diseases and sexual health.

(4) Patient referral resources and supplemental resources for pharmacists.

(5) Financial assistance programs for preexposure and postexposure prophylaxis, including the Office of AIDS' PrEP Assistance Program (Prep-AP).

(6) 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).

(b) The training program shall require the passing of an assessment with a score of 70% or higher to receive documentation of successful completion of the training program.

(c) A pharmacist who independently initiates or furnishes preexposure or postexposure prophylaxis pursuant to Business and Professions Code sections 4052.02 and/or 4052.03 shall maintain documentation of their successful completion of the training program for a period of four (4) years. Documentation maintained pursuant to this subdivision must be made available upon request of the board.

Chairperson Veale stated that following the Committee meeting, an additional policy consideration was identified related to ongoing continuing education (CE), specifically, if the Board should require ongoing CE for pharmacists who provide PrEP and PEP. Chairperson Veale explained that she believes ongoing CE is appropriate. She added that should the Board agree with ongoing CE, the following language could be used:

A pharmacist performing the services authorized in BPC section 4052.02 and section 4052.03 must complete one hour of continuing education focused on preexposure and postexposure prophylaxis therapy biennially for each subsequent renewal cycle following the completion of the training program established in this section.

Vice-Chairperson Butler, President Lippe, and Member Wong agreed with the need for ongoing CE for PrEP and PEP. Member Schaad stated he did not think CE was necessary or appropriate as those that are providing the service will seek the additional training needed without a Board mandate. Member Serpa questioned the consistency across all types of programs approved by the Board (i.e., nicotine, birth control) for ongoing CE. Chairperson Veale stated there is no consistency between ongoing CE requirements for the different programs.

The Board heard public comment in opposition of ongoing CE for PrEP and PEP as being problematic, limiting, and an additional burden on inspectors to monitor the training of those providers.

After discussion and hearing public comment, the Board ultimately decided they would not require ongoing CE.

Danny Martinez, speaking on behalf of CPhA, stated the training cannot be completed in 1.5 hours and spoke in favor of a three hour minimum. Other public comment stated increasing the length of the training up to three hours would ultimately increase barriers to access, which goes against the intent of the statute. It was noted that current students in pharmacy schools are being taught PrEP and PEP as part of the curriculum and ACPE requirements.

Member Brooks stated the number of hours of training is arbitrary and the Board should focus instead on the quality of the training by mandating what topics should be covered.

Chairperson Veale noted that CSHP provided a letter, which was included in the board meeting materials, breaking down the length of time and topics covered for the PrEP and PEP training to a total of 1.5 hours. She also stated that the Executive Officer provided her information on other CE lesson plans, including the National HIV Training, and the training is consistent with the Committee recommendation.

Executive Officer Sodergren stated that the statute requires the Board to work in consultation with the Medical Board. She reported that they have been kept apprised of the Committee's work and are in support of the recommendations.

After discussion above, the Board voted.

Committee Recommendation (Motion): Update the regulation text as discussed in the six policy areas (below). Recommend the Board's adoption of the proposed emergency regulations and delegate to the Interim Executive Officer the authority to make changes consistent with the policy.

Proposal to Add Section 1747 to Title 16 of the California Code of Regulations, to read as follows:

§ 1747. Independent HIV Preexposure and Postexposure Prophylaxis Furnishing.
(a) Prior to independently initiating and furnishing HIV preexposure and/or postexposure prophylaxis to a patient pursuant to Business and Professions Code sections 4052.02 and 4052.03, a pharmacist shall successfully complete a training program approved by the Board or provided by a provider accredited by an approved accreditation agency. To be approved or accredited, the 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:
(1) Preexposure and postexposure prophylaxis pharmacology.
(2) Requirements for independently initiating and furnishing preexposure and postexposure prophylaxis contained in Business and Professions Code sections 4052.02 and 4052.03.
(3) Patient counseling information and appropriate counseling techniques, including at least, counseling on sexually transmitted diseases and sexual health.
(4) Patient referral resources and supplemental resources for pharmacists.
(5) Financial assistance programs for preexposure and postexposure prophylaxis, including the Office of AIDS' PrEP Assistance Program (Prep-AP).
(6) 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).
(b) The training program shall require the passing of an assessment with a score of 70% or higher to receive documentation of successful completion of the training program.
(c) A pharmacist who independently initiates or furnishes preexposure or postexposure prophylaxis pursuant to Business and Professions Code sections 4052.02 and/or 4052.03 shall maintain documentation of their successful completion of the training program for a period of four (4) years. Documentation maintained pursuant to this subdivision must be made available upon request of the Board.

Support: 8 Oppose: 0 Abstain: 1

Board Member	Support	Oppose	Abstain	Not Present
Brooks			Abstain	
Butler	Support			
Kim	Support			
Lippe	Support			
Muñoz				Not Present
Sanchez	Support			
Schaad	Support			
Serpa	Support			
Veale	Support			
Wong	Support			

Chairperson Veale stated that under the provisions of the Administrative Procedures Act (APA), an agency may adopt an emergency regulation, however the regulation remains in effect for 180 days unless the Office of Administrative Law approves a readoption for an additional 90 days.

Chairperson Veale explained that although the statute directs the Board to adopt emergency regulations, it is recommended that the Board make a declaration of emergency. Such a declaration would be consistent with the statutory requirements of SB 159 as well as the APA. Chairperson Veale reiterated that creating access points in pharmacies is critical to save lives and reduce the spread of HIV, especially given the narrow window to start PEP following exposure.

Motion: The finding of emergency based on the statutory provisions contained with Senate Bill 159 (Weiner, Statutes of 2019) that mandates the Board to adopt emergency regulations by July 1, 2020 for the immediate preservation of the public peace, health, safety, or general welfare.

M/S: Veale/Wong

Support: 9 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks	Support			
Butler	Support			
Kim	Support			
Lippe	Support			
Muñoz				Not Present
Sanchez	Support			
Schaad	Support			
Serpa	Support			
Veale	Support			
Wong	Support			

In addition to the emergency declaration, Chairperson Veale suggested the Board clarify its intention to also pursue the change through the regular rulemaking process. She recommended that the Board, separately vote on concurrent initiation of the regular rulemaking process.

Motion: Approve the proposed addition to Title 16 CCR section 1747, Independent HIV Preexposure and Postexposure Prophylaxis Furnishing. Initiate the regular rulemaking process. Delegate to the Executive Officer the authority to make any non-substantive changes and clarifying changes consistent with the Board's policy direction upon recommendations of the control agencies.

M/S: Veale/Wong

Support: 9 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks	Support			
Butler	Support			
Kim	Support			
Lippe	Support			
Muñoz				Not Present
Sanchez	Support			
Schaad	Support			
Serpa	Support			
Veale	Support			
Wong	Support			

b. Discussion and Consideration of Board's Legislative Proposal to Establish New Licensing Programs Related to Advanced Pharmacy Technician Requirements and Functions

Chairperson Veale provided background on the proposal to establish a new licensing program for advanced pharmacy technicians (APT), stating the work on this proposal has been ongoing for several years, spanning multiple public meetings, offering stakeholders the opportunity to participate in the development of the proposal.

In response to comments and feedback received subsequent to the Board's initial proposal, the Committee determined it was appropriate to reassess some of the basic tenets of the proposal. The committee again provided an opportunity for stakeholders to provide comments to the proposal in a public meeting during the December 2019 meeting.

Board meeting materials provided for the meeting included a draft proposal of the Advanced Pharmacy Technician language. Chairperson Veale stated there was one element in the meeting material that was incorrectly summarized, specifically the Chair Report incorrectly indicates the recommended experience requirement as 3,000 hours instead of 2,050 hours. The board meeting materials included the correct proposed language.

Chairperson Veale reviewed the following changes to the Board's initial proposal:

1. When initially drafted, the proposal included two separate advanced pharmacy technician licenses – Advanced Pharmacy Technician (outpatient setting) and Advance Hospital Pharmacy Technician (inpatient setting).

   Recommendation: Given the similarity in application requirements, a single license type appears appropriate.

2. As the proposal developed, the pathways to licensure increased. There is concern that the minimum licensing requirements exceed what is necessary for minimum competence to perform the authorized duties, resulting in a barrier to licensure for this advanced license.

   Recommendation:

   - Current and active license as a pharmacy technician.
   - 3,000 hours of experience performing the duties of a licensed pharmacy technician or pharmacy intern.
   - **And** one the following:
     a. Current certification by a pharmacy technician certification program.
     b. Completion of an AA degree in pharmacy technology.
     c. Completion of a bachelor's degree.

3. The Board's initial proposal included specified authorized functions for community pharmacies and separate authorized functions for inpatient pharmacies.

   Recommendation: As the practice site models have evolved, it appears appropriate to consolidate authorized functions of an advanced pharmacy technician as well as consolidate the conditions under which pharmacy may employ such an individual.

Chairperson Veale noted that the requirement to pass an examination had been removed stating the that an examination was a required element for any of the three pathways listed above.

Chairperson Veale continued, stating the Committee received additional public comment on the proposal, including a suggestion for an additional meeting. She reminded everyone that the purpose of the agenda item was to provide an opportunity for Committee members to consider the proposal and for stakeholders to provide input during the meeting.

Chairperson Veale also stated that many stakeholders' comments were in relation to what appeared to be duplication of authority to perform tasks between pharmacy technicians and the proposed advanced pharmacy technicians. Chairperson Veale explained that the supervision requirement between the two is significantly different, most notably with the level of autonomy. A pharmacy technician by law, must work under the direct supervision and control of a pharmacist when performing nondiscretionary tasks where an advanced pharmacy technician does not require direct supervision and control. Chairperson Veale stated that as a result the language was amended to more directly highlight the supervision aspect.

Chairperson Veale stated that overall there was support for the revised proposal; however, some expressed concern the proposal was silent on the ratio aspect. She stated that after consideration and discussion, the Committee determined the issue of the ratio should be discussed with the full Board.

Chairperson Veale noted that information on the Committee and public discussion were included as an attachment to the Board meeting materials and written comments received were sent as supplemental materials and posted on the Board's website.

Chairperson Veale stated that subsequent to the meeting additional changes were made to reflect the Committee's direction. Further, counsel refined the proposal, restructured some of the proposal, and provided clarifying language regarding the supervision requirements. The updated language is provided below.

Proposed BPC 4038.5 (Definition)
"Advanced Pharmacy Technician" means an individual licensed by the board who is authorized to perform all the duties permitted by section 4115, and technical pharmacy tasks as authorized in Section 4115.6 under the indirect supervision of a pharmacist. For the purposes of this section, "indirect supervision" means that a pharmacist is on the premises at all times and is generally aware of all activities performed by the advanced pharmacy technician, but the advanced pharmacy technician may, if permitted by the pharmacist, perform authorized tasks without direction from the pharmacist.

Proposed 4115.6 (Specified Duties)
(a) A licensed advanced pharmacy technician may perform these technical tasks to allow the pharmacist to engage in more direct patient services:
(1) Verify the accuracy of the filling of a prescription container by confirming that the medication and quantity reflected on the label is accurately reflects the container's contents for refill drug orders.
(2) Accept new prescriptions from a prescriber's office unless the prescription requires the professional judgment of a pharmacist.

(3) Inquire about the intended purpose or indication for prescribed medication on verbal orders received from a prescriber's office.
(4) Accept refill authorizations from a prescriber's office unless the authorization requires the professional judgment of a pharmacist.
(5) Transfer a prescription to another pharmacy.
(6) Receive the transfer of a prescription from another pharmacy.
(7) Provide the technical task of administration of an immunization if appropriate training has been completed.
(8) Initiate post discharge contact with a patient or patient's agent for a patient recently discharged from a health facility.
(9) Provide medication guidance and referral services for pharmacy services post discharge from a health facility.
(10) Develop medication dosing schedules for discharge medications.
(11) Initiate post discharge contact with a patient or patient's agents.
(b) Other than as permitted by this section, an advanced pharmacy technician may not engage in direct patient services.

Proposed 4115.7 (Conditions for Use)
A pharmacy may use the services of an advanced pharmacy technician if all of the following conditions are met:
(a) The duties authorized in section 4115.6 are performed as specified in the pharmacy's policies and procedures.
(b) The pharmacist-in-charge is responsible for ongoing evaluation of the performance of personnel as authorized in subdivision (a) of section 4115.6.
(c) A pharmacist personally provides all new prescription medications and controlled substances medications directly to the patient or patient's agent, and provides patient information consistent with the provisions of Section 4052 (a) (8).
(d) A record is created identifying the personnel responsible for the preparing and dispensing of the prescription medication.
(e) Initiate and provide post discharge follow-up for a patient recently discharged from a health care facility consistent with the provisions of Section 4052(a)(8). Such discharge follow-up must be provided by a pharmacist at the request of the patient or patient's agent unless the patient is discharged to another health care facility.

Proposed BCP 4211 (Licensing Requirement)
(a) The board may issue an advanced pharmacy technician license to an individual who meets all the following requirements:
(1) Holds a pharmacy technician license issued pursuant to this chapter that has been active and in good standing for at least 1 year immediately preceding filing an application.
(2) Has obtained 2,050 hours of experience performing the duties of a licensed pharmacy technician or pharmacist intern in a pharmacy within the three (3) years immediately preceding filing an application.
(3) Satisfies at least one of the following requirements:
(A) Possesses a certification issued by a pharmacy technician certifying program as defined in Section 4202(a)(4).
(B) Has obtained a minimum of an associate degree in pharmacy technology.
(C) Has obtained a bachelor's degree.

(b) A license issued pursuant to this section, if not renewed, shall expire two years after issuance.

Proposed BPC 4234 (CE/Renewal Requirement)
As a condition of renewal, an advanced pharmacy technician shall complete 20 hours of continuing education each renewal cycle, including a minimum of two hours of education in medication error prevention and two hours of board sponsored law and ethics education.

Amendment to BPC 4400 (Fee)
…
(z) ~~This section shall become operative on July 1, 2017.~~ The fee for the advanced pharmacy technician application and examination shall be $260 dollars and may be increased to $285. The fee for initial licensure and biennial renewal of as an advanced pharmacy technician shall be $140 and may be increased to $195.

Public comment expressed concern that this proposal was not what was sent before the legislature and asked for additional time to discuss the proposal. Board members asked what specific issues needed to be discussed that would cause an additional delay after extensive discussion at the Committee meetings. Public commenters stated they wanted to have a larger conversation rather than outright oppose the proposal.

Jessica Langley, speaking on behalf of National Heathcareer Association, supported the advancement of the pharmacy technician profession as proposed but also provided feedback on the additional language which was included in the supplemental materials on the Board's website.

Lisa Gunther-Lum stated CSHP submitted a letter to the Board and, respectfully, are not in support of creating an APT license type because it is not in alignment with current practice and may generate unintended outcomes with respect to pharmacy support personnel. CSHP would also like to see additional discussion on the topic of APT. Ms. Gunther-Lum stated two major topics they would like addressed is the number of required hours of training and the transferring of prescriptions.

Public commenters, as well as Committee Members Wong and Butler, stated they had concerns with the liability of pharmacists and the indirect supervision of the APT. DCA Counsel Marks questioned whether the Committee was referring to civil liability versus disciplinary liability. Chairperson Veale and President Lippe stated it could be referred to as both.

Mr. Brooks left the meeting at 5:36 p.m.

The Board heard public comment encouraging the increase of training hours for the APT license and defining specific educational requirements rather than simply a bachelor's degree in any subject.

Mark Johnson, representing CVS Pharmacies, spoke in support of the Board and stated that if the legislation was not able to go through, perhaps the Board could expand the criteria for the APT through rulemaking.

Following the discussion and public comment the Board voted on the Committee's recommendation to move the language forward.

Committee Recommendation (Motion): Move the proposal to the Board with the discussed changes (removing the provision related to verifying the accuracy on new prescription labels, incorporate a training requirement for APTs technical task of administering an immunization, correct the fee provision to remove reference to the hospital), and provide authority for the chair of the Committee to work with staff and counsel to refine the language.

Support: 0 Oppose: 8 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				Not Present
Butler		Oppose		
Kim		Oppose		
Lippe		Oppose		
Muñoz				Not Present
Sanchez		Oppose		
Schaad		Oppose		
Serpa		Oppose		
Veale		Oppose		
Wong		Oppose		

Board Motion: Send the proposed APT language back to the Committee to discuss the liability and training hours as well as any other items that may come up.

M/S: Wong/Butler

Support: 8 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				Not Present
Butler	Support			
Kim	Support			
Lippe	Support			
Muñoz				Not Present
Sanchez	Support			
Schaad	Support			
Serpa	Support			
Veale	Support			
Wong	Support			

It was decided that the Committee will also discuss the issue of ratios at its next meeting.

c. Review of Licensing Statistics

Chairperson Veale stated the licensing statistics for July 1, 2019, through December 31, 2019, were provided as an attachment to the meeting materials. The Board received over 7,500 applications during the first six months of the fiscal year. During this period the Board issued over 7,100 licenses and renewed over 33,000 licenses.

Chairperson Veale reported that the processing times data was also included in the meeting materials. Unfortunately, processing times for initial applications and deficiency mail for some license types are outside of the Board's performance standards of 30 days and 10 days, respectively. She stated that the Board continues to be challenged with four vacant positions in licensing, which impacts meeting the standard performance processing times. Management continues to redirect workload to address the outstanding performance times.

Chairperson Veale stated that a Committee meeting is scheduled for May 6, 2020, but that an additional meeting will be scheduled before then. The meeting notice will be sent out when the date and location are solidified.

The meeting was adjourned at 5:59 p.m. for the day.

Thursday, January 30, 2020

President Lippe called the meeting to order at 9:05 a.m. Roll call was taken, and a quorum was established. Board members present: Albert Wong, Debbie Veale, Ryan Brooks, Lavanza Butler, Maria Serpa, Allen Schaad, and Ricardo Sanchez.

VIII. Communication and Public Education Committee

a. Discussion and Review of Online Registry Being Developed for Pharmacies Providing Health Care Services

Chairperson Sanchez and Board staff member Bob Dávila, provided background on the development of the online registry for pharmacies providing health care services, including medications pharmacists can furnish without a prescription pursuant to Senate Bill 493, or any other legislation. Chairperson Sanchez stated the Board approved the Committee's recommendation to direct staff to create the registry at the July 2019 Board Meeting.

At the Committee meeting, Mr. Dávila provided a demonstration of the registry, which is being developed by the Department of Consumer Affairs (DCA). He stated that pharmacies can choose to be listed or not and consumers will be able to search the registry to find pharmacies offering these specific health services. Mr. Dávila reported that DCA staff said the registry should be operational by this spring.

Mr. Dávila stated that the Committee suggested including pharmacists who do not work in pharmacies and finding a way to periodically contact pharmacies to see if they are still offering the services listed on the website. Mr. Schaad inquired if PrEP and PEP could be added to the registry. Mr. Dávila responded the PrEP and PEP will be added to the registry. Mr. Schaad also requested that a report be made to the Board on the use of the services. Mr. Dávila responded there would be regular reports made to the Board on the use of site.

No public comments were made.

b. Public Education Materials Regarding Senate Bill 159 (Weiner, Chapter 3532, Statutes of 2019) Related to HIV Preexposure and Postexposure Prophylaxis

Chairperson Sanchez reported that at the November 2019 Board meeting, the Board directed the Committee to develop public education materials regarding SB 159. He stated the Legislation and Regulations Committee is currently developing regulations to implement SB 159 by July 1, 2020.

Chairperson Sanchez reported that Board staff are currently monitoring the Licensing Committee's work on SB 159 to identify information that would be helpful to educate pharmacists and consumers. He stated that at the January 9, 2020, Licensing meeting, stakeholders discussed educating pharmacists about operational issues related to SB 159, such as what types of records to keep and how long to keep them.

Mr. Dávila suggested staff use the website, subscriber alerts, and *Script* articles to educate licensees about SB 159. He also stated staff is working with the Office of AIDS, other state agencies, and community organizations to develop effective educational materials for the public as the implementation of SB 159 rolls out.

Mr. Dávila also reported as part of the prior day's meeting, Committee members emphasized encouraging licensees to get involved in furnishing HIV medications, naloxone, and other medications authorized by SB 493. He stated the Committee recommended using videos, *The Script* articles, and other ways to share information about how pharmacists address operational issues related to SB 159.

Ms. Shirly Kim arrived at 9:14 a.m.

Ms. Veale reiterated what Mr. Dávila stated regarding the use of videos as a tool from those providers currently providing PrEP and PEP services. She also mentioned the use of patient forms as another tool.

Danny Martinez, representing CPhA, stated they are open to assist the Board in operationalizing SB 159.

c. Discussion and Consideration of Proposed Changes to Notice to Consumers Poster

Chairperson Sanchez stated that at the July 2019 Committee meeting, members asked staff to recommend ways to refresh the Notice to Consumers poster. California Code of Regulations section 1707.6 requires pharmacies to post the notice in a prominent location in the pharmacy. The regulation also provides specific wording for the notice. The current Notice to Consumers poster and the text of CCR section 1707.6 were provided as part of the meeting materials.

Mr. Dávila reported that staff suggested considering possible changes in the wording on the Notice to Consumers and that any change would require rulemaking to amend section 1707.6. He noted the poster does not reflect changes in prescription labeling requirements, which took effect in 2015. He also reported that staff suggested it may be appropriate to provide information on how to verify a license and how to file a complaint with the Board.

Mr. Dávila stated that Committee members suggested some information provided on the poster may no longer be urgent or relevant, such as information about interpretive services and drug pricing. He stated Committee members and members of the public noted that other types of information could

be more helpful to consumers.

Mr. Dávila reported the Committee directed staff to seek out information from consumers and report back on types of information that may be more relevant for the Notice to Consumers. In addition, he stated members directed staff to report back on what kind of statutory or regulatory changes would be required if the Board were to decide to repeal the Notice to Consumers requirement.

There were no Board or public comments.

d. Educating Licensees about Possible Consequences of DUI Conviction

Chairperson Sanchez provided background information stating that at the July 2019 Board meeting, members suggested providing education to warn licensees about the possible professional consequences if they are convicted of driving under the influence (DUI). The Board asked the Communication and Public Education Committee to discuss this matter.

Mr. Dávila reported that at the Committee meeting yesterday, members suggested running information in *The Script* explaining the potential serious consequences of a DUI conviction for licensees and the top 5 or ten causes for license revocation. Members of the public said licensees should understand the potential impact that actions outside the pharmacy can have on their license.

Mr. Wong inquired about the percentage of DUIs for licensees. Ms. Sodergren stated that Board staff would be able to gather the information. Ms. Butler thanked Mr. Dávila for the information and the Board's work on educating pharmacists on the consequences of DUI convictions. Mr. Brooks stated he would like to see the top 5 reasons for licensees to lose their license.

There were no public comments.

e. Update on Communication and Pubic Education Activities by Board Staff

1. <u>The Script</u>
   Chairperson Sanchez stated that Board staff reported articles for the next issue of *The Script* are undergoing legal review. The next issue will focus on new laws for 2020 and include articles include the top 10 citations, corresponding responsibility, and tips on reporting data to CURES.

   Mr. Dávila indicated that *The Script* will also include 2 case studies with prescription shortages and compounding errors and will be for educational use for licensees.

   There were no Board or public comments.

2. <u>Projects</u>
   Chairperson Sanchez reported that billboards with the Board's "Use, Don't Abuse" campaign were erected in September. He stated Outfront Media generously donated two billboards in the Sacramento area and one in Fresno while 2 additional locations are planned in Southern California. A photo of one billboard next to Highway 50 in West Sacramento and a press release issued by DCA were part of the meeting materials. Chairperson Sanchez thanked Mr. Brooks for the generosity.

Chairperson Sanchez stated that Board staff is working on a new pharmacy law update webinar for 2020 which will be posted on the Board's website.

There were no Board or public comments.

3. News Media
Chairperson Sanchez acknowledged the work of Mr. Dávila and thanked him. Mr. Dávila reported that a list of recent new media inquires was included as part of the meeting materials.

4. Public Outreach
Mr. Dávila reported that a list of recent outreach activities by Board inspectors and staff was included as part of the meeting materials.

There were no Board or public comment.

IX. Enforcement Committee

a. Discussion and Consideration of Inventory Reconciliation and Report Requirements for Controlled Substances, Including Discussion and Consideration of Possible Amendments to Title 16, California Code of Regulations Section 1715.65

Chairperson Schaad stated that during the last Committee meeting, discussion continued on the Board's inventory reconciliation and reporting requirements. He stated that as part of the review, clarity was required in the regulation regarding the use of ADDS and the term 'satellite location'. Additionally, in response to comments received, the Committee sought to provide clarification with respect to inventory reconciliation activities of Schedule III – V medications.

Chairperson Schaad said as part of the November 2019 Board meeting the Committee offered amendments to the regulation for consideration. Ultimately the Board referred the matter back to the Committee for additional consideration but released a policy statement regarding the requirements for inventory requirements ADDS used in an inpatient hospital as well as clarification on satellite pharmacies.

Chairperson Schaad reported that he worked with Board staff and counsel to draft amendments to the current regulations following the Board meeting, taking into consideration comments made by the Board and public. He stated that he is also suggesting changes to the regulation that will include an electronic signature provision and recommending a more targeted approach for annual inventory reconciliation and reporting.

Chairperson Schaad said that after review and consideration of drug loss reports for the last fiscal year, the proposal identifies specified medication/strengths that would require inventory reconciliation reporting on an annual basis including:

- Alprazolam 1mg
- Alprazolam 2mg
- Tramadol 50mg
- Promethazine/Codeine 6.25mg/10mg

The approximate dosage units lost during the prior fiscal year was included in the meeting materials. The list includes all medication/strengths that included more than 25,000 dosage units.

Chairperson Schaad explained the recommended changes that were used as a starting point for the Committee's discussion were included in the meeting materials.

Chairperson Schaad reported that during the meeting the previous day, the Committee received comments regarding the proposal. In general, comments were supportive of the four targeted medications/strengths included in the proposal; however, concerns were raised about the inventory reconciliation reporting requirement for all Schedule III-V medications on a periodic basis. He stated that the Committee modified the proposed language to require inventory reconciliation for schedule III-V medications every two years, and only require the full reconciliation report when a drug loss is identified. Chairperson Schaad also clarified that a single report can be completed for a hospital pharmacy that includes the satellite areas and ADDS.

Chairperson Schaad said the Committee considered a suggestion to include buprenorphine products as one of the targeted areas, but ultimately decided that was not appropriate at this time. Chairperson Schaad stated revised language has been provided as a handout during the Board meeting which incorporates the Committee's direction at the previous day's meeting.

Public comment again recommended the inclusion of buprenorphine. Additional public comment was received in support of the revised language.

Dr. Serpa expressed concerns regarding the term "inventory reconciliation" as it relates to reports. As a provider, she believed "inventory reconciliation" is defined as a full accounting, or an audit, from the time the pharmacy receives the medication to the time it is distributed; however, the context of the current language does not reflect this definition. She suggested removing the term "inventory reconciliation" unless it relates to an audit or report. Ms. Sodergren asked if there was another term that would be more appropriate. Dr. Serpa recommended using "inventory activities."

Dr. Serpa highlighted the fact that it is already a requirement for pharmacies to conduct an inventory every two years and the focus of the Board's proposal is the loss of certain drugs.

Provided below is the proposed language, including Dr. Serpa's suggested terminology.

§ 1715.65. Inventory Reconciliation Report of Controlled Substances.

(a) Every pharmacy, and every clinic licensed under sections 4180 or 4190 of the Business and Professions Code, shall perform periodic inventory and prepare inventory reconciliation ~~functions~~ reports to detect and prevent the loss of federal controlled substances. Except as provided in subdivisions (f) and (g), inventory reconciliation reports shall be prepared on the following ongoing basis:

(1) For Schedule II controlled substances, at least once every three months.

(2) For products containing controlled substances listed in this paragraph in the following strengths, at least once every 12 months:

(A) Alprazolam, 1 milligram.
(B) Alprazolam 2 milligrams
(C) Tramadol 50 milligrams.
(D) Promethazine/Codeine, 6.25 milligrams/10 milligrams per 5 milliliters of product
(3)(A) For ~~all other~~ any controlled ~~substances~~ substance not covered by paragraph (1) or (2), ~~on a periodic basis~~ no later than three months after any loss of that controlled substance is identified pursuant to an inventory ~~reconciliation~~ activities under subparagraph (B) or otherwise.
(B) Inventory ~~reconciliation~~ activities of a controlled substance not covered by paragraph (1) or (2) shall be performed at least once every two years. For purposes of this subparagraph, "inventory ~~reconciliation~~ activities" means the performance of an inventory and all other functions necessary to identify losses of the controlled substance. ~~since the last inventory reconciliation or reconciliation report covering the controlled substance, whichever is more recent.~~
(b) The pharmacist-in-charge of a pharmacy or ~~consultant~~ consulting pharmacist for a clinic shall review all inventory and inventory reconciliations performed and inventory reconciliation reports ~~taken~~ prepared pursuant to this section, and establish and maintain secure methods to prevent losses of federal controlled ~~drugs~~ substances. Written policies and procedures shall be developed for ~~performing~~ performing inventory reconciliation and preparing the inventory reconciliation reports required by this section.
(c) ~~A pharmacy or clinic shall compile an~~ An inventory reconciliation report ~~of all federal Schedule II controlled substances at least every three months. This compilation~~ prepared pursuant to this section shall ~~require~~ include all of the following:
(1) A physical count, not an estimate, of all quantities of ~~federal Schedule II~~ each federal controlled ~~substances~~ substance covered by the report that the pharmacy or clinic has in inventory, except as provided in subdivision (h). The biennial inventory of controlled substances required by federal law may serve as one of the mandated inventories under this section in the year where the federal biennial inventory is performed, provided the biennial inventory was taken no more than three months from the last inventory required by this section. An individual who performs the inventory required by this paragraph shall sign and date the inventory or the report in which it is included as provided in subdivision (e)(1);
(2) A review of all acquisitions and dispositions of each federal ~~Schedule II~~ controlled ~~substances~~ substance covered by the report since the last inventory reconciliation report covering that controlled substance;
(3) A comparison of (1) and (2) to determine if there are any variances;
(4) ~~All~~ Identification of all records used to compile ~~each inventory reconciliation~~ the report, which shall be maintained in the pharmacy or clinic ~~for at least three years in a readily retrievable form~~ pursuant to subdivision (e)(2); ~~and~~
(5) Identification of each individual involved in preparing the report; and
~~(5)~~ (6) Possible causes of overages ~~shall be identified in writing and incorporated into the inventory reconciliation report~~.
(d) A pharmacy or clinic shall report in writing identified losses and known causes to the board within 30 days of discovery unless the cause of the loss is theft, diversion, or self-use in which case the report shall be made within 14 days of discovery. If the pharmacy or clinic is unable to identify the cause of the loss, further investigation shall be undertaken to identify the cause and actions necessary to prevent additional losses of federal controlled substances.
(e)(1) ~~The~~ An inventory reconciliation report shall be dated and signed by ~~the individual(s) performing the inventory, and countersigned by~~ the pharmacist-in-charge or professional

director (if a clinic) ~~and~~, in addition to any signature required by subdivision (c)(1). An individual may use a digital or electronic signature or biometric identifier in lieu of a physical signature under this section if, in addition, the individual physically signs a printed statement confirming the accuracy of the inventory or report. The signature shall be dated, and the signed and dated statement shall be retained on file pursuant to paragraph (2).

(2) The report, and all records used to compile the report, shall be readily retrievable in the pharmacy or clinic for three years. ~~A countersignature is not required if the pharmacist-in-charge or professional director personally completed the inventory reconciliation report.~~

(f) A new pharmacist-in-charge of a pharmacy shall complete an inventory reconciliation report ~~as identified in subdivision (c)~~ for all federal controlled substances described in paragraphs (1) and (2) of subdivision (a) within 30 days of becoming pharmacist-in-charge. Whenever possible an outgoing pharmacist-in-charge should also complete an inventory reconciliation report ~~as required in subdivision (c)~~ for ~~all federal~~ those controlled substances.

(g) ~~For~~ Notwithstanding the periodic reporting requirements specified in paragraphs (1) and (2) of subdivision (a), inpatient hospital pharmacies~~,~~ shall prepare an inventory reconciliation report or reports ~~for all~~ covering the federal controlled substances described in paragraphs (1) and (2) of subdivision (a) on a ~~separate~~ quarterly ~~basis, inventory reconciliation report shall be required including separate quarterly reports for federal Schedule II~~ basis. The report or reports shall include controlled substances stored within the pharmacy ~~and, for~~ within each pharmacy satellite location, and ~~for~~ within each drug storage area ~~within~~ in the hospital under the pharmacy's control.

(h) ~~The pharmacist-in-charge of~~ If an inpatient hospital pharmacy ~~or of a pharmacy servicing onsite or offsite~~ uses an automated drug delivery ~~systems~~ system (ADDS), inventory in the ADDS may be accounted for under subdivision (c)(1) using means other than a physical count. ~~shall ensure that:~~

~~(1) All controlled substances added to an automated drug delivery system are accounted for;~~

~~(2) Access to automated drug delivery systems is limited to authorized facility personnel;~~

~~(3) An ongoing evaluation of discrepancies or unusual access associated with controlled substances is performed; and~~

~~(4) Confirmed losses of controlled substances are reported to the board.~~

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4008, 4037, 4080, 4081, 4101, 4104, 4105, 4105.5, 4110, 4113, 4119.1, 4180, 4181, 4182, 4186, 4190, 4191, 4192 and 4332, Business and Professions Code; and Section 1261.6, Health and Safety Code.

Board Motion: Initiate a rulemaking for the proposed amendment to Title 16 section 1715.65 "Relating to the Inventory Reconciliation and Report Requirements for Controlled Substances" as articulated by Dr. Serpa (above) and incorporate policy changes recommended by the Committee. Delegate to the executive officer the authority to make any non-substantive changes and clarifying changes consistent with the Board's policy direction upon recommendations of the control agencies.

M/S: Schaad/Lippe

Support: 9 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks	Support			

Board Member	Support	Oppose	Abstain	Not Present
Butler	Support			
Kim	Support			
Lippe	Support			
Muñoz				Not Present
Sanchez	Support			
Schaad	Support			
Serpa	Support			
Veale	Support			
Wong	Support			

Prior to the vote, Mr. Wong stated he would like to see a standard mandatory reporting requirement to the Board for all drugs, not just when there is a loss. Ms. Sodergren stated that was a topic that was suggested in the prior day's Committee meeting as a future agenda item.

b. Discussion and Consideration of Proposed Amendments to Title 16, California Code of Regulations, Section 1715.6 Relating to Reporting Drug Losses

Chairperson Schaad reported that the historical drug loss information provided as part of the meeting materials illustrates that the number of drug loss reports received by the Board has more than doubled since FY 2015/16, and continues to increase. He stated that the data also reflects that in the most recent fiscal year there has been a significant decrease in the overall dosage units reported lost and that the vast majority of reported losses involve 100 or less dosage units.

Chairperson Schaad stated the Committee considered a draft proposal intended to modify the reporting requirements; however, after discussion, it was determined that additional consideration was necessary. He reported that he met with Board staff and counsel to further evaluate the appropriate conditions under which a drug loss report should be filed to the Board.

Chairperson Schaad explained that while capsules and tablets are overwhelmingly the most common dosage forms for which drug loss reports are submitted, additional dosage forms of drugs are also included in the proposal. He stated that the intent of the language is to provide clarity on drug loss reporting requirements while also ensuring professional judgment can be used.

Chairperson Schaad reported that the Committee also discussed the incorporation of medications delivered via infusion, including patient-controlled analgesics. He stated that ultimately the Committee determined that continuous dose infusions should be incorporated into the provisions related to multi-use containers.

Chairperson Schaad stated the Committee recommends using the term "significant" when it relates to drug loss reporting that falls under the professional judgment of the pharmacist-in-charge because it is consistent with the terminology used by the DEA.

Chairperson Schaad noted that revised language was provided as a handout during the Board meeting which incorporates the Committee's direction from the previous day's meeting.

There were no Board or public comment.

Committee Motion: Recommend to the Board approve the proposed amendment to Title 16 section 1715.6 "Related to the reporting of Drug Losses" and policy changes recommended by the Committee (below). Delegate to the executive officer/counsel the authority to make any non-substantive changes and clarifying changes consistent with the Board's policy direction upon recommendations of the control agencies.

§ 1715.6. Reporting Drug Loss.

(a) The owner shall submit ~~report~~ to the Board a report containing the information in subdivision (b) ~~within~~ no later than thirty (30) days after the date of discovery of the following:
(1) ~~any~~ Any loss of ~~the~~ a controlled substance~~s, including their~~ in one of the following categories that causes the aggregate amount of unreported losses discovered in that category on or after the same day of the previous year to equal or exceed:
(A) For tablets, capsules, or other oral medication, 99 dosage units.
(B) For single-dose injectable medications, lozenges, film, suppositories, or patches, 10 dosage units.
(C) For injectable multi-dose medications, medications administered by continuous infusion, or any other multi-dose unit not described in subparagraph (A), two or more multi-dose vials, infusion bags, or other containers.
(2) Any loss of a controlled substance, regardless of the amount, attributed to employee theft.
(3) Any other ~~substantial~~ significant loss as determined by the pharmacist-in-charge.
(b) All reports under this section shall specify the identity, amount~~s~~ and strength~~s~~ of each controlled substance lost, and date of discovery of the loss, for all losses that have made the report necessary.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4081 and 4332, Business and Professions Code.

Support: 9 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks	Support			
Butler	Support			
Kim	Support			
Lippe	Support			
Muñoz				Not Present
Sanchez	Support			
Schaad	Support			
Serpa	Support			
Veale	Support			
Wong	Support			

c. Discussion and Consideration of Legislative Proposal to Establish an Alternative Disciplinary Process

Chairperson Schaad reported that this agenda item will be sent back to Committee for further discussion as there was confusion around this topic, by the public as well as the Board. He stated that the future discussion will focus on a collaborative process, including oral presentation, by both the respondent and the inspector. Chairperson Schaad said he intends to schedule another Committee meeting prior to the May 6, 2020 meeting.

Public comment was heard in support of the continued work at the Committee level.

d. Discussion and Consideration of Policy Regarding Referrals by Pharmacies and Pharmacists to Law Enforcement for Narcotic Diversion by Employees

Chairperson Schaad reported that the Board routinely investigates and takes action against licensees involved with drug diversion in pharmacies. He stated that as a Board, measures have been taken to encourage better inventory controls and developed trainings.

Chairperson Schaad stated that the Committee considered a requirement to refer such diversion to local law enforcement. He said the Board previously decided not to pursue mandating a referral of drug diversion cases to local law enforcement agencies. He said that as an alternative to a mandate, the Committee is recommending the Board consider adopting a policy statement regarding referral of drug diversion cases to local law enforcement.

Chairperson Schaad reported that the Committee discussed a draft policy statement intended to encourage licensees to contact law enforcement for guidance on drug diversion matters. There was general support for the statement which was modified based on the Committee's discussion and public comments (below).

In recognition of the ongoing national opioid crisis and in addition the mandatory reporting obligations to the Board included in BPC 4104, the Board encourages pharmacies and pharmacists to ~~contact~~ report to local law enforcement ~~for guidance on~~ matters involving ~~narcotics~~ drug diversion ~~by its employees~~.

There were no Board or public comments.

Committee Recommendation (Motion): The Committee is offering the following policy statement as a recommendation to the Board:

In recognition of the ongoing national opioid crisis and in addition the mandatory reporting obligations to the Board included in BPC 4104, the Board encourages pharmacies and pharmacists to report to law enforcement matters involving drug diversion.

Support: 9 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks	Support			
Butler	Support			
Kim	Support			
Lippe	Support			

Board Member	Support	Oppose	Abstain	Not Present
Muñoz				Not Present
Sanchez	Support			
Schaad	Support			
Serpa	Support			
Veale	Support			
Wong	Support			

e. Discussion and Consideration of DEA Suspicious Orders Report System (SORS) and Mandatory Reporting Requirement

Chairperson Schaad reported that on October 23, 2019, DEA launched the Suspicious Orders Report System (SORS) online which is a new centralized database required by the "Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act" (SUPPORT Act, Pub. L. 115-271). The S.U.P.P.O.R.T. Act requires all DEA registrants that distribute controlled substances report suspicious orders to DEA, including pharmacies, wholesalers and clinics. Public comment encouraged the Board to create a Frequently Asked Questions to inform pharmacies, wholesalers, and clinics that this applies to them. Dr. Serpa commented that she was unsure what additional information should be provided on the Board's website since SORS is a DEA program and not Board policy. Chairperson Schaad replied that further elaboration would be considered and sent via *The Script*.

f. Discussion and Consideration of Board's Enforcement Statistics

Chairperson Schaad stated the Board's enforcement statistics for the first two quarters of the year were included as part of the meeting materials**.**

Chairperson Schaad reported that since July 1, the Board received 1,307 complaints and has closed 1,437 investigations. The Board has issued 191 Letters of Admonishment, 785 Citations and referred 119 cases to the Office of the Attorney General. He stated the Board has secured six interim suspension orders, been granted two Penal Code 23 suspensions, and issued one cease and desist. Further, the Board has revoked 59 licenses, accepted the disciplinary surrender of 57 licenses, denied seven applications, and imposed other levels of discipline against 90 licensees and/or applicants. Chairperson Schaad stated that as of January 16, 2020, the Board had 1,473 field investigations pending. Below is a breakdown providing more detail in the various investigation process:

- 79 cases under review for assignment, averaging 20 days
- 1,010 cases under investigation, averaging 186 days
- 261 investigations under supervisor review, averaging 107 days
- 46 investigations under second level review, averaging 20 days
- 77 investigations waiting final closure (typically issuance of a citation or letter of admonishment) averaging 23 days

Chairperson Schaad stated that after reviewing the investigation timeframes, the Committee expressed concern with the current supervisor review time. He said that the Committee was advised that improvement will be reported during the next meeting.

The Enforcement Committee's next meeting is scheduled for May 6, 2020.

The Board took a break at 10:07 a.m. and reconvened at 10:28 a.m.

Out of Order – Public Comment on Items Not on the Agenda

President Lippe allowed for public comment from an individual not present at the prior day's meeting. The public comment was a concern for how pharmacies utilize single use only medications and additional education needed for opiate distribution to patients. The commenter also stated that pharmacists should call the physician when there is a conflict between a prescription for an antibiotic and the patient's other medications.

X. Legislation and Regulation Committee

a. Discussion and Consideration of Board Sponsored Legislation: 2019 Sunset Review Items Resulting in Possible Legislation

President Lippe stated that during the prior day's meeting, the Committee reviewed statutory language that was included in the Board's Sunset Report to ensure it appropriately reflects and would effectuate the Board's policy.

1. Amend Business and Professions (BPC) Code section 4427.3 and add a new BPC section to Expand the Locations in which Automated Drug Delivery Systems (ADDS) can be Licensed

   President Lippe reported this proposal would amend Business and Professions Code section 4427.3 and add a new section to expand the locations in which an ADDS can be licensed. He noted the expansion would include authority to license ADDS to be used in all facilities listed in Health and Safety Code section 1250 as well as other locations licensed by the state that, as a function of licensure, are authorized to offer medication services.

   President Lipped stated the Board approved this statutory proposal at its November 2019 Board Meeting and that no action was taken by the Committee.

   There were no Board or public comments.

2. Amend BPC section 4161 and 4400 to Provide an Alternative Pathway to Licensure as a Nonresident Third-Party Logistics Provider

   President Lippe reported that this is the first time the Board has reviewed the language for this proposal. He stated that this proposal will create an alternative pathway for the licensure of a nonresident third-party logistics provider, and would be similar to the out-of-state inspection process used for licensure of nonresident sterile compounding pharmacies.

President Lippe stated that as reported in the Sunset Report, some states continue to regulate 3PLs as wholesalers, in conflict with federal law, which creates a problem for licensure in California. This statutory change would remedy this issue by creating this alternative pathway.

President Lippe said the proposed language was included in the meeting materials and included the proposed amendment to BPC 4161(h). He stated that after discussion and consideration, the Committee determined it would also be appropriate to accept VAWD accreditation as an alternative pathway to licensure.

Public comment suggested amending the language in the proposal to clarify that the inspection is to be done prior to licensure. Ms. Sodergren offered to modify the language should the Board determine it appropriate.

There were no Board comments.

Committee Recommendation (Motion): Pursue a statutory change consistent with the language in the Board's Sunset Report, including VAWD accreditation as another alternative pathway to licensure. Delegate to the executive officer/counsel the authority to make any non-substantive changes and clarifying changes consistent with the Board's policy direction upon recommendations of the control agencies.

ARTICLE 11. Wholesalers, Third-Party Logistics Providers, and Manufacturers [4160 - 4169.1]
(Heading of Article 11 amended by Stats. 2014, Ch. 507, Sec. 16.)

4161.
(a) A person located outside this state that (1) ships, sells, mails, warehouses, distributes, or delivers dangerous drugs or dangerous devices into this state or (2) sells, brokers, warehouses, or distributes dangerous drugs or devices within this state shall be considered a nonresident wholesaler or a nonresident third-party logistics provider.
(b) A nonresident wholesaler or nonresident third-party logistics provider shall be licensed by the board prior to shipping, selling, mailing, warehousing, distributing, or delivering dangerous drugs or dangerous devices to a site located in this state or selling, brokering, warehousing, or distributing dangerous drugs or devices within this state.
(c) (1) A separate license shall be required for each place of business owned or operated by a nonresident wholesaler or nonresident third-party logistics provider from or through which dangerous drugs or dangerous devices are shipped, sold, mailed, warehoused, distributed, or delivered to a site located in this state or sold, brokered, warehoused, or distributed within this state. Each place of business may only be issued a single license by the board, except as provided in paragraph (2). A license shall be renewed annually and shall not be transferable.
(2) A nonresident wholesaler and a nonresident third-party logistics provider under common ownership may be licensed at the same place of business provided that all of the following requirements are satisfied:
(A) The wholesaler and the third-party logistics provider each separately maintain the records required under Section 4081.

(B) Dangerous drugs and dangerous devices owned by the wholesaler are not commingled with the dangerous drugs and dangerous devices handled by the third-party logistics provider.
(C) Any individual acting as a designated representative for the wholesaler is not concurrently acting as a designated representative-3PL on behalf of the third-party logistics provider. Nothing in this subparagraph shall be construed to prohibit an individual from concurrently holding a license to act as a designated representative and to act as a designated representative-3PL.
(D) The wholesaler has its own designated representative-in-charge responsible for the operations of the wholesaler and the third-party logistics provider has its own responsible manager responsible for the operations of the third-party logistics provider. The same individual shall not concurrently serve as the responsible manager and the designated representative-in-charge for a wholesaler and a third-party logistics provider licensed at the same place of business.
(E) The third-party logistics provider does not handle the prescription drugs or prescription devices owned by a prescriber.
(F) The third-party logistics provider is not a reverse third-party logistics provider.
(G) The wholesaler is not acting as a reverse distributor.
(d) The following information shall be reported, in writing, to the board at the time of initial application for licensure by a nonresident wholesaler or a nonresident third-party logistics provider, on renewal of a nonresident wholesaler or nonresident third-party logistics provider license, or within 30 days of a change in that information:
(1) Its agent for service of process in this state.
(2) Its principal corporate officers, as specified by the board, if any.
(3) Its general partners, as specified by the board, if any.
(4) Its owners if the applicant is not a corporation or partnership.
(e) A report containing the information in subdivision (d) shall be made within 30 days of any change of ownership, office, corporate officer, or partner.
(f) A nonresident wholesaler or nonresident third-party logistics provider shall comply with all directions and requests for information from the regulatory or licensing agency of the state in which it is licensed, as well as with all requests for information made by the board.
(g) A nonresident wholesaler or nonresident third-party logistics provider shall maintain records of dangerous drugs and dangerous devices sold, traded, transferred, warehoused, or distributed to persons in this state or within this state, so that the records are in a readily retrievable form.
(h) A nonresident wholesaler or nonresident third-party logistics provider shall at all times maintain a valid, unexpired license, permit, or registration to conduct the business of the wholesaler or nonresident third-party logistics provider in compliance with the laws of the state in which it is a resident. An application for a nonresident wholesaler or nonresident third-party logistics provider license in this state shall include a license verification from the licensing authority in the applicant's state of residence. <u>The board may waive the home state licensure requirement for a nonresident third-party logistics provider if the location is inspected by the board and found in compliance with this article and any regulations adopted by the board. The nonresident third-party logistics provider shall reimburse the board for all actual and necessary costs incurred by the board in conducting an inspection of the location, pursuant to subdivision (v) of Section 4400.</u>

(i) (1) The board shall not issue or renew a nonresident wholesaler license until the nonresident wholesaler identifies a designated representative-in-charge and notifies the board in writing of the identity and license number of the designated representative-in-charge.
(2) The board shall not issue or renew a nonresident third-party logistics provider license until the nonresident third-party logistics provider identifies a responsible manager and notifies the board in writing of the identity and license number of the designated representative-3PL who will be the responsible manager.
(j) The designated representative-in-charge shall be responsible for the compliance of the nonresident wholesaler with state and federal laws governing wholesalers. The responsible manager shall be responsible for the compliance of the nonresident third-party logistics provider's place of business with state and federal laws governing third-party logistics providers. A nonresident wholesaler or nonresident third-party logistics provider shall identify and notify the board of a new designated representative-in-charge or responsible manager within 30 days of the date that the prior designated representative-in-charge or responsible manager ceases to be the designated representative-in-charge or responsible manager.
(k) The board may issue a temporary license, upon conditions and for periods of time as the board determines to be in the public interest. A temporary license fee shall be five hundred fifty dollars ($550) or another amount established by the board not to exceed the annual fee for renewal of a license to compound sterile drug products. When needed to protect public safety, a temporary license may be issued for a period not to exceed 180 days, subject to terms and conditions that the board deems necessary. If the board determines that a temporary license was issued by mistake or denies the application for a permanent license, the temporary license shall terminate upon either personal service of the notice of termination upon the licenseholder or service by certified mail, return receipt requested, at the licenseholder's address of record with the board, whichever occurs first. Neither for purposes of retaining a temporary license, nor for purposes of any disciplinary or license denial proceeding before the board, shall the temporary licenseholder be deemed to have a vested property right or interest in the license.
(l) The registration fee shall be the fee specified in subdivision (f) of Section 4400.

Support: 9 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks	Support			
Butler	Support			
Kim	Support			
Lippe	Support			
Muñoz				Not Present
Sanchez	Support			
Schaad	Support			
Serpa	Support			
Veale	Support			
Wong	Support			

The Board took a break at 10:39 a.m. and reconvened at 10:48 a.m.

3. Amend BPC sections 4127.3, 4129.4, and 4316 Relating to the Cease and Desist Appeal Hearing

President Lippe stated that this proposal clarifies that a hearing date of a cease and desist appeal must occur within five *business* days. He stated that current law specifies that such an appeal must occur within five days, which is problematic for scheduling, especially if an appeal is requested over a holiday weekend.

President Lippe said that the scheduling of such hearings must be coordinated with counsel, the Board president, or vice president, as well as the respondent.

President Lippe reported that during the Committee meeting, public comment suggested that clarification of the timeframe may also be appropriate as it relates to the timeframe for the president to issue a decision. He said that the Committee agreed that such amendment would also be appropriate.

Committee Motion: Pursue this statutory change consistent with the language in the Board's Sunset Report, including five business days to issue the presidents response.

There were no Board or public comments.

Proposal to amend BPC section 4127.3. Cease and Desist Order; Hearing
(a) Whenever the board has a reasonable belief, based on information obtained during an inspection or investigation by the board, that a pharmacy compounding sterile drug products poses an immediate threat to the public health or safety, the executive officer of the board may issue an order to the pharmacy to immediately cease and desist from compounding sterile drug products. The cease and desist order shall remain in effect for no more than 30 days or the date of a hearing seeking an interim suspension order, whichever is earlier.

(b) Whenever the board issues a cease and desist order pursuant to subdivision (a), the board shall immediately issue the owner a notice setting forth the acts or omissions with which the owner is charged, specifying the pertinent code section or sections.

(c)The order shall provide that the owner, within 15 days of receipt of the notice, may request a hearing before the president of the board to contest the cease and desist order. Consideration of the owner's contest of the cease and desist order shall comply with the requirements of Section 11425.10 of the Government Code. The hearing shall be held no later than five business days from the date the request of the owner is received by the board. The president shall render a written decision within five business days of the hearing. In the absence of the president of the board, the vice president of the board may conduct the hearing permitted by this subdivision. Review of the decision of the president of the board may be sought by the owner or person in possession or control of the pharmacy pursuant to Section 1094.5 of the Code of Civil Procedure.

(d) Failure to comply with a cease and desist order issued pursuant to this section shall be unprofessional conduct.

Proposal to amend BPC section 4129.4. Cease and Desist Order
(a)Whenever the board has a reasonable belief, based on information obtained during an inspection or investigation by the board, that an outsourcing facility compounding sterile drug products or nonsterile drug products poses an immediate threat to the public health or safety, the executive officer of the board may issue an order to the outsourcing facility to immediately cease and desist compounding sterile drug products or nonsterile drug products. The cease and desist order shall remain in effect for no more than 30 days or the date of a hearing seeking an interim suspension order, whichever is earlier.

(b)Whenever the board issues a cease and desist order pursuant to subdivision (a), the board shall immediately issue a notice to the owner setting forth the acts or omissions with which the owner is charged, specifying the pertinent code section or sections and any regulations.

(c)The cease and desist order shall state that the owner, within 15 days of receipt of the notice, may request a hearing before the president of the board to contest the cease and desist order. Consideration of the owner's contest of the cease and desist order shall comply with the requirements of Section 11425.10 of the Government Code. The hearing shall be held no later than five business days after the date the request of the owner is received by the board. The president shall render a written decision within five business days after the hearing. In the absence of the president of the board, the vice president of the board may conduct the hearing permitted by this subdivision. Review of the decision may be sought by the owner or person in possession or control of the outsourcing facility pursuant to Section 1094.5 of the Code of Civil Procedure.

(d)Failure to comply with a cease and desist order issued pursuant to this section shall be unprofessional conduct.

Proposal to amend BPC section 4316. Board Authorized to Issue Cease and Desist Orders
(a)The board, through its executive officer, is authorized to issue a cease and desist order for operating any facility under this chapter that requires licensure without obtaining that licensure.

(b)Whenever the board issues a cease and desist order pursuant to subdivision (a), the board shall immediately issue the facility a notice setting forth the acts or omissions with which it is charged, specifying the pertinent code section or sections and any regulations.

(c)The order shall provide that the facility, within 15 days of receipt of the notice, may request a hearing before the president of the board to contest the cease and desist order. Consideration of the facility's contest of the cease and desist order shall comply with the requirements of Section 11425.10 of the Government Code. The hearing shall be held no later than five business days from the date the request of the owner is received by the board. The president shall render a written decision within five business days of the hearing. In the absence of the president of the board, the vice president of

the board may conduct the hearing permitted by this subdivision. Review of the decision of the president of the board may be sought by the owner or person in possession or control of the facility pursuant to Section 1094.5 of the Code of Civil Procedure.

Support: 9 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks	Support			
Butler	Support			
Kim	Support			
Lippe	Support			
Muñoz				Not Present
Sanchez	Support			
Schaad	Support			
Serpa	Support			
Veale	Support			
Wong	Support			

4. Amend BPC 4343 to Expand the Prohibition Against Non-Pharmacies Using any Words for Licensed Pharmacy

President Lippe explained that this proposal was a technical change but would prohibit any non-pharmacy website from using words like pharmacy, similar to the current prohibition on signs displayed within or affixed to buildings unless there is a licensed pharmacy within the building.

President Lippe stated that as part of the prior day's meeting, the Committee and public comment were in support of the proposal.

Committee Motion: Pursue this statutory change consistent with the Board's Sunset Report.

There were no Board comments. Public comment sought clarification of the current law.

Proposal to amend BPC section 4343 to read as follows: Buildings or Websites: Prohibition Against the Use of Certain Signs Unless Licensed Pharmacy Within

No building shall have upon it or displayed within it or affixed to or used in connection with it a sign bearing the word or words "Pharmacist," "Pharmacy," "Apothecary," "Drugstore," "Druggist," "Drugs," "Medicine," "Medicine Store," "Drug Sundries," "Remedies," or any word or words of similar or like import; or the characteristic symbols of pharmacy; or the characteristic prescription sign (Rx) or similar design, unless there is upon or within the building a pharmacy holding a license issued by the board pursuant to Section 4110. Further, no website shall have within it or used in connection with it a sign bearing the words "Pharmacist," "Pharmacy," "Apothecary," "Drugstore," "Druggist," "Drugs," "Medicine," "Medicine Store," "Drug Sundries," "Remedies," or any word or words of similar or like import; or the characteristic symbols of pharmacy; or the characteristic prescription sign (Rx) or similar design, unless the website is under the control of a pharmacy holding a license issued by the board pursuant to Section 4110.

Support: 9 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks	Support			
Butler	Support			
Kim	Support			
Lippe	Support			
Muñoz				Not Present
Sanchez	Support			
Schaad	Support			
Serpa	Support			
Veale	Support			
Wong	Support			

5. Amend BPC section 4400 and add a new BPC section to Assess a Fee for an Inspection Resulting from the Remodel of a Sterile Compounding Pharmacy

President Lippe stated that this proposal was developed through the Board's Licensing Committee and approved for sponsorship at the May 2019 Board Meeting. He said that as approved, this proposal would require an assessment of a remodel inspection fee for in-state sterile compounding pharmacies and further would assess an inspection fee and reimbursement for travel costs for an out-of-state sterile compounding inspection under similar conditions.

President Lippe said that since this proposal was previously approved for sponsorship, no action is required.

There were no Board or public comments.

6. Amend BPC section 4312 to Expand the Provisions for Cancellation of a Facility License

President Lippe reported that this proposal, which was included as a technical change in the Board's Sunset Report, expands the authority for the Board to cancel a facility license to include all Board licensed facilities. He stated that under current law, the provision is limited to only some facility licenses.

Committee Motion: Pursue this statutory change consistent with the Board's Sunset Report.

There were no Board or public comments.

Proposal to amend BPC Section 4312 - Voiding License of Entity Remaining Closed: Notice; Disposition of Stock; Distribution of Proceeds Where Board Sells Stock

(a) The board may cancel ~~the license of~~ a ~~wholesaler, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, or outsourcing~~ license of a facility which is licensed by the board if the licensed premises remain closed, as defined in subdivision (e), other than by order of the board. For good cause shown, the board

may cancel a license after a shorter period of closure. To cancel a license pursuant to this subdivision, the board shall make a diligent, good faith effort to give notice by personal service on the licensee. If a written objection is not received within 10 days after personal service is made or a diligent, good faith effort to give notice by personal service on the licensee has failed, the board may cancel the license without the necessity of a hearing. If the licensee files a written objection, the board shall file an accusation based on the licensee remaining closed. Proceedings shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code, and the board shall have all the powers granted in that chapter.

(b) If ~~the~~ a facility license issued by the board ~~of a wholesaler, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, or outsourcing facility~~ is canceled pursuant to subdivision (a) or revoked pursuant to Article 19 (commencing with Section 4300), or a ~~wholesaler, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, or outsourcing~~ facility notifies the board of its intent to remain closed or to discontinue business, the licensee shall, within 10 days thereafter, arrange for the transfer of all dangerous drugs and controlled substances or dangerous devices to another licensee authorized to possess the dangerous drugs and controlled substances or dangerous devices. The licensee transferring the dangerous drugs and controlled substances or dangerous devices shall immediately confirm in writing to the board that the transfer has taken place.

(c) If a ~~wholesaler, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, or outsourcing~~ licensed facility fails to comply with subdivision (b), the board may seek and obtain an order from the superior court in the county in which the ~~wholesaler, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, or outsourcing~~ facility licensed by the board is located, authorizing the board to enter the ~~wholesaler, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, or outsourcing~~ licensed facility and inventory and store, transfer, sell, or arrange for the sale of, all dangerous drugs and controlled substances and dangerous devices found in the ~~wholesaler, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, or outsourcing~~ licensed facility.

(d) If the board sells or arranges for the sale of any dangerous drugs, controlled substances, or dangerous devices pursuant to subdivision (c), the board may retain from the proceeds of the sale an amount equal to the cost to the board of obtaining and enforcing an order issued pursuant to subdivision (c), including the cost of disposing of the dangerous drugs, controlled substances, or dangerous devices. The remaining proceeds, if any, shall be returned to the licensee from whose premises the dangerous drugs or controlled substances or dangerous devices were removed.

(1) The licensee shall be notified of his or her right to the remaining proceeds by personal service or by certified mail, postage prepaid.

(2) If a statute or regulation requires the licensee to file with the board his or her address, and any change of address, the notice required by this subdivision may

be sent by certified mail, postage prepaid, to the latest address on file with the board and service of notice in this manner shall be deemed completed on the 10th day after the mailing.

(3) If the licensee is notified as provided in this subdivision, and the licensee fails to contact the board for the remaining proceeds within 30 calendar days after personal service has been made or service by certified mail, postage prepaid, is deemed completed, the remaining proceeds shall be deposited by the board into the Pharmacy Board Contingent Fund. These deposits shall be deemed to have been received pursuant to Chapter 7 (commencing with Section 1500) of Title 10 of Part 3 of the Code of Civil Procedure and shall be subject to claim or other disposition as provided in that chapter.

(e) For the purposes of this section, "closed" means not engaged in the ordinary activity for which a license has been issued for at least one day each calendar week during any 120 day period.

(f) Nothing in this section shall be construed as requiring a pharmacy to be open seven days a week.

Support: 9 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks	Support			
Butler	Support			
Kim	Support			
Lippe	Support			
Muñoz				Not Present
Sanchez	Support			
Schaad	Support			
Serpa	Support			
Veale	Support			
Wong	Support			

7. Amend BPC section 4314 to Clarify that a Citation is not Considered Disciplinary Action

President Lippe reported that this proposal was included as a technical change within the Board's Sunset Report and clarifies the Board does not consider a citation a disciplinary action.

President Lippe noted that the language in section (e) incorrectly refers to Letters of Admonishment. The language should read, "The issuance of a citation pursuant to subdivision (b) of section BPC 4314 shall not be construed as a disciplinary action or discipline for purposes of licensure or the reporting of discipline for licensure."

Committee Recommendation (Motion): Pursue this statutory change consistent with the Board's Sunset Report to amend BPC 4314.

There were no Board or public comments.

Proposal to amend BPC section 4314. Orders of Abatement

(a)The board may issue citations containing fines and orders of abatement for any violation of Section 733, for any violation of this chapter or regulations adopted pursuant to this chapter, or for any violation of Division 116 (commencing with Section 150200) of the Health and Safety Code, in accordance with Sections 125.9, 148, and 4005 and the regulations adopted pursuant to those sections.

(b)Where appropriate, a citation issued by the board, as specified in this section, may subject the person or entity to whom the citation is issued to an administrative fine.

(c)Notwithstanding any other provision of law, where appropriate, a citation issued by the board may contain an order of abatement. The order of abatement shall fix a reasonable time for abatement of the violation. It may also require the person or entity to whom the citation is issued to demonstrate how future compliance with the Pharmacy Law, and the regulations adopted pursuant thereto, will be accomplished. A demonstration may include, but is not limited to, submission of a corrective action plan, and requiring completion of up to six hours of continuing education courses in the subject matter specified in the order of abatement. Any continuing education courses required by the order of abatement shall be in addition to those required for license renewal.

(d)Nothing in this section shall in any way limit the board from issuing a citation, fine, and order of abatement pursuant to Section 4067 or Section 56.36 of the Civil Code, and the regulations adopted pursuant to those sections.

(e)~~The issuance of a letter of admonishment pursuant to subdivision (b) of section 4315 shall not be construed as a disciplinary action or discipline for purposes of licensure or the reporting of discipline for licensure.~~ The issuance of a citation pursuant to subdivision (b) of section BPC 4314 shall not be construed as a disciplinary action or discipline for purposes of licensure or the reporting of discipline for licensure.

Support: 9 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks	Support			
Butler	Support			
Kim	Support			
Lippe	Support			
Muñoz				Not Present
Sanchez	Support			
Schaad	Support			
Serpa	Support			
Veale	Support			
Wong	Support			

b. Discussion and Consideration of Board Approved Legislation for Sponsorship

President Lippe explained that the legislative items in this section have been approved by the Board for sponsorship. He noted that the approved language for each section was included as part of the meeting materials.

1. Amend BPC section 4052.11 Regarding Continuing Education Requirement for Pharmacists Prescribing Schedule II Drugs Under a Collaborative Practice Agreement

   President Lippe reported that this proposal requires pharmacists who prescribe Schedule II drugs under a Collaborative Practice Agreement to complete continuing education (CE) for prescribers on the hazards of opioid use. This measure was approved for sponsorship at the January 2019 Board meeting.

   He stated that as part of the prior day's meeting it was suggested that in the future the Committee should consider establishing a requirement for CE related to the risks of addiction associated with the use of Schedule II drugs.

2. Amend BPC section 4052 to Allow Pharmacists to Furnish Non-Opioid Medication-Assisted Treatment Pursuant to a Statewide Protocol

   President Lippe reported that this proposal would provide for the authority for a pharmacist to furnish non-opioid medication assisted treatment pursuant to a statewide protocol and was approved for sponsorship at the May 2019 Board Meeting.

3. Amend BPC sections 4052 and 4052.6 to Expand the Conditions for Pharmacists Operating Under a Collaborative Practice Agreement

   President Lippe stated that this proposal would expand the use of the conditions under which pharmacists could operate under a Collaborative Practice Agreement and was approved for sponsorship at the May 2019 Board Meeting.

4. Amend BPC sections 4022.5, 4022.7, 4053, 4053.1, and 4053.2 to Align Requirements for Designated Representatives Requirements

   President Lippe stated that this proposal clarifies and makes consistent the definition and requirements of designated representatives across various practice settings. This proposal was approved for sponsorship at the November 2019 Board Meeting.

5. Amend BPC section 4210 to Change the Requirements to Qualify for an Advanced Practice Pharmacist License

   President Lippe reported that this proposal recasts the requirements for licensure as an Advance Practice Pharmacist license to clarify that the completion of one requirement as identified in BPC 4210(a)(2) that is subsumed within completion of another requirement specified, would satisfy the requirement of the law in BPC 4210(a)(2). This proposal was approved for sponsorship at the November 2019 Board Meeting.

6. Amend BPC sections 4119.11 and 4427.7 Relating to Self-Assessment Form Requirements

President Lippe reported that this proposal will align the ADDS self-assessment requirements with the pharmacy self-assessment requirement in Title 16 CCR 1715 and was approved for sponsorship at the November 2019 Board Meeting.

There were no Board or public comments on this section.

c. Board Adopted Regulations Approved by the Office of Administrative Law

1. Title 16 CCR Section 1749 Related to the Board's Fee Structure

President Lippe reported that the Board's fees will be increasing to address the structural imbalance within the Board's budget. The new fees take effect April 1, 2020, and Board staff are working with the Department on implementation including making necessary programing changes and updating system generated notices. He stated that Board staff is also working on a communication plan to ensure licensees and applicants are aware of the upcoming changes.

President Lippe noted that the adopted language was included as part of the meeting materials.

There was no Board or public comment.

d. Discussion and Consideration of Board Adopted Regulations Undergoing Final Review by the Office of Administrative Law

1. Proposed Regulation to Amend Title 16 CCR Section 1746.3 Related to Naloxone Fact Sheet

President Lippe reported that the Board has one regulation package currently under post adoption review, the proposed Regulations to Amend Title 16 CCR Section 1746.3 related to the naloxone fact sheet.

President Lippe stated that the OAL was to review this regulation by January 27, 2020, and as such, it has been approved.

There was no Board or public comment.

e. Discussion and Consideration of Board Adopted Regulations Undergoing Formal Review by the Department of Consumer Affairs or the Business, Consumer Services and Housing Agency

1. Proposed Regulation to Amend Title 16 CCR Section 1706.2 Related to Abandonment of Applications

President Lippe reported that this proposal updates the application abandonment language to include all licensing programs to ensure that all applicants have appropriate notice about the requirements for abandoning an application. He noted that it also reduces the administrative workload associated with the need for frequent amendments when new licensing programs are established.

President Lippe stated that formal post-adoption review by DCA began on December 11, 2019.

There were no comments from the Board of from the public.

2. Proposed Regulation to Amend Title 16 CCR Section 1707.2 Related to Duty to Consult

President Lippe stated that this proposal amends the Board's regulations regarding the duty to provide consultation for mail-order pharmacies.

President Lippe reported that formal post-adoption review by DCA began on December 17, 2019.

There were no Board or public comments on this section.

f. Discussion and Consideration of Board Approved Regulations Undergoing Pre-Notice Review by the Department of Consumer Affairs or the Business, Consumer Services and Housing Agency

President Lippe explained that this section covers Board approved regulations undergoing pre-notice review. He noted that the approved language for each section was included as part of the meeting materials.

1. Proposed Regulation to Amend Title 16 CCR Section 1707 Related to Offsite Storage

President Lippe stated this proposal would amend the Board's regulations regarding the waiver requirements for off-site storage of records to allow those cited for a records violation to receive a waiver to store records off-site.

President Lippe reported that as of January 24, 2020, this package has been approved for notice. Board staff will be referring the matter to OAL to initiate the formal rulemaking process.

2. Proposed Regulation to Add Title 16 CCR Section 1717.5 Related to Automatic Refill Programs

President Lippe stated this proposal establishes regulatory requirements for automated refill programs, section 1717.5.

This package is currently under pre-notice review.

3. Proposed Regulations to Amend Title 16 CCR Sections 1702, 1702.1, 1702.2, and 1702.5 Related to Renewal Requirements

President Lippe reported this proposal updates the renewal requirement language to include all licensing programs and will reduce the administrative workload associated with the need for frequent amendments when new licensing programs are established.

President Lippe reported that as of January 24, 2020, this was approved for notice with OAL. Board staff will be referring the matter to OAL to initiate the formal rulemaking process

4. Proposed Regulations to Amend Title 16 CCR 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

   President Lippe reported this rulemaking was returned to the Board for additional changes. The identified changes are necessary to ensure compliance with the AB 2138 provisions relating to criminal conviction information. Specifically, the questions on the pharmacy technician application require updating to ensure compliance with the AB 2138 provisions that take effect July 1, 2020.

5. Proposed Regulation to Amend Title 16 CCR Section 1709 Related to Pharmacy Ownership, Management, and Control, Including Through Trusts

   President Lippe reported that this proposal is to amend Section 1709 relating to pharmacy ownership, management, and control, including through trusts.

6. Proposed Regulations to Amend Title 16 CCR Sections 1780-1783 et seq., Related to Dangerous Drug Distributors and Third-Party Logistics Provider

   President Lippe reported that this proposal includes the Board's proposal to amend Sections 1780-1783 et seq., to establish the regulatory framework for third-party logistics providers.

7. Proposed Regulation to Amend Title 16 CCR Section 1715 to Update Self-Assessment Forms 17M-13 and 17M-14

   President Lippe reported that this proposal includes the Board's proposal to amend Section 1715 to update self-assessment forms for community and hospital pharmacies, including clarifying language as to the completion and certification requirements as well as incorporating changes in pharmacy law.

8. Proposed Regulation to Amend Title 16 CCR Section 1784 to Update the Wholesaler/3PL Self-Assessment Form 17M-26

   President Lippe reported that this proposal includes the Board's proposal to amend Title 16 CCR Section 1784 to update the wholesaler/3PL self-assessment form.

9. Proposed Regulations to Amend Title 16 CCR Section 1711 Related to Quality Assurance Programs for ADDS, Section 1713 Related to Use of Receipt and Delivery of Prescriptions and Prescription Medications, and Add Section 1715.1 Related to ADDS Self-Assessment Form 17M-112

   President Lippe reported that this includes the Board's proposal to amend Section 1711 and 1713 and add Section 1715.1. Specifically, the proposal will require submission of quality assurance records to the Board, update the Board regulations with respect to the use of an APDS, and identify the specific requirements for the annual completion of the ADDS self-assessment form.

10. Proposed Regulations to Amend Title 16 CCR Sections 1769 and 1770 Related to Criminal Conviction Substantial Relationship and Rehabilitation Criteria

President Lippe reported that this includes the Board's proposal to amend Sections 1769 and 1770. This proposal is necessary to implement the provisions of AB 2138 and will increase transparency and provide clarity to license applicants with respect to the rehabilitation criteria the board considers when evaluating an applicant's eligibility for licensure.

11. Proposed Regulation to Add Title 16 CCR Section 1714.3 Related to Community Pharmacy Staffing

President Lippe reported that this includes the Board's proposal to add section 1714.3 related to community pharmacy staffing. This proposal will establish the criteria a pharmacy must meet to identify and ensure a person is assigned to assist the pharmacist as needed when the pharmacist is working as alone in compliance with B&P section 4113.5.

Ms. Butler encouraged the enforcement of B&P section 4113.5 and spoke in support of the proposed regulation to add Title 16 CCR Section 1714.3.

Public comment urged the Department to move forward with the proposed regulation to add Title 16 CCR Section 1714.3 and to make this rulemaking a priority.

XI. Update from the Department of Consumer Affairs

Note: Ms. Kimberly Kirchmeyer presented the update from the Department of Consumer Affairs on the first day of the Board meeting.

The Board recessed into closed session at 11:13 a.m.

XII. Closed Session Matters

a. Pursuant to Government Code Section 11126(c)(3), the Board Will Convene in Closed Session to Deliberate on Disciplinary Matters, Including Proposed Decisions, Stipulated Decisions, Defaults, Petitions for Reductions in Penalty, and Any Other Disciplinary Matters.
b. Pursuant to Government Code Section 11126(e), the Board Will Convene in Closed Session to Discuss Pending Litigation
c. Pursuant to Government Code Section 11126(c)(1), the Board Will Convene in Closed Session to Consider the Preparation, Approval, Grading or Administration of One or More Licensing Examination(s)

XIII. Reconvene Open Session

The Board returned to open session at 12:05 p.m. President Lippe adjourned the meeting at 12:05 p.m.